2009年5月 | 国际贸易与知识产权研究系列

生命的权利

泰国的艾滋病药物倡导经验

作　　者：卡妮卡·克遮特瓦查库（陈妙裳·泰国）
中文版译者：胡元琼　贾　平　王翔宇
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TWN
第三世界网络

药物可及性研究小组·中国

中国全球基金观察
China Global Fund Watch Initiative

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第三世界网络（TWN）是一个国际非营利组织联合，国际 秘书处设于 Penang（马来西亚），并在 Goa（印度）、日内瓦（瑞士）和北京有办公室，它积极地参与发展、第三世界和南北事务。 从成立时起，TWN 一直按照它的宗旨，积极地投入和参与不同国际事务的研究、媒体、出版、会议的组织及交流、研讨活动，包括与联合国机构一起，促进发展中国家之间的经验分享。

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Third World Network (TWN) is an independent non-profit international network of organizations and individuals involved in issues relating to development, Third World and North-South affairs. Its international secretariat is based in Penang, Malaysia,has offices in Goa (India) and Geneva (Switzerland) and Beijing (China). Since its formation, TWN has been involved in research, media and publications activities, organized and participated in meetings, workshops and seminars on various international issues, including with UN agency, to facilitate experience sharing between developing countries.

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出版者简介

中国全球基金观察项目是一家致力于善治和透明度以及公共政策和法律研究的非营利组织。通过支持艾滋病社区组织的发展，探索民间组织有序的、多元化的发展模式；促进国内国际相关非政府组织、政府机构、学术界和私营部门之间伙伴关系，倡导良好治理和有意义的公众参与，推动各利益相关方的参与和监督机制的建立，以期更有效地解决共同面对的社会问题。

中国全球基金观察的工作领域包括：公共参与、善治和透明度；伙伴关系的建立与非政府组织发展；公共政策法律研究如国际贸易、公共卫生与药物获得，以及探讨和研究中国社会可能面临的一系列由非传统危机引发的不确定性及其应对措施。

China Global Fund Watch Initiative is non-for-profit Organization working on the issue of good governance and transparency, with public policy and legal research. GF WATCH's mission is to promote the development of civil society in China – and hence good governance and public participation – by fostering the development of grassroots HIV/AIDS NGOs and building partnership among NGOs, governments, academics and private sector to address problems of common concern. GF WATCH supports the development of meaningful, pluralistic civil society by encouraging transparency, oversight and participation from all stakeholders, while encouraging their preparedness and response to the numerous societal problems.

GF WATCH's working area include: Public Participation, Good Governance and Transparency; Partnership Building and NGO Development; Public Policy and Legal Research such as International trade, Health and Access to Drugs; Non-traditional security issues that Chinese society faces.

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中文版序言

2009 年春夏之交，人类再次面临传染病流行的挑战，突然爆发的甲型 H1N1 流感迅速在全球蔓延。对于象流感这样不断变异的流行病，最有效的控制方法就是及时研制、生产和使用疫苗。但是，在旷日持久的争论之后，一个能有效应对全球性的流感威胁的一揽子预案仍未能实现。拖延了这个关乎全人类健康的重要协定的原因之一，是各国对于研制疫苗所必须的病毒毒株共享和利益分享过程中所涉及的知识产权问题难以达成一致意见。

在这样的时刻，《生命的权利》一书中文版的问世，无疑对于国内公共卫生界、法律政策界和公众读者都具有重要的意义。它在引导我们回顾泰国为保证公共健康利益而运用强制许可的历史的同时，更清晰地提醒我们，正确认识和使用医药知识产权，对于保障人民的生命健康是何等的重要。

在经济全球化迅速发展的今天，公共健康问题也明显呈现出全球化的趋势。传染性疾病的威胁不分国界和种族，但是社会、政治、经济和法律制度的差异却能够使贫穷和富裕人口获得有效治疗和药物的机会呈现巨大的反差。导致这种不平等的根源之一，是知识产权制度全球化过程中，医药专利的盈利性质与维护生命健康作用之间的平衡被打破了。

为了重置平衡，近年来国际社会做出了努力，以艾滋病药物为契机，世贸组织各成员国集体做出了承认国家有通过强制许可和平行进口等制度，来突破药品专利限制，维护人民生命和公共卫生利益的权利的历史性决定。虽然目前中国还没有正式在公共卫生领域运用强制许可制度，但是已经通过法律修改等方式，在持续地为提高药物可及性和公共健康做出努力。

作为一个人口众多的发展中国家，中国面临着更加严峻的各类疾病压力和公共卫生的考验。中国于 2003 年启动了国家艾滋病治疗项目，向患者免费提供部分抗病毒药物。但是由于专利等因素的影响，时至今日，各类有效抗艾滋病病毒药物的持续获得依然是一个悬而未决的问题。除了受到艾滋病、结核等重大传染性疾病的影响之外，中国也是许多非传染性疾病的病患大国，比如癌症、心脑血管疾病、高血压、糖尿病等等。很多这类疾病的有效治疗和预防药物及疫苗，对缺乏或只有很低水平医疗保障的广大民众来说依然是可望而不可及。正在启动的全民医改更显示了如何托善解决药物可及性这一问题的紧迫性。我们应该清醒地认识到，作为医改重要支柱的基本药物目录，决不应该是廉价药物清单，否则医改将难以成功。

在国内热心公益的几位年轻的法律界专业人士努力之下，《生命的权利》得以面世。我相信，面对新发传染病的不断侵袭的人类，在药品专利的商业利益和其维护健康生命的终极属性间是可以达到一种平衡的。泰国已经做出了有益的实践。我坚信，一个

能够发明一国两制化解国家间难题的党和政府，以及能够创造三十年经济发展奇迹的民族，也一定能找到一条既能满足自身药品需求，又能造福发展中国家民众的和谐之路。

邵一鸣　博士

中国疾病预防与控制中心艾滋病首席专家

第十、十一届全国政协委员

2009 年 5 月

Preface for Chinese version

In the spring and summer of 2009, our society faces the challenge of a new epidemic as the A-H1N1 flu rapidly spreads around the world. Pandemic flu is the type of disease that with possibilities of mutating into a new strain, and the most effective way of controlling its spread is to immediately develop, produce and distribute new vaccine. However, after several long debates, a comprehensive global Pandemic Flu Preparedness solution has not yet been agreed upon. One of the key reasons why the negotiators could not agreed upon such a critical protocol related to the fate of public health of the global community is because countries could not get an agreement on intellectual property issues related to the virus strain sharing and benefits sharing that required for vaccine development.

At such a moment, the publication of the Chinese version of "The Right to Life" carries great significance for experts from public health, law and policy fields, as well as the general Chinese public. The book not only reviews the history of Thailand's policy of compulsory licenses to safeguard public health but also clearly reminds us of how important it is to have an appropriate understanding and implementation of medical related intellectual property in order to protect people's life and health.

Today, with the continuing trend of economic globalization, public health issues have become globalized as well. The epidemic threatens people without regard for nationality or race, but the social, political and legal differences, will result a great discrepancy between rich and poor populations in getting access to effective treatment and medicines. One of the root reasons behind such inequality is that the balance between the profitable feature of intellectual property and public health protection was broken during the process of globalizing intellectual property norms.

In order to restore the balance, the international community has made great efforts in recent years, especially with HIV/AIDS medicines., WTO members have made a historical decision in all agreeing that countries have the right to use measures such as compulsory licensing and parallel importation, in order to overpass the patent barriers and to safeguard people's lives and public health interests. Though China has not yet formally used compulsory licensing for public health purposes, it has already taken steps such as amending relevant laws and regulations and increasing access to medicines to protect public health.

As a developing country with a large population, China is facing serious challenges from different diseases and public health issues. In 2003, China launched a national treatment program on HIV/AIDS, providing some antiretroviral drugs (ARVs) to patients for free. However, because of different obstacles, including patent issues, access to all effective ARVs in a sustainable manner is still a pending question for China. Apart from being affected by heavy epidemics such as HIV/AIDS and TB, China also has large number of patients with non-communicable diseases, including cancer, cardiovascular and cerebrovascular diseases, hypertension and diabetes. Many medications and vaccines that effectively treat these diseases are still not available for people who lack or only have limited coverage through medical insurance. The ongoing reform of the national health system in China has highlighted the urgent

and important need to create a practical solution for access to medicines. We should soberly realize that, as an essential pillar of health system reform, the essential medicines list should in no way mean a list of "cheap" medicines; otherwise health system reform will see little success.

With the efforts of a group of Chinese young legal professionals keen on advancing public interests issues, "The Right to Life" is now getting published in Chinese. I believe, as we face continuing attacks from new types of diseases, that human society will finally find a balance between the commercial profitability of medical patents and its ultimate goal of safeguarding human lives. Thailand has seen good results in this regard. I firmly believe, that if a party and government that can invent the "One county two systems" to address the difficulties in international affairs, if a nation that can create the miracle of thirty-years of rapid economic development, that this nation can also find a harmonized solution which can fulfill the need of medicines for its own people and benefits the people of developing countries.

Dr. SHAO Yiming, M.D.

Chief Expert, China National Center of Diseases Prevention and Control
Member of the 10th and 11th National Committee of Chinese People's Political Consultative Conference
May, 2009

中文版作者前言

2005 年初，我应邀去做一个小型的研究项目，该研究涉及关于在 8 个国家中的专利保护如何导致了必备药物无法获得的问题。这些关于如何促进药物获得的阶段性研究发现，已经在当年晚些时候在一个由泰国民间社会活动人士和学术界举办的关于强行仿制的会议上进行了发布。

从上述这些国家的经验中可以很很明显地看出，他们所面临的“药物短缺”的境遇，很大程度上是因为美国出于巨大的产业利益，正在寻求一种改变当今世界现存的知识产权法律体系的战略。通过这种改变，美国的制药产业在全球范围内试图以尽可能延长其所拥有的专利的保护期，从而尽可能地获取最大化的利润的方式，收紧对其所拥有的技术的垄断。由于发展中国家和全球公共卫生领域已经成功地再次确认公共卫生优先于世界贸易组织关于知识产权问题的规则，美国于是就将它的努力提升到通过双边和区域贸易协定谈判的方式去推动产业界的意图. 这样， 如果这一努力成功的话，将最终导致 TRIPS（与贸易相关的知识产权协定）的根本性改变，而 TRIPS 协定是知识产权领域最重要的国际标准性文件。进一步而言，美国如果坚持其咄咄逼人的追寻产业利益的政策，并进一步扩张其需求，那么将产生相当负面的后果，而这些后果在很大程度上将落到发展中国家身上。

当我在那次会议上就这些发现做报告的时候，我提出了一个关键性的问题——我们，民间社会的活动家，敢不敢站出来反对甚至挑战美国的这些努力？如果想让这样一场运动获得成功，就需要充满道德勇气的国家领袖们；有着社会责任感和良知的公共和私营部门；强有力的民间社会的参与，包括学者、专家、非政府组织、人民团体和媒体。如果没有类似的社会运动，我们将只有另外一个选择，那就是向美国所推动的专利制度俯首称臣，让这一制度继续剥削穷人并让他们继续的得不到所需的药物。

然而，就在会议结束的时候，当时的卫生部副部长向媒体发出了一个泰国关于强行仿制的态度的申明。他质疑了泰国强仿的能力，因为这只可能将泰国置于受到国际贸易制裁的境地。泰国政客这种短视而狭隘的观点，并没让已经在药物获得领域无畏战斗了二十余年的泰国民间社会消沉下去。有着学识渊博的政策制定者和强有力的泰国民间社会倡导团队，机遇之窗还是被打开了。

今天，我们已经目睹了一些人士是如何在屡战屡败后，依然以坚韧不拔的勇气和毅力去捍卫大众获得药物的权利。在持续的重重压力之下，泰国的活动家们依然推进他们的社会运动，以制定出能够确保泰国人民的公共利益得到保障的公共政策。

强行仿制不会凭空而生，它的产生源自于过去几十年泰国社会中草根组织的努力。并由“移动大山的国际铁三角”所带来。

“移动大山的国际铁三角”不会因为仅仅发了几个强行仿制就洋洋自得。他们现在正坚定地朝着将获得药物的国家战略转变为可操作的公共政策的方向稳步前进。我在所参加的不同的国家多次会议中与人分享过泰国的经验，并被告知，类似的社会运动永远

不可能在其环境与泰国不同的国家发生。然而，20 年前，泰国人自己也同样认为这一切不可能发生，但这却已经成为现实。

这一史诗般的、矫正商业逐利和人们对于获得药物的需求之间不平衡的战斗，是场依旧在行进中的社会运动。为了补救这种不平衡，需要民间社会和患者群体间共同的努力，以及推动大众对于基础的人权和健康方面的知识的普及和觉醒，还需要有政策制定者们的强有力的政治意愿。只有当这些因素都具备时，我们才能在商业利润和人们获得药物的权利之间达到一种可以接受的平衡 。

每个国家都有着类似的为健康权利而斗争的类似境遇，我为能够与中国人民一起分享我们的经验而倍感骄傲。

卡尼卡（陈妙裳）

2009 年 5 月

Preface from the Author for Chinese Edition

In early 2005, I was invited to conduct a small research project addressing the problem of lack of access to necessary medicines caused by the patent regime in eight countries. The findings on ways to improve access to medicines were presented at a conference on compulsory licensing held later that year by Thai civil society advocates and academics.

From the experiences of these countries, it is clear that they face a "lack of access to medicines" in large part because the US is pursuing a strategy to change the existing global intellectual property legal regime, primarily because of strong industry interests. Through these changes, the US pharmaceutical industry with global markets is trying to tighten its monopoly on technologies it owns by extending its patents for the longest possible period to allow it to make the highest profits possible. As developing countries and the global public health community succeeded in reaffirming the priority of public health over World Intellectual Property Organization (WTO) rules on intellectual property, the US stepped up its efforts to push industry's agenda through bilateral and regional trade agreement negotiations. If this is successful, it will ultimately lead to fundamental changes in the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), the most important international standard on intellectual property issues. Therefore, if the US persists in aggressively pursuing its industry's interest and it is expected to demand more, there will be negative consequences falling mostly on developing countries.

While presenting my findings at this conference, I posed one crucial question--dare we, civil society activists, stand against and even challenge these efforts by the US? For such a campaign to be successful, it would need: many heads of state with moral courage; public and private sectors with social responsibility and conscience; and strong civil society participation comprised of academics, professionals, non-governmental organizations (NGOs), people's organizations and the media. The alternative to such a campaign would be to simply give in to the US-pushed patent regime and let it continue to deprive the poor and the sick of their needed medicines.

However, as the conference ended, the then deputy health minister issued a statement to the press concerning Thailand's position on compulsory licensing (CL). He questioned Thailand's ability to issue CLs because it would only put Thailand at risk of international trade sanctions. However, such short-sighted and narrow vision by Thai politicians did not demoralize the Thai civil society, who has fought a tireless campaign for access to medicines for over 2 decades. With knowledgeable policymakers and a strong team of Thai civil society advocates, the windows of opportunity then opened.

Today, we have seen how a group of people fighting with determined courage and persistent efforts continue to defend everyone's right to access to medicines despite countless defeats. Amid ongoing pressure, these Thai activists still move forward with their campaigns to create a public policy to ensure that the public interest of Thai people is met.

The CL phenomenon did not materialize out of thin air. Rather, it flourishes because of the grassroots efforts by Thai society over the past few decades. It has been brought by the "Globalized Triangle that Moves the Mountain."

The "Globalized Triangle that Moves the Mountain" will not be happy with just the issuance of CLs on a handful of medicines. Now they are moving forward with single-minded determination to develop national strategies on access to medicines to turn into practicable public policies.

I shared the Thai experience in many conferences in different countries and was told that such campaigns would never happen in countries with different contexts from Thailand. However, 20 years ago, no one in Thailand ever thought this would happen to them but it has.

Our epic battle to correct the imbalance between profit-driven business and people's need to access medicines is an ongoing campaign. To redress this imbalance, there needs to be concerted efforts between the civil society and patients, together with the promotion of public knowledge and awareness of the fundamental human right to health, and strong political will of policymakers. Only when these factors align will an acceptable balance be struck between business and people's right to medicine.

I am proud to share our story with the people of China because similar struggles for the right to health are in every country.

Kannikar Kijtiwatchakul

May, 2009

中文版序言

对健康的权利是一项人权，当需要药物治疗危及生命的疾病却不能获取时，则侵害了生命的基本权利。当获得这些救命药物的障碍是一项专利或以其它形式垄断的知识产权保护时，此种情形当然是不可接受的。

对艾滋病感染者和患者来说，已经有许多困难障碍要克服。在泰国，这些有勇气的人们自己组织起来，发出强烈的声音，彼此帮助，成功得到了政府良好的卫生政策支持。然而，由于一些制药公司拥有专利导致的非常高的药价，却阻断了他们获得治疗艾滋病药物的途径。10 多年来，一个由艾滋病感染者和患者、非政府组织、学术界、法律制订者、关注此议题的卫生官员和媒体组成的联盟一起行动，发起了一场令人鼓舞的运动，揭示出那些专利是如何侵犯了生命的权利。泰国卫生部在经过研究和咨询后，决定对一些紧迫需要的艾滋病药物颁发进口和制造的强制许可，这是一个全世界公众健康团体都为之庆贺的胜利。

本书由 Kannikar Kijtiwatchakul 所著，首先以泰文出版，它记录了泰国公民社会运动的发展，及在有关制药公司激烈反对政府行动时，公民社会给予的有力支持。由于本书的社会和教育价值，它也被翻译成了英文。

现在我们也有了这个了不起的故事的中文版。除原著外，我们还增加了泰国卫生部颁布的白皮书文本，它解释了为尊重泰国人民生命的权利，泰国政府做出这个历史性决定所采用的法理依据和谨慎步骤。

Chee Yoke Ling (徐玉玲)

项目总监
第三世界网络（Third World Network）
2009 年 5 月

Preface for Chinese Version

"The right to health is a human right and when medicines are needed for diseases that can kill, the inability to get those medicines violates the right to life. When the barrier to get access to life-saving medicines is a patent or other form of monopolistic intellectual property protection, such a situation is certainly unacceptable.

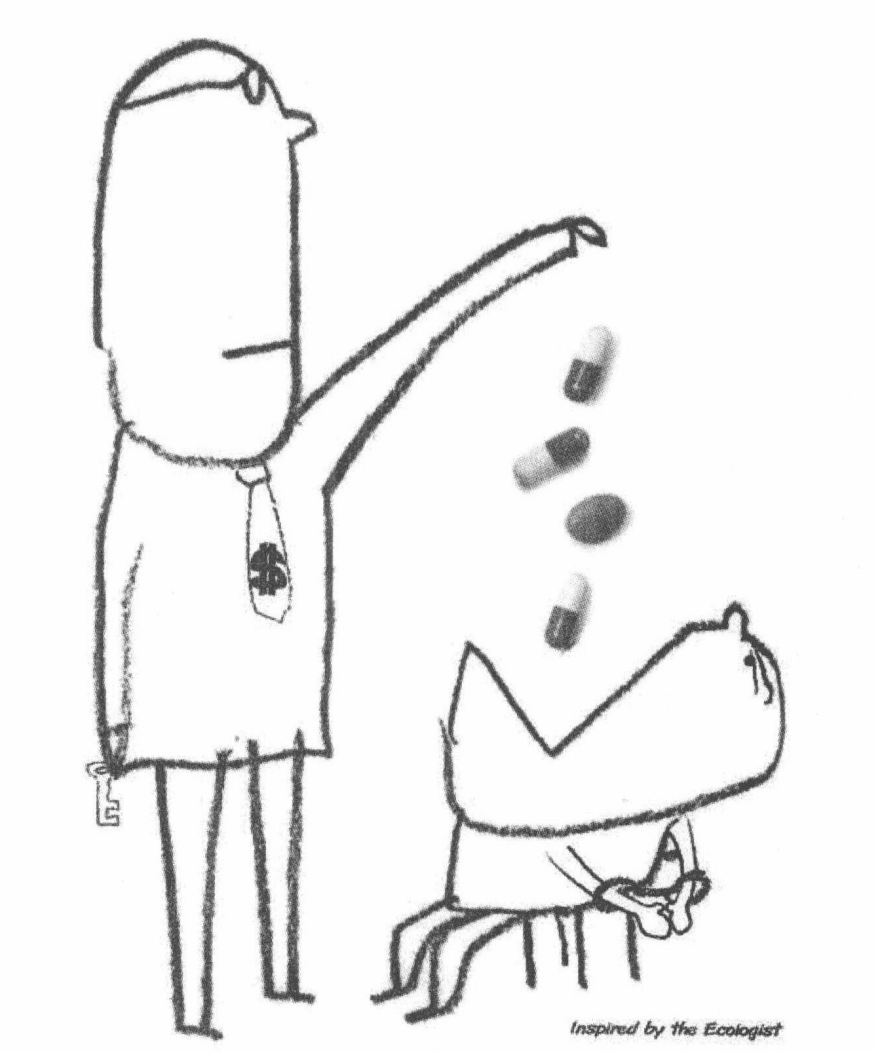
For People Living with HIV/AIDS (PLHA) there are already many difficult obstacles to overcome. In Thailand these courageous people organized themselves to create a strong voice, help each other and succeeded in achieving good government health policies. However, their access to HIV/AIDS medicines was blocked by the very high prices that resulted from patents owned by a few pharmaceutical companies. Over more than 10 years, a coalition of PLHA, NGOs, academics, lawmakers, concerned health officials and the media joined together and created an inspiring movement to expose how patents violate the right to life. When the Ministry of Health, after conducting studies and consultations, decided to issue compulsory licenses to import and manufacture urgently needed ARVs, it was a victory celebrated by public health groups all over the world.

This book by Kannikar Kijtiwatchakul was first published in the Thai language to record the struggle of the Thai civil society movement and its strong support for the government's actions when intense pressure was shown by the pharmaceutical companies concerned. The book was translated to English because of its social and educational value.

We are now very honored to be able to have this remarkable story available in Chinese. In addition to the original book we have added the White paper issued by the Thai Ministry of Public Health that explains the philosophy and careful steps taken by the government in making its historic decision to honor its people's right to life."

Chee Yoke Ling

Director of Programmes
Third World Network
May, 2009



ซีแอล การใช้สิทธิเพื่อมีชีวิต

Right to CL = Right to Live

强行仿制的权利=生命的权利

目 录

第一部分　生命的权利

“你过真而似伪，让人无法释怀。”

自从我将泰国作为一个冷战后美国帝国主义政策的副产品开始进行研究以来，这是泰国政府的行为第一次让我感到惊讶。我从未想到过，它居然胆敢施行强制许可，我真的非常惊讶。更为重要的是，那时侯的泰国政府还不是一个民选的政府，这简直就更让人感到崇拜了。看来，许多教科书真需要被撕掉并扔到一边去了。

苏拉特. 哈拉查库（Surat Horachaikul） 副教授

泰国朱拉隆功大学政治学系教员

泰语中有一大堆的词汇等同于英文中的“强制许可（强仿）”，在国家实施的情况下，“强制许可”也可以被称为“政府使用”。“强仿”通常被用于描述泰国政府卫生部行使权力就三种药物发布强制许可令，以使本国能够从从印度进口更为便宜的仿制的上述药物。这三种药物分别是：依非韦伦（*Efavirenz*），默沙东公司生产的艾滋病一线抗病毒药物；氯吡格雷（*Clopidogrel*）,赛诺菲－安万特生产的一种治疗心脏病的药物；以及洛匹那韦/利托那韦（*Lopinavir+Ritonavir*），雅培公司实验室生产的二线艾滋病治疗药物。

一个国际社会中小小的、柔顺的发展中国家，是如何象恐怖杀手杰克般成为全球谈资的呢？它的行为属于侵犯知识产权吗？这一行为会不会破坏世界范围内的创新力？这一事件将会对这个扭曲的世界产生什么影响？

请容下文细细分说。

知识产权制度介绍：制造利润的权利

为了让读者就泰国强制许可之路得到一个信息量丰富且有趣的阅读体验，首先介绍一下知识产权体制显然是必要的。这一介绍并不是要读者们成为学识渊博的职业知识产权律师，而是希望读者们籍此获得一个去理解知识产权相关知识的语境，因为知识产权恰恰是这一事件的核心。

艾滋通路基金会（AIDS ACCESS Foundation）的总裁尼米特·天努达姆（Nimit Tienudom）曾经以一种简单而有趣的方式，就什么是知识产权和强制许可做出了解释："简单地说，知识产权就是关于那些发明药物和化学品的体制。这些发明人自然而然地希望拥有垄断地管理、制造和交易他们的产品的权利。为了认可发明者，并提供给发明者以某种激励，我们于是就建立了知识产权机制。"

"但当涉及药物时，我们也许需要区别对待，因为药物对于病患来说至关重要。如果没有药物，一些病患依旧可以生存；但对另外一些人来说，缺少药物意味着生命的终结。由于药物和其他产品有所不同，所以他们必须被在伦理上予以控制。当一个人生病且因为无法获得药物而无法被治愈，那么没有任何东西能够替代他的损失。所以，药物知识产权的概念应该被区别对待。"

"当人们发明了某种东西并在他们的产品、发明和改进上设置专利，他们就对他们的产品拥有了长达20年的垄断权利。这一期间足以阻止其他（同类的）仿制药物和专利药物进行竞争。问题就出在这里：专利药物的制造商处在一个能够对其产品随意定价（想定多高就多高）的位置上。"

"在那些没有替代品的实质性的药物上，价格设定的高度将是惊人的。艾滋病患者必须服用抗病毒药物。如果使用原研药（原始的拥有知识产权的药物），患者需要每月支付9000—13000泰铢（大致相当于人民币1800－2600元，依照配方浮动）。患者们能够承担得起吗？ 他们能不能不服用这些药物呢？或者，他们能不能只在能够付得起的月份里，服用这些药物？回答是否定的。"

“如果你去接受关于抗病毒方面的治疗，你就必须持续地治疗下去。否则的话，病毒就会对药物产生抗药性。如果你需要买药，那你就必须掏钱。如果你不能支付汽车或房贷的月供，你的车子仅仅可能被扣押。但是如果你无法支付你生命的月供，就意味着生命的终结。这样，药物就成为一个伦理问题，因为他们对人的生命有实质性的（影响）作用。

“专利药物十分昂贵。那些无法获得这些药物的人将十分痛苦。虽然我们尊重知识产权，但是我们必须寻找到一条法律途径去解决这一问题。

“如果你身边的人需要药物，却又因为药物太贵而无法购买，你该如何作出决定呢？你是会让他们苦苦挣扎（赚到足够的钱）以购买这些药物，还是依据现行法律规则去降低药价以使得所有需要的病患能够支付得起？”

现在，让我们来展开进一步的分析。

1985年，美国经受了严重的预算和贸易赤字。其制造业产品无法与来自中国和日本的产品竞争，而中日对美国的出口额又非常之高。但是美国的力量在于其服务业和知识产权产品。美国成功地于1994年世界贸易组织会议中，将《服务贸易总协定》（GATS）和《与贸易相关的知识产权协定》（TRIPS）加入了世界贸易组织的议程。

《与贸易相关的知识产权协定》（TRIPS）包含了一系列的主要指向保护专利所有人或持有人的规则、规定和实践。幸运的是，一些来自发展中国家的学者也参加了协定的起草工作。当时在阿根廷布宜诺斯艾利斯大学任教的卡洛斯·柯里亚（Carlos Corea）博士就是其中的一位。

那个时候，作为世界顶级的知识产权法专家，卡洛斯·柯里亚博士是阿根廷的科技部长。他竭尽其所能将弹性机制和保护条款嵌入该协定，为普通大众对抗幕后欲壑难填的利益集团的贪欲赢得些许空间。而强制许可就是上述弹性条款之一。

“自 1925 年以来，强制许可被写入到了几乎所有国家的专利法当中，这其中包括巴黎公约。甚至在 TRIPS 协定当中，该事项也被允许并得到清晰的确认，对于实施强制许可也没有限制。其具体操作，是各国依据他们想实施的原则进行选择。”

TRIPS协定的第31款明确指出，成员国可以在全国处于**紧急状态**或在其他**极端紧急**的情况下，或在**公共非商业性使用**的情况下，豁免“尊重专利权持有人权利并从权利持有人处获得授权”的义务。在公共非商业性使用的情况下，无需与权利持有人谈判磋商，只需**迅速通知**即可。

“这意味着专利持有人垄断权利依然存在，但当国家在上述三种情况之下认为有必要时，可以发出强制许可，而专利持有人应该获得充分的补偿。

尼米特解释说：“这（一规定）令人沮丧，因为许多人无法获得必需的药物。这是一种亟需纠正的不平衡。所以该条款提出，在危机或者某些问题出现的情况下，一国政府应被允许制造或进口仿制的专利药物，并承担补偿专利持有人的义务。该补偿的支付意味着尊重知识产权的拥有者。”

杰斯·托纳瓦尼克（Jeth Tonavanik）博士提供了一个进一步的解释，他是暹罗大学法学院院长，同时也是泰国顶级的知识产权律师之一。他指出，强制许可的实施是一个法律程序，并不需得到专利权人的允许，而是政府认为有必要迫使所有权人这么做。这种对于专利权人权利的使用依据的是现行法律框架，与盗版光碟或CD大异其趣----后者是属于著作权侵权。强制许可是、法律框架内进行的。

但是，鲜有发展中国家有足够的勇气去利用和实施这些弹性条款，即便他们经受了药物获得问题的严峻挑战。相反，发达国家，诸如美国、加拿大和许多欧盟国家都曾经有规律地将这些弹性机制作为法律手段予以使用。究其原因，这不仅仅是因为国家能力方面的限制，而且也是因为来自美国这样一些超级霸权的国际压力，这些强制性的压力使得追寻强制许可的意图一再流产。这就是他们过去一贯的傲慢态度：只许州官放火，不许百姓点灯。

但是到了 2001 年，在卡塔尔首都多哈举办的世界贸易组织部长级会议需要进一步澄清 TRIPS 协定的相关规定，尤其是关于公共卫生的部分。多亏了发展中国家和国际社会的努力，《关 TRIPS 协定和公共卫生的多哈宣言》得以发表。

多哈宣言宣称，WTO 的成员拥有保障公共卫生的权利，尤其是利用强制许可去推进药物获得。另外，成员国被赋予（去自己）确定什么是全国处于“紧急状态”或“其他紧急情况”的权利。更为重要的是，“公共卫生危机”被理解为应该包括艾滋病、结核和疟疾以及其他接触传染性疾病，上述所有的疾病都可以构成“国家紧急状态或其他紧急情况”。

许多发展中国家和地区，包括马来西亚、印度尼西亚、台湾、赞比亚、莫桑比克、喀麦隆、圭亚那、加纳和厄立特里亚都曾经依照 TRIPS 协定和公共卫生的多哈宣言，通过使用强制许可展示过勇气。但是与公众无法获得药物这一问题的程度相比，采取类似行动的国家数量就显得太少，而且其采取的强制许可仅仅局限于并不十分昂贵的基本抗病毒治疗药物。

所以，制药企业的利润赚取还从没有遭遇过一次真正意义上的挑战。玛莎亚·安吉尔（Marcia Angel）博士在她的《药企真相》一书中写道：“药品企业们在自己的畅销药物上扩展市场垄断权利已经到了无所不用其极的地步……在自由贸易的每一个方面，制药工业的生命线都源自于政府犒赏的垄断权利，这些垄断权利以美国专利和商标局颁发的专利作为其存在的形式。”

泰国的专利制度：贸易束缚

泰国于1979年颁行了它的第一部专利法。该法为除第九章规定以外的所有的其它发明提供保护。在第九章规定的例外中，就包括了药物和医疗产品。这意味着，根据该法，只有制药“方法”可以得到保护，而医药物质和医药产品则不能得到保护。依据该法，专利的保护期为15年，保护期自申请专利之日起开始计算。

那么，什么是“制药方法”呢？

这里有一个简单的解释。如果A、B和C三种物质的组合，可以生成药品Z,那么该专利就只保护通过A、B和C的途径制造Z的过程（方法）。如果任何一个人通过将C与A、B组合，或者将B与C、A组合，从而生成药物Z,这种行为将根本不构成侵犯专利。相反，医药产品（或物质）专利禁止任何A、B和C的物质组合，只要这些组合能够生成药品Z，就是不允许的。

由此，授予方法专利意味着鼓励国内创新。制药行业，尤其是发展中国家的制药行业，必须从组合药物（compounding drug）开始，慢慢才能进展到自主发明和创新。此外，在一个合理的时间内授予市场垄断权利，在仿制药物进入市场并使得原研药价格得以降低之前，会使得专利药物在一定时间内变得昂贵。

但是，泰国的路径并非一条洒满鲜花之路。事实上，这条路上荆棘漫布，让泰国人民伤痕累累。美国于1985年开始了与泰国的双边贸易谈判，并授予泰国普惠制待遇，以换取泰国将对产品专利进行保护，并将保护期延升至15-20年。

美国对泰国采取了胡萝卜加大棒的政策，把泰国列为“优先的外国国家”。这就使得泰国被置于随时被剔除出享受普惠制待遇的威胁的前列。

在那个时候，学术界、公共卫生界人士和非政府组织在药物研究小组的带领下，就专利保障问题对于泰国药物和卫生体系产生的负面影响展开了研究。研究结果显示，如果产品专利得以通过，1988年进口药物的价值就会相应高出72%，同时，国内医药行业

关于普通药品生产技术的研发就会相应滞后，因为国内药企被禁止生产专利药物。这种争论在几届政权更迭的时间里一直持续着。

威差·楚克威瓦特（Vichai Chokevivat）博士回忆了20年前的情况："1979年药品专利法（BE2522）对我们来说很公平，因为我们的技术水平与发达国家相比要低很多。对我们来说，只保护方法专利很公平。但是从1985年起，我们就一直处在被要求修改专利法以保护产品专利的压力之下。我们那时为阻止修改专利法作了很多抗争，其中最活跃和最坚定的领导人物是药物研究小组的阿加恩·苏木里·加德（Ajarn Sumlee Jaidee）以及她在药学院的学生。我只是其中一个并不重要的部分。

但是最后我们失败了。该法案在1992年就被修改，但直到8年以后的2000年，我们才被要求遵循世界贸易组织的相应规则——世界贸易组织的豁免条款让穷国能够获得另外5年的延长期（到2005年），印度就充分行使了这一豁免权利，直到2005年才修改了自己的专利法。"

1991年，国家维持和平委员会发动政变，阿南德·班雅拉春（Anand Panyarachun）政府上台。由于该届政府极其需要来自国际的承认，于是就同意了美国对专利法修改的要求，这使得泰国专利法早于世界贸易组织TRIPS协定的相关要求生效8年就进行了修订，更别提依照该协定，发展中国家还有长达5年的豁免权，即可以将本国专利法的修改义务推迟5年。就这样，泰国整整失去了13年的宝贵时间以去发展本国的医药产业。

"这种让步——虽然反对声浪巨大——将使得药物变得更加昂贵。药品是人的四大需求之一，是一种无法回避的需求。疾病并不会在乎药价的高低。我们可以选择花2000泰铢还是28泰铢吃一顿饭，住房和服装也一样，我们都可以有选择。但是对专利药物而言，我们就没得选择了。依照当时的谈判，需要建立药品价格控制委员会，并提供一个8年期的技术转让。但是，这一承诺没有被兑现，价格控制机制并没有被建立起来。1999年，专利法被修订，关于药品价格控制委员会的章节也被删除掉了"，威差博士补充说。

专利法修订对泰国的冲击是显而易见的，尤其是在和印度竭力（推迟修改专利法）并充分运用延长期以获益这件事情进行比较时可以看得出来。在 1980 年代，两国制药行业的能力是相近的。但是现在，泰国部分的制药企业已经消失了，其他企业则已经落后，原因是严苛的专利法条款阻碍了企业的研发。与此相对应的是，印度制药产业在仿制药和原研药两个方面都得到了发展。直到 2005 年初，印度专利法依照 TRIPS 协定进行了修订并随后予以颁行，但是，这时的印度本土制药产业已经成长起来，可以随时应对挑战。即便如此 ，这部法律还是在一定程度上误导性地阻碍了印度本国制药工业的发展。

其他国家也曾经有过类似的经验。他们被要求修订自己的专利法以使其规定变得更加严苛，这使得药物变得更加昂贵，导致更少的人能够获得药物。本土制药企业逐渐萎缩，并逐渐变成受雇的制造商。一系列的专利相关规则与规定，似乎使得专利变得拥有了永不到期的不死之身。各种策略被运用于拖延专利保护期，虽然一些药物早已不再有被授予专利的资质。

这样，步步高企的药价已经成为国家预算的沉重负担。但这一负担过重而无法被承受时，政府就停止支付费用，最后导致我们的公共卫生危机。

黑暗中，隧道尽头仍有一丝光明

一方面，由学术界、公共卫生专家、律师、非政府组织和学生们发起的抵制修订专利法的运动以失败告终，公众关于这一事件的觉醒度仍然很低。公众并没有意识到专利制度是如何影响到他们的日常生活的，他们也不感兴趣。另一方面，许多个人和组织的决心在彼时变得如此坚决，并最终在日后开花结果。

大约在1998年，由艾滋通路基金会领导的艾滋病非政府组织联盟开始对艾滋病病人的抗病毒治疗施以更多关注。以前社会大众以为这种病无药可治，一旦有人感染了这种疾病，那么他们必死无疑。然而，大部分的抗病毒药物是专利药物，这样价格就很高。这就使得非政府组织的工作者们不可避免地了解到了专利问题，而这一问题正是药物研究小组不间断地跟踪的问题。药物工作小组由来自多所大学的教师们联合形成，数十年来致力于保障消费者公平使用药物的权利。药物研究小组的产出之一消费者基金会，也对这一议题非常感兴趣。

在同一时期，此前就开始监测抗病毒药品专利问题，由克里沙娜•克莱斯图（Krisana Kraisintu）博士和她的研究团队领导的政府医药组织研究与发展研究所开始准备制造更便宜的抗病毒药物。

一旦想认识感染者以及艾滋病非政府组织的需求得到不同组织的支持，一个强有力的网络就逐渐形成了。一开始它表现为感染者的自助群体，逐渐这个网络组织的工作开始扩展到为其成员争取权利和保障其成员的权利。

希望由此被再次点燃了。虽然泰国的专利法已经被彻底修改，但是第 51 节的相关规定依然可以被作为一个重要的手段去保障公共利益。该条款允许政府发布强制许可去制造专利药物，或者进口这些专利药物的仿制品。这是一个（利益）平衡的机制，这一机制也同样出现在 TRIPS 协定中。

以前，政府制药组织（GPO）准备制造去胫肌苷（ddI），这种药物和百时美施贵宝（BMS）制药厂生产的该种药物配方很相似。在对施贵宝的专利进行跟踪研究后，政

府制药组织认为不能授予施贵宝的产品以专利，因为该药物不是一种新药，而且其申请所依据的是以前的旧专利法，该法只承认方法专利。进而，施贵宝的相关专利申请在美国已经遭到拒绝，这就促使政府制药组织开始继续其研究。

1996年4月29日，施贵宝法律部通知政府制药组织，称施贵宝已经获得了一个去胫肌苷的专利，政府制药组织应被绝对禁止生产它。该公司指“如果有任何权利侵害的话，它将严格地保护它的知识产权”。所以，政府制药组织被迫停止制造去胫肌苷，即便他们已经购买好了所有的原材料。

正是因为去胫肌苷专利的这一段不一般的历史，以及减轻昂贵的抗病毒药物引起的压力的需求，艾滋病感染者和与艾滋病工作相关的非政府组织网络就开始一个推动强制许可的运动，敦促政府制药组织根据专利法第51节去制造去胫肌苷。但是却没有任何进展。

《小人物挑战大问题之路：从挑战去胫肌苷专利习得的经验》一书描述了在1999年12月22-23日，约100位与艾滋病工作相关的非政府组织以及感染者网络代表如何在卫生部门口的旗杆前建立起一个“推动去胫肌苷发展的第51节社区”营地的情况。

设立该营地目的是为了让全社会去理解药品专利，并为国家就施贵宝的专利发布强制许可提出（法律和伦理方面的）理由。

卫生部接受了示威者的要求，并承诺将努力让艾滋病患者能以更便宜的价格购买去胫肌苷。卫生部也承诺在2000年1月17日给出解决方案。但是在卫生部长科恩·达巴尔安斯（Korn Dabbaransi）和在艾滋病领域工作的NGO以及感染者网络之间长达两个小时的对话后，出于避免得罪美国和招致报复性贸易措施的考虑，最终决定由政府制药组织生产去胫肌苷的粉剂，而非片剂。此举或可使去胫肌苷的价格降低，但是粉剂使用不方便，许多患者由于感觉恶心或腹泻等原因，也不能服用粉剂。因此这是一个令示威者们感觉失望的决定。

然而，感染者网络没有放弃他们的努力。2000年1月18日，他们在无线街上的美国大使馆门口举行示威，向比尔·克林顿总统递交了公开信，敦促美国承诺，如果泰国就去胫肌苷的生产发布强制许可，美国将不采取报复性贸易措施。

美国贸易代表于2000年1月27日对此做出了回复，并引用克林顿总统在西雅图世界贸易组织大会上的发言，说美国愿意放弃部分权利来解决健康危机的问题。这份回复明确了美国将不会反对泰国在这种情况下使用强制许可，并进一步强调这样的举动与TRIPS协议的精神是相吻合的。

虽然美国确认，根据泰国相关法律规定和国际协定，泰国使用强制许可是法定的权利，并且称美国不会采取报复措施，但泰国卫生部的决定依然没有得到改变。疾病控制部门要求政府制药组织只制造去胫肌苷的粉剂，并辩称，施贵宝已经将本公司生产的去胫肌苷片剂价格降低到了一个令人满意的程度。

对于参与抗议行动的艾滋病非政府组织网络和感染者而言，在泰国卫生部前面的抗议阵营以及随后的抗议运动以一种令人失望的方式结束了。然而他们的努力对疾病控制部门产生了一些影响，许多医生开始更多地关注抗病毒治疗政策，并最终推动了国家艾滋病感染者和艾滋病病人抗病毒治疗获得政策施行，这一政策为50000个人提供了抗病毒治疗。

现任的卫生部部长蒙克尔·那·宋克拉（Mongkol Na Songkhla）博士就曾经是这些医生中的一员。“一般来说，每当12月1日（世界艾滋病日）邻近时，病人们就会来要求这样的服务（抗病毒治疗），而这样的服务是我们那时永远不可能提供的。这是一种很典型的情况，我在食品药品管理局以及医疗服务部门工作时，就看见过他们，我们没办法帮助他们。当然，事实上有些事情还是可以做得到的，但是对这些问题的支持性（政策）不是很明晰”他回忆说。

彼时由感染者、各组织联盟、各非政府组织、学术界人士、卫生专家和律师组成的工作网络所推动进行的反去胫肌苷专利运动，不仅使得泰国社会得以觉醒，而且这一公

众运动和法律斗争，也为在其后展开的一系列泰国国内的药物获得运动提供了重要的支撑。

在艾滋病领域和消费者权益领域工作的非政府组织开始学习关于药物、法律和专利（的知识），以使得他们能够将他们的相关信息传布到国内的感染者组织当中去。

“那时我们感到很困惑，因为对我们来说，一切都是新的，以前我们对此一无所知，”赛恩斯里·特里马卡（Saengsiri Trimakkha）在《普通人之路》一书中，以诙谐的口吻做出了这一准确的结论。他当时是艾滋通路基金会的协调人，是艾滋病领域的非政府组织工作者的代表，他完全负责药物倡导运动这一工作。

“那时候，此前投身到这项运动和培训工作中去的在艾滋病领域工作的非政府组织，不得不因此开始完整地学习什么是抗病毒治疗，专利，与贸易相关的知识产权和世界贸易组织的相关知识。

与此相对，艾滋通路基金会的经理尼米特·天努达姆也做出了类似的回应（他曾经作为原告之一发起了对施贵宝的诉讼）。“我们那时不得不持续更新对法律事件的认识，并不断获取药学界在谈论的信息。我们必须获得关于药物、每种治疗方案及其效果的准确的信息。”

赛恩斯里和尼米特负责跟泰国艾滋病感染者网络以及与艾滋病相关的非政府组织打交道，他们必须纪录并理解不同的故事和细节，以使得自己能够将这些故事和细节简化后复述给在其他领域的朋友。这些活动的目标是寻求一个共识，并将少数感染者的支持者们推行的运动形成合力。事实上，正是这些支持者们使得全国范围内成千上万的感染者们加入了进来。

赛恩斯里回忆说：“我们四处奔波，在多达近100个区域和省级层面的论坛上传布关于专利、药物和各种社会运动的信息。”

这样，全国性的感染者网络形成了，该网络起先由61个感染者组织发起，继而扩展成为超过400个组织的参与。这些组织分别在国家、区域、省级和区级层面进行协调。现在，参与这一网络的组织数量达到了1020个。

这些感染者网络可以说是最为强大的学习和权利保障的网络。后来，他们在检审政府在自由贸易区谈判中的政策和推动强制许可的使用方面，扮演了一个重要的角色。

强制许可不是天上掉下来的，而是从根而生

政府制药组织的总裁威差·楚克威瓦特博士以这样一个问题，把我们带回到了40年前的场景。那时他还很年轻，并苦苦求索这一问题的答案：

“40年前，当我们在乡村改造营的时候，我们每天晚上都辩论并实践我们的演说技巧。有人提出为什么人们在生病的时候需要付费？为什么政府不给我们提供这样的服务？这些问题反复困扰着我。当我还是一个乡村医生的时候，我看到过很多人要么忍受疾病要么变得一贫如洗。他们不得不卖掉田地或者甚至他们的女儿，来换取足够的医疗费用。这是如此令人痛苦的经历，它促使我们梦想着有朝一日能够为病痛者提供免费的医疗服务。

“其实在1973年曾经一度有过免费的医疗项目。在1991至1992年间，一项社会保险体系开始运作。2001年，全民医疗服务制度开始实施，目的是为全国所有的公民都提供医疗服务。我没想到在我有生之年能够看到这样的变化。

“我们的下一个努力目标，是确保这些项目不会仅仅存在很短的时间就破灭掉。”

全民医疗保障制度或称之为金卡项目，原来最为人所知的标志是“每项医疗服务30泰铢”，到最后成为了一项集合了学术界人士、医疗卫生专业人士、艾滋病感染者网络和消费者的民间社会运动。这些社会活动家们力图运用1997年宪法的相关规定，收集了5万个合格选民的签名，支持推动向所有公民提供免费医疗服务的动议，但是没有效果。后来，泰国泰爱泰党采纳了这个理念，并将其作为自己政治纲领的一个部分。

开始的时候，全民医疗保障项目并没有涵盖严重并且昂贵的疾病治疗，比如艾滋病治疗。由于来自国内外的压力，国家医疗保障项目办公室（NHSO）2003年开始将艾滋病纳入医疗服务范围，这时该项目已经开始运行了两年的时间。

威差·楚克威瓦特医生介绍说：“在2004年曼谷举行的世界艾滋病日活动中，‘全面可及’运动得以推进。但是政府依然不能作出任何决定。我们在医疗界工作的人士也

无法确定未来的情况。我们不能确定我们是否应该采取较为‘理想化’的行动，因为那样的话也许会使政府方面变得更加不近人情。 但是，当政府制药组织将三种专利已经过期的药物进行组合，生产出了了本地的抗逆转录病毒药物‘GPO-VIR’时，事情出现了转机。克里沙娜·克莱斯图医生和她的研究团队对国家做出了巨大的贡献。GPO-VIR的生产是及时的，是一种不错的药物，并且使原来数千泰铢的治疗费用下降到每月仅1200泰铢。由于全球基金提供了部分的资金支持，所以我们决定开始我们的项目。”

无国界医生组织内森·福特（Nathan Ford）医生的研究显示：“多亏了仿制药品进入市场后所带来的价格上的竞争，使得每年的治疗费用从原来的40万泰铢下降到了14400泰铢（每年），下降幅度达到97%。”从2001年开始，艾滋病患者的死亡率也下降了79%。

威差医生说：“当我们决定将艾滋病纳入到医疗保障项目中来的时候，项目成员都意识到我们不得不同时使用专利药品。一些患者服用奈韦拉平时出现了副作用，而奈韦拉平是GPO-VIR的三种成分之一，我们当时没能成功地通过谈判获得依非韦伦的折扣价。2004年我们又努力了一次，该药的专利持有人默沙东公司同意降低药品的价格，但条件是卫生部要就此成立一个委员会，同时由FDA和国内贸易部进行监管，但是该谈判最后无疾而终。所以，我们不得不从知识产权法中寻找机会，**这实在是我们最后的招数了。**”

时任卫生部长的苏达特·克拉凡（Sudadart Keyuraphan）医生还曾要求疾病控制部门和食品药品监督管理局就关键药物进行价格谈判。当发现医疗系统中缺乏依非韦伦的时候，还曾经开展了一项关于使用强制许可的可行性研究。

但是这一切都成为了过眼烟云。

使用强制许可的真实需求

除了其亲民政策以外，他信·西纳瓦特拉(Thaksin Sinawatra）政权积极着手促进的另一个政策，是加快与18个国家的自由贸易谈判。迅速结束谈判并实施泰--美自由贸易协定，似乎是这位总理最想做的一件事。

由于美国未能实现在世界贸易组织的多边谈判中推动其支持更加严格的知识产权保护的主张，它必须借助了双边谈判，或者自由贸易协定，来推行其要求。

研究发现，美国从前与其他国家——比如新加坡、摩洛哥、约旦和澳大利亚等——签署的自由贸易协定中，都有相似的条款，即要求提供比TRIPS协定更严格的专利保护（超TRIPS条款）。对药品信息垄断权利进行扩大的专利保护，将使仿制药品进入市场的时间再延后五年。这些要求也会限制使用强制许可，破坏质疑专利有限性的程序，并更容易影响专利授权工作。

2005年12月，联合国开发计划署与世界卫生组织、联合国艾滋病规划署、卫生部以及朱拉隆功大学一起举办了一个研讨会，主题为自由贸易协定与知识产权：对药物可及性的影响。来自世界各地的学者应邀参会，分享了他们对于自由贸易协定与药物可及性问题的研究成果。

研讨会认为，美国超出TRIPS协议的要求，或者说超TRIPS条款，会影响泰国药物可及性问题的解决。会议对泰国提出了政策建议，敦促其全面保留TRIPS协议所允许的运用强制许可的主权。同时也建议对艾滋病二线治疗药物运用强制许可，并且拒绝接受自由贸易协定中超出TRIPS要求的内容。

会议的结论在时任世界卫生组织驻泰国办事处代表的威廉姆·阿迪斯（William Aldis）医生的一篇文章中有所介绍，并在2006年1月9日的曼谷邮报上发表。这正是泰--美自由贸易协定在清迈举行第六轮谈判的前一天。

此举激怒了美国当局，世界卫生组织被迫将阿迪斯医生撤离了泰国的职位。

在清迈举行的泰--美自由贸易谈判期间，来自11个全国性人民运动网络组织的大约1万名代表举行了示威游行。这11个组织分别是：泰国艾滋病感染者网络（TNP+）、农业替代网络、消费者组织联盟、四地区森林保护网络、北方农民联盟、四地区贫民窟网络、泰国人民组织网络理事会、国家企业工人同盟、泰国学生联盟和自由贸易观察组织。他们联合发表了一个声明，表示：

“我们反对他信总理的立场，因为他的政府用人民的生死存亡和福利幸福作为谈判筹码。如果政府坚持这样做，他必须明确这种政策的受益者是谁；为什么电信服务不进行自由化改革，因为他们与人民的生死问题毫无关联。

这十一个个人民组织网络一致要求政府终止与美国的自由贸易谈判，尤其是在以下领域：

1．**知识产权**，尤其涉及以下问题：

1．1 药品专利，政府同意了延长专利保护期限，取消消费者保护条款等超出世界贸易组织TRIPS协定规定和美国的合法要求；以及

1．2 对生命体的专利，这将对生物多样性和本地智慧造成负面影响

2．**农业的自由化**，农业自由化会导致美国将受到高度政府补贴的农产品，如玉米和大豆，向泰国市场倾销，并因此使上百万本国农民家庭失去支持；以及

3．**投资自由化**，即给予美国投资者相当于泰国公民的待遇，尤其是在公共事业方面，比如电气、供水和对国家粮食安全可能构成影响的农业投资。政府必须公开确保上述三个问题不会包括在泰--美自由贸易协定中，否则，11个人民组织网络将采取一切措施使谈判终止。”

虽然泰--美自由贸易谈判并没有完全停止，但是谈判者们不得不另找地址继续谈判。人民、知识和公众意志的力量使得泰--美自由贸易谈判充满悬疑，尤其是美国对医药产品专利保护提出的超TRIPS标准。许多人的担忧先前曾被认为是夸大其辞，但是美国在清迈第六轮谈判中向泰国谈判人员提交的详细要求被http://www.bilaterals.org 网站

曝光之后，这些担忧得到了证实。而且，后来知识产权部总干事卡尼松·纳瓦努格拉哈（Kanissorn Navanugraha）先生也承认曝光的这些材料是真实的。事实证明，那些看似悲观的担忧却是具有现实意义的观点。

更为糟糕的是，美国在泰--美自由贸易区协定中所提出的要求，比原先担心的还要过分。

朱拉隆功大学药学院社会医药研究所主任吉拉蓬·利姆帕纳南特（Jiraporn Limpananont）副教授总结说，制药公司通过美国的谈判团队提出了贪婪的要求。这些制药公司想尽了一切办法来利用这次谈判以达到多重利益目标。他们想要在药品市场、治疗和手术领域拥有垄断权，而这一切恰恰构成了救助生命的四大要素之一。他们想要毁坏泰国的卫生保健系统，尤其是国家医疗保障项目，以及国家自主医疗体系发展的机会。

许多在早期曾经强烈支持与美国谈判的政府经济学家，也开始同意持与此相类似的观点，即“这太过分了”。

对于泰--美自由贸易谈判会对泰国医疗体系带来破坏性影响的担忧，不仅仅来自于国际医疗保健机构。世界银行这样的超国家机构表示了同样的担忧。在世界银行的《艾滋病治疗的经济影响—泰国政策评估》报告中，对泰国发出了相似的信息。是时候勇敢出击和运用强制许可了！该报告评估了泰国卫生部三年来为了扩大艾滋病治疗所做出的努力，指出持续上升的治疗费用，对于政府而言将变得过于昂贵，从而使其难以继续通过国家抗病毒治疗项目提供抗病毒药物，而这个国家治疗项目已经得到了高度赞扬。

问题在于，新的药物都被授予了专利，而且比艾滋病患者现在使用的一线配方药物价格昂贵许多。根据世界银行的报告，还没有什么地方能够采取行动以降低这三种药物价格。政府运行治疗项目的预算将在15年时间内因此而上升5倍。

世界银行的报告清楚地指出，这可能意味着人的生命还不及贸易重要，“因为泰国力图通过双边自由贸易协定降低贸易壁垒，从诸如美国这样的贸易伙伴那里获得利益，

泰国政府在这样的诱惑前，可能或放弃在艾滋病药物上发布强制许可的权利，来换取贸易优惠。报告发现，这种权利让度的代价将是巨大的。比如，如果运用强制许可，可以使二线药物的价格降低90%，政府到2025年的治疗项目预算将节省32亿美元。”

要达到这个目标确实需要一个非常强烈的政治意愿。

接下去的问题就是：我们要做什么？

国家医疗保障项目办公室的药剂师素拉差·加木年达木荣卡恩（Sorachai Jamniandamrongkarn）在2005年下半年时曾说，泰国艾滋病感染者网络主席库马尔·乌帕靠（Kamol Uppakaew）先生曾经向当时的卫生部长皮尼基·加卢梭巴特（Pinij Jarusombat）先生递交过一封信。那封信敦请卫生部长使用强制许可来解决药价过高而导致贫困人口无法负担的问题。面对请愿者强烈反对泰--美自由贸易协定谈判和美国“比预计情况还要糟糕”的要求，国家医疗保障项目委员会决定谈论这个问题。

委员会成员中的一个学者在会议上指出，泰国甚至从来没有使用过TRIPS协定中的豁免权利。现在，与美国的谈判中又提出了更多的超TRIPS的要求，这会让TRIPS协定所允许的弹性规则无法发挥作用。因此，委员会同意，为应对国内的高药价问题和医疗保健服务问题，将考虑采用WTO规则的弹性。这样的努力将有利于提高药物可及性，也会同时使美国的渗透搁浅。

“国家医疗保障项目办公室秘书长桑沽安·妮塔亚卢姆风（Sanguan Nitayarumphong）医生，卫生部长兼委员会主席皮尼基先生都同意，强制许可是一个可以支持国家医疗保障体系的制度。他们决定该问题应该严肃对待并取得一个成功的结果。为此，成立了一个专门负责这个问题的工作小组。”

“2006年1月12日，政府使用药品专利及药物供应问题工作组成立，成员来自多方利益相关主体，包括卫生部长、商务部长、国务院、泰国法学会、医院医生以及艾滋病和癌症患者网络的成员。工作组设定了工作框架，并通过研究提出了结论性意见，建议

发布强制许可，生产依非韦伦。该建议得到了国家医疗保障项目委员会的批准。”

“这么说并不意味着我们在规避责任。虽然国家医疗保障项目办公室参与了这个过程，但它并不是整个运动的发起人。我想这应该归功于泰国艾滋病感染者网络，是他们与数十年来一直观察此事的学者们合作，才促成了最后的结果。国家医疗保障项目办公室只是一个支持者。”

“泰国成功运用强制许可并不是来自一个军政府仓促而自我满足的决定。这个由老练的前政府官僚们组成的政权之所以能够做成此事，是由于有了蒙克尔• 那•宋克拉医生这样的卫生部长，他的支持团队对这个问题已经十分精通。当人们向前卫生部长皮尼基先生提出同样的建议的时候，花了很长时间才有所进展，因为他的团队对这个问题知之甚少，需要从最基础的知识开始了解。竭尽全力让这些人理解这件事情以及不得不一遍遍地打电话与他们沟通，都不是轻松的事情。所以，皮尼基部长错过了在强制许可令上签下自己名字的机会。”

公共健康利益和人民的生命必须优先于商业利益

这句话被用粗体字印刷在泰国卫生部的白皮书上，以强调对三个专利药物发布强制许可来保障公共利益的法定权利基础及合理性。对这三个药品专利权的利用是出于非商业化的目的，且运用范围限于在三个政府福利项目中的患者：国家医疗保障项目、社会保障项目，以及公务员和政府雇员医疗福利项目。三个专利权被利用的药物是：艾滋病一线治疗药物依非韦伦，默沙东公司出品，商业用名称：施多宁，强制许可发布时间：2006 年 11 月 29 日；艾滋病二线治疗药物洛匹那韦/利托那韦组合，雅培公司出品，商业用名称：克立芝，强制许可发布时间：2007 年 1 月 24 日；心血管病治疗药物氯吡格雷，赛诺非--安万特公司出品，商业用名称：保栓通（Plavix），强制许可发布时间：2007 年 1 月 25 日。

卫生部发表的白皮书指出了做出强制许可决定的原因："药品是具有伦理意义的产品，对生命至关重要。对药品的适用条件应该区别于对一般产品的要求。**对作为基本人权的生命权的保护应该比保护商业利益更加重要。**因此，卫生部对这些药品专利的"政府使用"符合法律及人道的原则。这同样是政府在履行向所有享受医保的泰国公民按照国家基本药物目录提供基本药物的义务。"这将每年节省10.35亿至16.65亿泰铢的政府预算，能够获得基本药物的患者人数将因此上升6-12倍。该决定也受到了国内外民间社会的赞赏。

国家立法大会公共卫生委员会主席坦朴英·普瑞拉·卡瑟姆桑（Thanphuying Preeya Kasemsan）夫人在2007年2月20日致信称赞政府发布强制许可令。她说道，"这样的决定使很多人民受益，并将提高人民获得基本药物的比率。由于政府预算是有限的，这样的行动是合法的，也符合国际社会中普遍承认的国际规则。"

在给美国国务卿康多雷萨·赖斯（Condoleezza Rice）的一封信中，美国贸易代表（USTR）苏珊·斯克瓦布（Susan Schwab）要求美国停止干涉泰国运用强制许可一事，信中指出："不仅是对泰国，也是对发展中国家获得价格更可负担的仿制药品而言，泰国的这一决定是重要的。如果泰国开始向仿制药厂购买药品，那些仿制药厂就会

得到发展，引导积极的竞争并使得新药的价格得到普遍降低。”

“仿制药竞争升级带来的益处是有利的。但是到目前为止，发展中国家对于运用强制许可都犹豫不决，因为担心美国采取报复性措施或施加压力。

一方面，泰国卫生部对人民的生命权利应该优先于商业利益的承诺得到了实现。另一方面，这也攻破了那些以人的生命权利为筹码来谋取暴利的利益集团采用的所有伎俩。

美国药物研究与生产企业联合会（PhRMA）下属的药物研究与生产联盟（PReMA）是跨国制药企业间最有影响力的组织，它率先发起反对泰国运用强制许可的行动，宣称这是对私人财产的掠夺。它也发出了在泰国暂停投资的警告。

这些策略并没有奏效，因为泰国的行为既符合泰国法律的规定也符合国际条约的规则。另外，使用强制许可并不是对私人财产的掠夺，而是对一项合法的弹性规定的运用。而且，出于对专利持有人权利的承认，也会向其支付一定的费用。

根据泰国关于政府使用药品专利的声明，对专利持有人支付了0.5%的使用费，而专利持有人有权对使用费提出协商。但是没有任何专利持有人提出协商的要求。印度尼西亚和马来西亚在2004年发布政府使用强制许可的时候，也有过类似的经验。这是因为跨国制药公司不承认发展中国家的合法权利。他们谁都不愿意成为从其他国家接受使用费的先例。

跨国制药公司们也企图运用法律解释来反对泰国的强制许可。2007年2月15日，默沙东公司的法律代表提特勒 & 吉布森（Tilleke and Gibbins Co.）律师事务所向知识产权部提交了一份申诉，认为卫生部的强制许可没有遵循法定程序，并且没有和专利持有人进行先前协商。

当时，新闻报道说卫生部提请国务院对此进行解释。但是许多国际知名的法学专家，包括美国大学的布鲁克·巴克尔（Brook Baker）教授和西恩·福林（Sean

Flynn）教授、布宜诺斯艾利斯大学的卡洛斯·柯里亚教授和加利特·库安普斯（Jakkrit Kuanpoth）副教授，都对那份申诉表示了反对。

泰国艾滋病感染者网络的代表们和一些艾滋病非政府组织也举行了聚会，要求知识产权部的主席普安格拉特·阿萨瓦皮斯特（Puangrat Assawapisit）先生就此事进行澄清。2007年2月21日，知识产权部否决了制药公司的申诉，建议其就卫生部发布强制许可是否符合法定程序的问题，向行政法院提出起诉。知识产权部仅在当事人对专利使用费有异议的时候受理申诉。

除了亲自进行游说以外，跨国制药企业们也通过他们所在国家的驻外外交机构施加压力。

艾滋通路基金会的主席尼米特·天努达姆先生透露，雅培公司曾经要求和泰国艾滋病感染者网络的成员见面，以提供折扣价的克立芝为条件作交换，让网络成员去游说卫生部撤销强制许可决定。

与此同时，美国、欧盟、法国和瑞士的大使与泰国卫生部长、商务部长和外交部长进行了多次会面，表达了对于泰国运用强制许可的不满。他们都强调泰国没有履行事先谈判程序，而事实上，这种程序并非法律的要求。

另外，22个美国的国会议员，在亨利·瓦克斯曼（Henry Waxman）先生的带领下，向美国贸易代表发出公开信，敦促美国停止干涉泰国行使其法定权利的事务。贸易代表苏珊·斯克瓦布在回复中承认，泰国有权利发布强制许可。

泰国卫生部宣称："一直以来，我们的行为都做到了充分尊重多哈宣言，并使之与泰国适当地运用WTO弹性规则的权利相协调。"然而，多名共和党议员和说客（约1000多名被制药产业雇佣的对美国国会做工作的人），错误地声称泰国准备对20-30种专利药品发布强制许可，并因此敦促美国政府采取报复性措施来抵制泰国。

雅培公司的实验室则更采取了强硬的策略，它们向泰国药监局发出了一封信，声称将在泰国停止注册雅培的新药。雅培停止注册的药物包括：Zemplar, 用于治疗慢性肾病；Simdax，用于治疗心脏功能失调；Humira，用于治疗自身免疫性疾病；Aluvia片剂（克立芝片剂），一种艾滋病二线治疗药物的新热稳定剂型。停止注册药物正是为了报复泰国对洛匹那韦/利托纳韦，或称克立芝发布了强制许可。

《民意日报》（Matichon Daily）和《华尔街日报》（Wall Street Journal）的报道称，“雅培公司将不会申请新药注册申请，并将撤销所有在泰国的新药注册申请，直到泰国政府认真对待知识产权，包括采取撤销强制许可的行动。”

当雅培的行为被广泛报道之后，艾滋病感染者网络、艾滋通路基金会、艾滋病权利中心、泰国艾滋病NGO联盟和消费者联盟共同谴责制药企业向泰国政府施加压力，因为泰国政府只是在努力扩大国内医疗服务项目中药物全面可及的范围；这样的行动反映了制药产业持续而无休止的贪婪，以及对人民权利的完全漠视。这些持反对观点的组织敦促泰国人民抵制雅培的产品，并转向购买其他厂商生产的仿制药和其他替代商品。

抵制雅培的运动深入到了父母网络、乡村医生俱乐部、乡村药剂师俱乐部以及肾病和心脏病患者的网络之中。这些组织网络都反对雅培在泰国政府没有违反任何国内法和国际法的情况下，挟持患者和消费者来威胁政府撤消强制许可的做法。

对雅培公司的愤怒在全球范围内上升并蔓延开来。2007年4月26日，雅培公司在美国芝加哥召开年度股东会议的前一天，在雅培公司办公室门前的示威活动在全球各地同时举行，包括美国、法国、英国、德国 、印度、南非、中国、巴西、阿根廷、澳大利亚、加拿大、印度尼西亚、日本和新加坡，这些活动同时敦促公众抵制雅培产品。在法国，艾滋病感染者组织ACT UP组织了一个名为“网上罢工”的网络示威活动，最后导致了雅培公司网站的瘫痪。

当雅培的年度股东大会在芝加哥举行的时候，泰国的一个前国会议员兼艾滋通路基金会秘书长周·乌帕克恩（Jon Ungphakorn）和泰国艾滋病感染者网络TNP+主席韦拉

特·普拉洪（Wirat Purahong）先生应邀作为宗教团体股东的代表出席，并质疑了雅培的不道德行为。

位于麦迪逊的威斯康星大学在校学生和毕业校友联合签署了一封公开信，以全球学生抗击艾滋病运动的名义发送给了威斯康星学联研究基金会。公开信呼吁基金会谴责雅培利用由该校发明的肾病药品Zemplar作为要挟泰国政府放弃强制许可决定的筹码。

公开信这样写道："基于这些原则，我们希望基金会能够公开敦促雅培立即恢复申请注册Zemplar。4月27日，患者、医生和全世界的其他人将在雅培举办股东大会的之际共同关注雅培的举动。泰国患者社区的领袖们将利用这个机会直接与雅培的管理层对话，要求他们不要把药物当作政治谈判的工具，不要把患者当作政治对抗的筹码。"

"我们要求，作为这其中一种关键药物的专利权人，威斯康星学联研究基金会在为发展中国家的正义呼吁中发出其独特和有力的声音 。"

世界各地都表示不能接受雅培的自私行为。当持有雅培股份的宗教团体也开始谴责雅培并呼吁其停止其行为时，转折点出现了。

最终，为了挽回自己的错误决策，雅培只得和世界卫生组织总干事陈冯富珍合作，发布了一个全球降价计划，将克立芝在中低收入发展中国家的售价从每人每年2200美元降至1000美元。但是这个降价优惠只有在泰国取消在新的热稳定剂型克立芝（Aluvia，即洛匹那韦/利托纳韦）上发布的强制许可之后才能在泰国适用。

泰国的民间社会在消费者基金会、艾滋通路基金会、艾滋病感染者网络和泰国艾滋病NGO联盟的领导下，力图促使对雅培公司的行为适用商业竞争法。他们认为雅培违反了1999年（泰国）竞争法（B.E 2542）第25（3）和28条的规定，并呼吁竞争委员会追究其作为一个商业经营者进行市场垄断的法律责任。

"这会产生一种不合理的现象，即取消进口，并将导致可备选的具有相近疗效的药品数量减少，甚至减少至无法满足向需要药品的患者提供医疗服务的程度。"

“竞争委员会应根据竞争法第31条的规定，责令雅培实验室申请注册其新药，并重新递交其从泰国撤回的10种药品注册申请。”

而与此同时，制药企业也更为变本加厉地展开了媒体和公关攻势。

许多国外媒体，尤其是《华尔街日报》，严厉地批评泰国违反了知识产权规则。同时，其他一些媒体使用“打破专利”或“跨越专利”等字眼，试图营造违反法律之意的暗示，尽管那些文章可能承认泰国的行为是WTO规则所允许的。

最让人难以忍受的，是一个号称非营利组织的团体“美国创新（USA for Innovation）”所发起的充满诽谤意味的运动。它在泰国和国际的媒体上购买了广告位，并建立起了自己的网站，谴责泰国军政府通过非法发布强制许可，将泰国变成了一个象缅甸那样的独裁国家。这个组织还声称，政府制药组织生产的GPO-VIR质量低下，并向美国议会和政府递交建议，敦促他们对泰国采取报复行动。

美国创新组织的举动十分引人注目，这倒不在于其行动的内容如何，因为其核心主张已经被卫生部和医学专家所否定。这个组织之所以有趣，是在于它和Edelman国际公共关系事务（公关公司）所之间的关系。该公关公司的客户包括了许多跨国制药公司，并和因被指控贪污而遭驱逐的泰国总理他信也有关联。

《曼谷邮报》和《国家》杂志分别用了一整版来报道泰国民间社会对美国创新组织的回应：

“美国创新组织是一个为美国制药企业利益服务的组织，这些企业由于泰国运用了WTO所允许的强制许可而感到沮丧。这个组织惯于用扭曲和操纵事实的手法来达到其目的。”

“几天前在英文媒体见诸报端的一则宣传稿中，美国创新组织歪曲事实，认为泰国政府制药组织生产的抗病毒药物毫无价值。但真相是，GPO-VIR在降低泰国艾滋病患死

亡率的努力的过程中扮演了重要的角色，因艾滋病死亡的人数从2001年的8246人下降到了2006年的1613人。在过去三、四年的时间中，这挽救了数以万计的生命。美国创新组织引用了玛希顿大学的研究数据，来证明GPO-VIR造成了39.6-58%的耐药性，但事实上，这项研究所针对的是长期接受治疗并且已经治疗失败的患者的耐药情况。目前还没有研究结果来比较GPO-VIR和其他同类药物之间耐药几率的异同。”

“泰国为达到全面医疗保障的目标和确保艾滋病患者治疗药物全面可及方面所作出的努力已经得到了国际社会的认可。发布强制许可的决定表明了泰国政府和卫生部勇气可嘉，他们将泰国人民的生命权利置于商业利益之上进行保护。”

政府制药组织（GPO）正在以诽谤名誉的理由起诉美国创新组织，并要求其支付数十亿泰铢的赔偿。

泰国卫生部疾病控制司的专家苏韦特·维布尔普拉斯尔特（Suwit Wibulpolprasert）医生回忆起泰国面对多方压力和反对而运用强制许可的艰难历程。他说，当蒙克尔·那·宋克拉医生就任卫生部长时，由于前部长皮尼基先生的保守，国家医疗保障项目办公室关于使用强制许可的提议已经被搁置了很长时间。

苏韦特医生回忆道，“他（部长）让我研究强制许可问题的合法性问题。我问他是否确定要这样做，因为这是很大的一件事情。他回答说，如果这有助于帮助贫穷的人们得到药物，他将这样做。我再次问他，是否咨询过总理，他说总理了解并且说如果事关重大就尽管去做。”

“所以，我请部长的秘书召集各相关方开会，包括知识产权部、国务院、国家医疗保障项目办公室和泰国法学会，来谈论我们运用强制许可是否合法。在开会的那天，我学到的第一件事情，就是TRIPS协定第31（b）条和泰国专利法第51条的内容，它们规定在特定的情形下，如为了公共非商业性目的使用而运用强制许可，专利持有人应该立即得到通知。我想我们应该尽快告知我们的意图，以保证整个过程的透明。”

“但当我们发布声明的时候，制药企业抗议了。我再次询问蒙克尔部长，总理是否真的批准了强制许可的决定。部长说，总理非常了解事态进展，但是提醒我们保持谨慎。”

“当认为我们的强制许可不合法的抗议越来越激烈的时候，我给我们在海外的同盟者们发出了邮件询问原因。在强制许可令发出之前，我们没有和这些网络有太多的沟通。当反对的声音越来越强烈的时候，我联系了第三世界网络的马丁·科恩（Martin Khor）、布宜诺斯艾利斯大学的卡洛斯·柯里亚教授和知识生态国际组织的詹姆斯·拉夫（James Love）先生。詹姆斯·拉夫最先回复了我的邮件，他肯定地说，我们没有做错任何事。我们真的学到了许多。”

当被问及他的团队是否曾经因受到反对而士气低落的时候，苏韦特医生立即回答说：“挫败感是时常会有的，我们不过是普通的人。我们无法改变局面。但是当有了更多的支持者之后，我们决定开始还击。当我最后一次问蒙克尔部长，总理是否同意强制许可的时候，他攥紧我的胳膊说：‘你已经问过我三遍了，医生’，但是我依然不能信服。后来有一天，我遇到了总理和联合国艾滋病规划署的主席彼得·皮奥特（Peter Piot）先生。我亲耳听见总理告诉彼得，泰国由于发布强制许可而受到了严重的影响和压力。但是为了公众的利益，这依然是必需做的。从那以后，我就再也没有疑问了。”国家医疗保障项目办公室秘书长桑沽安医生说，当他明白了蒙克尔医生作为卫生部长的意图之后，他倍感欣慰并立即开始和整个团队一起为之工作。

“蒙克尔医生就任卫生部长让我感到非常高兴。我告诉他，我有一项未完成的使命。他首先告诉我要认真地确认商务部是否参加这个过程。我告诉他所有相关方面都已经会谈和咨询过。他们中没有任何人反对这一行动。”

“当事情变得沸沸扬扬之后，我曾经担心他，并曾经接受采访以表示支持他的工作。但是事实表明，他比我想象的更加意志坚定。因为这是为了公众的利益，蒙克尔医生决定为之奋战到底。他真地应当受到赞扬。”

“我并不担心蒙克尔医生会感到沮丧。我已经启动并敦促整个计划的施行，所以我必须对此负责。但是我的担心来自于我的团队或许将一个身居高位的官员放到了一个困难的境地。现在，看到他意志坚定，我感到轻松多了。并且，整个过程进展得很不错。”

“正如我们预料的那样，这件事情的影响力不仅限于国家层面。但是令人振奋的是由此而形成了国际社会团结支持我们的力量。以前我曾经预计我们运用强制许可能会得到一些支持，但是没有料到现在这种支持竟然如此广泛。这证明了呼唤正义的力量是无处不在的。一旦有非正义出现，这些力量就会出现并采取行动。”

恶性循环的回归：恐惧与奴役的陷阱

2007 年 5 月 1 日，美国贸易代表把泰国从关注目录提升到了优先观察目录（PWL）中。尽管美国驻泰国大使拉尔夫·博伊斯坚持声称，这一举措与泰国颁发强制许可无关或原则上无关，但美方在超级 301 条款报告上依然非常明确地做出了如下表述：

“除了继续对泰国知识产权保护不力表示担忧以外，在 2006 年底和 2007 年，泰国政府宣布对一系列专利药品实施强制许可的举措，进一步地削弱了专利体系。”

朱拉隆功大学消费者卫生保护项目副教授维萨亚·库颂木布（Vithaya Kulsomboon）争辩说，认为泰国政府在颁发强制许可过程中缺乏透明度和程序正义的说法是站不住脚的。这种说法可以被认为是一种威胁，以迫使泰国终止其为急需救命药的患者提供药物的努力。

“泰国和国外的法律专家、立法者和很多国际学术机构都认为，泰国就三种专利药颁发强制许可的做法是合法和符合道德的。尽管很多致力于药物可获得性的国际组织都对泰国颁发强制许可的行为提供了热情和广泛的支持，美国依然在通过贸易制裁措施打击泰国的努力。值得注意的是，美国驻泰国大使拉尔夫·博伊斯一直否认那些贸易报复措施是在制裁泰国向三种药物颁发强制许可。但美国在曼谷使馆的经济事务参赞詹姆斯·卡洛索一直在批评泰国政府颁发强制许可的行为缺乏透明度和程序正义。”

不仅如此，超级 301 报告反映出美国一直在积极推行超 TRIPS 条款，而这种举措随着美泰暂停自由贸易区谈判而告停止。

“美国推行优先观察目录举措的另一个特点，就是通过指责泰国未能达到美国关于数据独占性保护和仿制药注册专利链接，从而阻止仿制药在专利到期前上市的要求，来推动超 TRIPS 条款。所有的这些借口都为美国在今后的美泰自由贸易谈判中提出更高的要求铺平了道路。”

在泰语商务报纸 *Prachachat Thurakit* 的一份报告中，引用了商务部官员的一段话，称美国已经向泰国提出了一份行动计划，只有照做才能从优先观察目录退回到关注目录之中。这个计划与美国在 2006 年初第六轮美泰自由贸易谈判中的要价基本类似，包括：

- 按照美国的要求修订所有的知识产权法律；
- 把一些违反知识产权的行为视为刑事犯罪；
- 加入专利合作条约（PCT）；
- 延长 20 年的专利保护期；
- 不允许专利批准前的异议；
- 把颁发强制许可的条件限定在国家紧急状况下；
- 颁发数据独占权。

在 2007 年 5 月 18 日，泰国国家人权委员会发布了一项声明，敦促美国政府停止影响与药物可获得性相关的人权的措施。委员会对泰国政府不肯接受超出 TRIPS 条款的额外要求的立场表示了支持，同时对政府颁布强制许可以满足人民用药需要表示了赞赏。

幸运的是，泰国商务部并没有屈服于美国政府的建议。在 2007 年 5 月 8 日接受《泰叻报》采访时，商务部部长卡伦·克特萨塔蓬（Karun Kittisataporn）表示，他已经指示了知识产权部部长普安格拉特·阿萨瓦皮斯特（Puangrat Assawapisit）女士，不接受美国方面提出的任何要求。鉴于一部分美国方面的要求可能已经在泰国能力范围之外，或者超出了泰国有义务遵守的国际协议的范围，在该部做出任何行动之前，必须咨询所有相关机构并获得泰国内阁的批准。

“接受美国方面提出的行动计划，从而使得美方将泰国从优先观察目录中移到关注目录，这是我们可以做的事情。但是这并不意味着美国方面就会满意。我们可能还是会被留在优先观察目录之中。但是我还是决定不满足美方的条件，因为它们已经超出了我

们的能力范围。在过去的谈判中，如果我们想要从优先观察目录中被移出，美方都会要求我们采取一系列的行动，而这其中很多都是过分的要求。”

卡伦先生进一步表示，留在优先观察目录之上可能导致美国减少泰国产品的关税普惠制收益，这很可能只是一种警告。在过去，美国从来没有因为超级 301 审查而减少任何国家的关税普惠制收益。卡伦先生相信，泰国出口商的生产能力很强，在美国市场也有着很强的竞争力。即便是取消了关税普惠制收益也不会带来太大的问题。所以他认为就算是放弃了关税普惠制收益也是一种可能的选择，而且这样美国就再也不能用这个机制来压制泰国了。

他说：“被放在优先观察目录上也不是一个大问题，我认为这个事情被夸大了，让所有人都担心。美国用这种担心来当作讨价还价的筹码。在就行动计划进行谈判的时候，我们还是有法可依的。即便是削减关税普惠制收益，也必须依照有关法律法规的要求进行。侵犯知识产权不是唯一的标准。但是，我们也要知道美国掌握着向任何国家颁发或不颁发关税普惠制收益的独占权力。当然，我还是有信心，认为泰国不会被列入到优先外国国家的目录之中。

在 2007 年 5 月 9 日，知识产权部部长普安格拉特·阿萨瓦皮斯特在接受媒体采访时明确表示，商务部不会接受任何超出国际协议要求的额外条件，包括美国提出的被纳入到美泰自由贸易协定中的数据独占权保护。

这个反馈意见暂停了知识产权部此前向内阁办公室提出的专利法修正案。卫生部和民间团体对该修正案提出了批评，认为它与美国在第六轮美泰自由贸易协议谈判中提出的要价类似。

“学术界和民间团体继续对专利法的修正案进行监测，并发现商务部所提出的草案需要进行修改，以获得最大化的收益。原则上来说，修正案草案应该基于以下原则：

1. 为泰国和本国各利益集团带来最大化的收益；

2. 为专利制度的发展作出准备，使其专注于保护患者/消费者的利益，同时鼓励发明人和向泰国人转让技术；
3. 遵循且并不超出《与贸易有关的知识产权协议》（TRIPS）和《关于 TRIPS 协议和公共卫生的多哈宣言》（2001 年 11 月 14 日颁布）；
4. 遵守泰国已接受的国际协议；

与 1985 年至 1992 年那个时代不同，商业界这次很明显地并没有向政府施加太大的压力，要求修订专利法以满足美国的需求。

泰国贸易委员会的贸易分委会主席布通·汪色拉书特（Butoon Wongseelashote）先生在一个名为"强制许可：经济和社会角度"的研讨会上指出，贸易委员会同意泰国政府颁发强制许可。他认为，把泰国被列入优先观察目录从而损失关税普惠制收益和颁发强制许可两者联系起来是一个误解。这两个事件，优先观察目录和强制许可，是两件分开的事情。

在 7 月 1 日，他进一步表示说，美国为泰国出口产品所提供的关税普惠制收益会被削减。但是也不用为此杞人忧天，因为很多产品，例如冻虾、珠宝、橡胶、黄金，本来就是要被解除关税普惠制收益。因此，是否颁发强制许可，对这些产品是否会失去关税普惠制收益并没有什么关系，毕竟这些产品在市场上本来就具有足够的竞争力。

"很多企业家担心颁发强制许可会导致更多的产品失去关税普惠制收益，从而使得其在美国市场失去竞争力。但是，在事实上因为汇率问题，我们早就无法与其他国家的产品进行竞争。出口问题主要是源于泰铢的过度升值。泰国银行已经就这个问题做出了解释。所以现在也没有必要紧张，或者责备强制许可导致了关税普惠制收益的削减。如果 40 泰铢能换 1 美元，我将很高兴没有关税普惠制收益。"

布通先生赞扬了巴西的强制许可，认为其时机很恰当。在得知美国将哪些国家置于优先观察目录之后，巴西在 2007 年 5 月 4 日宣布实施强制许可。如果美国想把巴西放在优先观察目录中，他们必须得等到 2008 年才行。所以泰国下一轮的强制许可，应该在每年 4 月 30 日之后再颁发。

贸易委员会的贸易分委会主席进一步阐述了关于专利产品尤其是专利药品方面的知识产权制度。制药公司应该基于各国的平均国民收入来确定药品在当地的价格。举泰国为例，泰国的平均国民收入约为美国的 1/5。如果一种教科书在美国的价格是 1500 泰铢，那么其在泰国的价格就应该是 300 泰铢。类似的定价也应该适用于药品。但是正好相反的是，在泰国销售的药品价格只比诸如美国的发达国家的价格便宜 10%或不到 150 泰铢。

在 2006 年 5 月，泰国发展研究中心（TDRI）的研究员吴拉杜·图尔拉克（Woradul Tularak）发表了一篇题为《用关税普惠制的小苍蝇来钓自由贸易协定这条大鱼？》的文章，生动地描述了美国的贸易战略：

“最近不断有报道宣称，如果泰国不能在今年完成与美国的自由贸易协定谈判，美国将削减其给予泰国的关税普惠制收益。与此同时，泰国商务部表达了对因为关税普惠制收益减少而给贸易带来损失的担忧。到目前为止，我们还不清楚美国是否会将定于 2006 年底到期的关税普惠制继续延长五年。”

“美国授予他国关税普惠制需要很多要求，比如国家发展水平。例如，在 2002 年，国民平均收入超过 9266 美元的国家将自动失去其关税普惠制。此外，一个获得关税普惠制的国家还必须确保其市场向美国的产品和服务开放，确保提供严格的知识产权保护、劳工保护、清晰的投资政策，并减少贸易和投资限制措施。”

“美国提出的另一个条件是，一旦某种产品在美国市场的份额超过 50%或者总进口量超过了上限（该上限每年都在变化），那么美国也将停止其关税普惠制收益。在 2006 年，该上限大约是 12.5 亿美元（大约 50 亿泰铢）。但是，如果全球向美国出口的该货物仍少于该上限，则该出口国依然能保有其普惠制收益。”

到目前为止，美国已经基于各种原因取消了对一些国家和地区的关税普惠制。例如中国台湾、新加坡、中国香港、韩国等都因为其经济发展的高水平及相应的竞争力而失去了普惠制地位。以色列丧失普惠制地位的原因是其国民收入超过了要求的水平，阿根廷是因为保护知识产权不力，而尼加拉瓜和乌克兰则是因为违反了劳工权利。”

“在 20 种符合关税普惠制的出口产品中，最依赖美国普惠制的那些产品将收到最大的冲击，这些产品是珠宝、装饰品、餐具和铝。最不受影响的产品则是石化产品和塑料制品，因为这些产品向全世界其他国家都有出口，且不受美国的普惠制影响。”

“最重要的是，如果普惠制收益被取消，泰国企业就得按照通常的进口关税来出口，而这并不构成任何问题。目前塑料容器、珠宝和彩色电视机的关税分别是 3%、5.5%和 3.9%，泰国出口商还将继续保持其竞争力。”

“泰国不用太在意美国的威胁，仅仅因为失去普惠制收益就急于结束与美国的自由贸易协议谈判。仓促同意签署自由贸易协议，从而对知识产权给予更严格的保护，这并不是一个明智的决定，因为它将带来更广泛更永久性的影响。”

泰国是否能够摆脱这个恐惧与奴役陷阱的恶性循环，让我们拭目以待。

泰国强制许可的影响

2007 年初，从印度兰伯希（Ranbaxy）公司购买的第一批伊菲韦伦（Efavirenz）运抵泰国。该药品的价格下降很多，由每人每月 1400 泰铢降到了只有 650 泰铢，从而可以为 20000 人提供药品。在泰国颁发强制许可后不久，伊菲韦伦专利持有者默沙东公司宣布在全球的发展中国家和主要艾滋病流行国家（包括泰国）降低药品价格。该药品原来的价格是每人每月 1500 泰铢（医院价格为 1300 泰铢），而降价后的价格成为了 700 泰铢，从而可以与仿制药进行竞争。很多发展中国家都从泰国的强制许可中受益。

蒙克尔·那·宋克拉博士表示："我与默沙东公司达成了协议，如果该公司的药品价格不超过仿制药价格的 105%，我将从该公司购买药品。但是我们也保留继续购买仿制药的权利，以确保以后不会出现反复。每次我们要购买药品的时候，都会比较仿制药的价格。如果默沙东公司的价格不比仿制药高出 5 %，我就会从他们那里购买一些，同时也从仿制药生产企业购买另一批。默沙东公司希望与我们达成长期购买协议，但是我们没有同意。"

国际新闻社（Inter Press Service）报道说，巴西卫生部已经致信泰国政府，了解泰国强制许可的情况。这封信明确表示："泰国的强制许可对巴西非常有启发。"

在犹豫了很长时间之后，巴西于 2007 年 5 月 4 日做出了重要决定，就伊菲韦伦颁发了其第一个强制许可。这个决定有很多内容是直接翻译自泰国卫生部的白皮书。

在泰国，只有 20%的需要稀释血液药物氯吡格雷的心脏病患者有钱购买该药品。毫不奇怪的是，心脏病目前是泰国第二大致死疾病。药品价格过高，使得政府无法向患者提供福利。该药品的零售价格是每片 140 泰铢。在政府医院该药品的价格虽然是 73 泰铢，但相比于印度生产的仿制药只有 6 到 12 泰铢的价格，原研药依然过于昂贵。有了强制许可，可预见能获得该药物治疗的患者人数将增加 6 到 12 倍。在写作本文的时候，塞诺菲-安万特公司已经将价格降低到了 22 泰铢每片。

“如果心脏病患者可以获得仿制的氯吡格雷，心脏病致死率将显著下降。”蒙克尔博士表示。

在对泰国的强制许可做出恐吓性反应之后，雅培公司在全球都受到了谴责。该公司不得不宣布将其治疗艾滋病的二线药物克立芝（Kaletra）的价格，由每人每年 2200 美元降低到 500 美元（贫穷国家）或 1000 美元（中等收入国家），约合每月 3260 泰铢。在实施强制许可之前，该药品的价格是每月 11580 泰铢。该公司还表示，如果泰国不继续向 Aluvia（Kaletra 的新剂型）实施强制许可，那么就可以在泰国适用上述降低的价格。但是雅培公司没有提及撤回其 6 种药品的 10 项注册申请一事。

在另一方面，泰国卫生部与其他十六个发展中国家一起参加了克林顿基金会主导的集体采购，以每人每年 695 美元的价格采购到了所需的药品，低于雅培公司的报价。看起来克立芝的价格还将得到进一步的降低。

威差医生表示：“我们通过克林顿基金会进行谈判，帮助向印度的仿制药厂提供原材料，以帮助十六个发展中国家一起进行集体采购。事实上，基于优质低价的原则（而不是相反），克林顿基金会向包括原研药厂和仿制药厂在内的所有生产企业都提出了购买其药品的要约。这也符合中国的一句老话，薄利多销利润更大——这种利润更加健康，也更加持久。因此，价格被降低到了 695 美元。”

苏韦特·维布尔普拉斯尔特博士谈到了此事的相关背景。“当蒙克尔博士正在就 Khorat 开展工作的时候，他也开始着手通过集体采购将药品价格降低 30%。当阿赫梯·乌拉伊拉特（Arthit Urairat）博士成为卫生部长之后，他被告知蒙克尔博士有效降低 Khorat 采购价格的做法，于是决定将继续采取此项政策。”

“克林顿基金会的代表约见了我，并问我泰国是否有兴趣加入艾滋病药物的集体采购。于是我邀请蒙克尔博士来听取这一汇报，他立刻同意开绿灯，因为他此前就这么干过，也知道这种做法的好处。但是当我们最终可以单独获得更便宜的药物时，我们也就没有必要再参加集体采购了。”

泰国历史性的强制许可决定在全球取得了里程碑式的影响，这主要是因为以下原因：

1. 作为一个发展中国家，泰国大胆地连续两次宣布就昂贵的专利药颁发强制许可，而且随后还很有可能要继续颁发。这与其他一些国家的做法是不同的，因为那些国家往往只是颁发一次强制许可，随即就销声匿迹。

2. 除了艾滋病药物以外，泰国还就心脏病药物颁发了强制许可。此前，美国在世界贸易组织会议上一直建议将 TRIPS 协议和多哈宣言所赋予的弹性限制在艾滋病、疟疾和结核病上面，当然并没有获得成功。但是，此前并没有一个发展中国家曾经宣布就心脏病药物颁发强制许可。

3. 泰国的强制许可突出了本国和海外仿制药生产企业的重要性，并使得国内制药工业对此产生越来越多的兴趣。

4. 泰国的强制许可从根本上动摇了现有的专利制度。基于专利制度，认为垄断性的权利请求将促进研究和开发的想法被看作是不正确的。现在，制药工业的兴趣不在生产那些救命的药物，而在于为富人生产那些生活方式类药物，并通过严格的知识产权保护来垄断并攫取最大化的利润。

5. 泰国的强制许可很清晰地暴露了跨国制药企业的不道德，也暴露了美国的政治在很大程度上受到了制药工业的影响。

6. 泰国的强制许可鼓励其他国家（尤其是那些发展中国家）去质疑现有的制度。

在 2007 年 5 月 14 日至 23 日于日内瓦召开的第六十届世界卫生大会之前，国际医疗人道救援组织无国界医生（MSF）向世界卫生组织各成员国代表发出了一封公开信，敦促各国关注全世界人民的药物可获得性问题。

世界卫生组织政府间工作组（IGWG）的一份报告指出了药物可获得性和研发失败问题。世界卫生大会应该严肃地考虑其全球战略，以解决这些问题。

在无国界医生向世界卫生组织各成员国提交的信上，包括以下一些内容：

世界卫生组织成员国应该坚决要求世界卫生组织在研究药品可获得性和知识产权制度方面发挥作用。世界卫生组织的作用不能仅仅被限制在那些最受忽视的疾病上，也不能让其他机构，如世界贸易组织、世界知识产权组织来替代其行使职能——因为没有任何一个国际组织能够替代世界卫生组织在公共卫生方面的职能。

世界卫生组织应该积极向有提高药物可获得性需求的成员国提供政策和技术建议，使用在多哈宣言上被认可的 TRIPS 的弹性条款。世界卫生组织在对待泰国颁发强制许可一事上提供的支持不多，这使得很多人担心该组织促进各国获得药物的发展方向是否会动摇。现在世界卫生组织和世界卫生大会应该旗帜鲜明地表达其对使用专利法弹性条款以促进药物可获得性的支持。

世界卫生组织政府间工作组应该确认解决药物可获得性问题的方法，并制订创新性的方法，把药品价格和研发费用支付系统分离开来。通过专利制度和昂贵的药品价格来为研发提供激励机制，导致了发展中国家广大人民的药物可获得性问题——尤其是那些制药公司在全世界范围内注册其药品专利，从而将全球的仿制药生产资源一网打尽。因此，政府间工作组应该基于将药品价格和研发费用支付系统分离开来的原则，来找到新的解决方法。必须考虑新的财政激励机制，例如税收机制、关于基本疾病的研发协议和研发奖励机制。

5 月 23 日，经过长达 9 个半小时的讨论，《关于公共卫生、创新和知识产权的决议》终于完成。只有美国拒绝接受该决议，并离开了会场。

泰国代表彭洒红·普科皮穆德（Pongsadhorn Pokpermdee）博士参加了本次会议的全过程，他报告说：

“世界卫生大会同意，世界卫生组织将于其他机构一道，为需要根据 TRIPS 协议和其他潜在国际协议（包括双边自由贸易协定或自由贸易区协定）来使用强制许可机制的发展中国家提供技术和政策建议，并就此问题进行研究。大会鼓励所有的国家都参加关于公共卫生、创新和知识产权的政府间工作组。世界卫生组织被要求来支持区域性的相关会议，支持政府间工作组的工作，从而创造新的研发激励机制，并研究在支付研发费用和开发每种药物之间的关系。”

彭洒红博士在报告的最后部分说道：“这一决议表明：

1. 泰国和巴西使用强制许可是符合 TRIPS 协议和多哈宣言的；

2. 在世界卫生组织所有成员国中，美国是唯一不同意该决议的。即使是发达国家，例如欧盟、加拿大、英国、澳大利亚、新西兰和斯堪的纳维亚国家，都接受了本决议。

3. 从现在开始，世界卫生组织可以向那些需要为公共卫生利益和药物（以及非药用产品）的可获得性来使用 TRIPS 协议弹性条款的国家，提供技术和政策建议。”

因此，泰国的这一壮举不仅仅是一个小国为自身利益所作的决定，更是一个发展中国家的重要举措：他们站起来告诉世界，**是站出来抵制和谴责制药行业无耻而欲壑难填的垄断性权利的时候了！**

移开大山的全球铁三角

泰国的强制许可不是巧合，也不是从天而降的馅饼。这个决定有着深深的基础。长期以来，强制许可之树都得到了精心的呵护，并终于结出了丰硕的果实。

在全世界范围内，一些国内和国际机构纷纷参与到此过程中，这是国际合作的重要产物。

有记者向泰国卫生部长蒙克尔博士提问，询问他对其团队在颁发强制许可所需要的数据和法律精确性是否具有信心。蒙克尔博士回答说：

“这个工作团队具有非常丰富的知识，并且涉足这个领域已经有了很多年。我们不仅与国内联盟精诚合作，而且也和很多国际组织密切联系，共同研究制药行业和诸如 TRIPS 和多哈宣言的国际协议。甚至有超过 20 名美国的国会议员支持了我们的斗争。”

“除了国内协调以外，我们也在寻求与其他贫穷的发展中国家建立联系，因为他们也有权照顾本国贫穷的人民。这就是为什么我们的工作团队包括那么多人，大家在卫生部、国家卫生安全办公室、大学和海外一起团结工作。”

回顾当年为获得去胫肌苷所进行的努力，整个运动的主角包括以下三方：

- 协调整个网络的联系组织：艾滋通路基金会、消费者基金会、卫生和发展基金会，他们负责将信息转达给各个艾滋病非政府组织和艾滋病患者。

- 学术和信息组织：药品研究组织、社会药房行动研究组织、卫生和发展基金会、无国界医生组织（比利时）。（通过其学术研究活动，泰国和政府制药组织的研究和发展机构帮助分析了去胫肌苷在泰国和世界其他国家的专利情况）

- 泰国律师协会的律师们。

强制许可运动是另一个重要的发展步骤，*Prachachat Thurakit* 商报称之为**患者权利的三线战斗：**

- 国家层面：通过卫生部、国家卫生安全办公室、政府制药组织、食品药品管理局、知识产权司和国务院。

- 公共利害相关方层面：对于坚持和要求在考虑商业利益的同时，必须兼顾患者权益和卫生改善，从而促进国家和经济发展这个领域，泰国 HIV 阳性人群网络（TNP+）有着长期的经验。这项争取强制许可权利的斗争，使得新的患者网络不断涌现，例如慢性肾病、心脏病和肿瘤。

- 民间社会层面：这些民间团体包括医学、药学、法律等学术机构，自 1985 年以来他们就不断地监测着有关情况。这些组织包括：药品研究组织、社会药房行动研究组织、朱拉隆功大学消费者健康保护项目、农村药师基金会、农村医生基金会、泰国法律协会、在艾滋病和消费者权益方面的非政府组织、艾滋通路基金会、AIDS 权利中心、泰国 AIDS 非政府组织联盟、消费者基金会、卫生与发展基金会，还有自由贸易协议观察组织。

Prachachat Thurakit 商报认为，“这是另一组人，他们帮助提供知识与信息以教育社区，并解释泰国和其他发展中国家所面临的困难。” 该报建议说，“我们必须通过向公众传播信息，提供学术界和制药界的研究成果，来把泰国患者的福祉和权利，放在同外国商人的信心和贸易价值同等地位上来考量。”

以上三组人马还分别与其国外的合作方精诚合作。例如，泰国和巴西卫生部之间，泰国政府药品机构与印度仿制药工业之间，都有很密切的联系。

在很多国家，医学、药学和法律等学术界也有其网络。国际上的非政府组织，如无

国界医生（比利时部驻泰国办）、乐施会（Oxfam）、南南聚焦（Focus on Global South）、（设在美国的）知识生态国际、第三世界网络、健康差距（Health Gap）和实质行动（Essential Action）等，也都是如此。

同时，泰国本地的民众组织和非政府组织也都通过泰国艾滋病感染者网络、外国非政府组织和大学学生运动被联系在一起。

另一个不可被忽视的方面就是大众传媒。因为问题的复杂性以及媒体对政府禁止酒类广告决定的不满，在 2006 年底颁发第一个强制许可的时候，有些媒体还没有给予全方位的支持。但是，在目睹了跨国公司和美国政府对泰国政府所施加的重重压力之后，大众传媒通过在电视、报纸和在线媒体上发布新闻、文章、专题报道、常规专栏和社论等形式，积极促进公众对此事的了解。整个协调机制最终在为药物可获得性而努力的社会各界之间，营造出一条联合阵线。简单来说，强制许可成为了大众关注的焦点。

在其关于**患者权利的三线战斗（这一战斗得到了众多国内外媒体的支持）**的报告中，Prachachat Thurakit 商报用了以下一段文字进行了总结：

“这次运动尝试着告诉泰国和全球社会，在以金钱为主要目的的贸易世界里，还存在着另一个考虑生命和健康价值的世界，而药品则是每个人获得安康的基础因素。”

“因此，尽管受到了跨国制药公司和那些在运动中利益受损的人的肆意攻击，我们的人民运动还将继续。”

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第二部分　语录

蒙克尔・那・宋克拉医生

“……不要担心没有药品。那些公司不会关闭工厂和停止卖药。现在的措施只不过是他们保护自己利益的一个警告。泰国的强制许可不是随意发放的，而是由于这些药物过于昂贵。我们的预算如此有限，令我们不得不用其他方法得到价格便宜的药物。在1月25日，我已经签署了强制许可令，这将于1月29日正式生效。如果我们在他们的威胁面前萎缩，我们将永远被奴役……”

经理人日报，2007年1月26日

蒙克尔・那・宋克拉医生

“……我很高兴看到许多国家给我们发来了鼓励的信息。我坚信我们的诉求是建立在合法基础上的。……”

今日邮报，2007年5月4日

蒙克尔・那・宋克拉医生

“……我坚称我们的强制许可不是一个欺骗行为。我们一直都谨慎谦虚地行事，因为我们贫穷的人民无法获得足够的药物。我们不能让他们没有尊严的死去……”

每日新闻，2007年5月4日

蒙克尔・那・宋克拉医生

“……我们已经连续的警告我们要使用强制许可。在过去的10年中，虽然受到威胁，但我们还是在履行的义务而且一贯行事妥当。因此，批评我们缺乏透明度是不对的，夸大其词地说我们侵犯了30种药品的专利权更是无稽之谈。让我重申，我们并没有受到影响。我们是在透明的程序下完成这件事的。撒谎者必然会为自己的言行后果付出代价。我们已经尝试谈判了2年的时间，但是他们并不让步……”

Komchadluek 日报, 2007年5月4日

蒙克尔·那·宋克拉医生

“……**我不知道如何计算人的生命，并将其价值与美国的出口贸易值相比较。**我真的绞尽脑汁也不知道要如何解决我们人民面临的这些问题，他们中的许多人不得不因为无力负担医药费而死去。外国人不同意我们使用强制许可是其典型的反应。但是，相比之下，听到我的泰国同胞说我是废物将更使我痛苦一百倍……”

每日新闻，2007年5月6日

蒙克尔·那·宋克拉医生

“……我能够向你们保证，贫穷的人将能够获得药物。我曾经看到一个母亲的脸上挂着泪水，因为她没钱买3800泰铢一片的癌症治疗药物给她的孩子，而只能转而求助于草药。这种癌症药物的价格应该可以下降到每天200泰铢，而且如果批量购买还能再便宜100泰铢。没错，人终有一死，但问题是如果我们有能力的话，为什么我们不去帮助那些不够富裕的人民活得长久一些呢。我重申，我不会浪费我在任剩下的6个月时间，不会对你们无所作为……”

Khao Sod 日报，2007年5月29日

蒙克尔·那·宋克拉医生

“……过去关于强制许可的争论教会我们如何改进我们方法并弄清问题所在。我们将更加坚定。从前，我们试图最大限度地在争论中保持谦逊，但这于事无补。

从现在开始，我们将对任何关于我们强制许可的威胁和压力予以反击。我们不再是只会保持谦虚的泰国人，我们不会为其他人的攻击和批评而屈服……”

Matichon 日报，2007年5月31日

桑沽安·妮塔亚卢姆风医生，国家医疗保障项目办公室秘书长

“……泰国没有违反国际法的规定，相反，国际公认的原则是，在事关人民生死的问题上，一个国家利用专利不构成侵权……”

今日邮报，2007年5月8日

尼米特·天努达姆，艾滋通路基金会主席

“……如果没有治疗，有些患者仍可能会活下来。但是对有一些疾病而言，这就意味着死亡。药品和其他商品的不一样的，所以他们必须上升到伦理层面而受到控制……”

尼米特·天努达姆，艾滋通路基金会主席

“如果人们靠近我们，索求药物但是由于价格太贵而买不起，我们是将听天由命地购买药物，还是运用现有的法律手段使药价下降，让每个人都负担得起？问一问你自己，会选择哪种方法。”

克里沙娜·克莱斯图医生，政府制药组织研究开发部前主任

“制药企业说他们每年都要花费8亿美元来对每个药物进行研究是不正确的。药品的定价应该更加现实，而不应该随着执行总裁们的高收入和股东们的巨额分红而膨胀。盈利是没有问题的，但是不应该太过分。制药工业通常获得是翻番的利润。没有其他什么行业会有如此的暴利。全世界有80亿人口（原文如此—译者注），70亿人是贫困的。我们必须帮助他们生存。不要以为在贫穷的人们成群死去的时候富裕的人不会受到影响。”

威差·楚克威瓦特医生，政府制药组织董事会主席

“使用强制许可是对商业的不公”这一指责是错误的。实际上，商业从1992年开始就不公正地对待人民了。人们从那时开始不得不购买昂贵的药物。让我举个例子看看药可以贵到什么程度。当我还是疾病控制司的长官时，治疗机会性感染的药物Fluconasole的价格是200泰铢一片。

不论我如何努力想要协商一个折扣价，都不能成功。所以我开玩笑说，能不能给我一个四分之一泰铢的折扣，这样不至于太丢脸，我也可以说我在价格谈判中取得了进展。但回答是不。一个折扣价可能影响到药物目录上药品的价格，这些药物可能不是专利药，但是由于政府在当时屈就地修改了专利法并交付讨论，对这样的新药能够给予垄

断性的保护。一旦这种垄断权利到期，价格能够从200泰铢下降到12泰铢。现在，这个药的价格是每片5泰铢。”

素拉差·加木年达木荣卡恩药剂师，国家医疗保障项目办公室

“人们通常认为，国家医疗保障项目办公室是第一个想到要这样做的。我想说的是，虽然我们的办公室参与其中，但却不是想到这个办法的发起人。最负责任的说法，是将此事归功于泰国艾滋病感染者网络的工作，他们和学者一起，对事态进行了数十年的观察研究。国家医疗保障项目办公室只是这个过程的支持者之一。整个事件的成功，并不是由于这个一个军方力量支持的政府，也不是因为政府想要炫耀它的成就。“姜还是老的辣”，事情的成功主要是因为我们有蒙克尔医生这样的卫生部长，他的工作团队对这个问题已经十分精通。”

素拉差·加木年达木荣卡恩药剂师，国家医疗保障项目办公室

“对这件事情的批评中最令人心烦的是说我们缺乏透明度，因为我们没有事先和那些公司协商。我个人认为，和百万富翁协商才更是不透明的。

许多在2000年参加过去胫肌苷强制许可倡导运动的人都还记得，与制药公司的谈判最终导致了运用的失败。谈判者们组织到湄南河的一次晚间一夜航游为强制许可提议画上了句号。

务实地讲，外交部长和商务部长们都同意这（夜间游乐）是完全合法的，但是出于一种仪式性的考虑，他们依然认为这个过程缺乏透明度。我觉得他们从药厂方面得到的资讯可能会更多一些；或者，他们可能把巴西的做法视为标准。

在最终仿效泰国的做法之前，巴西已经在价格谈判中多次运用强制许可作为威胁。”

坦朴英·普瑞拉·卡瑟姆桑夫人，国家公共卫生委员会主席

“……国家公共卫生委员会认为发布强制许可的行为可以使许多人受益，并且符合法律规定和国际规则……”

沙恩·查玛里克（Saneh Chamarik）教授，国家人权委员会主席

“国家人权委员会对政府的此举表示赞赏和支持，尤其是对卫生部长蒙克尔·那·宋克拉医生和他的团队。虽然他们不得不因此而面对来自工业化国家和利润受到影响的跨国制药公司的政治和经济压力，但他们依然为公众利益而做出了决定。”

比尔·克林顿，美国前总统，克林顿基金会主席

“我强烈支持泰国和巴西政府的立场，以及他们在谈判无效之后对专利权的利用。我相信知识产权，但是这不应该阻止我们向有需要的人民提供救命的基本药物，无论在低收入国家还是中等收入国家都是如此。

没有哪个制药公司会因为在中等收入国家出售艾滋病药物无法赚取高额利润而破产，但是患者如果负担不起那些药物则会死亡。”

詹姆斯·拉夫，知识生态国际组织主席

“当世界贸易组织成员同意通过多哈宣言的时候，各国的商务部长们表现的尤其高兴，因为他们内心深处都有保护公共健康利益的愿望。泰国2001年的情况和现在发生的情况的不同之处在于，通过将更多的精力放在了患者的身上，而不仅仅是表扬那个在宣言上签了字的部长，泰国使多哈宣言变成了现实。”

本杰明·克鲁姆阿（Benjamin Krohmal），消费者技术项目主席

“在1950年以前的美国，有超过40000件使用强制许可的例子。虽然1950年后运用强制许可的数量减少了，但是依然有10000件之多。

在美国，强制许可不是照字面上这样来理解的，而是有三项制度的功能类似于强制许可制度，当政府认为的必要性与专利所有人的意志相违背的时候启动。

这三种政府使用的强制许可形式通过竞争法和法庭判决得以实现。许多公司从这种强制许可中受益。

由于竞争委员会发布了防止商业垄断的命令，雅培得到授权生产一种心血管扩张的仪器，该仪器的专利持有人是强生公司。雅培因为生产这个仪器获得了巨大的利润。最新的报道显示，基于公共利益的原因，雅培再次要求法院允许其利用一项检测丙型肝炎病毒的仪器，其专利持有人是比利时的InnoGenetic公司；专利持有人因此将获得补偿。

因此，制药公司们说美国没有强制许可不仅仅是颠倒黑白，更是双重标准。”

亨利·瓦克斯曼，美国国会议员

“泰国是美国的重要盟国，它正在努力拯救人民的生命。泰国有超过50万的艾滋病感染者和患者。泰国的艾滋病治疗项目已经被认为是世界上最成功的治疗项目之一，而昂贵的药价对于这个项目的持续和扩大形成了显著的障碍。

蒙克尔医生向我保证，泰国承诺遵守在保护创新和促进药物可及性之间保持平衡。基于这个原则，泰国政府尤其认识到知识产权问题，并确认其只会在WTO规则允许的限度范围内运用强制许可。因此，美国应该对此表示赞成，并对维持我们双边的长久友谊而提供支持，而不是采取惩罚性的行动，就像最近美国贸易代表将泰国收录到‘优先观察目录’中去那样。”

罗伯特·维斯曼（Robert Weissman），美国基本行动组织药物可及性问题倡导

“美国创新组织的Ken Edelman之所以强烈谴责泰国的原因，是因为雅培和默沙东公司是Edelman公关公司的大客户，而Ken正是该公司的老板。”

桑沽安·妮塔亚卢姆风医生，国家医疗保障项目办公室秘书长

“强制许可问题的波及面如此广泛，以至于国家医疗保障项目办公室都难以跟上事态发展的速度了。因此这个体系需要重现组合。我们认为我们必须形成一个工作团队：一个法律团队、一个倡导团队和三个次级委员会，而不是去找个人对这个问题提出建议、评论和批准。

第一个工作小组的组长是Vichai Chkevivat医生，负责控制整体局面；第二个工作小组的组长是Siriwat Thiptaradol医生，负责处理价格谈判问题，这个问题我们有时也会参与，但是很少取得进展；第三个工作小组，由国家医疗保障项目办公室的原有团队组成，以提升整个工作的效率，负责甄别需要运用强制许可的品。”

阿荣·克拉差瓦拉（Aroon Chirachawala），今日邮报金融版，2007年5月3日

“我不得不承认，当时事情刚刚发生的时候，我不敢发表我的观点，因为我对它的了解不多，无法判断这是否公平，或者是否会得到国际社会的认可。

现在许多亚洲、非洲和拉丁美洲的发展中国家都在说，他们会跟随泰国的先例，在他们的人民受到艾滋病和其他严重疾病折磨，而需要以可以负担的价格获得现代的药物和医疗技术时，维护他们的权利。

蒙克尔医生现在名扬四方，成为这场运动的领袖人物。他所作的一切成为了一个其它国家可以效仿的精神象征和典范。蒙克尔医生的成功绝非侥幸。这并不是撞大运。这是一步步深思熟虑和对国际社会反应进行认真评估之后的结果。”

普勒·斯·纳恩(Plew Si Ngern，艾伯伦银焰教派成员)，泰国邮报后街人群专栏，2007年5月4日

“美国当局、国会和制药公司历来‘合作’进行立法、专利授权和通过药品监管规则。这完全是一种‘阴谋’通过只保护单方利益的邪恶法律,阻碍和抑制其他国家自己生产药品，赢得长达20年垄断性权利的专利保护，并且允许持续地‘延展’他们最初的专利保护期限。所有这一切都完全没有考虑过‘同胞’或‘人道’的因素。

因此，蒙克尔医生的‘异端言词’直指美国制药公司的不公正行为，赢得了泰国民众的赞扬。许多国家也表示愿意参加这场运动的先遣者。

这些潜在的同盟在为蒙克尔医生呐喊、鼓掌和祝贺！

结果，美国忙不迭地要采取“惩罚泰国”的行动，以此告诫其他国家不要像泰国一样，去使用明明符合WTO规则的强制许可，生产或购买“廉价”的药物，来帮助他们的病人。”

世界银行报告：《艾滋病治疗的经济影响—对泰国政策选择的评估》

“让政府对于二线药开支减少的第二种方法，就是发布强制许可，来生产受到专利保护的二线药品。这样做要求有基于对泰国治疗项目成本、健康利益、预算节约和如此行动带来的贸易影响等问题准确理解基础上的高层政治解决方案。”

陈冯富珍，世界卫生组织总干事

“世界卫生组织明确的支持发展中国家运用 TRIPS 协议的弹性规定，来确保对优质的价格可负担药物的获得。”

蒙克尔·那·宋克拉，泰国卫生部长

“您能否告诉我，生命价值几何？这样我可以和（泰国）对美国的出口额做一个比较。”

比尔·克林顿，美国前总统

“没有一家公司会因为在中等收入国家高价出售艾滋病药物而出现生或死的问题，但是患者会！”

第三部分　大事年表

2006 年 3 月

无国界医生开始敦促雅培公司在发展中国家注册热稳定剂型的洛匹那韦/利托那韦（一种艾滋病二线治疗的关键药物“克立芝”的新剂型）。该药于 2005 年 10 月在美国注册，但在发展中国家却无法得到。雅培公司从 2002 年 5 月开始以 500 美元/每人每年的价格在非洲和最不发达国家出售该药，但是对于像泰国这样的中等收入国家却没有差别定价的政策。

2006 年 3 月 6 日

在一封致雅培公司首席执行官米勒斯·怀特（Miles White）的公开信中，无国界医生和其他知名的医生、研究人员以及艾滋病感染者团体一起，表达了对于在发展中国家难以获得热稳定的洛匹那韦/利托那韦这一问题的关注。公开信敦促雅培立即在该药旧剂型已经注册或等待注册的国家提交新剂型的注册申请，并在其他发展中国家立即申请注册。无国界医生也要求雅培公司公布新剂型在最不发达国家和中等收入国家的价格表，解释适用差别定价国家的目录，并公布药品注册申请提交的日期。

2006 年 3 月 13 日

雅培公司回复了无国界医生，但没有提供价格信息和新剂型申请注册的时间表，并辩称欧洲审批是注册的前提。

2006 年 3 月 15 日

无国界医生对包括泰国在内的 9 个国家中的 400 名无国界医生诊所患者，下了一份订单。该订单旨在争取于 2006 年底前让 800 名患者用上新剂型克立芝。

2006 年 3 月

雅培公司宣布对非洲和最不发达国家以 500 美元/每人每年的价格出售新剂型克立芝，但除南非外，雅培没有采取任何行动使该药在任何这些国家中可以获得。

2006 年 7 月

经过一个复杂而漫长的过程，雅培开始以每人每年 500 美元的价格向数量有限的无国界医生在非洲的项目销售新剂型克立芝。但是，雅培公司依然拒绝向无国界医生在泰国的项目以同样价格出售该药，那里旧剂型的克立芝售价是每人每年 2800 美元。无国界医生敦促雅培加快其药品注册的速度，因为在大多数的发展中国家，该药还是无法获得的。

2006 年 8 月

雅培对热稳定的克立芝剂型，发布了低收入和中低收入国家价格，比如泰国，其售价为每人每年 2200 美元。

2006 年 11 月

泰国对由默沙东公司拥有专利权的一线艾滋病药物依菲韦仑发布了一个强制许可。默克在泰国销售依菲韦仑的非营利性价格为每月 1400 泰铢（约合 38.84 美元）。政府药业公司（GPO）表示，他们将从印度兰伯西公司进口仿制的依菲韦仑，其售价是每月 800 泰铢，这种进口将持续到 2007 年 6 月政府药业公司可以自行生产依菲韦仑为止。泰国因此向兰伯西公司下了 66000 瓶依菲韦仑的订单，售价为每瓶 650 泰铢。

2007 年 2 月 6 日

默沙东提出依菲韦仑的新价格，即每片 72 美分（大约合每瓶 780 泰铢），这个价格接近于仿制药公司的价格。该公司也发布了一个依菲韦仑全球降价的政策，在艾滋病感染率占人口 1%以上的国家中，以每月 700 泰铢的价格销售依菲韦仑。

2007 年 1 月

第一批 16000 瓶依菲韦仑运抵泰国。泰国卫生部表示，因此而降下的价格可以让泰国政府再向 20000 名艾滋病患者提供依菲韦仑。

2007 年 1 月 10 日

22 个美国国会议员向美国贸易代表苏珊·斯克瓦布联名致信，敦促美国尊重泰国对依菲韦仑发布强制许可的权利。

2007 年 1 月 17 日

苏珊·斯克瓦布女士认同了强制许可的法律和社会基础："我们不认为泰国违反了任何国内或国际法的规定。我们认真地尊重泰国政府发布强制许可的能力……这与其作为世界贸易组织成员的义务是相符的。"

2007 年 1 月 24-25 日

泰国发布了两项强制许可，一个是对雅培公司拥有专利权的艾滋病药物克立芝，另一个是对赛诺菲-安万特公司拥有专利权的心血管病药物硫酸氢氯吡格雷。

2007 年 2 月 7 日

世界卫生组织总干事陈冯富珍致信泰国卫生部长，表达世界卫生组织对发展中国家运用 TRIPS 协议弹性规定来确保获得优质的价格可负担药物的明确支持。

2007 年 3 月 13 日

雅培针对泰国发布强制许可一事，撤回了其七种新药在泰国的注册申请，其中包括新剂型克立芝。

2007 年 3 月 14 日

无国界医生对雅培的行为声明谴责，并对于《华尔街日报》发表的一篇评论文章中称泰国的强制许可是"窃取外国药品专利"和批评泰国政府试图节省药物开支以增加军费的说法，进行了回应。

2007 年 3 月 20 日

泰国的艾滋病活动团体和世界范围内的许多国家呼吁抵制雅培产品，抗议、致信和谴责雅培公司的行为。无国界医生表达了对活动团体的支持，但是没有呼吁抵制雅培产品。另一方面，无国界医生敦促世界卫生组织、联合国艾滋病规划署和其他相关的决策者及政府，高调支持愿意运用世界贸易组织 TRIPS 协议中促进获得基本药物的弹性条款的国家。

2007 年 3 月 26 日

雅培向泰国卫生部提出以每人每年（税后）1700 美元（合 5938 泰铢）的价格出售克立芝。

2007 年 3 月 27 日

法国外交部长菲利普·杜斯特·布拉兹（Philippe Douste- Blazy）公开支持泰国的强制许可。他是欧盟国家唯一一个表达正式支持立场的代表。其他国家都对此保持了沉默。

2007 年 4 月 10 日

在与世界卫生组织总干事陈冯富珍交谈之后，雅培公司表示，愿意在低收入和中低收入国家中降低一半的价格出售新剂型克立芝，以此使该药价格从原来的每人每年 2200 美元降至每人每年 1000 美元（合 34500 泰铢）。该公司说，将在 150 个国家注册该药，但不在泰国，其将在泰国继续销售旧剂型的克立芝。

2007 年 4 月 23 日

雅培公司表示，如果泰国收回强制许可，其将以 1000 美元的新价格在泰国注册热稳定的新剂型克立芝。泰国卫生部严辞拒绝了这一条件。

2007 年 4 月 26 日

全球行动日：也是雅培芝加哥股东大会召开的前一天，艾滋病活动团体和感染者组织在曼谷以及其他国家的雅培公司办公室前聚集，谴责雅培在泰国撤回新药注册。世界各地组织了多起抗议活动和新闻发布会。

2007 年 4 月 26 日

“美国创新”，一个为美国制药企业进行游说活动的团体，伪装成 NGO，在《华尔街日报》上发表了一整页的文章，名为《进军缅甸——泰国的激进新政》。

2007 年 4 月 27 日

活动者在雅培公司年度股东会议在伊利诺伊斯州的雅培工业园召开期间举行抗议活动。

2007 年 4 月 30 日

美国贸易代表团将泰国列入“特别 301 条款”，该名单列入了一些其认为知识产权保护记录较差，有可能对之采取贸易制裁政策的国家。除了书籍和 DVD 产品的版权侵权问题外，强制许可成为泰国被列入该名单的另一个理由。该报告称，泰国获取仿制药物的努力“进一步反映了其对于专利缺乏尊重”。

2007 年 5 月 3 日

艾滋病活动人士在美国大使馆前集会，抗议美国贸易代表团将泰国列入“特别 301 条款”。

2007 年 5 月 4 日

巴西为政府使用而发布了一个强制许可，允许进口仿制的依菲韦仑。这个决定是在依菲韦仑的专利权持有人默克公司拒绝提供巴西政府所要求的 60%降价条件后做出的。

2007 年 5 月 8 日

泰国卫生部长蒙克尔·那·宋克拉访问华盛顿。泰国加入克林顿基金会采购联盟。克林顿基金会表示，其已经和印度 Matrix 公司谈判，以 695 美元的价格，大宗采购新剂型克立芝。与仿制药公司希普拉和 Matrix 之间的新协议不仅会显著降低艾滋病二线治疗的价格，也会降低一种每天一片的药物的价格——这种药物目前在发展中国家的售价十分昂贵。通过克林顿基金会的联合采购计划，对 16 种艾滋病治疗药物的降价，将在非洲、亚洲、拉丁美洲和加勒比海地区的 66 个发展中国家成为现实。

2007 年 5 月 9 日

根据泰媒体（Prachachart）报道，美国提出一个将泰国从“特别 301 条款”中删除的“行动计划”。其要求十分类似于美国与泰国商谈自由贸易协定时提出的条件。它们

包括，在通常的 20 年基础上延长专利保护期，将专利保护延及诊断和手术方法，并对发布强制许可的权利加以限制。

2007 年 5 月 11 日

泰国商务部拒绝了美国的“行动计划”。

2007 年 5 月 9—13 日

“美国创新”组织开始了一系列攻击泰国强制许可的活动。他们启动了名为 www.thailies.com 的网站，以“呼吁大家注意泰国不诚实地窃取美国和欧洲的创新成果”，并向国内媒体声称，泰国自行生产的艾滋病一线药物“GPOVIR”是全球最易产生耐药的产品。

2007 年 5 月 13 日

无国界医生和其他 NGO 在曼谷邮报和瑞士的“The Nation”上（免费）发表了一篇反驳“美国创新”的文章。

2007 年 5 月 14 日

雅培向泰国卫生部提出新剂型克立芝每人每年 1000 美元的售价（合 34000 泰铢），条件是泰国不对新剂型克立芝发布强制许可，而且新剂型克立芝的价格以后不会再降低。

2007 年 5 月 15 日

泰国卫生部长蒙克尔·那·宋克拉说，如果制药公司提供的价格能够低于仿制药公司提供的价格，泰国不会对降价后的专利药发布强制许可。

GPO-VIR 的生产者政府药业公司（GPO）表示考虑以诽谤之由起诉“美国创新”，因为该组织的公开宣传损害了 GPO 及其产品。

2007 年 5 月 21-22 日

泰国卫生部长蒙克尔·那·宋克拉访问华盛顿，拜访了国会议员，解释泰国政府决定发布强制许可的原因。

2007 年 5 月 23 日

雅培公司起诉法国艾滋病活动团体“巴黎行动起来（Act Up Paris）”，原因是该组织发起了网上抗议的活动，使雅培实验室的网站在 2007 年 4 月 27 日被关闭。雅培诉请该组织赔偿 100000 美元。

2007 年 6 月

泰国卫生部长蒙克尔·那·宋克拉表示，如果默克公司接受以不高于仿制药价格 5% 的价格出售依菲韦仑，他会从默克公司购买依菲韦仑。但是，他强调仍将从仿制药公司购买部分药物，因为如果泰国完全依赖原研药公司，默克可能会进行遏制。

2007 年 6 月 28 日

GPO 提交了一份印度 Matrix 公司生产的仿制新剂型克立芝的注册申请。泰国食品药品监督管理局承诺快速审批该申请，这将为向新剂型克立芝发布强制许可铺平道路。

2007 年 7 月 1 日

美国结束对泰国三种出口产品的“普遍优惠待遇”：黄金首饰、平面电视和聚对苯二甲酸乙二醇酯。美国声称，该措施和泰国对专利药物发布强制许可所造成的争议之间没有联系。

2007 年 7 月 10 日

欧盟贸易代表彼得·曼德尔森（Peter Mandelson）向泰国卫生部、商务部和食品与农业部致函，反对泰国广泛的运用强制许可，认为“这将损伤专利制度、创新和对新药的开发”，并强调“TRIPS”协议和多哈宣言都没有授权在药物价格高出一定限度时就可以运用强制许可”。其函敦促泰国政府与相关的制药公司展开直接对话。

2007 年 7 月 20 日

美国驻泰国大使拉尔夫·博伊斯（Ralph Boyce）致函泰国外交部长，警告说“WTO 的弹性规则不应该轻易运用，而应该作为最后的一个手段。”

2007 年 7 月 22 日

雅培公司就“巴黎行动起来”一案撤诉

2007 年 8 月 9 日

《金融时报》刊登了一篇披露了关于曼德尔森信函内容的文章

2007 年 8 月 8 日

泰国商务部回应曼德尔森信函时强调，泰国发布强制许可的决定完全符合世界贸易组织 TRIPS 协议的规定，并呼吁欧盟承认多哈宣言所确认的 WTO 成员国发布强制许可的权利。

2007 年 8 月 20 日

泰国卫生部对曼德尔森的信函逐点进行了回复。

2007 年 8 月 25 日

赛诺菲—安万特公司在泰国的法律顾问 Tilleke & Gibbins 律师事务所，向生物科技公司—印度制药企业 Emcure 公司在泰国的代表—发出信函，声称将就生物科技公司向 GPO 提交一份仿制氯吡格雷的文件，而对其提起民事或刑事起诉。生物科技公司被要求在 10 天内答复该律师函。

2007 年 8 月 27 日

无国界医生和乐施会共同组织了一个新闻发布会，对曼德尔森试图阻止进一步对专利药物使用强制许可的行为表示关注。他们敦促欧洲委员会全力支持各国为确保获得基本药物而做出的努力。

2007 年 8 月底至 9 月

赛诺菲—安万特公司开始向 Cadila 保健公司发布一系列威胁，试图阻止该仿制药生产者依强制许可令生产氯吡格雷。

2007 年 8 月底

泰国卫生部决定从 Emcure 制药公司进口仿制的氯吡格雷，价格为每片 1.01 泰铢，而市场售价为每片 70 泰铢。

Emcure 公司要求泰国卫生部确认购买氯吡格雷不构成赛诺菲-安万特所声称的专利侵权。

Emcure 公司没有向泰国注册其氯吡格雷，泰国卫生部决定转向另一家印度公司 Cadila 保健公司购买。

2007 年 12 月 27 日

泰国大选。沙马顺达卫（Samak Sundaravej）领导的人民力量党赢得多数席位。

2008 年 1 月初

卡利达（Cadila）保健公司成功在泰国注册其仿制氯吡格雷，以向泰国出口该药。

2008 年 1 月 4 日

泰国卫生部长蒙克尔医生批准了 4 个针对癌症药物的新的强制许可[1]：

1. 多烯紫杉醇—Docetexel （商品名：Taxotere—泰索帝，赛诺菲-安万特公司生产），用于肺癌和乳癌治疗。（专利药价格为每 800 毫克注射剂 25000 泰铢，相同剂量的仿制药价格为 4000 泰铢）
2. 来曲唑—Letrozole （商品名：Femara—弗隆，诺华制药公司拥有专利），用于乳癌治疗。（专利药价格为每 2.5 毫克片 230 泰铢，相同剂量的仿制药价格为 6-7 泰铢）
3. 埃罗替尼—Erlotinib（商品名：Tarceva—塔西瓦，罗氏制药公司拥有专利），用于肺癌治疗。（专利药价格为每 150 毫克片 2750 泰铢，相同剂量的仿制药价格为 735 泰铢）
4. 伊马替尼—Imatinib（商品名：Glivec-格列卫，诺华制药公司拥有专利），用于慢性粒细胞白血病和胃肠道间质瘤的治疗。（专利药价格为每 100 毫克片 917 泰铢，相同剂量的仿制药价格为 50-70 泰铢）

[1] 见“关于泰国对 4 种癌症药物发布政府使用强制许可的 10 个常见问题”

2008 年 1 月 23 日

诺华制药公司同意通过泰国全民医疗保障体系，向所有无法负担伊马替尼价格并真正需要药物的患者免费提供该药。该药每天的剂量通常需花费 3600 泰铢，每年的治疗费用相当于 1 千 3 百万泰铢（合 40000 美元）。

但是，通过几个月的谈判，对于乳癌治疗药物来曲唑、乳癌和肺癌治疗药物多烯紫杉醇以及肺癌治疗药物埃罗替尼没有达成任何协议，因为制药公司方面提出的条件过于复杂。

2008 年 1 月 24 日

泰国卫生部长蒙克尔·那·宋克拉宣布，在诺华公司的免费药物项目结束前，对白血病治疗药物伊马替尼的强制许可将不再执行。

2008 年 1 月 31 日—2 月 6 日

世界卫生组织驻泰国办事处，组织来自世界卫生组织、世界贸易组织、联合国开发计划署及联合国贸易和发展会议的专家，与泰国的相关合作伙伴会晤，对执行专利的政府使用提供技术援助和分析。该专家组发表报告，建议泰国政府在专利授予之前和之后都运用 TRIPS 协议的弹性规定。

2008 年 2 月初

GPO 向卡利达公司就仿制的氯吡格雷开出 2 百万片药物的订单。

2008 年 2 月 11—16 日

泰国新政府就职，差亚.沙松姆沙（Chaiya Sasomsab）成为卫生部长。新政府对于前任政府针对癌症药物发布强制许可的政策进行了审查。差亚认为正确的程序应该包括得到商务部和外交部的批准。

内阁关于强制许可的决定被搁置，计划延迟到 3 月底。

2008 年 2 月 19 日

乐施会组织了一个新闻发布会，讨论如果泰国新政府撤销前任政府关于强制许可的政策，将对其他发展中国家造成何种潜在影响的问题。

九个国际法专家向泰国首相和卫生部长致函，支持使用强制许可。

2008 年 2 月 26 日

泰国食品药品监督管理局长官斯利瓦尔.特普沙拉达尔（Siriwar Thiptharadal）医生被调任卫生部中一个虚职，他曾经积极的支持对艾滋病治疗药物和癌症治疗药物实施强制许可。斯利瓦尔医生表示将向行政法院申诉该任职决定。

2008 年 2 月 29 日

GPO 董事会主席威差·科克威瓦特（Vichai Chokewiwat） 医生——强制许可政策背后关键的卫生官员——表示，虽然面临新卫生部长差亚·沙松姆沙的压力，但他不会辞职。

2008 年 3 月 3 日[2]

GPO 主任韦斯蒂·阿塔为柴库（Vithit Attavejchakul）表示，卡利达公司已经告知 GPO，第一批出口的 2 百万片药物，由于生产和法律程序的原因，将由 3 月推迟至 4 月出口。

2008 年 3 月 6 日

一个由患者和健康权运动人士组成的联盟开始征集 20000 份签名，向参议院要求罢免卫生部长差亚·沙松姆沙。

2008 年 3 月 11 日

国家健康保障办公室、癌症研究所和卫生专家完成的一份研究显示，继续执行对癌症药物的强制许可，将在 5 年内节约 30 亿泰铢的政府开支。据此，新的卫生部长差亚表示，他将继续执行对癌症药物的强制许可。但差亚补充说，商务部现在应该与制药公司进行价格谈判。

[2] 国家杂志（Nations）报道:“药物许可的修改应在 4 月完成”

2008 年 3 月 12 日

患者和健康权运动人士联盟表示，他们将继续征集 20000 份签名，向参议院要求罢免卫生部长差亚·沙松姆沙。

最新数据来源：

国家健康保障办公室《关于获取 3 种癌症药物的报告》，2008 年 2 月 14 日

依菲韦仑 600 毫克

- 第一批订单：66000 瓶，已经用完
- 第二批订单：100000 瓶—从 2007 年 10 月起（在前任政府时期开始）

洛匹那韦 133.33 毫克/利托那韦 33.3 毫克

- 还有 571 瓶克立芝—旧剂型克立芝的库存量
- 2008 年 1 月 28 日—目前有 957 例患者服用克立芝（588 成年人和 369 儿童）
- 从 2008 年 2 月 12 日起，接收到印度进口 4000 瓶

氯吡格雷 75 毫克

- GPO 已经注册了 Cadila 公司的仿制版本，订购的 2 百万片药物仍未到位

第四部分　附件：《泰国政府白皮书》

关于泰国就三种基本专利药物进行政府使用的

10个焦点的问题的相关的事实和依据

支持加强对药品专利事务社会共识的文本纪录

泰国卫生部

和

国家卫生安全办公室

2007年2月

ISBN 978-974-94591-5-7

问题 1：对此三种药品专利进行政府使用背后的依据是什么？这种作法是否符合国内法和国际法？

对此三种药品专利进行政府使用的依据主要是根据《2002 年国民卫生安全法案》的授权，即使所有泰国国民能够普遍获得基本药物。自 2001 年起，每个泰国国民都可以享受以下三种主要国民公共卫生保险计划（图 1）之一，即：

2.1 公务员医疗福利计划(Civil Servant Medical Benefit Scheme, CSMBS)，该计划适用于约 500 万公务员，公共雇员及其受赡养人。该计划基于（付费一服务）的回溯报销制度，完全由一般税收支付。该计划下，公共资源是主要的服务提供者。

2.2 社会保障计划(Social Security Scheme, SSS)，是一种由雇主、雇员和政府均等出资的三方体系。它适用于约 8500 万私人雇员和临时公共雇员。公共和私人资源按大致相同的比例平分提供对受益人的服务。该计划通过合同按人收费制度支付给服务提供者。

2.3 普遍覆盖计划（Universal Coverage Scheme,也称金卡计划），自 2001 年 10 月起，健康保险的普遍覆盖结合之前的社会福利健康服务和自愿健康卡计划而实施，并且进一步扩大适用于 1800 多万人。目前这一计划适用于约 4850 万人，占总人口的 78%。该计划的资金全部源于一般税收收入。公立医院是主要服务提供者；它们覆盖了约 95%的受益人。80%的私立医院参加了这一计划，覆盖了约 4%的受益人。这一计划也通过合同按人收费制度对服务提供者进行支付。

泰国较富裕的人中约 2%购买了私人健康保险，很多被上述三种公共健康保险计划之一所覆盖的富人，尽管他们享有由政府支付而获得免费医疗的权利，却自费去私立医疗机构接受健康服务，大约有 20%的泰国人在私立医疗机构接受门诊服务时都是自费的。

适用以上三种国民公共卫生保险计划之一的 6200 万泰国人有权完全获得基本药物清单上的所有药品，大约包括近 900 种药物，其中许多都受专利保护。

自 2003 年 10 月以来，泰国政府也不遗余力地推动使艾滋病患者普遍获得抗逆转录酶病毒药物(anti-retroviral drugs, ARVs)的政策。

政府通过一些方式来履行这些对国民的承诺。一是增加公共卫生的预算。公共卫生的预算从 80 年代占总体国家预算的约 4%到 90 年代的 7%，然后到现在的超过 10%。用于获取 ARVs 的预算也从 2001 年的约 1000 万美元增加到 2007 年的超过 1 亿美元，在这 6 年中提高了 10 倍多。这种用于获取 ARV 的国家公共资源投入水平在中低收入的发展中国家是最高的。自 2003 年以来，泰国采取了目标为长期持续普遍获得 ARVs 的政策。全球基金给予的资助主要用于购买设备和人员培训。ARVs 的药品总支出中不到 20%来自全球基金。有着如此高的费用支出，公共健康保险计划仍然不足以支付普遍获取基本药物清单上的专利药品，包括基本的 ARVs。保障普遍获取基本药品的权利是卫生部和国家卫生安全办公室共同的责任。到目前为止，由于药品价格高昂，且预算有限，

这两个部门还无法完全实现这一目标。因此，通过政府使用专利的方式为政府覆盖计划内的病人获取较低价格的仿制药品是更好地实现该目标的一个重要方式。

正如对《佛历 2522 年泰国专利法》作出修改的《佛历 2542 年泰国专利法（第 3 号）》（文件 1、2、3）中清晰反映的，根据 TRIPS 协议第 31（b）条以及 2001 年《关于 TRIPS 与公共健康的多哈部长级宣言》的条款，专利权人以外的其他人使用专利可能有三种方法：

1. 专利的非公共使用：在这种情况下，如有人为了商业目的，想要使用某些产品，如药品的专利权，首先必须与专利权人进行谈判获得他们许可。谈判包括使用专利的条件以及向专利权人支付的许可使用费。如果谈判成功，就是专利的自愿许可。但一旦失败，可以请求泰国商务部知识产权局局长就是否允许使用专利作出决定，并且确定专利使用条件和许可使用费。这就成了强制许可。（泰国专利法 46 条至 50 条）。

   因为是为了商业目的使用，事先须与专利权人谈判。

2. 专利权的公共使用：专利权的公共使用分两种情况。

   2.1 为满足公共消费的需要、对国家防务有重大意义、为保护和利用自然资源或环境、避免或缓解食品、药品和其他消费物资的短缺或其他任何公共服务需要，任何部、局或政府机构可以自行或通过其他机构行使第 36 条规定的权利，向专利权人支付使用费而无需就是否允许使用、许可使用费或专利使用条件进行事先协商。（《泰国专利法》第 51 条）

   2.2 在战争或紧急状态，总理经内阁批准，有权发布命令，为国防和国家安全需要行使任何专利权利，并向专利权人支付合理的报酬。（《泰国专利法》第 52 条）

   因此，泰国疾病控制局局长和公共卫生常务秘书对国家基本药物清单上的三种药物，即依非韦仑，洛匹那韦/利托那韦和氯吡格雷作出的政府使用专利宣示完全符合泰国国内法和国际法（上述 2.1 的机制）。美利坚大学华盛顿法学院肖恩.弗林的相关论述（文件 4）对政府使用许可在法律上符合泰国国内法作出了更为详细的解释。这三个宣示以及致这三位专利权人的信函是表明该举措符合现有法律的依据，具体内容在文件 5—10 中。

   22 位美国国会议员在写给美国贸易代表尊敬的苏珊·施瓦布的信（文件 11 号）中确认了该举措符合法律。而她在给 22 位国会议员的回信中也确认了这一点，她在信中说：“我们并未提示泰国违反了特定的国内法或国际法”。她还说：“我们并没有寻求使美国政府卷入任何（泰国当局和制药工业之间的）此种讨论中”。世界卫生组织总干事陈冯富珍博士在致泰国卫生部长的信中同样确认了三个政府使用专利的宣示完全符合 TRIPS 协议，无需与制药企业进行事先谈判。（文件 13）

在这样的法律框架下，专利的政府使用并不仅仅限于紧急或特别紧急状态，并且也不仅仅限于药品或 ARVs。此外，泰国不是第一个运用强制许可或政府使用专利的国家，包括美国、欧洲国家在内的发达国家以及其它发展中国家之前都曾尝试且实施过强制许可和政府使用专利。文件 14 和 15 对一些近期使用药物专利和其它专利的实例有详细介绍。

总之，泰国当局对三个有专利的基本药品宣告政府使用专利是完全符合泰国国内法和国际法的。它使政府更好地履行了它所作出的致力于普遍获取基本药物清单上药品的承诺，也证明了政府承诺将生命权置于贸易利益之上。

问题 2：为什么泰国当局不决定以建设性的姿态与制药企业事先进行谈判，从而避免不必要的冲突且同时能够降低药品价格，使更多的人能够获得药品？我们能否将专利的政府使用视为国家对私有财产采取未通知的征用行为（如制药企业的一位高级经理所说）？

正如对问题 1 的回答所提到的，根据所有的国内法和国际法，在前述 2.1 中宣示和实施政府使用专利前，没有必要与专利权人进行事先谈判。

然而，即便事先的谈判和讨论没有必要，在 2004－2006 年间，卫生部也曾尝试通过一些方式和机制与专利权人进行讨论和谈判。2005 年 4 月，成立了一个工作组进行降低专利药品价格的谈判（文件 16）。该工作组由泰国食品药品管理局（FDA）秘书长主持，还有来自泰国卫生部和商务部相关部门的代表。为了谈判，工作组希望专利权人能提供足够的信息，但是专利权人并没有给予配合。一年后，工作组一份简短报告总结了它们降低专利药品价格工作的失败（文件 17）。而且，2004 年至 2005 年间，疾病控制局——泰国最大的 ARVs 购买者与专利权人已经有了几次会面并有过几次正式的交流，要求降低受专利保护的 ARVs 的价格。他们也报告了没能大幅降低价格。一些公司也正式回应了价格为何不能降低（文件 18）。直到 2006 年初泰国货币迅速升值，一些专利权人才决定降低其产品的泰铢价格。最大的降价幅度少于 20%，并没有比货币升值水平高出多少。

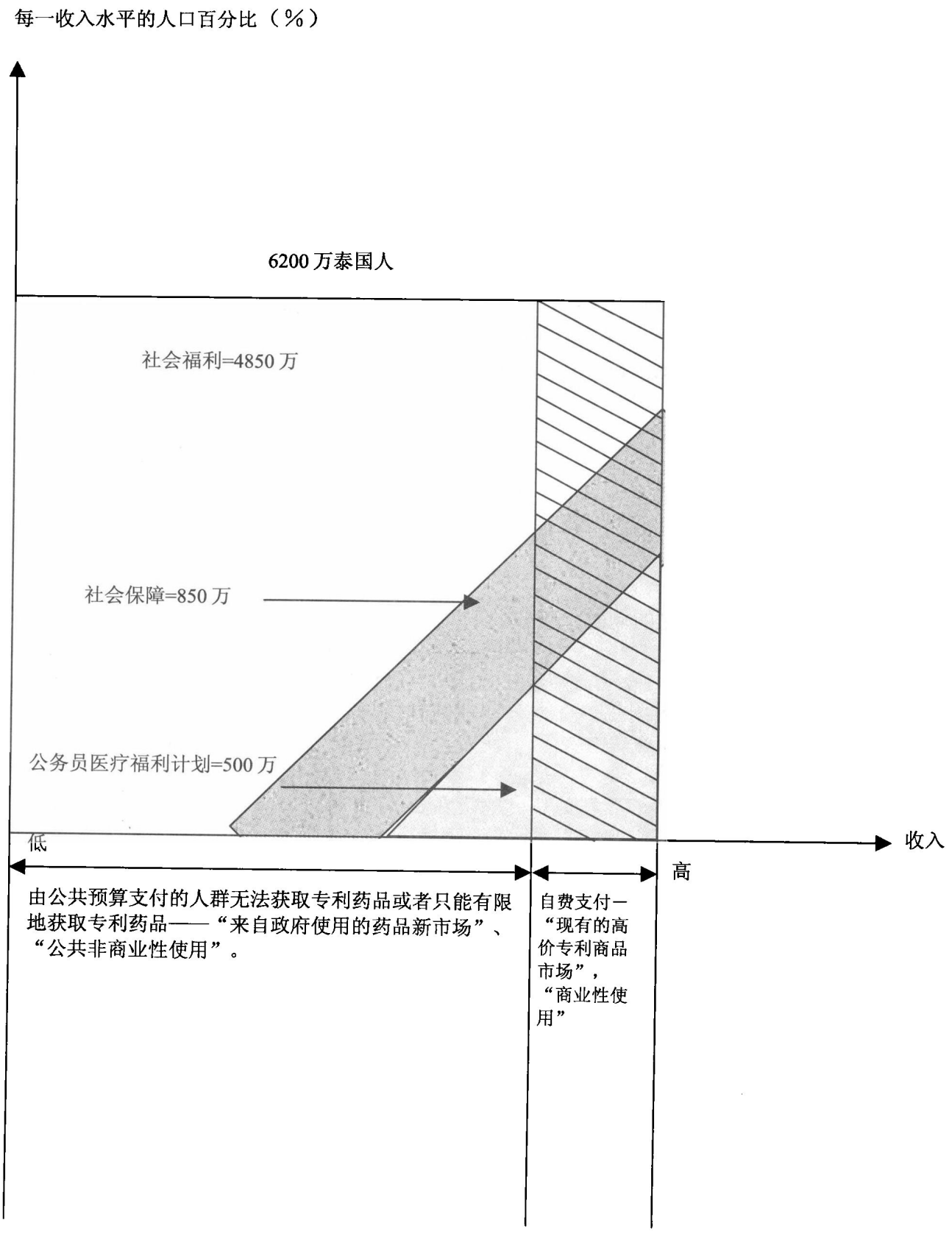
在泰国，无法通过谈判降低垄断药品的价格并不鲜见。1997 年，用于治疗艾滋病人机会感染的抗真菌药物——氟康唑还处于垄断状态，疾病控制局曾努力尝试通过谈判将价格从每片 250 多泰铢降低一些，但失败了。然而，在垄断状态结束并且出现了一些氟康唑的仿制药后，现在的价格降低了约 50 倍。这是全球公认的经验，表明**“与专利权人事先谈判并不是有效的作法，只会延误对基本药品获取的改善。只有在威胁或决定运用和实施强制许可或政府使用专利后，谈判才会更加成功和有效。”**

那些主张事先谈判的人应该认识到这些事实。推动事先谈判的尝试只会延误获取受专利保护之基本药品的改善，将更多生命置于不良健康甚至危险的境地。

同样应该注意到，泰国由政府使用专利而获得的药品只分配给那些政府保险计划覆盖的病人。那些富人和包括 200 万外国病人在内有自付能力的人仍需支付高昂的专利药品价格，他们实际是目前唯一的专利药市场。绝大多数泰国人的医药费用都由政府支

付，他们很少或根本无法获得那些专利药品。所以他们并不是专利药品的有效市场。专利的政府使用开辟了无力负担这些药品的人的新市场（参见图 1）。但是，由于预算有限并且要实现普遍获取药品，政府也无力支付专利药品的费用。开辟这片新的市场让所有仿制药和专利药品形成竞争，使政府能向所有泰国国民以可负担的价格提供质量上乘的基本药品，从而兑现普遍获取基本药品的法律和政治承诺。在政府使用专利下，专利权人仍然有权生产、进口和销售他们的产品。他们仍然保留向任何人授予自愿许可的权利。所以他们的专利权仍然得以完整的保全。因此，这不能被认定为是对私有财产的征收。而且，《泰国专利法》第 51 条和第 52 条中规定的政府使用专利与第 36 条规定的给予他们生产、进口、销售和分销专利产品的独占权利是一致的。因而，专利权人自申请专利时就完全意识到泰国法律中的这些灵活性规定。

图 1 说明专利的政府使用不会对专利药品市场现有规模有很大影响的图表。



问题 3 即便在发布政府使用专利后，为什么卫生部拒绝制药公司提出讨论和谈判的请求？有没有比强制许可更好的方法来改善药品获取的状况？

卫生部以及政府的政策是与所有私人企业建立建设性的、透明的和公正的联系。因而，建设性的讨论一直都是卫生部的主要策略。坦诚的建设性讨论的大门在宣示政府使用专利前、 后都是敞开的。卫生部从来都没有拒绝任何制药公司在友好基础上展开建设性讨论的请求。即便是通过进口专利药品实施政府使用专利之后，进行深入讨论和谈判的大门也一直敞开着。

然而，我们不能等待讨论和谈判产生结果，因为我们不想延缓改善我们国民获取这些药品的状况。因此我们在讨论和谈判的同时启动了生产和进口这些药品的程序。如 2007 年 1 月 5 日，在宣示政府使用专利的 5 周后，政府制药组织（GPO）与一印度制药公司，兰伯西签订了进口 66,000 瓶依非韦仑的合同。自 2007 年 1 月底，第一批依非韦仑运抵泰国。这种仿制依非韦仑使价格已经降低了一半以上，从每瓶 1400 泰铢降到每瓶 650 泰铢。这使卫生部能以同样的费用为另外的 20000 名艾滋病患者提供依非韦仑。尽管讨论和谈判仍在进行中，我们现也在政府使用下积极进口另两种专利药品的过程中。

自 2006 年 11 月 29 日起，我们与默沙东和雅培公司至少进行了两次正式讨论，另外还有一些非正式的商议。我们和赛诺菲－安万特公司（泰国）有限公司也进行了一些非正式的商议。

双方都理解对方关注的问题，讨论一直都非常友好和富有建设意义。制药公司理解卫生部和国家卫生安全办公室要完成普遍获取基本药品的使命，也了解他们目前专利药品的市场不会受到扰乱。他们准备提出更好的更为慷慨的计划帮助政府实现普遍获取药品的目标。卫生部和国家卫生安全办公室理解制药公司关注保护自己知识产权以及保证利润从而弥补他们在药品研发中的巨大花费，并且准备考虑制药公司提出的任何慷慨建议。所有人都认为这种建设性的讨论应该继续进行。2007 年 2 月 16 日，卫生部签发了一份部长令，设立一个新的专利药品价格谈判委员会（文件 19）。这个委员会代替了先前代表性更为广泛的工作组，将负责政府使用专利宣示和实施前后所有形式的谈判。

2007 年 2 月 6 日，默沙东公司友好地提出在满足 6 个条件的情况下可以给依非韦仑以 600 毫克每片 72 美分的新优惠价格（文件 20）。这相当于每瓶 780 泰铢，更加接近仿制药每瓶 650 泰铢的价格。我们正在认真地考虑这个建议。但是，从印度进口的 66000 瓶依非韦仑还能维持接下来的三到四个月，我们在作出最后决定之前仍有时间将专利药和仿制药的价格和条件进行比较。

该公司还宣布在全球范围内降低依非韦仑的价格（文件 21）。该公司的这一举措非常受欢迎。这证明泰国的政府使用专利不仅使泰国国民受益，还使全世界人受益。

必须重申的是世界卫生组织/公共健康、知识产权和创新委员会的报告明确认为获得基本健康技术应依赖于“3Ds”：即发现、发展和发送（discovery, development, delivery）。首先有必要对疾病病因学和发病机理以及一些治疗疾病的潜在技术研究进

行投资。然后，需要进一步投资开发这些潜在的技术，使之成为所需的有效、安全和高质量的基本技术。最后，有足够的资金通过充分、有效的卫生保健传输体系生产、购买和传播这些技术是最后一个基本要素。传统的以知识产权来刺激技术的研发投资在应对人们获取可负担的基本技术需求上已被证实是不够的。它为这种获取设置了很大的经济障碍。强制许可只是在某些情况下缓解这一问题和减少经济障碍的一种机制。它并不对每种药品或每项技术都有效。（见问题 4）

除了知识产权手段以外，世界确实需要能刺激对基本健康技术研发及以较低价格技术生产投资的创新手段。有人提出了一些新的刺激措施，如研发条约，预先采购机制和支持药品研发的特别税收。

“如果人类要生存，我们应该需要一种本质上的新思考方式。”

——艾尔伯特.爱因斯坦

问题 4：用什么机制和标准确定对哪些药品发布专利的政府使用以及使用费？在不久的将来会对更多的药品发布更多的政府使用专利吗？这些举措最终是否会导致知识产权制度的失灵？

2006 年 4 月 17 日国家卫生安全委员会为实施药品和医疗供应的政府使用专利而设立的小组委员会是一个考虑对哪种药品发布政府使用专利的机制（文件 22）。这个小组委员会由国家卫生安全办公室的秘书长担任主席，成员包括卫生部和商务部的所有相关部门、消费者团体和病人群体以及医学专家。决定对哪种药品发布政府使用专利的标准包括以下的药品和医疗供应：

－列入国家基本药物清单的；
－解决重要公共卫生问题所必需的；
－紧急或极端紧急状态所必需的；
－预防和控制疾病暴发、传染病和流行病所必需的；
－挽救生命所必需的。

这些药品和医疗供应的价格必须异常高昂，而政府无力向国家卫生保险计划下的受益人提供，以执行普遍获取政策。

专利权人的使用费支付水平确定在销售价值的 0.5%－2%之间。这是大部分发展中国家在公共非商业性使用情况下通常采用的范围。对于那些高零售价药品，使用费设定在 0.5%的最低水平。对于那些低零售价药品，使用费设定在 2%的最高水平。对于已经宣布政府使用的三种药品，需求很大，而且期望的零售价值很高。所以使用费已经设定在 0.5%.但是，如果制药公司对卫生部的这项建议不满意，可以就这些使用费进行谈判。如果谈判失败，泰国知识产权局局长将根据《泰国专利法》第 51 条的一些标准来确定使用费（文件 3）。

是否决定对其它基本药品实施政府使用专利，取决于小组委员会的工作和根据上述标准产生的证据。国家卫生安全委员会小组委员会以个案评估的方式将考虑是否宣告政

府使用的建议提交给卫生部。这是因为国家卫生安全办公室不是政府的一个部、局或部门；它是一个根据《国家卫生安全法》设立的独立公共机构。卫生部只在对实现对基本药品普遍获取真正有必要时才会考虑宣布政府使用专利。小组委员会的建议必须附有清楚证据来支持卫生部的决定。所以，未来如果确实需要且小组委员会提供足够证据，卫生部会做个案评估，来考虑实施政府使用专利。

从泰国的经验看，强制许可或政府使用专利可能只在所有专利药品中不到 15%适用。泰国的数据显示，绝大多数非专利药品主要是由于生产的复杂性仍然被垄断。另外，绝大多数专利药品并不适宜政府使用。其中有一些不符合标准，比如用于治疗勃起功能障碍综合症的药物、脱发药、痤疮药。此外，大部分新专利药品只是“仿效”药品，并不比那些现有的低价非专利药更好。

此外，在政府使用下，专利权人仍然保留着他们的权利和先前的市场垄断地位（如问题 2 中所描述的那样）。因此，无需担心政府使用和强制许可会导致知识产权制度的失灵。

问题 5 专利的政府使用会节省一些政府的资金，但会给人民带来什么益处？

宣布和实施政府使用专利的主要目标是增加泰国国民对基本药品的获取。政府并没有节省任何预算，在有些情况下甚至花得更多。对于那些覆盖范围有限的 ARVs，如依非韦仑和洛匹那韦/利托那韦，在同样的预算水平上，将有更多的人获得这些药品。而对于氯吡格雷而言，过去国家公共卫生保险计划下的病人无法获取或只能极少量获取，政府必须支付额外的费用获取价格较低的氯吡格雷仿制药。应该重申的是三种政府使用专利所获得的药品只能给政府负担的三个公共卫生保险计划下的那些病人。**药品不能出售给私营部门或者愿意自费购买药品的人。**

对每种药品而言，专利的政府使用给泰国人民带来的益处是：

1. 默沙东（泰国）有限公司拥有专利权的依非韦仑案

依非韦仑是一种有效的一线 ARV。它比泰国国产的“鸡尾酒疗法”中抗逆转录病毒三联配方 GPO-VIR 用的奈维拉平毒性要小。约 20%使用 GPO-VIR 的病人会有药物副反应，轻重不一，严重时有可能危及生命。发达国家和通过外部援助预算购买药品的发展中国家病人都基于三联 ARV 中，以依非韦仑作为一线治疗药物。在泰国，由于依非韦仑价格很高，所有新增艾滋病人基于三联 ARV 治疗，不得不以毒性更强的奈维拉平作为一线治疗药物。大约有 20%病人出现了 GPO-VIR 的副反应。只有当他们出现严重的副反应时，才会转向基于依非韦仑的 ARV，其价格是 GPO-VIR 的两倍多。在政府使用专利下，依非韦仑的价格从每月 1400 泰铢降至每月 650 泰铢。这让 20000 名新病人获得这种基于依非韦仑的三联 ARV，并且降低了三联 ARV 中用奈维拉平的毒性风险。如果我们允许在政府使用下的继续竞争，价格可能会进一步走低。如果价格降至原来药价的 20%，那么我们可以用同样的预算支持 10 万名病人，今后的 5 年，所有新病人都可以在三联 ARV 中使用依非韦仑。没有必要再让新的艾滋病人使用更具毒性的奈维拉平的 ARV 治疗。

2、雅培有限公司拥有专利权的洛匹那韦/利托那韦案

疾病控制局曾做过一项服用一线ARVs病人的抗药性研究。他们发现约10%的病人会在最初的几年产生抗药性因而需要二线ARVs。这主要取决于病人的依从性和病毒特性。泰国现在有50万艾滋感染者/病人。在不久的将来，他们中至少有5万人需要二线ARVs。有一种好的二线药是雅培公司拥有专利权的洛匹那韦和利托那韦的组合制剂，注册商标是Kaletra®。2007年专利药品的价格是每月约6000泰铢。这意味着一个病人每年要花72000泰铢。治疗5万病人所需的预算将高达36亿泰铢。这比2007年用于ARVs预算的100%还多。此外，仍然需要为10万多名病人支付一线ARVs。如果他们不接受二线ARVs，他们很快就会有机会感染而死亡。这是在接受适当治疗的过程中发生的死亡。高昂的二线ARVs价格是阻碍努力挽救他们生命的主要因素。现在，我们能够支持不到2000名已产生耐药的病人。有了政府使用专利，我们希望药品的价格能至少下跌至目前价格的20%，这样我们就能挽救另外8000人的生命。随着竞争的加剧和预算的增加，在不久的将来，我们能挽救更多人的生命。

3. 赛诺菲-安万特有限公司拥有专利权的氯吡格雷案

这是一种抗血小板药，在预防冠状动脉血管阻塞方面的功效至少和阿司匹林一样甚至更好。患有冠心病的病人一般服用这种药品，在泰国，这样的病人大约有 30 万。它几乎是唯一能够用于应用冠状动脉支架病例的药品。然而，由于每天 73 泰铢这样高昂的价格，只有 3 万病人能够负担得起，主要是自费。所以，剩下无力支付的穷人只能忍受乙酰水杨酸了。常务秘书作出的政府使用专利宣示至少会将价格降低 10 倍至不超过 7 泰铢，让在普遍卫生保险计划下的病人也能获得这种药品。在这种情况下，政府，尤其是签约的医院必须支付额外的预算来支持获取这种仿制药。但是，比较低廉的仿制药价格使得政府也有能力承担了。

通过以上三个案例，可以很清楚地看到，泰国政府实施政府使用专利的目标是增加对基本专利药品的获取，*而不是节省预算*。就氯吡格雷而言，很显然需要更多的资金，但在可负担的范围内。

问题 6：此举措对泰国的出口、经济以及在泰国的跨国公司会有什么影响？

阐述这一问题首先需要考虑的是泰国正实施的政府使用专利，符合国内法和国际法，是建立在需要使泰国公民获得更多受专利保护基本药物的有力证据基础上的。此外，我们很愿意为了所有利益相关者的利益以建设性的姿态与所有的专利权人进行谈判和讨论。因此，我们的贸易伙伴不应该作出不适当的反应和进行贸易报复。

卫生部完全知道我们的经济至少有三分之二依赖于产品和服务的出口。而且，我们15%－18%的出口是往美国，- 我们实施政府使用专利的两个专利权人来源国。如果美国政府对我们的出口进行报复，将导致对美国市场的出口降低 10%，这将意味着 1%－1.2%的经济损失和丧失数十万个就业岗位。所以这是一个非常敏感的问题。除非有非常有力的证据证明为国民的利益所必需，否则我们不会作出这些决定。因此，对三种药品政府使用专利的决定是在具备坚实的法律和社会依据基础上谨慎作出的。

应该注意到一些泰国的日报在 2 月中旬曾报道称美国驻泰国大使馆商务参赞曾知会泰国商务部高级官员，美国在考虑国家贸易关系清单中泰国的地位时不会参考这一事件。这是好消息，可以成为美国公平贸易政策的证明。但是，到目前为止，双方都没有正式确认这一点。不过，如果对泰国的产品和服务采取不符合 WTO 贸易规则的不公平贸易报复措施，我们就有权利将案件提交 WTO 的争端解决机构。

而且，应该重申的是政府使用专利不会触及自费市场，即目前专利药品的市场。政府使用仅仅开辟了那些以前无法获得这些药品病人的新市场。在这一新市场中，专利权人完全有权降低价格与仿制药竞争。所以，在政府使用专利之后，泰国将会有两个药品市场。一个针对自费支付高价垄断专利药品的富人和 200 万外国患者。这个市场占人口总数的 15%－20%。另一个针对由政府支付低价竞争性药品的人群。这一市场占泰国国民的绝大多数，普遍卫生保险计划赋予了他们应享有的权利。

另外， 泰国药品市场的规模不到全球药品市场的 0.5%.专利药品的市场占有率就更小了。所以这对研究型制药公司的市场和收入不应该有显著影响。

相反，政府使用让本国制药厂尤其是政府制药组织能够开发产能和产品。当谈判和讨论达成自愿许可协议，也会发生技术转让从而进一步加强泰国本国的制造能力。

问题 7：卫生部是否曾与其它部委磋商？为什么不把此事呈交内阁决定？

长期以来，卫生部不仅在这一问题上，还包括其它健康发展问题，已与所有相关部委建立起紧密的富有建设性的联系。商务部的代表也参与了专利药品价格谈判临时工作组以及实施政府使用专利药品小组委员会的工作。而且，在宣告政府使用专利之前，卫生部还举行了另一个咨询会议，就宣告的法律层面做最后分析。商务部代表，国务院办公厅、律师委员会和其它相关各方都受到邀请并且积极参与其中。

在与制药公司的后续谈判中，我们也邀请了外交部的代表。新成立的专利药品价格谈判委员会由泰国食品药品管理局秘书长主管，也包括了来自所有相关部门和消费者团体及专家的代表。

最后，卫生部也与商务部贸易谈判局、知识产权局、国际经济事务局和外交部美洲与南太平洋局等部门密切合作，为解释泰国政府使用专利情况制订通用指导原则发挥了积极作用。

这里应该重申，**根据《泰国专利法》第 51 条，政府的部、局、署均有权发布政府使用专利，没有必要事先得到商务部和内阁的批准。**这与第 52 条不同，第 52 条适用于战争和极端紧急状态；总理得到内阁的批准，可以发布政府使用专利命令。

最后，由于很多与实施专利的政府使用相关的问题还不清楚，卫生部向总理提交了一份解释性说明，同时抄送给商务部、外交部和科技部。

2007 年 2 月 16 日，卫生部还出版分发了一份长达 80 页的解释和呈现有关政府使用

专利证据的白皮书。可登录 www.moph.go.th 和 www.nhso.go.th 查阅。最后，白皮书的英文版于 2007 年 3 月 6 日完稿和公布。登录前述两个网站也能查阅。

问题 8：发布政府使用会造成泰国药品研发的退步吗？

在泰国，大多数研究性制药公司仅在一些临床和市场研究上进行投资。目的主要是为了获得其产品市场销售的有用信息。泰国的制药公司，尽管规模仍然很小，但是正在扩大，并且大于大多数东盟国家的市场。所以这些研究型制药公司继续在泰国经营是符合其利益的。因此，他们仍然不得不投资于前述的临床和市场研究。

泰国正在提高其能力和标准从而支持药品研发，包括良好实验室规范、良好临床实验规范和良好生产质量规范。这些能力与良好的研究设施和大量具有良好依从性的各类病人一起，将会吸引制药企业开展更多的研究。将来，如果这些能力达到国际标准并且有成本效益，便会自动吸引制药企业来泰国投资。如果我们的质量没有达到这些标准，并且成本过高，制药企业必然会在其它地方开展研究。这与政府使用专利或知识产权的保护水平没有关系。

现在，大部分基础生物医学研究都是由国内或国际组织的公共预算支持的。在泰国，制药企业很少投入资源支持这种研究，也没有迹象表明会加强这方面的努力。

在 90 年代早期，当我们面临压力要强化我们的专利法，将产品专利纳入其中时，我们也得知，如果我们这样做的话，制药企业将会有更多的药品研发投资和技术转让。为了遵守 TRIPS 协议，我们确实在 1992 年修改我们的专利法，比 2000 年 WTO 的最后期限早了 8 年。但是，制药企业对药品研发并没有显著的增加。而对技术转让而言，我们只看到他们将其在泰国的制药工厂转移到工资和成本更为低廉的国家。泰国制药工厂的数量从 1992 年的 188 家减少到 2006 年的 166 家。

问题 9：世界卫生组织（WHO）以及其它国际组织对泰国的这一举措如何看待？泰国公众支持这一举措吗？

2007 年 2 月 7 日，WHO 总干事陈冯富珍博士写信给泰国卫生部长（文件 13），明确表示 WHO 坚定支持运用包括强制许可在内的 TRIPS 灵活性。她也确认泰国的行动完全符合 TRIPS 协议，没有必要与制药公司进行事先谈判。她还支持与制药公司进行富有建设性的讨论，如问题 3 中所述，她与泰国持同样的观点。

此外，22 位美国国会议员致美国贸易代表的信以及美国贸易代表的回信，与 WHO 总干事的信同样都确认了政府使用专利的法律及社会依据。

而且，各类国际组织也给予了强有力的支持，如联合国艾滋病规划署（文件 23）、无国界医生（MSF，文件 24）、第三世界网络（文件 25），消费者技术项目（文件 26）和克林顿基金会（文件 27）（限于篇幅，这些文件本书没有收录——编者）。

国家统计局 2007 年 2 月的公众投票显示，卫生部的这一决定助其当选为新一届政府

最受欢迎的部。除了当地发行量多的报纸上许多支持性的文章和评论外，这是泰国公众支持的最好证明。

问题 10：我们如何能保证通过专利的政府使用获得的药品与专利药品的质量是相当的？

至少有 5 项机制能保证药品与那些专利产品相当：

1. 对于有 WHO 药品预认证的药物，尤其是治疗艾滋病、肺结核和疟疾等疾病的药物，只有通过 WHO 预认证的产品才能在专利的政府使用体系下进口。

2. 对于所有药品，产品的质量必须由卫生部医学科学局审核通过。

3. 所有药品都必须在泰国食品药品督管理局注册，在注册过程中，需要进行生物等效性研究。

4. 在向公众销售之前，政府制药组织和实施政府使用专利的指定机构都必须采取产品质量保证措施。

5. 泰国的食品药品监督管理局、疾病控制局和国家卫生安全办公室将联合对这些药品执行上市后的监督从而确保其质量。

第三世界网络 （Third World Network）翻译

译者：陈惜平　朱贞艳

注：如文中所述，有若干引用文献为泰国作出政府使用专利决定过程中的支持性法律、相关政府部门建议、决定，以及一些联合国机构和非政府组织的支持、公司的建议等，这些文件未随此译文翻译并附于此。

国际人士支持泰国强行仿制记者招待会

泰国艾滋病感染者与非政府组织的倡导活动

在雅培公司外进行的抗议活动

May 2009 | International Trade & Intellectual Property Rights Series

The Rights to Life

Advocacy Experience of Access to ARVS in Thailand

Author: Kannikar Kijtiwatchakul (Thailand)

Chinese Version Translator: Hu Yuanqiong Wang Xiangyu Jia Ping

TWN
Third World Network Access to Medicine Research Group•China China Global Fund Watch Initiative 中国全球基金观察项目

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Part 1: The Right to Life

"You're just too good to be true, can't take my eyes off of you."
This is the first time the Thai government amazed me since my study of Thailand as a post-Cold War by-product of American imperialism. I've never thought it would dare to implement compulsory licensing. I'm very surprised. Most importantly, this government is not an elected one. Admirable indeed. Many textbooks will have to be torn up and thrown away."

Assoc Prof Surat Horachaikul
Faculty of Political Science, Chulalongkorn University

There are a number of Thai terms which all refer to the English term 'Compulsory Licensing', which is also known as 'Government Use' if implemented by the state. 'CL' is the term often used to describe the Public Health Ministry of Thailand's exercise of its right to issue compulsory licenses on three drugs, so that the country can import cheaper generic versions of the medicines from India. These three patented drugs are *Efavirenz,* MSD's first-line antiretroviral (ARV) drug; Sanofi-Aventis' *Clopidogrel*, a heart disease medicine; and *Lopinavir+Ritonavir*, Abbott Laboratories' second-line HIV/AIDS therapy.

How did a small and submissive developing country in the global community become the 'Talk of the Globe' as Jack the Giant Killer? Is this an act of "intellectual property piracy"? Will it destroy innovation in the world? What repercussions will it have on this distorted world?

Please tune in to what has been going on.

Introduction to the Intellectual Property Regime: the Right to Make Profit

To provide the reader with an informative and enjoyable read of Thailand's path to CL, an introduction to the intellectual property regime is first needed. This introduction does not expect the reader to become as knowledgeable as a professional intellectual property rights lawyer, but it is hoped that the reader will gain a contextual understanding of almost everything about the intellectual property regime, which is the focus of the issue.

Nimit Tienudom, director of AIDS ACCESS Foundation, has been able to explain about the intellectual property regime and the exercise of CL in a simple but interesting manner.

"Simply put, the intellectual property regime is about those who invent new medicines and chemicals. Naturally, they would want to own and have monopoly rights to manage, produce and trade their products. To recognize and provide incentives to these innovators, we established the intellectual property regime.

"But when it comes to medicines, we may have to think somewhat differently. Medicines are important to patients. Some patients could survive without the drugs. But for others, a lack of medicines means an end to their lives. As drugs are different from other goods, so they must be ethically controlled. When a person is ill and cannot be cured because s/he has no access to medicines, nothing can substitute for his/her loss. Therefore, the concept of medical intellectual property must be developed differently.

"When people invent something and file a patent on their product, invention and development, they can hold monopoly rights to their products for 20 years. This was long enough to prevent other generic drugs from competing with the patented ones. Problems arise here. The manufacturers of patented medicines are in a position to set the prices of their products as high as they like.

"In the case of essential drugs for which there is no alternative, prices will be exorbitant. AIDS patients must take anti-retroviral medicines. The original drugs will cost the patients about 9,000-13,000 baht per month, depending on the formula. Can the patients afford that? Can they not take the drugs? Can they take them only in the months when they can afford it? The answer is no.

"If you take medication to contain a virus, you must do it continuously; otherwise, the virus will become resistant to the medication. If you have to buy the medication, then you must pay the price. If you fail to pay your instalments on a car or a house, your car might be seized. But if you have to pay for your life in instalments, it means an end to it. Drugs are therefore an ethical issue because they are essential to human life.

"Patented drugs are expensive. Those who cannot get access to them are suffering. As we respect intellectual property rights, we have to find a legal means to address the problem.

"What will you decide to do if people around you need the drugs that are too expensive for them to buy? Will you let them struggle to buy those drugs, or pursue existing legal rules to lower the prices of the drugs so that they are affordable to all the patients who need them?"

Now, let us elaborate a bit further.

In 1985, the US suffered severe budget and trade deficits. Its manufactured goods could not compete with those from China and Japan, whose exports to the US were very high. But the strength of the US lay in its services and intellectual property goods. The US succeeded in putting the General Agreement on Trade in Services (GATS) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) on the World Trade Organization agenda at the WTO meeting held in 1994.

The Agreement on Trade Related Aspects of Intellectual Property Rights or TRIPS contains regulations, rules and practices that mainly aim at protecting the interests of patent owners or patent holders. It was fortunate that some academics from developing countries had managed to take part in the drafting of the agreement. Dr Carlos Correa, a lecturer from the University of Buenos Aires, was one of them.

At the time, Dr Carlos Correa--the world's top expert on intellectual property rights laws--was Argentina's science minister. He tried his utmost to incorporate flexible mechanisms and protective measures into the agreement to provide breathing space for the public against a backdrop of endless greed. One of the TRIPS flexibilities was compulsory licensing.

"Compulsory licensing has been incorporated into the patent laws of almost all countries since 1925, including the Paris Convention. Even in the TRIPS Agreement itself, the issue is clearly recognized as permitted and there are no restrictions on the exercise of compulsory licensing. It is up to each country to choose which principles it wants to apply."

Article 31 of the TRIPS Agreement clearly specifies that the agreement to respect the rights of a patent holder can be waived by a Member State in cases of ***national emergency*** or other circumstances of ***extreme urgency*** or in cases of ***public non-commercial use***. In the case of public non-commercial use, there is no need for prior negotiation with the right holder, who needs only to be informed promptly.

This means that the monopoly rights of the patent holder still exist, but when the state sees any necessity under the three conditions, it can pursue compulsory licensing while the patent holder shall be paid adequate remuneration.

Nimit explains: "It is distressing. Many people cannot get access to necessary medicines. It is an imbalance which needs to be corrected. So this Article provides that in the case of crisis or problems, a government is permitted to produce or import generic versions of the patented drugs and obliged to pay remuneration to the patent holder. The compensation paid signifies respect for the intellectual property owner."

Dr Jeth Tonavanik, Dean of the Faculty of Law of Siam University and one of Thailand's top intellectual property lawyers, provided a further explanation. The exercise of compulsory licensing, or CL, is a legal procedure. The patent owner does not give permission. But the government considers it necessary to force the owner to do so. This use of the owner's rights is in accordance with the existing legal framework, and is not an illegal act like pirating videos or CDs—which is a copyright violation and piracy. CL is conducted within the framework of laws.

Nevertheless, very few developing countries have been brave enough to exercise these flexibilities even though they have experienced severe problems of access to medication. On the contrary, developed countries such as the US, Canada and many European Union countries have used these flexible mechanisms regularly as legal measures. This resulted not only from national capacity constraints but also from trade pressure from superpowers like the US, whose coercion has constantly aborted any pursuit of CL. Such was their cavalier attitude: "I'm allowed to do it, but you're not".

Therefore, in 2001, the WTO Ministerial Meeting at Doha in Qatar had to clarify the TRIPS Agreement, especially the part on public health. Thanks to the efforts of developing countries and the global community, the Doha Declaration on TRIPS and Public Health was issued.

The Doha Declaration states that WTO members have the right to protect public health and, in particular, to **promote access to medicines for all through use of compulsory licensing.** Also, **member countries are free to determine the needs as a reason to use compulsory licensing.** Moreover, member countries are entitled to specify the conditions of national emergency or urgency. Most importantly, it is to be understood that a public health crisis shall include AIDS, tuberculosis, malaria and other communicable diseases, all of which can be deemed as cases of national emergency or urgency.

Many developing countries, including Malaysia, Indonesia, Taiwan, Zambia, Mozambique, Cameroon, Guinea, Ghana and Eritrea, have shown courage by engaging in the use of compulsory licensing, based on the Doha Declaration on TRIPS and Public Health. But compared with the magnitude of problems relating to the public's lack of access to medicines, the number of countries is too small and the compulsory licenses are applicable only to the basic (inexpensive) antiretroviral therapy.

So, the pharmaceutical industry's profit making has not been really challenged even once.

In her book *The Truth About Drug Companies,* Dr Marcia Angell wrote:

"*There is nothing drug companies do better than extending their monopoly rights to their top-selling medicines in the market* ... In every aspect of the free trade business, the drug industry's lifeline comes from its monopoly rights awarded by the government in the forms of patents issued by the US Patent and Trademark Office."

Thailand's Patent Regime: Trade Bondage

Thailand enacted its first Patent Act in 1979. The law provides protection for all inventions, except those specified in Section 9 of the Act. Among these exceptions are drugs and medical products. This means that only medical procedures are protected while the medicinal substances and medical products are not. A patent shall have a term of 15 years, counting from the date of filing the application.

What does 'medical procedures' mean?

Here is a simple explanation. If the combination of substances A, B, and C results in drug Z, the patenting will protect only the procedure of putting together A, B, and C. If anyone combines C with B and A, or puts together B with C and A, to come up with drug Z, such act will not be a patent violation at all. On the contrary, a patent on medical products or medical substance prohibits any combination of substances A, B, and C whatsoever. If the combination results in drug Z, it is not permitted.

Granting a process patent is therefore a means of encouraging domestic inventions. The drug industry, particularly in developing countries, must begin with compounding drugs before gradually progressing to invention and innovation. In addition, granting a marketing monopoly right for a reasonable period will make patented drugs expensive for some time before generic versions can enter the market to lower the prices of the original drugs.

However, Thailand's path has not been strewn with rose petals. In fact, it is a road paved with sharp gravel, which so far has cut and soaked the feet of the Thai people in blood.

The US started bilateral trade negotiations with Thailand in 1985, by granting its Generalized System of Preferences (GSP) to Thailand in exchange for an extension of the protection of drug and medical patents from 15 to 20 years.

The US adopted an approach using both carrot and stick in designating Thailand a 'Priority Foreign Country'. This put Thailand at the top of the list to be dealt with by threatening to cut the GSP status given to Thailand.

At the time, academics, public health personnel and non-governmental organizations led by the Drug Study Group conducted a study on the adverse effects of patent protection on Thailand's drug and health system. The study found that if product patent protection had been given, the value of drug imports of 1988 would have been 72 percent higher, while the national drug industry's research and development of production technology of common medicines would have been hindered because it would be prohibited from producing patented drugs. The dispute lasted many governments.

Dr Vichai Chokevivat recalled the situation over 20 years ago. "The Drug Patent Act BE 2522 (1979) was fair for us because our level of technology was much lower than that of developed countries. It was fair for us to protect only process patents. But since 1985, we were under pressure to amend the Act to further protect product

patents. We struggled hard at the time to prevent amendment of the Act. The most active and unyielding leaders were Ajarn Sumlee Jaidee of the Drug Study Group and her students at the Faculty of Pharmacy. I was just an unimportant part of the group.

"At the end, we were defeated. The Act was amended in 1992, eight years before we were required to comply with the World Trade Organization's rules in 2000. But the WTO rules had a waiver entitling poor countries to prolong compliance for another five years (until 2005). India fully exercised this right and had its laws amended in 2005."

In 1991, the National Peace-Keeping Council staged a coup and appointed the Anand Panyarachun administration. In extreme need of international recognition, the administration agreed to the US demand for patent law amendment. The amendment was carried out eight years before the WTO TRIPS requirements came into force, not to mention the five-year waiver given to developing countries to modify their laws in compliance with the agreement. Thus, Thailand did lose 13 significant years to develop its domestic drug industry.

"Such assent—given against very strong opposition—would make drugs more expensive. Medicine is one of the four necessities. It is indispensable. Diseases know nothing about drug prices. With food, we can choose to spend 2,000 baht or 28 baht for a meal. Also with housing and clothing, we can make a choice. But with patented drugs, we have no choice. Negotiations at that time established the Drug Price Control Committee and provided an eight-year period of technology transfer. But the promise was broken; no price control mechanism was set up. In 1999, the law was amended and the section on the Drug Price Control Committee was deleted," Dr Vichai added.

The impact on Thailand could be clearly seen, when compared with India's defiant efforts to fully benefit from the extra time given to it. In the 1980s, the capacities of the pharmaceutical industries of the two countries were similar. At present, parts of the drug industry of Thailand have disappeared while others have gone backwards because its research and development efforts have been impeded by the strict patent laws. India, on the other hand, has seen its drug industry develop in terms of both generic and original drugs. India's legal amendments in early 2005 in compliance with the TRIPS Agreement were therefore carried out when the local industry was actually ready to enter into competition, and did misguidedly made to stunt domestic industry.

Other countries have had similar experiences. They were required to amend their patent laws to make them stricter, drugs became more expensive and fewer people could get access to them. Local drug industries gradually folded or became mere hired producers. Patent rules and regulations seemed to make patents immortal and non-expiring. A variety of tactics were deployed to extend patent terms although some drugs did not have the necessary properties to be granted any patents at all.

So, drug prices tended to go so high that they became a heavy burden on the national budget. When the burden was too heavy to bear, governments stopped providing the money. In the end, we got a health crisis.

Amidst darkness, there is still the light at the end of the tunnel

On the one hand, the campaign by academics, health professionals, lawyers, NGOs and the student movement against the amendment of the patent law ended in defeat. Public awareness of the issue was still low. The public was not interested and did not realize how the patent regime would affect their daily lives. On the other hand, the resolve of many individuals and groups became so firm that it bore fruit later on.

Around 1998, the NGO Coalition on AIDS, led by AIDS ACCESS Foundation, began to pay more attention to the treatment of AIDS patients with antiretroviral therapy (ART). Formerly, society believed that there was no treatment for this disease. Once people were infected, they would inevitably die. Nevertheless, most ART medication was patented, thus highly priced. So it was inevitable for these NGO workers to get to know about patents, which was the issue the Drug Study Group had ceaselessly monitored. The Group consisted of lecturers from various universities collaborating to protect the consumer's right to fair use of drugs for many decades. The Foundation for Consumers, an outgrowth of the Drug Study Group, was also interested in this topic.

At the same time, the Government Pharmaceutical Organization's Research and Development Institute, led by Dr Krisana Kraisintu and her research team that had monitored the ART patenting, was preparing to produce cheaper ART medications.

Once the need to know of persons with AIDS (PWAs) and NGOs working on AIDS was supported by different groups, it gradually turned into a strong network. Initially started as a self-help support group of PWAs, the organization's work expanded to include demands for the rights of its members and the protection of their rights.

Then hope was rekindled. Although the Thai Patent Act had been completely amended, Section 51 still remained as an important tool to protect public interest. It allows the state to exercise compulsory licensing to produce patented drugs or import the generic versions of them. This is an equilibrium mechanism that also appears in the TRIPS Agreement.

Previously, the GPO was prepared to produce ddI (Didanosine), an ART drug of similar formula to one produced by Bristol-Myers Squibb (BMS). Following the BMS patent on this drug, the GPO thought its patent would not be granted because the drug was not new and the application was filed according to the former Patent Act granting only a process patent. Moreover, the BMS patent application had earlier been denied in the US, which prompted the GPO to continue its research.

On 29 April 1996, the BMS law office informed the GPO that BMS had already acquired a patent on ddI and the GPO was absolutely prohibited from producing it. The company stated that "it will strictly protect its intellectual property if there is any violation of its rights". So, the GPO had to suspend production of ddI, even though all the raw material had already been purchased.

Because of the unusual patent history of the ddI drug and the need to alleviate the distress caused by expensive ARV drugs, networks of PWAs and NGOs working on

AIDS began a campaign for compulsory licensing by urging the GPO to produce ddI according to Section 51 of the Patent Act. But no progress was made.

The book "Road of Ordinary People Fighting against Big Issues: Lessons Learned from Revoking the ddI Patent" describes how, during 22-23 December 1999, about 100 representatives of NGOs working on AIDS and networks of PWAs set up a "Section 51 Community for ddI Development" camp at the flagpole in front of the Ministry of Public Health.

The camp aimed to make society understand drug patents and to present the (legal and ethical) justification for the state to use compulsory licensing on BMS patent.

The Ministry of Public Health accepted the demands of the demonstrators and promised to see to it that AIDS patients got ddI at a cheaper price. It also pledged to provide solutions to the problems on 17 January 2000. But the two-hour-long negotiation between the Public Health Minister Korn Dabbaransi and NGOs working on AIDS and networks of PWAs resulted in the GPO being instructed to produce ddI in powder form instead of in tablets to avoid upsetting the relations with the US and retaliatory trade barriers.

This outcome might make cheaper ddI available, but it was inconvenient to use and a lot of patients could not take it because they suffered nausea or diarrhoea. This was a great disappointment to the demonstrators.

But the networks of PWAs did not abandon their attempt. On 18 January 2000, they went to demonstrate in front of the US Embassy on Wireless Road to submit their petition letter to President Bill Clinton, urging the US not to retaliate against Thailand if the Thai government used compulsory licensing to produce ddI.

The US Trade Representative sent a reply dated 27 January 2000, citing President Clinton's speech to the World Trade Organization conference in Seattle that the US would waive its rights in order to mitigate the health crisis. The reply clearly stated that the US would not oppose the use of compulsory licensing in this case and further asserted that such an act would definitely be consistent with the TRIPS Agreement.

Despite this confirmation from the US that Thailand's use of compulsory licensing was a legal right according to Thai law and international agreements and that the US would not retaliate, the Ministry of Public Health's decision remained unchanged. The Department of Disease Control ordered the GPO to produce ddI in powder form only, arguing that the BMS had already lowered the price of its ddI tablets to a satisfactory level.

The camp in front of the Ministry of Public Health and the subsequent campaign ended as a disappointment to the protesting networks of NGOs on AIDS and PWAs. Their efforts did have some effect on the Department of Disease Control, and many doctors started to pay more attention to ART policy and finally implemented the National Access to ARV for People with HIV and AIDS, which provided antiretroviral medication for 50,000 people.

Dr Mongkol Na Songkhla—who is currently the Minister of Public Health—was one of those doctors. "Practically every year when the first of December (World's AIDS Day) is approaching, patients will come to demand such service, which we can never give them. It's a typical scene. I saw them when I worked at the FDA and Department of Medical Services. We couldn't do anything for them. In fact, something could have done, but the support on this issue was not clear," he recalled.

Not only had Thai society been made aware of the campaign against the ddI patent carried out by networks of PWAs, allied organizations, NGOs, academics, health professionals, and lawyers, but Thai society's subsequent moves for drug access were also significantly underpinned by the public campaign and legal battle of that time.

The NGOs working on AIDS and consumer rights had to get down to learning about drugs, laws and patents so that they could transfer their information to groups of PWAs all over the country.

"We were very puzzled because everything was new and we knew nothing about it before," was a concise conclusion, jokingly mentioned in a book entitled the "Road of Ordinary People" by Saengsiri Trimakkha, a representative of NGO workers on AIDS, who was at the time coordinator of AIDS ACCESS Foundation and fully responsible for this work.

"At that time, the NGOs working on AIDS that had previously engaged in campaigning and training had to learn all about ART, patenting, TRIPS and the WTO."

This response was similar to that of Nimit Tienudom, manager of AIDS ACCESS Foundation (who had been one of the plaintiffs in the initial case filed against BMS). "We had to be updated on legal issues and be informed of what the pharmaceutical academics were talking about. We had to have accurate information about drugs, each therapy and its efficacy."

Saengsiri and Nimit were obliged to communicate with the Thai networks of PWAs and NGOs working on AIDS, s they had to memorize and understand stories and details so that they could simplify and retell them to their friends in remote areas. These activities aimed at seeking a consensus on and consolidation of the movement were carried out by a few PWA well-wishers. They in fact involved the participation of hundreds of thousands of PWAs nationwide.

Saengsiri recalled: "We had to travel far and wide, giving information to nearly 100 forums about patents, drugs and various movements at regional and provincial levels."

The 61 founding groups of PWAs expanded into more than 400 nationwide networks of PWAs at the time, coordinated at national, regional, provincial and district levels. Now the networks number more than 1,020.

It could be claimed that these networks of PWAs are the strongest learning and rights protection networks. They played an important later role in examining the government's policy on FTA negotiations and pushing for the use of compulsory licensing.

Where did CL come from?Not from the sky, but out of the ground

Asked this question, Dr Vichai Chokevivat, president of the Government Pharmaceutical Organization, took us back 40 years to when he was young and seeking answers.

"Our rural reconstruction camp 40 years ago saw us practicing our verbal skills and debating every night. It was asked why people had to pay when they were ill. Why didn't the government provide such services? These questions haunted me all the time. When I worked as a rural doctor, I saw many people taken ill and becoming almost penniless. They had to sell their farmland or even their daughter to get enough money to pay for their medical treatment. It was such a painful and bitter experience that we dreamt of providing free medical treatment to the sick.

"There was a free medical treatment project in October 1973. In 1991-1992, a social security system started. In 2001, a health care system for all was put in place to give medical services to all citizens throughout the country. I hadn't expected to see this kind of thing in my lifetime.

"Our next effort is to ensure that these projects will not be last for a short while and then go bankrupt."

The Healthcare Security for All Project or the Gold Card Project, formerly known as the "Thirty Baht for Each Medical Treatment", ultimately resulted from the social movement of civil society consisting of academics, health professionals, networks of PWAs and consumers. These social activists tried to use the provisions of the 1997 Constitution by collecting 50,000 signatures of eligible voters to propose legislation on free medical treatment services to all citizens, but to no avail. Later on, the Thai Rak Thai Party took up the concept and promoted it as part of its political platform.

At first, the Healthcare Security for All Project did not cover serious and expensive illnesses like HIV/AIDS.

Due to domestic and international pressure, the National Healthcare Security system began to include HIV/AIDS in its services in 2003, two years after it came into force.

According to Dr Vichai Chokevivat, "At the World's AIDS Day event held in Bangkok in 2004, the Access for All campaign was promoted. But the government could not come to any decision. We in the healthcare circle were not certain too. We were not sure if we should start something too idealistic, as the government might become disheartened. But a turning point came when the Government Pharmaceutical Organization was able to produce a generic antiretroviral drug—GPO-VIR—by combining three drugs whose patents had already expired. Dr Krisana Kraisintu and her research team made a great contribution to the country. The production of the GPO-VIR combination drug was timely. It was good and helped reduce treatment costs from tens of thousands of baht to only 1,200 baht. As the Global Fund had given us partial funding, so we decided to start our project."

Research by Dr Nathan Ford of Médicins Sans Frontières showed: "Thanks to the competition of generic drugs entering the market, the annual cost of first-line treatment was lowered from 400,000 baht per patient to only 14,400 baht, a drastic reduction of 97%." Since 2001, the mortality rate of AIDS patients has also been reduced by 79%.

Dr Vichai said: "When we decided to include HIV/AIDS in the healthcare security programme, those involved knew full well that we had to use patented drugs too. Some patients suffered side effects from taking Nevirapine, one of the three components of GPO-VIR. We didn't succeed in negotiating the price of Efavirenz. We tried again in 2004. The MSD Company, the patent holder of the drug, agreed to lower the drug price on condition that the Ministry of Public Health must set up a committee, jointly supervised by the FDA and Department of Internal Trade. But the negotiations came to nothing. So we had to look for an opportunity in the intellectual property laws. ***It was really our last resort.***"

Mrs Sudarat Keyuraphan, Minister of Public Health at the time, ordered the Department of Disease Control and the Food and Drug Administration to negotiate the prices of essential drugs. A feasibility study of compulsory licensing was to be conducted too when it was found that the health system was short of Efavirenz.

But things were simply forgotten.

The real need to use CL

Apart from its populist policies, another actively promoted policy of the Thaksin Shinawatra administration was to speed up free trade agreement negotiations with over 18 countries. A quick conclusion and implementation of the Thai-US FTA appears to have been what the Prime Minister wanted most.

Because the US failed in its attempt to push for the stricter protection of intellectual property at multilateral negotiations in the World Trade Organization, it had to resort to bilateral talks, or FTA mediation, to press its demands.

It was found that the content of the FTAs previously signed by the US with such countries as Singapore, Morocco, Jordan and Australia, was similar in demanding stricter patent protection (TRIPS-plus) than is required under the TRIPS Agreement. Expanded patent protection of medical information monopoly rights would prevent generic drugs from being marketed for another five years. It would also restrict the use of compulsory licensing, destroy the process for challenging patents, and make it easier to intervene in the approval of a patent.

In December 2005, the UN Development Programme in cooperation with the World Health Organization, the UN Programme on HIV/AIDS (UNAIDS), the Ministry of Public Health and Chulalongkorn University, held a Conference on Free Trade Agreement-related Intellectual Property Rights: the Case of Drug Consumption. Academics from around the world were invited to share their experiences in research work relevant to the FTA and access to medicines.

The conference agreed that the US excessive demands for more than the TRIPS conditions, or TRIPS-plus, would undermine Thailand's access to essential medicines.

The meeting presented its policy proposals to Thailand, which was urged to fully preserve its sovereignty over the use of compulsory licensing, provided by the TRIPS Agreement. Thailand was also recommended to apply compulsory licensing to second-line ART drugs and refuse to accept the content of an FTA that exceeded the expectations of the TRIPS Agreement.

The conclusions of the conference were put into an article written by Dr William Aldis, then the representative of the World Health Organization in Thailand, and published in the *Bangkok Post* of 9 January 2006, one day before the sixth round of Thai-US FTA negotiations in Chiang Mai. This upset the US administration so much that the WHO's director was forced to remove Dr Aldis from his position in Thailand.

About ten thousand people representing eleven networks of nationwide people's organizations—Thai Network of People Living with HIV/AIDS (TNP+), Alternative Agriculture Network, Federation of Consumer Organizations, Four-Region Forest Network, Federation of Northern Farmers, Four-Region Slums Network, Council of the People's Organizations of Thailand Network, Confederation of State Enterprise Workers, Students Federation of Thailand and the FTA Watch Group—came together to protest the Thai-US FTA talks in Chiang Mai. They issued a statement, saying:

"We oppose the stance of the Prime Minister (Thaksin Shinawatra) because what the government puts on offer is a matter of life and death and the well-being of the people. If the government insists on doing this, it must reveal who the beneficiaries are and why telecommunications services will not be liberalized, as they are not relevant to the life and death of the people at all.

"All eleven networks of the people's organizations demand the government end its free trade negotiations with the US, particularly on the following issues:

1. ***Intellectual Property,*** especially with regard to:
1.1. Drug patents, where the government agrees to extension of the patent protection terms and cancellation of the consumer protection measures that exceed the WTO agreement and US legal requirements; and
1.2. Patents on life forms, which will negatively affect biological diversity and local wisdom;

2. ***Liberalization of Agriculture,*** which will allow the dumping on the Thai market of highly-subsidized agricultural products such as corn and soybean from the US and the consequent ruin of hundreds of thousands of farmer families; and

3. ***Liberalization of Investment,*** which will treat American investors as Thai nationals, particularly in relation to public utilities such as electricity, water and investment in agriculture that concerns national food security.

"The government must publicly ensure that the three issues mentioned above will not be included in the Thai-US free trade negotiations, otherwise, the 11 networks of people's organizations will do everything to end the negotiations."

Although the Thai-US FTA talks did not completely break down, the negotiators had to frantically find new meeting places. The power of the people, knowledge and public awareness made the Thai-US free trade deal very questionable, especially the US demands for patent protection.

Many people's concerns that previously seemed to be exaggerated were proved right when the http://www.bilaterals.org website revealed the details of the US demands submitted to the Thai negotiators in the sixth round of the talks in Chiang Mai (and Mr Kanissorn Navanugraha, Director-General of the Department of Intellectual Property subsequently admitted that they were true). It turned out that the pessimistic concerns were a realistic viewpoint.

What was worse was that these demands had been accepted by international experts monitoring the Thai-US FTA deal as worse than feared.

Assoc Prof Jiraporn Limpananont, head of the Social Pharmaceutical Action Research Unit, Faculty of Pharmacy of Chulalongkorn University, concluded that the drug companies had made their greedy demands through the US negotiating team. These drug firms did everything to exploit the deal by demanding multiple benefits. They wanted monopoly rights to medical markets, treatments and operations, all of which comprise one of the four necessities of life. They wanted to destroy Thailand's

healthcare system, especially its healthcare security and the opportunity to develop national medical self-reliance.

A lot of government economists, who had strongly supported the negotiations with the US at the beginning, began to share a similar view that "this is too much".

Concern over the destructive impact of the Thai-US FTA on Thailand's healthcare system did not come from international healthcare institutions only. A supranational organization like the World Bank was also worried.

Through the World Bank's report on "The Economics of Effective AIDS Treatment - Evaluating Policy in Thailand", a similar message was sent to Thailand. It was time to brave it out and use compulsory licensing.

This report was an evaluation of the three-year-long attempts by the Ministry of Public Health to expand its ART treatment services. It also warned that without a prompt decision to ensure access to newer drugs, the increasing costs of treatment would be too high for the government to continue its ART provision through national access to the ART programme, which has been highly praised.

The problem is newer drugs are all patented and much more expensive than the first-line therapy currently used by the PWAs. According to the World Bank's report, no action has been taken to lower the prices of these drugs. The government's budget to run this programme will increase fivefold within 15 years.

Human lives might be seen as less important than trade, the Bank's report clearly stated.

"Because Thailand stands to gain a great deal from bilateral agreements to reduce trade barriers with trading partners such as the United States, the Royal Thai government may be tempted to relinquish its rights to grant compulsory licenses for AIDS drugs in exchange for proffered trade advantages. The report finds that the cost of such concessions would be large. For example, by exercising compulsory licensing to reduce the cost of second-line therapy by 90 percent, the government would reduce its future budgetary obligations by US$3.2 billion discounted through 2025."

That will require a very strong political commitment...indeed.

The next question is: what are we going to do?

Pharmacist Sorachai Jamniandamrongkarn of the National Health Security Office said in late 2005 that Mr Kamol Uppakaew, President of the Thai Network of People living with HIV/AIDS, had submitted a letter to Mr Pinij Jarusombat, who was then Minister of Public Health. The letter urged the minister to exercise compulsory licensing to deal with the high medicine prices that prevented the poor from accessing drugs. Prompted by the demonstrators' strong opposition to the Thai-US FTA negotiations and the "worse than feared" demands of the US, the National Health Security Board decided to discuss this issue.

"An academic who was a Board member pointed out in the meeting that Thailand had never used even the waivers of the TRIPS Agreement. Now more TRIPS-plus demands were being foisted on us by the US negotiators that would result in the cancellation of the TRIPS flexibilities. So the Board agreed that use of WTO flexibilities should be considered to address the internal problems of expensive drugs and healthcare services. This attempt would benefit medicine access to medicines, but it would also impede US penetration.

"Dr Sanguan Nitayarumphong, Secretary-General of the National Health Security Office (NHSO) and Chair of its Board, and Minister Pinij agreed that CL was a mechanism that would support the national health system. They decided that the matter must be treated seriously for it to reach a successful conclusion. Therefore, a sub-committee was established to deal with the matter."

This Sub-committee to Implement Government Use of Patents on Drugs and Medical Supplies was set up on 12 January 2006, consisting of representatives from a wide range of concerned parties including the Commerce and Public Health Ministries, the Council of State, the Law Society of Thailand, hospital doctors, and networks of PWAs and cancer patients. The sub-committee laid down its framework and produced research before passing its resolution calling for a compulsory license to produce Efavirenz, which was finally approved by the meeting of the National Health Security Board.

"Having said that does not mean we are evading our responsibility. Though the NHSO was involved in these moves, it's not the initiator of the whole movement. I want to give credit to the Thai Network of People living with HIV/AIDS, which has been cooperating with the academics that have been monitored the matter for many decades. The NHSO is only a facilitator.

"The success of Thailand's use of compulsory licensing did not result from a rash and self-satisfied decision of the military-backed government. 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 the issue. When the idea was proposed to Minister Pinij, it took a lot of time since his working team knew nothing about the matter and had to start from square one. Trying to make those people understand and having to make many phone calls with them was rather annoying. So Minister Pinij missed the opportunity to sign his name."

Public health interest and the life of the people must come before commercial interest

This sentence was printed in bold in the White Paper issued by the Ministry of Public Health, citing its legal rights and justification to use compulsory licensing on three patented drugs for the public interest. The use of these patent rights aims for non-commercial purposes and will be limited to those patients covered under three government welfare systems: the National Health Security System, Social Security, and the medical benefits scheme for civil servants and government employee.

The three patented drugs, whose rights have been overridden, are the first-line drug Efavirenz, commercially known as Stocrin, of MSD (on 29 November 2006); the second-line drug Lopinavir/Ritonavir, commercially known as Kaletra, made by Abbott (on 24 January 2007); and Clopidogrel, commercially known as Plavix, made by Sanofi-Aventis (on 25 January 2007).

The Ministry of Public Health's White Paper pointed out the reasons behind this decision: "Drugs are ethical products and essential to life. Conditions applicable to drugs should be separated from those imposed on general products. **The human right to life ought to be more important than commercial interests.** Thus, the Ministry of Public Health's implementation of Government Use of Patents on patented drugs is carried out according to legal and humanitarian principles. It is also the obligation of the government to provide essential drugs on to the National Essential Drug List to every Thai citizen covered by all health security systems." This will save as much as 1,035-1,665 million baht of the government's annual budget, and provide an increase of drug access for patients of 6-12 times. The decision has been lauded by domestic and foreign civil society sectors.

Thanphuying (Dame) Preeya Kasemsan, Chair of the Public Health Committee of the National Legislative Assembly, sent a letter dated 20 February 2007 praising the government's announcement of the exercise of compulsory licensing. "Such implementation is beneficial to a great number of people and will increase the people's access to essential drugs. As the government has a limited budget, such enforcement is legitimate and in compliance with international principles currently adopted by the global community."

In a letter sent to Dr Condoleezza Rice, the US Secretary of State and United States Trade Representative (USTR) Susan Schwab to demand that the US stop interfering in Thailand's compulsory licensing, it was pointed out:

"Thailand's decision was significant not only for Thailand, but also for other developing countries that need cheaper generic drugs. If Thailand begins to buy drugs from generic drug producers, the generic drug market will get bigger, leading to active competition and reduction of the price of new medicines everywhere.

"The benefits resulted from generic drugs' increasing competitiveness are desirable. But so far, developing countries have been hesitant about implementing compulsory licensing for fear of retaliation and pressure from the US in response."

On the one hand, the Thai Ministry of Public Health's commitment to the view that the right to life of the people must come before commercial interests has been commended. On the other hand, it has been disapproved of, opposed and lobbied against by all manner of tactics deployed by those groups profiteering from human life trafficking.

The Pharmaceutical Research and Manufacturers Association (PReMA), an affiliate of the Pharmaceutical Research and Manufacturers of America (PhRMA), which is the most powerful association of the multinational drug industry, took a leading role in initially opposing Thailand's compulsory licensing by denouncing it as the taking away the private sector's property. It also threatened to suspend its investment in Thailand.

This tactic did not work because Thailand did comply with Thai law as well as international agreements. And the use of compulsory licensing is not taking away the private sector's property, but one of lawful flexibilities. Also, reasonable remuneration was offered as recognition of the patent holders' rights.

According to Thailand's announcement on the Public Use of Patents for Pharmaceutical Products, a 0.5 percent royalty fee is offered to patent holders, who are legally entitled to negotiate the remuneration. But no patent holders entered into negotiations. Indonesia and Malaysia had similar experiences when they announced their public use of compulsory licensing in 2004. This was because the multinational pharmaceutical companies did not recognize developing countries' legal rights. Neither did they want to set an example of accepting remuneration for other countries to follow.

The multinational pharmaceutical companies attempted to use legal interpretations to oppose Thailand's exercise of compulsory licensing. On 15 February 2007, Tilleke and Gibbins Co., the law representative of MSD, filed an appeal with the Department of Intellectual Property stating that the Ministry of Public Health's compulsory licensing did not follow legal procedures, as no prior negotiations with the patent holder had been held.

At the time, the newspapers reported that the Department of Intellectual Property was about to ask for the Council of State's interpretation. But many of the world's leading law experts, including Professors Brook Baker and Sean Flynn of the American University, Dr Carlos Correa of the University of Buenos Aires and Assoc Prof Jakkrit Kuanpoth, expressed their objections to the move.

Representatives of the Thai Network of People living with HIV/AIDS and AIDS NGOs also met and asked Mrs Puangrat Assawapisit, Director-General of the Department of Intellectual Property, for clarification on the matter. On 21 February 2007, the Department of Intellectual Property turned down the appeal and suggested that a complaint about the Ministry of Public Health's failure to follow legal procedures be filed to the Administrative Court. The Department would accept only an appeal based on dissatisfaction with the remuneration.

Apart from engaging in lobbying themselves, these multinational pharmaceutical companies also exerted pressure through their diplomats in each country.

Nimit Tienudom, director of the AIDS ACCESS Foundation, revealed that Abbott had asked to meet with the Thai Network of People living with HIV/AIDS and offer to reduce the price of Kaletra in exchange for the network's lobbying with the Ministry of Public Health to cancel its use of compulsory licensing.

At the same time, the ambassadors of the US, EU, France and Switzerland met with the Ministers of Public Health, Commerce and Foreign Affairs many times, signalling their disapproval of Thailand's pursuit of CL. They cited Thailand's failure to hold prior negotiations with the patent holder, despite acknowledging that such negotiations were not legally required.

Meanwhile 22 members of the US Congress, led by Mr Henry Waxman, sent a letter urging the USTR not to impede Thailand's implementation of its legal rights. In her reply, USTR Susan Schwab admitted that Thailand was authorized to issue compulsory licenses.

"What we have done consistently to date full respects the Doha Declaration and Thailand's ability to make appropriate use of the flexibilities embodied in the WTO rules." Nevertheless, a number of Republican Congressmen in collaboration with lobbyists (numbering over 1,000 persons hired by the pharmaceutical industry to work with the US Congress) falsely claimed that Thailand was about to issue compulsory licenses on an additional 20-30 patented drugs and urged the US administration to use retaliatory measures against Thailand.

Abbott Labs resisted by resorting to the tactic of sending a letter to the FDA's Drug Control Division to withdraw all applications to register its new drugs in Thailand. The withdrawal of the drugs—Zemplar for the treatment chronic kidney disease; Simdax for heart failure treatment, Humira, a medicine for treating autoimmune disease, and Aluvia tablets, a new formulation of the heat-stable second-line Aids drug—was made in retaliation against the Thai government's use of compulsory licensing on *Lopinavir/Ritonavir* or Kaletra.

Matichon Daily and the *Wall Street Journal* reported that "Abbott will not apply for the registration of new drugs and will withdraw all applications to register new drugs in Thailand until the government takes heed of intellectual property, including the cancellation of compulsory licensing."

As soon as Abbott's move was widely reported, the TNP+, AIDS ACCESS Foundation, Centre for AIDS Rights, Thai NGO Coalition on AIDS, and Foundation for Consumers condemned the company for maliciously putting pressure on Thailand, which has attempted to expand its universal drug access to solve the country's internal health services. Such action reflected the pharmaceutical industry's lasting and endless greed as well as its total lack of concern for the people. These opposing organizations urged the Thai people to boycott Abbott's products and turn to generic versions of drugs by other makers and alternative goods.

The move to hit back at Abbott's decision spread to networks of parents, rural doctors club, rural pharmacists club, and networks of patients with kidney and heart diseases. These groups also denounced Abbott's action as holding patients/consumers as hostages to force the government to end its use of compulsory licensing, even though the Thai government had done nothing in contravention of domestic law and international rules.

Growing anger against Abbott spread globally. On 26 April 2007, one day before Abbott's Annual Shareholders Meeting in Chicago, protest demonstrations were held in front of the company's offices in many cities in France, the US, UK, Germany, India, South Africa, China, Brazil, Argentina, Australia, Canada, Indonesia, Japan and Singapore while the public were also urged to boycott Abbott's products. In France, a group of PWAs known as ACT UP organized a demonstration called Netstrike through the Internet, which finally led to the collapse of Abbott's website.

At Abbott's Annual Shareholders Meeting in Chicago, Jon Ungphakorn, a former Senator of Thailand and Secretary General of AIDS ACCESS Foundation and Mr Wirat Purahong, chairperson of TNP+ were invited to participate in the meeting as proxies for the shareholders from religious groups and question the unethical action of Abbott.

The Student Global AIDS Campaign sent a letter, signed by former and present students of the University of Wisconsin at Madison, to the Wisconsin Alumni Research Foundation (WARF). The letter called on the Foundation to reprove Abbott for its use of the drug for treating kidney disease—one of the University's innovations—as a bargaining tool to press Thailand's Ministry of Public Health to cease its implementation of compulsory licensing.

"In accordance with these principles, we look to WARF to publicly call on Abbott to immediately resume registration of Zemplar.

"On 27 April, patients, doctors, and others around the world will focus on Abbott, coinciding with the organization's general shareholders meeting. Leaders from the patient community in Thailand will use the opportunity to speak directly to Abbott executives to demand that drugs not be used as political leverage and patients not be used as political hostages.

"We ask that WARF, as the owner of the patents on one of these critical drugs, add its unique and powerful voice to the call for justice in the developing world," said the letter.

The "unacceptability" of Abbott's selfish act arose around the world. A critical turning point arose when religious groups holding Abbott's shares, also condemned the company and called on it to end their action.

Finally, in an attempt to redeem itself from its miscalculation, Abbott had to cooperate with WHO Director Dr Margaret Chan in announcing a global price reduction of Kaletra for middle-income developing countries from US$2,200 per patient per year to US$1,000 per patient per year. But this reduced price would be available in Thailand

only if no compulsory license was imposed on the new heat-stable form of Lopinavir/Ritonavir (Aluvia).

Thai civil society led by Foundation for Consumers, AIDS ACCESS Foundation, TNP+, and the Thai NGO Coalition on AIDS tried appealing for effective enforcement of the law on commercial competition. It called on the Competition Commission to hold Abbott accountable for its violation of Sections 25 (3) and 28 of the Competition Act B.E 2542 (1999) as a business operator having market domination designated by the Act.

"This resulted in an unreasonable cancellation of imports, leading to a decrease in available choice of drugs with similar indications to the point where the range of choice does not meet the needs of medical services to the patients who need such drugs.

"The Competition Commission is thus urged, by virtue of Section 31, to order Abbott Laboratories to apply for registration of its new drugs and resume application for the 10 withdrawn drug registrations in Thailand."

Simultaneously, the pharmaceutical industry intensified its media and publicity campaign.

Many foreign media, especially the *Wall Street Journal*, strongly accused Thailand of violating intellectual property rules. Meanwhile several others attempted to engage in a discourse on "breaking the patent" or "overriding the patent", all of which connoted law-breaking, although the content of the articles would admit that the measures undertaken by Thailand were permitted by WTO rules.

But most insufferable was the smear campaign run by the USA for Innovation, an organization claiming to be a non-profit agency. It bought advertising space in the Thai and foreign print media and created its own website accusing the military-backed government of Thailand of turning the country into a dictatorship like Burma by illegally issuing compulsory licenses. The agency also claimed that GPO-VIR, produced by the GPO, was of low quality and submitted letters to the US Congress and administration urging them to retaliate against Thailand.

The actions of the USA for Innovation were very significant, not in terms of its content, whose main topics had been refuted by the Ministry of Public Health and medical academics. Its organization was interesting because of its connection with Edelman Public Relations Worldwide, a firm whose clients include many multinational drug corporations and the ousted Prime Minister of Thailand, Thaksin Shinawatra, who has been charged with corruption.

The Bangkok Post and *The Nation* newspapers dedicated one full page each to Thai civil society to publish its responses to the allegations of USA for Innovation.

"USA for Innovation is an organisation set up to serve the interests of US drug companies upset by Thailand's recent announcements of compulsory licenses permitted by the WTO Agreement. This organization is adept at manipulating and distorting the facts to achieve its purposes.

"The accusations by USA for Innovation, which appeared in an advertisement in the English-language press a few days ago, distort the facts by denigrating the anti-viral drugs produced by Thailand's Government Pharmaceutical Organization as being worthless. The truth is that GPO-VIR has played a significant role in reducing the annual mortality rate among Thai AIDS patients from 8,246 in 2001 to 1,613 in 2006. More than tens of thousands of lives have been saved over the past 3-4 years.

"The study by Mahidol University cited by the USA for Innovation to claim that GPO-VIR had a high resistance of between 39.6 and 58 per cent is in fact research which attempted to study the resistance among long-term patients who had already failed the treatment. There are no research findings available to compare the rates of resistance to GPO-VIR with the rates of resistance to equivalent originator products.

"Thailand is internationally recognized for its efforts to provide health coverage for all and to ensure that HIV/AIDS patients have universal access to the appropriate drugs.

"The decision to authorize the compulsory licensing of necessary drugs shows the praiseworthy courage of the Thai government and the Ministry of Public Health, to put the lives of the Thai people before commercial benefits."

The Government Pharmaceutical Organisation (GPO) is in the process of suing the USA for Innovation for defaming its reputation and demanding billions of baht in compensation.

Dr Suwit Wibulpolprasert, a specialist at the Ministry of Public Health's Department of Disease Control recalled Thailand's struggle to use compulsory licensing against opposition and attack from several parties. He said when Dr Mongkol Na Songkhla took office as Minister of Public Health, the use of CL proposed by the NHSO had been pending since Mr Pinij Jarusombat's tenure.

"He asked me to check the legality of the matter. I asked if he was to do it for sure because it's a big deal. He said if it would help poor people get access to drugs, he was for it. I asked him again if he had consulted the Prime Minister and he said the Prime Minister had understood and told him to go ahead if it was essential.

"So I asked the secretary of the Minister to invite concerned parties, such as the Department of Intellectual Property, the Council of State, NHSO and the Law Society of Thailand to discuss if it was lawful for us to do it. On the day of the meeting, I was first introduced to Sections 51 of the Thai Patent Act and 31 (b) of the TRIPS Agreement, that specifies that in the case of public non-commercial use, the patent holder must be notified without delay. I thought we should make our intention known for the sake of transparency.

"When the announcement was made, the drug companies protested. I asked Dr Mongkol again if the Prime Minister had definitely given the green light to CL. Dr Mongkol said the Prime Minister was well aware of it but reminded us to proceed with caution.

"When there were strong protests that our CL was unlawful, I e-mailed our allied networks overseas asking this question. Prior to the CL announcement, we didn't communicate much with these networks. With the increasingly vociferous opposition, I contacted Martin Khor of Third World Network, Dr Carlos Correa of the University of Buenos Aires, and James Love of the Knowledge Ecology International. James Love was most active in replying to me and assured us that we had done nothing wrong. We did learn a lot really."

When asked if the team had ever been discouraged by the objections, Dr Suwit instantly replied: "Discouraged all the time; we're just human. We can't help it. But with more supporters, we decided to fight back.

"The last time I asked Dr Mongkol if the Prime Minister agreed with the announcement, he squeezed my arm and said, 'you've asked me three times already, doc.' but still I was not convinced. Then one day, I met the Prime Minister and Dr Peter Piot, UNAIDS director. I heard with my own ears the Prime Minister tell Peter that Thailand had been seriously affected and pressured by its announcement on CL. But for the public good, it had to be pursued. From then on, I have had no doubts about it."

Dr Sanguan Nitayarumphong, Secretary General of the National Health Security Office (NHSO), said that as soon as he learned about Dr Mongkol's appointment as Minister of Public Health, he was glad and instantly proceeded with the scheme.

"I was very glad that Dr Mongkol became the Minister. I told him I had a job left unfinished. At first, he told me to have it carefully checked whether the Ministry of Commerce would join in. I told him that all concerned parties had met and been consulted. None of them opposed the move.

"When the uproar began, I was worried about him and gave interviews in support of his work. But he turned out to be more determined than I had thought. Because it was for the public good, Dr Mongkol was resolute to fight for it. He deserved credit for this job indeed.

"I was not afraid that Dr Mongkol would be discouraged. I had started and urged the scheme, so I must be responsible for it one way or another. But my worry lay in the fact that my scheme might have put a senior official in a difficult position. Now I'm much relieved to see him very determined. And the move has gone quite well.

"The impact was, as expected, not limited to a national level. But the positive side of it was the emergence of the solidarity of global community. Previously, I had expected some support for our compulsory licensing effort, but had never thought it would be this extensive. This proves that advocates of justice are everywhere in the world. Once injustice is caused, these advocates of will come out to take action."

Return of the vicious circle of fear and the slavery trap

On 1 May 2007, the US Trade representative elevated Thailand from its Watch list to the Priority Watch List (PWL) category. Although the US Ambassador to Thailand Ralph Boyce Jr insisted that this had nothing, or nothing principally, to do with the country's compulsory licensing, the Special 301 Report clearly stated:

"Apart from continued concern over Thailand's inadequacy of intellectual property rights protection, in late 2006 and 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products."

Assoc Prof Wittaya Kulsomboon of Chulalongkorn University's Consumers' Health Protection Programme argued that to accuse Thailand's compulsory licensing of lacking transparency and due process was unreasonable. It could also be deemed as a threatening move to compel Thailand to end its attempts to provide access to life-saving medicines for patients who needed them.

"Thailand's imposition of compulsory licenses on the three patented drugs was a legal and moral act, confirmed by Thai and foreign law experts, the current legislators and a lot of international academic agencies. Despite the enthusiastic and extensive support given to Thailand's CL by a great number of international organizations committed to drug access, the US still resorted to use trade measures in retaliation against the Thai move. It should be noted that the US Ambassador to Thailand Ralph Boyce tried to deny that such retaliation was a trade counterattack against Thailand's compulsory licensing on the three drugs. But James Carouso, Chief of Economic Affairs at the American Embassy in Bangkok, criticized Thailand's compulsory licenses for lacking transparency and due process."

Moreover, the Special 301 Report reflected the aggressive US move on TRIPS-plus, which became inactive after the suspension of the Thai-US FTA negotiations.

"Another feature of the US's imposition of PWL measures is its aggressive demands for TRIPS-plus concessions by accusing Thailand of failure to meet US standards of protection of data exclusivity and the lack of linkage between patent status and registration of generic drugs to prevent the marketing of generic drugs before the expiration of drug patents. All these excuses were made to pave the way for more aggressive US demands in future Thai-US FTA negotiations."

In a report by *Prachachat Thurakit*, a Thai-language business newspaper, a source in the Ministry of Commerce was quoting as saying that the US had proposed a plan of action for Thailand to follow if it wanted to be removed from the PWL and be placed on the WL. The content of the plan was similar to the demands made by the US in the sixth-round of Thai-US FTA negotiations in early 2006, which included:

- amending all intellectual property laws as demanded by the US;
- designating intellectual property rights violation as a criminal offence;
- acceding to the Patent Cooperation Treaty and Matrix;
- extending the 20-year patent term;

- disallowing pre-grant opposition;
- limiting grounds for compulsory licenses to national emergencies; and
- granting data exclusivity.

On 18 May 2007, the National Human Rights Commission issued a statement urging the US administration to stop any action that would preclude the human right to drug access. The commission expressed its support for the Thai government's stand not to accept any additional demands exceeding the TRIPS requirements. It also sided with the government's announcement of compulsory licensing to provide universal drug access to meet the needs of the people.

It was fortunate that the Ministry of Commerce did not give in to the US proposed plan of action. In an interview given to *Thai Rath Daily* on 8 May 2007, Mr Karun Kittisataporn, Permanent Secretary of the Ministry of Commerce, said that he had instructed Mrs Puangrat Assawapisit, Director-General of the Department of Intellectual Property, not to accept any requirements imposed by the US. Before the department could take any action, other concerned agencies must be consulted and cabinet approval given because some of the US requirements may be beyond Thailand's ability to comply or may exceed international agreements, to which the country is already obliged.

"To join in the plan of action proposed by the US so that Thailand will be removed from the PWL to the WL is something we could do. But that doesn't mean that the US will be satisfied. We could still be on the PWL. But I gave instructions that no demands of the US should be accepted because some of them might be beyond our ability to follow. In past negotiations, if we wanted to be removed from the PWL, the US would give us a specific list of actions, some of which were excessive."

Mr Karun added that being on the PWL could lead to the US cutting Thailand's generalized system of preferences (GSP) benefits given to certain Thai products and was more likely to be a warning. In the past, the US never cut any country's GSP benefits as a result of Special 301 reviews. Mr Karun believed that Thai exporters were quite productive and competitive in the US market. Being deprived of GSP benefits could not be any problem. He thought that the absence of GSP benefits would be preferable, as the US would no longer be able to use them to put pressure on Thailand.

"Being placed on the PWL is no big deal to worry about. I think the issue has been so exaggerated that everybody is worried. The US could use this concern as a bargaining chip. In negotiating all plans of action, there are governing regulations. Even cutting GSP benefits must be based on many rules and regulations. Violations of intellectual property rights are not the only criterion. However, we must be aware that the US has the exclusive right to grant or not to grant GSP benefits to any country. But I'm positive that Thailand will not be elevated to the Priority Foreign Country category."

On 9 May 2007, Mrs Puangrat Assawapisit, Director-General of the Department of Intellectual Property, stated clearly in her interview with the mass media that the Ministry of Commerce would not accept any conditions exceeding international

agreements, including particularly data exclusivity protection as demanded by the US to be incorporated in the Thai-US FTA.

This response led to the suspension of the Patent Act amendments, previously submitted by the Department of Intellectual Property to the Secretariat Office of the Cabinet of the ousted administration. The drafted amendments were criticized by the Ministry of Public Health and civil society for being similar to the US demands made during the sixth round of the Thai-US FTA negotiations.

"The academics and civil society organizations continuously monitored the amendment of the Patent Act and found that the draft Patent Act amendments submitted by the Ministry of Commerce needed to be revised to achieve maximum benefits. In principle, the revision of the draft amendments should be based on the following principles:

1. to bring maximum benefit to the Thais and all sectors of the country;
2. to pave the way for the development of a patent regime that focuses on protecting patients/consumers as well as encouraging inventors and technology transfer to Thai people;
3. to be pursuant to and not exceeding the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Doha Declaration on the TRIPS Agreement and Public Health/WT/MIN/DEC/W/2, dated 14 November 2001; and
4. to be pursuant to the commitments of international agreements to which Thailand has already acceded."

Apparently not much pressure was put on the government by the business sector to revise the Patent Act to accommodate the US demands as had been done during 1985-1992.

Mr Buntoon Wongseelashote, Chair of the sub-committee on trade of the Board of Trade of Thailand, pointed out in a seminar on "CL: Economic and Social Perspectives" that the BOT agreed with Thailand's issuance of compulsory licenses. It was a misunderstanding to connect the placing of Thailand on the PWL, leading to the loss of GSP benefits, with the country's use of CL. These two incidents, the PWL and CL, were separate issues, he said.

He further added that on 1 July, US GSP benefits granted to Thai exports would be cut. There was no reason to be alarmed because many export items, such as frozen shrimp, jewelry, rubber and gold, were about to be deprived of GSP benefits. Therefore, the presence or absence of CL would have no effect since these products were not eligible for GSP benefits because they were already competitive in the market.

"Most entrepreneurs were worried that the announcement of CL will lead to more export products losing their GSP benefits, making them less competitive in the US market. But in reality, we can't compete with others because of the currency exchange rate; export problems have resulted from the excessive appreciation of the baht. The Bank of Thailand has to explain the issue. It's not time to get nervous and

blame CL as a major cause of GSP cuts. We're happy to be without GSP if the baht is at 40 per dollar."

Mr Buntoon cited Brazil's CL as an example of good timing. Brazil announced its compulsory licenses on 4 May 2007, after learning which countries the US had placed of on the PWL. If the US wanted to put Brazil on the PWL, it would now have to wait until 2008 to do so. So, Thailand's next round of CL should be issued after 30 April of each year.

The Board of Trade's Chair of the Sub-committee on Trade further elaborated on the intellectual property regime regarding patented products, especially drugs. Drug companies should base their local drug prices on each country's per capita income. Take Thailand for example. Thailand's per capita income is five times lower than that of the US. If a textbook costs 1,500 baht in the US, it should be priced at 300 baht in Thailand. Similar pricing should apply to drugs. On the contrary, drug prices in Thailand are about 10% or not more than 150 baht lower than the prices of drugs sold in developed countries such as the US.

An article "Using a tiny GSP fly to catch a big FTA fish?" by Woradul Tularak, a researcher at the Thailand Development Research Institute (TDRI), published in May 2006, interestingly described the US's trade stratagem.

"It was recently reported that the US would cut GSP benefits granted to Thailand if the latter could not conclude its FTA deal with the US by this year. At the same time, Thailand's Ministry of Commerce expressed its concern over the loss of trade benefits resulting from GSP cuts. It was unclear if the US GSP programme for Thailand, which was about to expire at the end of 2006, would be extended for another five years.

"There are a number of requirements for US GSP eligibility, such as national level of development. In 2002, for instance, a country with a per capita income of more than US$9,266 would automatically have its GSP benefits withdrawn. A GSP beneficiary country must ensure an open market for goods and services to the US and provide stringent intellectual property protection, good labour protection, a clear investment policy, and reduced trade and investment restrictions.

"Another condition stated that the US could suspend GSP benefits if a product had a market share of over 50% of the US market, or had a total value of imports exceeding designated ceilings, which varied from year to year. In 2006, the ceiling was around US$125 million (about 5,000 million baht). However, exporting countries could keep their privileges if the total value of global imports of the US was lower than the designated figure.

"So far, the US has withdrawn GSP benefits from several countries for various reasons. Taiwan, Singapore, Hong Kong and South Korea had their privileges withdrawn because of their high levels of economic development and adequate competitiveness. Israel's national income exceeding the required level while Argentina committed violations of intellectual property rights. Nicaragua and Ukraine violated labour rights.

"Of the 20 top GSP-eligible export items, the products relying most on US GSP eligibility which would be hardest hit if GSP benefits were withdrawn were jewelry and ornaments, tableware and aluminium. The least affected items would be petrochemical and plastic products, which were globally exported to other countries as well as the US outside of GSP programme.

"Most importantly, if the GSP benefits were revoked, the Thai entrepreneurs could export under normal import tariffs, which would not be any problem. Under the normal and not very high tariff rates of 3%, 5.5%, and 3.9% imposed on plastic containers, jewelry and colour televisions respectively, the Thai exporters could maintain their competitive edge.

"Thailand should not heed the US threats and hasten to conclude its FTA deal with the US just because of the fear of losing GSP advantages. It would not be worthwhile for Thailand to accede to a hasty agreement requiring too stringent protection of intellectual property, which would have wider and more permanent effects."

It remains to be seen if Thailand will be able to free itself from this vicious circle of fear and the slavery trap.

The impact of Thailand's CL

The first shipments of Efavirenz bought from India's Ranbaxy Laboratories arrived in early 2007. The price was much reduced, from 1,400 baht to only 650 baht per person per month, thus providing drug access to 20,000 people. Not long after Thailand's issuance of compulsory licences, MSD, the Efavirenz patent holder, announced a global reduction of drug prices in developing countries and in countries with a major HIV/AIDS epidemic, including Thailand. The drug price was reduced from the normal cost of 1,500 baht (hospital price was 1,300 baht) per person per month to 700 baht, in order to compete with its generic version. Many developing countries benefited from Thailand's compulsory licensing.

Dr Mongkol Na Songkhla said "I made a agreement with MSD that I would buy from the company if the price of the original drug was not more than 5% higher than its generic counterpart. But we would reserve the right to also buy the generic drug to ensure that we would not be let down later. Each time we make our purchase, we will compare with the price of the generic drug, and if the company's price is not more than 5% higher, we will buy some from them and buy the generic drug too. MSD has asked for a long-term purchase contract but we haven't agreed to it."

The Inter Press Service reported that Brazil's Ministry of Public Health sent a letter asking for the information about Thailand's CL. The letter stated: "Thailand's CL is a great inspiration to Brazil."

Brazil's significant decision to start on its first CL on Efavirenz on 4 May 2007, after hesitating for a long time, was prompted by the freshly translated information from the White Paper (of Thailand's Ministry of Public Health).

Only 20% of Thai patients suffering from heart disease and in need of the blood-thinning *Clopidogrel* could afford to buy the drug. It was not surprising that heart disease was Thailand's number two killer. The drug price was too high for the government's welfare service to provide it for patients. The retail market price was 140 baht per tablet. It was available at government hospitals at 73 baht per tablet, which was still too expensive, compared with the proposed price of its generic version produced in India of 6-12 baht per tablet. With CL, it is expected that the number of patients who will have access to the drug will increase 6-12 times. At the time of writing, Sanofi-Aventis had offered to reduce its price to about 22 baht.

"If heart disease patients can get access to the generic version of *Clopidogrel,* the death rate caused by heart disease will be greatly reduced," said Dr Mongkol.

Abbott, after its bullying response to Thailand's CL and met with international condemnation, announced a global price reduction of its second-line AIDS drug Kaletra from US$2,200 per person per year to US$500 for poor countries and to US$1,000 for middle-income countries, or about 3,260 baht per month. Before the CL exercise, the monthly drug cost was 11,580 baht. The reduced price would be available to Thailand on condition that the country did not continue its CL on Aluvia, the new form of Kaletra. But the company did not mention the withdrawal of the 10 remaining applications for registration of its six drugs.

The Thai Ministry of Public Health, on the other hand, made a better move by joining the pool procurement programme with the Clinton Foundation and 16 other developing countries to get a the needed drug at US$695 per person per year, cheaper than Abbott's proposed price. It was likely that the price could be further reduced.

"We negotiated through the Clinton Foundation, which had helped supply raw materials to a generic drug producer in India and facilitated the pool procurement by the 16 countries. In fact, the Clinton Foundation sent an open invitation to all manufacturers, of both original and generic drugs, for proposals to supply their medicines, based on the principle of high volume low profit and not vice versa. This is consistent with the Chinese saying that low volume of high prices does not make high profit, but high volume of low prices does not make a small profit, which has to be a healthy and sustainable profit too. Thus, the price was lowered to only US$695," said Dr Vichai.

Dr Suwit Wibulpolprasert related to the background to this issue: "While Dr Mongkol was working in Khorat, he began pool procurement that was able to lower the drug prices by as much as 30%. When Dr Arthit Urairat became the Minister of Public Health and was told about Dr Mongkol's effective price-reducing procurement in Khorat, he decided to make the initiative ministerial policy to be generally practised.

"The Clinton Foundation's representative met and asked me if Thailand was interested in joining the pool procurement of AIDS drugs. I then invited Dr Mongkol to listen to the briefing and he immediately gave the green light because he had done it before and aware of its advantages. But when we can buy at even cheaper prices, we will not buy from the pool."

These are the main reasons why Thailand's historic compulsory licensing had a global groundbreaking impact:

1. As a developing country, Thailand took a very bold step to announce compulsory licensing two times at a row (and more is likely to follow) and on very expensive patented drugs. This is different from other countries, which made a CL announcement once and stopped.
2. Besides AIDS drugs, Thailand also issued a compulsory licenses on heart disease drugs. Previously, the US urged the WTO meeting to limit the application of the TRIPS Agreement and Doha Declaration flexibilities to AIDS, malaria and tuberculosis only, but to no avail. Nevertheless, no developing country has ever dared to issue compulsory licenses on drugs for this group of diseases before.
3. Thailand's compulsory licensing has highlighted the importance of the generic drug industry in Thailand and overseas, as well as increased interest among those in the domestic drug industry.
4. Thailand's compulsory licensing has radically shaken the patent regime and clearly proved that the claim that monopoly rights will stimulate research and development is untrue. Currently, the drug industry is not interested in producing life-saving medicines but focuses more on lifestyle drugs for rich people and attempts to impose stringent protection of intellectual property to enjoy a monopoly of making maximum profit.

5. Thailand's compulsory licensing makes explicit how unethical the multinational drug industry can be and how far US politics has been dominated by the drug industry.
6. Thailand's compulsory licensing has encouraged countries, particularly those in developing world, to question the existing regime.

Prior to the 60th World Health Assembly held in Switzerland's Geneva during 14-23 May 2007, the Médecins Sans Frontières (MSF), an international medical philanthropic organization, submitted a letter to representatives of member countries of the World Health Organization urging them to focus on the ongoing drug access problems suffered by people all over the world.

A report by WHO's Intergovernmental Working Group (IGWG) pointed to the problems of drug access and failure of research and development. It noted that the World Health Assembly should seriously consider its proposed global strategies and be committed to addressing these problems.

Suggestions of the MSF letter to representatives of the WHO's member countries included the following issues.

WHO members should strongly insist on the role of the World Health Organization in research and development of drug access and the intellectual property regime. The role of WHO should neither be limited to the most neglected diseases nor be left to other agencies, such as the World Trade Organization or World Intellectual Property Organization, because no other organization has the public health perspective of the WHO.

The WHO should actively provide policy and technical advice to countries that need to improve access to drugs by using the TRIPS flexibilities, which were recognized in the Doha Declaration on the TRIPS Agreement and Public Health. WHO's initial lack of support for Thailand's compulsory licensing caused some concern over the organization's expected direction on the promotion of national capacity to secure public access to medicines. Now, the WHO and World Health Assembly should thus clearly express their support for the use of patent law flexibilities by countries to increase their access to medicines.

WHO's Intergovernmental Working Group should recognize the solution to access problems and development of innovative means separating the price of pharmaceuticals from the system of paying for R&D. The provision of incentives to R&D through the patent regime and high drug prices causes access problems to the populations of developing countries, particularly when drug companies can register their patents anywhere in the world, thus wiping out generic drug-making sources around the world. Therefore, the IGWG should find a way forward based on the principle of separating the price of pharmaceuticals from the systems for paying for R&D. It must consider new financial incentive mechanisms and developments, such as tax mechanisms, R&D agreements on essential diseases and presentation of R&D rewards.

The preparation for the resolution on Public Health, Innovation and Intellectual Property in the evening of 23 May, after a discussion of over nine and a half hours, was finally concluded. Only the US refused to accept the resolution and walked out of the conference.

According to a report by Dr Pongsadhorn Pokpermdee, Thailand's representative, who was present throughout the conference:

"The Assembly agreed that the World Health Organization in cooperation with other agencies could provide technical and policy advice to developing countries wanting to use compulsory licensing according to the TRIPS Agreement and other potential international pacts (including bi-lateral free trade agreements or FTAs) and R&D relating to this issue. All countries were encouraged to participate in the operation of the IGWG on Public Health, Innovation and Intellectual Property. The World Health Organization was urged to support regional meetings held throughout the world in support of the IGWG's process and create new incentive mechanisms for R&D and proposals for addressing the linkage between paying for the cost of R&D and the development of each drug."

The end of Dr Pongsadhorn's report reads:

"Such resolution proved that

1. The use of compulsory licensing by Thailand and Brazil was lawful according to the TRIPS Agreement and Doha Declaration.
2. The US was the only country out of step with the total WHO member countries in disagreeing with the resolution. Even developed countries, such as the European Union, Canada, UK, Australia, New Zealand and the Scandinavian nations, accepted the conference resolution.
3. From now on, the World Health Organization can provide technical and policy advice to countries wanting to use the flexibilities in the TRIPS Agreement for the sake of public health benefits and public access to necessary drugs and non-medical products."

Therefore, Thailand's bold step was not the self-serving act of a small country, but a significant move by a developing country that stood up to tell the world ***it is time the industry's insane and unchecked monopoly of profit-making must be resisted and reprimanded.***

The globalized triangle that moves the mountain

Thailand's compulsory licensing was neither a coincidence nor something that fell from the sky. With its roots firmly established in the ground, Thailand's CL tree has been carefully nurtured for a long time to bear its fine fruit.

It was also a phenomenal collaboration of global significance, with the participation of several national and international sectors.

When the Thai Minister of Public Health was asked about his confidence in the data and legal precision of his work team that encouraged the country to issue its compulsory licenses, Dr Mongkol said:

"The work team is profoundly knowledgeable and has been involved in the matter for a very long time. We not only coordinated with internal alliances but also with international organizations working on the pharmaceutical business and international agreements, such as TRIPS and the Doha Declaration. Even over 20 US Congressmen came out to support our fight.

"Apart from the domestic coordination of these issues, we also sought ways to link up with poor and developing countries so that they were entitled to take care of their poor populations. That's why our work team consists of many people, collectively working at the ministry, the National Health Security Office, universities and overseas."

Looking back at the past campaign for ddI access, the movement's actors consisted of:

- Liaison groups coordinating with networks dealing with the issue: AIDS ACCESS Foundation, the Foundation for Consumers, and the Health and Development Foundation acted as a link to transfer information to networks of AIDS NGOs and PWAs;
- Academic and information groups: the Drug Study Group, the Social Pharmacy Action Research Unit, the Health and Development Foundation, Médecins Sans Frontières-Belgium (Thailand) and the Government Pharmaceutical Organization's Research and Development Institute, whose academics helped analyze the problems of ddI patenting in Thailand and abroad; and
- Lawyers from the Law Society of Thailand.
-

The CL campaign was another significant development step, called the **Tripartite Fight for Patients' Rights** by *Prachachat Thurakit* business newspaper:

- **The State:** through the Ministry of Public Health, National Health Security Office, Government Pharmaceutical Organization, Food and Drug Administration, Department of Intellectual Property, and Council of State;
- **Public stakeholders:** The TNP+ had the longest experiences 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 disease, heart disease 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, Chulalongkorn University's Consumers' Health Protection Programme, Rural Pharmacists Foundation, Rural Doctors Foundation, Law Society of Thailand, NGOs working on AIDS and consumers' rights, AIDS ACCESS Foundation, Centre for AIDS Rights, Thai NGO Coalition on AIDS, Foundation for Consumers and Health and Development Foundation, as well as the FTA Watch group monitoring free trade negotiations

Prachachat Thurakit thought that "this is another group helping to give information and knowledge to educate society and explain the difficulties confronting the governments of Thailand and other developing countries." The newspaper suggested "the importance of foreign businesspersons' confidence and the value of trade must be weighed against the well-being and rights protection of Thai patients by providing the public with the information and research findings carried out by academics and those engaged in the drug business."

The three groups also coordinated with their foreign counterparts. For example, close contacts were made between the Thai and Brazilian Ministries of Public Health and the Thai Government Pharmaceutical Organization and the Indian generic drug industry.

The medical, pharmaceutical and law academics had networks in many countries. So did the international NGOs, such as Médecins Sans Frontières-Belgium (Thailand), Oxfam, Focus on the Global South, the US-based Knowledge Ecology International, Third World Network, Health Gap, and Essential Action.

Meanwhile, the work of local networks of people's organizations and NGOs was connected with the TNP+, foreign NGOs and movements of university students.

Another sector that could not be overlooked was the mass media. Some of the mass media did not appear to give full support to the compulsory licensing of the first patented drug in late 2006, because of the complications of the issue and the mass media's discontent with the government's ban on alcoholic drink advertisements. But after witnessing the intense pressure put on the Thai government by the multinational drug industry and the US administration, the mass media took an active role in promoting public learning of the issue by presenting news reports, articles, special reports, regular columns, and editorials through the printed media, radio, television and online media. This concerted campaign brought about an unprecedented united front among wider society to fight for drug access. Simply put, CL has become a watchword to the public.

Prachachat Thurakit concluded its reporting of the **Tripartite Fight for Patients' Rights (with tremendous support from the local and international mass media)** with the following statement.

"The campaign tried to tell Thai society and the global community that in the world of trade, whose aim is to make monetary gains, there is also a world that has to take into

account the value of life and healthcare, whereby medicines are a fundamental factor relevant to everybody's well-being.

"Thus, the movement of these people will continue in spite of the vigorous attacks from the multinational pharmaceutical industry and those who will lose their benefits because of this campaign."

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Part 2 Quotes

Box 1
Dr Mongkol Na Songkhla
"... Don't worry that medicines will not be available. The companies won't close down factories and stop selling drugs. The measures are just their warning to protect their interests. 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..."
Manager Daily, 26 January 2007

Box 2
Dr Mongkol Na Songkhla
"... I'm glad that many countries have sent encouraging email messages to us. I insist that our claims are based on a legal justification..."
Post Today Daily, 4 May 2007

Box 3
Dr Mongkol Na Songkhla
"... I insist that our CL is not a conceited act. We have always been courteous and unassuming because our poor people do not have access to medicines. We can't let them die without dignity..."
Daily News, 4 May 2007

Box 4
Dr Mongkol Na Songkhla
"... We have consistently been warned about our compulsory licensing. Over the past 10 years, we have been obliging and done things properly in spite of always being threatened. So it's not true to accuse us of lacking transparency and even exaggerated to say 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 didn't give a damn..."
Komchadluek Daily, 4 May 2007

Box 5
Dr Mongkol Na Songkhla
"... I don't know how to calculate a human life and compare its worth against the value of exports 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 people call me a robber..."
Daily News, 6 May 2007

Box 6

Dr Mongkol Na Songkhla

"... I can assure you that the poor must get access to medicines. I once saw tears streaming down a mother's face because she couldn't afford to pay 3,800 baht for a cancer tablet for her child and had to turn to herbal medicines instead. The price of such cancer tablets could be lowered to only 200 baht per day and it would cost less than 100 baht if bought in bulk. All right, everybody must die but the question is why we won't help those who are not rich enough to live longer if we can. I reiterate that I won't waste the remaining six months not doing what I ought to do..."
Khao Sod Daily, 29 May 2007

Box 7

Dr Mongkol Na Songkhla

"... Past negotiations on CL taught us to revise our approach and clarifications. We'll be more assertive. Previously, we tried to be most modest about our negotiations but to no avail. From now on, we will strike back at any threat or pressure put on our CL. No longer will we be the modest Thais, who succumb to other people's attacks and criticisms..."
Matichon Daily, 31 May 2007

Box 8

Dr Sanguan Nitayarumphong, Secretary General of the National Health Security Office

"... Thailand is not violating international law because it was internationally agreed that if it was relevant to people's life and death, the country could be exempt from the use of patents..."
Post Today, 8 May 2007

Box 9

Nimit Tienudom, director of AIDS ACCESS Foundation

"... Without treatment, some patients could survive. But with some diseases, it means an end to life. As drugs are different from other goods, so they must be ethically controlled..."

Box 10

Nimit Tienudom, director of AIDS ACCESS Foundation

If the people are close to us, and need medicines but cannot afford them because they are expensive, will we submissively continue to buy them, or find existing legal rules to make the medicines cheap enough for anyone to afford them? Ask yourself which way you will choose.

Box 11

Dr Krisana Kraisintu, former Director of the Government Pharmaceutical Organization's Research and Development Institute

The claim made by drug companies that they had to spend US$800 million on research for each drug is not true. The pricing of drugs should be more realistic, not inflated by the CEO's remuneration and shareholders' interests. Making a profit is all right but should not be too excessive. The drug industry has always made double digit profits. No other business has gained this much.

The world has 8,000 million people, 7,000 million of which are poor. We have to help them survive. Don't think that the rich won't be affected when the poor die in droves.

Box 12

Dr Vichai Chokevivat, Chair of the Government Pharmaceutical Organization Board

So to charge that the use of CL is mistreating business is wrong. In fact, business has been mistreating the people since 1992, when they had to buy expensive medicines. Take this for example of how expensive the drugs were. When I was Deputy Director-General of the Department of Disease Control, medicine for treating opportunistic infection called Fluconasole cost 200 baht per tablet.

However hard I tried to negotiate for a price reduction, I did not succeed. So I jokingly suggested that a face-saving discount of quarter of one baht should be given so that I could boast about my successful negotiations. The answer was no. A discount would affect the list price of the medicine, which was not patented but was protected by the monopoly rights granted to a new drug during the discussion of the Patent Act amendments submissively made by the government at that time. Once the monopoly right expired, the price went down from 200 baht to 12 baht. Now it is available at five baht per tablet.

Box 13

Pharmacist Sorachai Jamniandamrongkarn, National Health Security Office

People often thought that the NHSO first got the idea of doing this. All I'm saying is just that even though the NHSO has been involved, it was not the author of the idea. This is not being irresponsible, but to give due credit to the Thai Network of People Living with HIV/AIDS for its work, done in cooperation with the academics monitoring the issue for several decades. The NHSO is just one of the facilitating mechanisms.

The success resulted neither because of being a military-backed government nor because of the government's boastful attempt to show off its achievement. It was successful during the "old ginger" administration because it had a minister named Dr Mongkol, whose work team was already well-versed in the matter.

Box 14

Pharmacist Sorachai Jamniandamrongkarn, National Health Security Office

What was very annoying about handling this issue was the accusation of a lack of transparency because we didn't conduct prior negotiations with the firms. Personally, I think negotiating with millionaires would lack greater transparency.

Many people engaged in the ddI CL campaign organized in 2000 would remember the negotiations with the drug companies that led to the campaign's collapse. A one-night cruise taken by the negotiators on the Chao Phraya River put an end to the CL initiative.

Practically, the officials of the Foreign Affairs and Commerce Ministries all agreed that it was lawful, but as a matter of etiquette, they thought there had been a lack of transparency. I think they were more informed by the drug firms. Or they might take Brazil as a yardstick.

Brazil threatened to use CL many times before finally following Thailand's lead.

Box 15

Thanphuying (Dame) Preeya Kasemsan, Chairperson of the National Public Health Committee

"... The National Public Health Committee deems this act (of compulsory licensing) as beneficial to a lot of people and consistent with legal and international rules..."

Box 16

Prof Saneh Chamarik, Chairperson of the National Human Rights Commission

"The National Human Rights Commission would like to express its appreciation and support for the government's action, and particularly for Dr Mongkol Na Songkhla, Minister of Public Health, and his team for their decision to act for the public good although they had to face the consequent political and economic pressure put on them by industrialized countries and multinational drug corporations that will lose their economic benefits."

Box 17

Bill Clinton, former US President and Chairperson of the Bill Clinton Foundation

I strongly support the position of the governments of Thailand and Brazil and their decision after futile negotiations to break these patents.

I believe in intellectual property, but that does not need to prevent us from providing essential life-saving drugs to the people, either in low-income or middle-income countries, which need them.

No companies have ever died because of (the lack of) high premiums from (the sales of) AIDS drugs in middle-income countries, but the patients could.

Box 18

James Love. Director of the US-based Knowledge Ecology International

When WTO member countries agreed to the Doha Declaration, the commerce ministers of these countries were tremendously delighted to show that they had the public's health protection interests at heart. The difference between what happened in 2001 and what Thailand is doing now lies in the fact that Thailand is making the declaration come true by focusing more on the patients to be treated than the credit of the minister who signed the declaration.

Box 19

Benjamin Krohmal, Director of the US-based Consumer Project for Technology

"In the US before 1950, there were over 40,000 cases of compulsory licensing. Although the number of compulsory licences was lower after 1950, it still amounted to more than 10,000. Compulsory licensing is not known in the US under such terms, but there are three mechanisms whose effect is similar to compulsory licensing, where the State sees a necessity contrary to the patent owners' willingness.

"The three methods of Government Use of compulsory licensing are employed through competition law and court orders. Many companies benefited from such compulsory licenses. By the order of the Competition Commission to prevent commercial monopoly, Abbott was granted the right to produce a device to enlarge blood vessels in the heart, whose patent was held by Johnson and Johnson. Abbott has made a huge profit on this device. Latest reports had it that Abbot, on the grounds of public good, has asked the court to allow it to continue breaking the patent

on a device to detect the hepatitis C virus, owned by InnoGenetic, which would be compensated.
"Therefore, the drug companies' claim that there is no compulsory licensing in the US is not only untrue but also a double standard."

Box 20
Henry A. Waxman, US Congressman
Thailand is an important US ally that is trying to save the lives of its citizens. More than 500,000 people in Thailand are living with HIV/AIDS. While Thailand's HIV/AIDS treatment initiative has been recognized as among the most successful in the world, the high price of medicine has created a significant obstacle to the expansion and sustainability of the programme.
Dr Mongkol assured me that the government of Thailand is committed to the principle of balancing the protection of innovation and access to medicines. Adhering to this principle, the government of Thailand is particularly aware of the intellectual property issues and affirms that it will only use compulsory licensing in accordance with WTO rules.
Thus, the US should show sympathy and provide support to our long-time friend rather than impose punitive action as the US Trade Representative's recent announcement that Thailand has been put on the agency's "Priority Watch List."

Box 21
Robert Weissman. Drug access advocate of US-based Essential Action
"The reason Ken Edelman of USA for Innovation had to strongly condemn Thailand is because Abbott and MSD are the biggest clients of Edelman Public Relations, owned by Ken."

Box 22
Dr Sanguan Nitayarumphong, Secretary-General of the National Health Security Office
"The CL issue has spread so extensively that the NHSO could not move fast enough to keep up. So the system had to be re-organized. Instead of having someone propose, review and approve the issue, we think we must work as a team: a legal team, a campaign team and three sub-committees.
"First sub-committee, headed by Dr Vichai Chokevivat, responsible for the overall picture;
"Second sub-committee, headed by Dr Siriwat Thiptaradol, dealing with price negotiations, which we have been conducting for some time, but are still accused of failing to do; and
"Third sub-committee, headed by the same old team of the NHSO to enhance the initiative's efficiency, responsible for identifying target medicines for CL."

Box 23
Aroon Chirachawala, Money Column of Post Today, 3 May 2007
I had to admit that when it was first announced, I didn't dare to voice my view because I didn't know enough to judge if it was fair or would be accepted by the global community.
Now many developing countries in Asia, Africa and Latin America are saying they will follow Thailand's lead in demanding that the rights of the patients suffering from AIDS

and other serious diseases be treated with medicines and modern technology at a lower price.

The reputation of Dr Mongkol began to spread far and wide as the movement's champion. What he did has become an inspiration and an example for other countries to follow.

This success of Dr Mongkol is not a fluke. Nor is it a stroke of luck. It resulted from much deliberation at every step and a careful evaluation of the global community's response.

Box 24

Plew Si Ngern (Silver Flame), People of the Back Lane Column of Thai Post, 4 May 2007

The US administration, Congress and drug companies have "collaborated" with each other to enact laws, grant patents and pass FDA rules. This is all a "conspiracy" to promulgate vicious laws to extract one-sided benefits; obstruct and subjugate other countries' production of medicines; gain a long-lasting "monopoly" of 20-year patent terms; and allow for continuous "expansion" of their own original patent term.

All was done without taking into account "fellow humans" or "humanity" at all.

Thus, Dr Mongkol's "dissenting voice" directed against the unfair actions of the US drug companies has been praised by the Thais. And many countries expressed their willingness to be parts of the "vanguard" of the movement.

These potential allies are vociferously whistling, applauding and cheering for Dr Mongkol!

As a result, the US has to make haste to "prosecute Thailand" as a way of warning other countries not to use CL in compliance with WTO rules, as Thailand has done, to produce or buy "cheaper" drugs to help their own patients.

Part 3: Chronology

- **March 2006:** MSF begins a campaign to push Abbott to register the heat-stable lopinavir/ritonavir (a new formulation of key second AIDS drug Kaletra) in developing countries. The drug has been registered in the US since October 2005 but is not available in developing countries. Abbott has been selling the old formulation of the drug in African and Least Developed countries at US$500 since May 2002, but offers no differential prices in middle-income countries like Thailand.

- **6 March 2006:** In an open letter to the CEO of Abbott, Miles White, MSF and prominent doctors, researchers and People Living with HIV/AIDS express concerns about the lack of availability in developing countries of the new heat-stable formulation of lopinavir/ritonavir. The letter urges Abbott to immediately file for registration of the new formulation in all countries where the old formulation is registered or pending as well as in other developing countries. MSF also asks Abbott to publish a price for the new formulation for Least Developed countries and middle-income countries and to communicate the list of countries eligible and the filing date for registration.

- **13 March 2006:** Abbott responds to MSF but fails to provide a price and timeline for registering the new formulation, stating that European approval was a prerequisite to registration.

- **15 March 2006**: MSF places an order for the drug for 400 MSF patients in 9 countries including Thailand. The order aims to put nearly 800 patients on the new formulation by the end of 2006.

- **March 2006**: Abbott announces a price of US$ 500 pppy for heat stable formulation of Kaletra in Africa and Least Developed Countries, but takes no step to make the drug available in any of these countries except South Africa.

- **July 2006:** After a cumbersome and time-consuming procedure, Abbott begins to ship the new formulation to a limited number of MSF projects in Africa for US$500 pppy. But the company still refuses to sell the drug to MSF's programmes in Thailand where it still charges at least US$2,800 pppy for the old version of lopinavir/ritonavir. MSF urges Abbott to speed up its registration process, as the drug is still unavailable in most developing countries.

- **August 2006**: Abbott announces a price of US$ 2200 pppy for heat-stable Kaletra in low and low- middle income countries such as Thailand

- **November 2006:** Thailand issues a compulsory license for first-line AIDS drug efavirenz patented by Merck. Merck sells efavirenz for a non-profit price of Bt 1,400 ($38.84) per month in Thailand. The Government Pharmaceutical Organisation (GPO) says it would import generic efavirenz, sold by Indian drug-maker Ranbaxy for Bt 800 per month, until the GPO made its own version in June 2007. Thailand places an order for 66 000 bottles of efavirenz from Ranbaxy at Bt 650 per bottle.

- **6 February 2007**: Merck proposes a new price for Efavirenz at US$ 72 cents per tablet, (around Bt 780 per bottle) a price closer to what is offered by generic competitors. The company also announces a global price reduction of Efavirenz to Bt

700 per month for countries whose prevalence rate of HIV/AIDS is 1% or higher.

- **January 2007**: The first batch of 16,000 bottles arrives in Thailand. The MOPH says this price cut will allow to provide Efavirenz to an additional 20 000 AIDS patients.

- **10 January 2007:** 22 US Congressmen wrote a letter to US Trade Representative Susan Schwab, to urge the US to respect Thailand's decision to issue a compulsory license for Efavirenz.

- **17 January 2007:** Mrs Susan Schwab confirms the legal and social ground of the CL: "We have not suggested that Thailand has failed to comply with particular national or international rules. We have taken care to respect fully the Thai government's ability to issue CL (...) in accordance with his obligations as a member of WTO".

- **24 - 25 January 2007:** Thailand issues two compulsory licenses, one for the key secondline AIDS drug Lopinavir/ritonavir (Kaletra) patented by Abbott, as well as one for the heart medication clopidogrel bisulfate (Plavix) patented by Sanofi Aventis.

- **7 February 2007:** WHO's executive Director, Dr Margaret Chan sends a letter to the Public Health Minister of Thailand expressing WHO's unequivocally support for the use by developing countries of the flexibilities within the TRIPS Agreement to ensure access to affordable high quality drugs.

- **13 March:** Abbott responds to Thailand's compulsory licensing by withdrawing registration applications for seven new drugs including the heat stable version of Kaletra, Kaletra/Aluvia, in the country.

- **14 March 2007**: MSF denounces Abbott's action and writes a response to the World Street Journal after the newspaper publishes a series of editorials calling Thailand's compulsory licensing a "seizure of foreign drug patents" and accusing the government of trying to save money on medicines to increase the military budget.

- **20 March 2007:** AIDS activists in Thailand and dozens of countries around the world call for a boycott of Abbott's products, and demonstrate, send letters and speak out to condemns the company's actions. MSF expresses its support to the activists but doesn't call for a boycott. Instead MSF urges WHO, UNAIDS, and all relevant policy makers and governments to vocally support countries wishing to use the flexibilities within the WTO's TRIPS Agreement to provide access to essential medicines.

- **26 March 2007:** Abbott offers Kaletra to the MOPH for US$1700 pppy (Bt 5,938 pppy) excluding VAT.

- **27 March 2007:** French minister for Foreign Affairs, Philippe Douste- Blazy gives public support for Thailand's compulsory licenses. He is the only representative from the EU to take an official position. Stony silence from the other countries.

- **10 April 2007**: After discussions with the WHO DG Chan, Abbott says it will more than halve the price of Kaletra/Aluvia in low and low and middle-income countries, bringing the cost of treatment to US$ 1000 pppy (Bt 34 500) from the original rate of US$ 2200 pppy. The company says it would register the drug in 150 countries but not in Thailand where it will continue to sell the old formulation.

- **23 April 2003**: Abbott announces it will offer the new heat-stable version at the new US$ 1000 price to Thailand only if the country withdraws the compulsory license. The Thai MOPH strongly refuses.

- **26 April 2007:** Global Action Day: One day before Abbott's annual shareholder meeting in Chicago, AIDS activists and PLHA groups rally in front of Abbott's office in Bangkok and in other countries over Abbott's decision to withdraw new medicines from Thailand. Several protests, press conferences are also organised around the world.

- **26 April 2007:** USA for Innovation, a lobby group working for the US pharmaceutical industry and pretending to be a NGO publishes a full page add entitled "Slouching towards Burma – Thailand's radical new regime" in the World Street Journal.

- **27 April 2007:** Activists protest at the Abbott's Annual General Meeting for shareholders, held in Abbott Park, Illinois.

- **30 April 2007**: The US Trade Representative (USTR) includes Thailand on a Priority Watch List that singles out countries with poor record of intellectual property protection and exposes them to potential trade sanctions. Thailand's compulsory licensing is one of the reasons invoked for the downgrade, among copyright violations on books and DVDs. The report says Thailand's generic drug efforts are "further indications of a weakening of respect for patents".

- **3 May 2007**: AIDS activists protest outside the US embassy against the US Trade Representative's decision to put Thailand on the Priority Watch List.

- **4 May 2007**: Brazil issues a compulsory licence for governmental use to allow the import of a generic version of Efavirenz, after the drug's patent holder Merck & Co failed to match the 60-per-cent price reduction requested.

- **8 May 2007**: Health Minister Mongkol Na Songkhla' visit to Washington. Thailand joins the Clinton Foundation's pool procurement. The Foundation announces it has negotiated with Indian generic producer Matrix for bulk purchases of Kaletra/Aluvia at US$ 695. The new agreements with generic drug manufacturers Cipla and Matrix not only significantly lower the price of AIDS treatment for second-line ARV drugs but also for a new, once-a-day pill that is currently cost prohibitive in the developing world. Lower prices for 16 formulations of ARVs will be available to 66 developing countries in Africa, Asia, Latin America and the Caribbean through the Clinton Foundation's Procurement Consortium.

- **9 May 2007**: According to the media (Prachachart), the US proposed an "action plan" to remove Thailand from its priority watch list. The demands are similar to those made by the US during talks with the Thai government about a FTA. They include an extension of drug patents from the normal 20 years, an expansion of drug patents to cover the diagnosis process and surgery; and restrictions on the right to issue compulsory licences.

- **11 May 2007**: The Thai ministry of Commerce rejects US "action plan"

- **9- 13 May 2007**: USA for Innovation begins a series of attacks against Thailand's compulsory licensing. They launch www.thailies.com to "draw attention to the deceit in Thailand's decision to steal American and European innovation" and claim in the national press that GPOvir, the 1st line Aids produced in Thailand, has world-record levels of resistance.

- **13 May 2007**: MSF and other NGOs publish (for free) a counter add in the Bangkok Post and the Nation.

- **14 May 2007:** Abbott offers the MOPH to sell Aluvia for about US$1,000 pppy (Bt 34,000) provided that Thailand doesn't seek compulsory licensing for Aluvia and the price of Aluvia can't be reduced any further in the future.

- **15 May 2007**: Health Minister Mongkol Na Songkhla says that Thailand will not issue compulsory licenses to produce reduced-cost versions of patented drugs if pharmaceutical companies offer prices lower than those charged by generic drug makers

_ GPO manufacturer of GPO-vir threatens to file a libel charge against USA for Innovation, on the ground that the firm's adds published were damaging to GPO and its product.

- **21 – 22 May 2007**: Thai Minister of Health Dr Mongkol visits Washington on May 21-22 to meet congressmen and explain the government's decision to issue compulsory licenses.

- **23rd May 2007**: Abbott files a lawsuit against French HIV activist group Act Up Paris after the group launched a cyber protest that briefly shut down Abbott Laboratories' Web site on April 27th, 2007. Abbott is suing the group to the tune of $100,000.

- **June 2007**: Health Minister Mongkol Na Songkhla says he would buy Efavirenz from Merck if the pharmaceutical company accepted to sell its drugs at a price not higher than 5% above its generic competitors. But he stressed he would continue to buy part of the drugs from generic companies as Merck would "blackmail" Thailand if the country relied entirely on the originator company.

- **28 June 2007*** –GPO submits an application for the registration of the generic heat-stable formulation of Kaletra produced by Indian generic manufacturer Matrix. The Thai FDA promises to fast track the application which could pave the way for a compulsory license on Aluvia.

- **1st July 2007**: The US ends Generalized System of preference (GSP) eligibility for three Thai exports: gold jewellery, flat panel televisions and polyethylene terepthelate. The US stresses the move is not linked to the controversy over compulsory licenses of patented pharmaceutical products in Thailand.

- **10 July 2007:** EU Trade Commissioner Peter Mandelson sends a letter to the Thai MOPH, MOC, MFA protesting against a broad use of compulsory licenses in Thailand, "which would be detrimental to the patent system and to innovation and development of new medicines", and stressing that "neither the TRIPS Agreement not the Doha Declaration appears to justify compulsory licensing whenever medicines exceed certain prices." The letter urges the Thai government to engage in direct consultations

with the concerned drug companies.

- **20 July 2007:** US Ambassador in Thailand, Ralph Boyce writes to the Thai prime minister warning that the decision to use WTO's flexibilities "should not be made lightly and only as a last resort"

- **22 July 2007**: *Abbott drops case against Act Up*

- **9 August 2007:** Leak to the Financial Times who writes an article about Mandelson's letter.

- ***8* August 2007:** *Response from the Thai MOC to Mandelson's letter stressing that* Thailand's decision to issue compulsory licenses is fully compliant with the WTO TRIPS Agreement and asking the EU's to recognise the right of WTO's members to grant compulsory licenses as stated in the Doha Declaration.

- **20 August 2007:** Point by point response from the Thai MOH to Mandelson's letter.

- **25 August 2007:** Tilleke & Gibbins, attorneys for Sanofi-Aventis in Thailand, send a letter to Bioscience Co. Ltd., which represents the Indian pharmaceutical company Emcure in Thailand, threatening civil and/or criminal action in a Thai court against Bioscience who have submitted a quotation for the supply of generic clopidogrel (Plavix) to GPO. Bioscience are given 10 days in which to reply to the letter.

- **27 August 2007:** MSF and Oxfam organise a press conference and express concern about Mandelson's effort to discourage further use of compulsory licensing for patented drugs. They urge the EC to fully support countries in their effort to ensure access to medicines.

- **End of August - September 2007:** Sanofi- Aventis begins sending a series of threats to Cadila Healthcare Ltd to prevent the generic manufacturer to fulfil the compulsory license for clopidogrel (Plavix).

- **End of August 2007** – *The ministry of health decides to import a generic version of* clopidogrel (Plavix) from Emcure pharmaceuticals -offering the drug at 1.01 baht a tablet against market price of 70 baht a tablet.

  - Emcure asks the Public Health Ministry to confirm that buying clopidogrel is not a violation of patent law as claimed by Sanofi-Aventis.

  - Emcure fails to register the drug and the ministry of health decide to go with another Indian company Cadila healthcare Ltd.

- **27 December 2007:** General elections in Thailand. The People Power Party led by Samak Sundaravej wins a majority of seats.

- **Early January 2008**: Cadila Healthcare Ltd registers its generic version in Thailand to *be able to export the generic clopidogrel.*

- **4 January 2008** – Minister of health Dr Mongkol approves 4 new CLs on four cancer drugs[3]:

[3] "The 10 burning questions on the Government Use of Patent on the 4 anti- cancer drugs in Thailand"

1) Docetexel (trade name Taxotere – produced by Sanofi Aventis) uses for lung and breast cancer – *(patented price of an 800 mg injection is 25 000 Baht – generic equivalent costs 4 000 Baht)*
2) Letrozole (trade name Femara patented by Novartis) for breast cancer – *(patented price for one tablet of 2.5 mg is 230 Baht – genetic equivalent costs 6-7 Baht)*
3) Erlotinib (trade name Tarceva patented by (Roche) fur lung cancer *(patented price for one table of 150 mg is 2 750 Baht – generic equivalent costs 735 Baht)*
4) Imatinib (trade name Glivec) for Chronic Myeloid Leukemia and Gastrointestinal Stromal Tumor *(patented price for a 100 mg tablet 917 Baht – generic equivalent costs 50-70 Baht)*

- **23 January 2008**: Novartis agrees to provide imatinub for free to all patients under the universal health scheme who can't afford it if the patient is not override. A daily dose tablet normally costs 3600 Baht or 1.3 million Baht ($40 000) for a year treatment.

  But after months of negotiations, no agreement is reached for breast cancer drug letrozole, breast and lung drug docetexel and lung cancer drug erlotinib because of complex conditions imposed by the drugs companies.

- **24 January 2008** –Minister of health Mongkol Na Songkla announces the CL for leukaemia drug imatinib will not be implemented, until Novartis' free programme ends.

- **31 January – 6 Feb 2008:** WHO mission in Thailand: A group of technical experts from WHO, as well as WTO, UNDP, UNCTAD meet with relevant partners in Thailand to provide technical assistance and analyse processes of implementing government use of patent. The group issued a report advising Thailand to apply TRIPS flexibilities both before and after granting the patent.

- **Early February 2008**: GPO placed an order of 2 million tablets to Cadila for its generic version of Clopidogrel (Plavix)

- **February 11 – 16 2008** The new government takes office, Chaiya Sasomsab becomes Public Health Minister. The new government announces a review of its predecessor's policy on CLs for cancer drugs. Chaiya says proper procedures should have required approval from ministry of Commerce and Foreign Affairs.

  The Cabinet decision on CLs is delayed and planned for end of March.

- **19 February 2008:** Oxfam organises a press conference to about the potential impact on Thailand and other developing countries if the new Thai government reverses its predecessor's policy to implement CLs.
  _ Nine international law experts send a letter to Prime Minister and Minister of Public Health to support the use of CLs

- **February 26 2008:** FDA chief Dr Siriwar Thiptharadol who supported the implementation of CLs for AIDS and Cancer drugs during the previous government is transferred to an inactive post in the Health Ministry. Siriwat announces he's considering appealing the decision to the Administrative court.

- **February 29 2008**: Chairman of GPO board committee, Dr.Vichai Chokewiwat, a key

health official behind the compulsory licensing says he will not resign despite pressure to do so from Chaiya Sasomsab.

- **March 3 2008**[4] **:** GPO Director Vithit Attavejchakul says Cadila has informed the GPO that the export of the first lot of 2 million tablets to Thailand would be delayed from March to April due to production and legal processes.

- **March 6 2008:** An alliance of patients and health activists start gathering 20,000 signatures to petition the senate to remove public health minister Chaiya Sasomsab. _ —

- **March 11 2008:** New health minister announced that he would push ahead with compulsory licensing for cancer drugs after a study by the National Health Security Office, Cancer Institute and health experts found the government would save about three billion baht in five years by continuing with the cancer drug licences. Chaiya adds that the Commerce Ministry will now have to negotiate with drug firms on pricing.

- **March 12 2008**: The alliance of patients and health activists announce they will continue gathering 20,000 signatures to petition the senate to remove public health minister Chaiya Sasomsab

Latest data available – Report on Access to 3 cancer drugs from NHSO – 14 February 2008

Efavirenz 600mg
_ 1st order: 66 000 bottles – already run out
_ 2nd order: 100 000 – since oct 2007 under the VMI system

Lopinavir 133.33 mg Ritonavir 33.3 mg
_ still 571 bottle of Kaletra – "old kaletra" in stock
_ 28 January 2008 – currently 957 case on Kaletra (588 adults and 369 children)
_ Since Feb 12 2008 – 4000 bottles were received from India

Clopidogrel 75 mg
_ GPO has registered the generic Cadila and placed an order of 2 million tablets not yet
arrived.

[4] Nation, " Drug licensing revision should be ready by April"

Part IV Attachment:
Thailand Government White Paper

Facts and Evidences on

The 10 Burning Issues

Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand

Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent

By

The Ministry of Public Health

And

The National Health Security Office

Thailand

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Preface

The recent decisions of the Thai Ministry of Public Health to announce the Government Use of Patents on three patented drugs, i.e., Efavirenz (Stocrin) of Merck Sharp and Dohme), Lopinavir+Ritonavir (Kaletra) of Abbott Laboratory) and Clopidogrel (Plavix) of Sanofi-Aventis), based on proposals from the National Health Security Office, have raised several questions among the public and also the concerned partners as well as the pharmaceutical industries, both in the country and internationally. Some questions and concerns are due to lack of information; Others are intentional with the aim to create misunderstanding and objections to the announcements. Thus there is a need to clarify all the questions with the right information and evidences. The Ministry of Public Health staff had compiled all the questions and summarized into 10 burning issues that need to be addressed. Relevant answers and evidences have been collected to address each issue.

The Thai Ministry of Public Health views these decisions on the Government Use of Patents as a form of social movement that aims at improving access to essential medicines and the health of the people. The public health interest is thus the main and final goal of this social movement. We believe that for the sustainability and success of any big social movement, there need to be a good combination of three factors, i.e., knowledge and evidence, social support, and political commitment. This forms the so-called triangle that moves the mountain. It is the educated and motivated society that will push for and support the political commitment to bring real and sustainable success to any social reform movement.

Thus this white paper on the Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand does not only aim at answering all the questions raised, but more importantly as a tool to inform and educate the Thai and Global Society as a whole, on the issue of pharmaceutical patent and the public health. This is to ensure the success of the future movements to improve the intellectual property systems so that it is more conducive to social development.

The Thai Ministry of Public Health firmly believes in a moderate and public interest oriented approach to implement the intellectual property right. We are convinced and committed to the view that "Public Health interest and the life of the people must come before commercial interest".

We do need innovative ways to provide incentives for drug research and development to improve access to essential drugs for all. We believe in what Albert Einstein once said: ***"we shall require a substantially new manner of thinking if mankind is to survive."***

This white paper was prepared with time constraint, so there may be some unintentional mistakes and we would expect the readers to understand the limitation and also read it with their own wise and fair judgment.

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Issue No. 1: What is the rationale behind the Government Use of Patents on the three drugs? Is this movement in compliance with the national and international legal framework?

The rationale mainly lies in the mandate to achieve universal access to essential medicine for all Thais, under the National Health Security Act 2002. Since 2001, every Thai citizen is covered under one of the three main national public health insurance schemes (Figure 1), i.e.:

2.1 The Civil Servant Medical Benefit Scheme (CSMBS) covers around 5 million civil servants, public employees and their dependants. The scheme is paid totally from the general tax revenue based on a fee-for-services retrospective reimbursement system. Public facilities are the main providers under this scheme.

2.2 The Social Security Scheme (SSS), a tripartite system contributed by employers, employees and the government on an equal share basis. It covers around 8.5 million private employees and temporary public employees. Public and private facilities have approximately equal
share of the beneficiaries. This scheme pays the providers by the contract capitation system.

2.3 Universal Coverage Scheme (the gold card scheme) Since October 2001 universal coverage of the health insurance system was implemented by combining the previous social welfare health services and the voluntary health card scheme, and further expanded coverage to 18 million more people. This scheme covers around 48.5 million people, or 78 per cent of the population. It is financed solely from the general tax revenue. Public hospitals are the main providers; they cover more than 95 percent of the beneficiaries. About 80 private hospitals joined the system
and register around 4 percent of the beneficiaries. It also pays the providers by the contract capitation system.

Some of the better off Thais, around 2 per cent buy private health insurance, and many of those better off who are covered by one of the above-mentioned three public health insurance schemes go to private facilities for their health services and pay out of pocket, in spite of their right to access to free care paid by the government. Around 20 percent of Thais pay out of their own pocket when receiving out patient services at private facilities.

All of the 62 million Thais who are covered by one of the three above-mentioned national public health insurance schemes **are entitled to full access of all medicines in the essential drugs list, including almost 900 items of drugs, many of them patented.**

The Thai government is also committed to the policy of **universal access to antiretroviral drugs (ARVs) for AIDS patients, since October 2003.**

The government responded to these national commitments through several means. One was to raise the public health budget. The public health budget has been increasing from around 4 percent of the overall national budget in the 1980s to 7 per

cent in the 1990s and now to more than 10 per cent. The budget for access to ARVs also increased from around $US 10 million in 2001 to more than $US 100 million in 2007; increasing of more than 10 folds in 6 years. This level of spending from national public resources on access to ARVs is highest among the lower middle income developing countries. Thailand has employed the policy towards long-term sustainability of the universal access to ARVs since 2003. The budget supported by the Global Fund is used mainly for purchasing equipment and training of personnel. Less than 20 per cent of the total expenses on ARVs come from the Global Fund. With this quite high spending, the public health insurance schemes still can not afford to pay for the universal access to patented drugs in the essential drug list, including essential ARVs. It is the joint responsibility of the Ministry of Public Health and the National Health Security Office to ensure the right of universal access to essential drugs. So far the two organizations have not been able to fully achieve that goal due to high drug prices and a limited budget. Thus Government Use of Patent to get lower price generics for patients who are covered by the government is one important means to better achieve that goal.

According to the TRIPS agreement article 31 (b), and the Doha Ministerial Declaration on TRIPS and Public Health in 2001, which are clearly reflected in the Thai Patent Act B.E. 2522 as amended by the Thai Patent Act (No. 3) B.E. 2542 (Document No. 1, 2 and 3), there may be three broad mechanisms of using the patent rights by others than the patent holder.

1. Non public use of patent right : Under this category, those who would like to use the patent rights of some products, for example drugs, for commercial purposes, must first negotiate with the patent holders to seek for their permission. The negotiation will include the terms of patent use as well as the royalty paid to the patent holder. If the negotiation is successful, it will then become a **Voluntary Licensing** of patent. But if it fails, then the Director General of the Department of Intellectual Property, Ministry of Commerce can be requested to rule on whether to allow the use of patent and also to fix the terms of patent use as well as the royalty fees. This then becomes **Compulsory Licensing.** (Thai Patent Act section 46 to 50).

As this is for commercial use, prior negotiation with the patent holder is needed.

2. Public use of patent rights: There are two categories on the public use of patents.

2.1 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 and department of government may,*** by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee ***without the requirement for prior negotiation on the permission, the royalty fees or the term of patent use*** (Thai Patent Act section 51).

2.2 During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee (Thai Patent Act section 52).

The announcements of the Government Use of Patents on the three drugs in the National Essential Drug List, namely Efavirenz, Lopinavir+Ritonavir, and Clopidogrel, by the Director General of the Department of Disease Control and the Permanent Secretary of Public Health, are thus in full compliance with the Thai national and the international legal framework (mechanism 2.1 above).A more detailed explanation on the legal compliance with the Thai Law on Government Use Licenses has been clarified by Sean Flynn from the American University, Washington College of Law (Document No. 4). The details of the three announcements and the letters to the three patent holders as evidences of complying with the existing legal framework are shown in Document No.5-10.

This compliance with all legal frameworks has also been confirmed by the 22 US Congressmen in their letter to the Honorable Susan C. Schwarb (Document No. 11), the United States Trade Representative. It is also confirmed in her letter responding to the 22 US Congressmen (Document No. 12), stating that *"we have not suggested that Thailand has failed to comply with particular national or international law."* She also stated that "*we have not sought to insert the US government into any such discussion*" (between the Thai authorities and the pharmaceutical industries). The Director General of the World Health Organization, Dr. Margaret Chan, also confirmed in her letter to the Thai Public Health Minister, that the announcement of the three Government Use of Patents,
are fully in line with the TRIPS agreement and there is no need for prior negotiation with the drug companies (Document No. 13).

Under such legal frameworks, the announcement of Government Use of Patent is not limited to only emergency or extreme urgency situations and is also not limit to only drugs or ARVs. Further more, Thailand is not the first country to apply compulsory licensing or the Government Use of patent, developed countries including the USA, European countries, and other developing countries have previously attempted and implemented compulsory licensing and Government Use of Patents. Some recent examples of the use on drug patents and other patents are detailed in Document No. 14 and No. 15.

In conclusion, the announcement of the Thai authorities on the Government Use of Patents on three patented essential drugs is fully complied with the national and international legal framework. It allows the government to better achieve its commitment to universal access to medicine in the essential drug list and also is clear evidence of the government's commitment to **put the right to life above the trade interest.**

Issue No. 2: Why did the Thai authority decide not to have prior negotiation in a constructive manner with the drug companies and avoid unnecessary conflict as well as achieve lower drug prices and more access to essential drugs? Can we consider the Government Use of Patent as a kind of uninformed

expropriation of private property by the state, as mentioned by one of the senior managers in the drug industry?

As mentioned in the response to issue No.1 that under all national and international legal frameworks, there is no need for prior negotiation with the patent holders before announcing and implementing the Government Use of Patent under category 2.1 above.

Nevertheless, even without the need for prior negotiation and discussion, the Ministry of Public Health had tried through several means and mechanisms between 2004 and 2006, to discuss and negotiate with the patent holders. In April 2005, a Working Group to negotiate for price reduction on patented drugs was established (Document No. 16). This working group is chaired by the Secretary General of the Thai Food and Drug Administration (FDA) with the representatives from the relevant departments in the Ministry of Public Health and the Ministry of Commerce. The working group received little cooperation from the patent holders to provide adequate information for the negotiation. After one year, a short report of the working group concluded the failure of their work to reduce the price of the patented drugs (Document No. 17). Furthermore, during 2004 to 2005, the Department of Disease Control, the biggest purchaser of ARVs in Thailand had several meetings with the patent holders as well as some official communications to request for the reduction of patented ARVs. They also reported the failure to achieve any significant price reduction. Some companies responded officially as to why prices could not be reduced (Document No. 18). Not until the rapid appreciation of the local Thai currency since early 2006 did a few patent holders decide to reduce the price of their products in Thai currency. The maximum price reduction was less than 20 per cent, not much higher than the level of currency appreciation.

Failure to negotiate for price reduction of monopolized drugs is not new in Thailand. In 1997, when the anti-fungal for opportunistic infection in AIDS patients, Fluconazole, was still monopolized, the Department of Disease Control tried hard to negotiate to reduce the price from more than 250 Baht per tablet, but were unsuccessful. However, after the monopolistic condition ended and with the emergence of several generic versions of Fluconazole, the price is now reduced by approximately 50 times. This is an experience that has been recognized globally and it has been concluded that ***"Prior negotiation with the patent holders is not an effective measure and only delays the improvement of access to essential medicines. It is only after the threat or the decision to use and implement Compulsory Licensing or Government Use of Patent that the negotiation will be more successful and effective".***

Those who advocate for prior negotiation should realize these facts. The attempt to push for prior negotiation only delays improvement in access to patented essential medicines and puts more lives in less healthy or even dangerous situations.

It should also be noted here that the drugs derived from the Government Use of Patent in Thailand *will be distributed only to those patients who are covered by the government.* Those who are well off and can afford to pay out of their own pocket including around 2 million foreign patients still have to pay the high price of patented

products. These well off people and the foreign patients are actually the only current market of the patented products. The patented products have little or no access at all, by the majority of Thais whose medicine cost are paid by the government.

So they are not the effective market of the patented products. The Government Use of Patents has opened this new market, among those who cannot afford them, for these drugs (Figure 1). However, due to limited budget and the mandate to achieve universal access, the government cannot afford to pay the price of the patented products. Opening of this new market for competition among all generics as well as with the patented products will allow the government to provide good quality essential drugs at an affordable price to all Thais, to fulfill the legal and political commitment to universal access to essential medicine. With the Government Use of Patents, the patent holder still has the right to produce, import and sell their products. They still preserve the right to grant voluntary licensing to anybody. So their patent rights are still fully preserved. Thus this cannot be considered as the expropriation of private asset. Furthermore, the Government Use of patent as determined in section 51 and 52 of the Thai Patent Act are in the same act as section 36 which provides them the monopolistic right to produce, import, sell and distribute the patented products. Thus the patent holders are all well aware of these flexibilities in the Thai law since the time that they apply for the patent.

Figure 1 Diagram to demonstrate that the Government Use of Patent does not affect much on the existing market size of patented products
(See Chinese Version)

Issue No. 3: Why has the Ministry of Public Health turned down request from drug companies to discuss and negotiate, even after issuing the Government Use of patent? Is there any better way than compulsory licensing to improve access to medicines?

The policy of the Ministry of Public Health and also the government is to build constructive, transparent and fair relationships with all private firms. Thus constructive discussion is always the main strategy of the ministry. The door for open constructive discussion was available before and after the announcement of the Government Use of Patent. The Ministry of Public Health has never turned down a request from any drug company to hold constructive discussion based on friendship terms. Even after the implementation of the Government Use of patent by importing patented drugs, the door for further discussion and negotiation is always open.

However, we cannot wait for the results of the discussion and negotiation as we do not want to delay the increase in access to these drugs for our people. Thus we started the process of production and importation of these drugs in parallel to the discussion and negotiation. For example, the GPO signed the contract with the Indian drug firm, Ranbaxy, to import 66,000 bottles of Efavirenz on January 5th 2007, 5 weeks after the announcement of the Government Use of Patents. The first batch of the drugs arrived in Thailand since the end of January 2007. This generic Efavirenz has reduced the price by more than half, from around 1,400 Baht per bottle to 650 Baht per bottle. This will allow the ministry to provide Efavirenz to an additional 20,000 AIDS patients with the same cost. We are also in the process of actively importing two

other patented drugs under Government Use, while negotiation and discussion are in process.

Since November 29th 2006, at least two official discussions with Merck Sharp and Dohme and Abbott Laboratories Limited have been carried out in addition to a few more informal discussions. Some informal discussions have also been held with Sanofi-Aventis (Thailand) Ltd.

The discussions are all very friendly and constructive with both sides understanding the concerns of each other. The drug companies understand the mandate of the Ministry and the National Health Security Office to achieve universal access to essential drugs and also understand that their current market for patented drugs will not be disturbed. They are ready to come up with better and more generous proposals to help the government to achieve the goal of universal access. The Ministry and the National Health Security Office understand the concerns of the drug companies in protecting their intellectual properties rights and profits to compensate for the huge expense on the drug research and development and are ready to consider any generous proposal from the companies. All agreed that this kind of constructive discussion should carry on. The Minister of Public Health signed a ministerial order to establish a new Committee for negotiation of patented drug prices, on February 16th 2007 (Document No. 19). This committee replaces the previous working group with wider participations. This committee will be responsible for all forms of negotiation, before and after announcing and implementing the Government Use of patents.

On February 6th 2007, Merck Sharp and Dohme has kindly proposed a very favourable new price for Efavirenz at 72 cents per tablet of 600 mg, with six conditions (Document No. 20). This is around 780 Baht per bottle, a price much closer to that of generics, which is 650 Baht per bottle.We are seriously considering this proposal. However, as the 66,000 bottles of Efavirenz from India will last for the next three to four months, we will have some time to compare the prices and conditions of the patented products with the generics before making the final decision.

The company also announced a global price reduction of Efavirenz (Document No. 21). This is a very welcome movement from the company. *This proves that the Government Use of Patents in Thailand does not benefit only the Thai people, but also people around the world.*

It should be reiterated that the report of the WHO commission on Public Health, Intellectual Properties and Innovation clearly concluded that the access to essential health technologies depend on □3Ds□, i.e., discovery, development and delivery. There is a need to invest on research to discover the etiologies and mechanisms of diseases and some potential technologies to deal with them. Then further investment on developing these potential technologies into effective, safe and good quality essential technologies is needed. Finally adequate financing to produce, purchase and distribute the technologies through adequate and effective health care delivery system is the last essential component. The conventional intellectual property based incentives for investment in the research and development of technologies has proved to be inadequate in response to the need of the people to get access to affordable

essential technologies. It creates big financial barrier to the access. *The compulsory licensing is just one mechanism* to alleviate this problem and reduce the financial barrier only in some instance. It is not effective for every drug or technology. (See Issue No.4)

The world do need more innovative ways of providing incentives for research and development of essential health technologies as well as production of lower price technologies, apart from the intellectual properties based one. Several innovative incentives have been proposed, for example the R&D treaty, the advance procurement mechanism, and the special tax to support drug research and development.

"We shall require a substantially new manner of thinking if mankind is to survive"

Albert Einstein

Issue No. 4: What are the mechanisms and criteria used to determine which drugs to issue Government Use of Patent and also the royalty fees? Will there be additional Government Use for more drugs in the near future? Would these movements eventually lead to the failure of the intellectual property systems?

The Subcommittee to implement the Government Use of patent on drugs and medical supplies established by the National Health Security Board on 17 April 2006 is a mechanism to consider which drugs to issue Government Use of patent (Document No. 22). This subcommittee is chaired by the Secretary General of the National Health Security Office, and involves all concerned departments in the Ministry of Public Health and Ministry of Commerce as well as consumer groups, communities of people living with diseases and medical specialists. The criteria to determine which drugs to issue a Government Use of patent includes drugs and medical supplies that are:

- listed in the National Essential Drug List, or
- necessary to solve important public health problems, or
- necessary in emergency or extreme urgency, or
- necessary for the prevention and control of outbreaks/epidemic/pandemics, or
- necessary for life saving

The price of these drugs and medical supplies must be too high to be affordable by the government to supply to the beneficiaries of the national health insurance schemes to achieve the universal access policy.

The level of royalty fees payable to the patent holders have been set at between 0.5 to 2 per cent of the sale value. This is the common range used in most developing countries in the case of public non-commercial use. For those drugs with high retail value, the royalty will be set at the lowest level of 0.5 per cent. For those with low retail value, the royalty will be set at the top level of 2 per cent. For the three drugs that Government Use has been announced, they are all in high demand and the expected retail value is high. So the royalty fees have been set at 0.5 per cent. However, these royalty fees can be negotiated if drug companies are not satisfied with the proposal from the Ministry of Public Health. If the negotiation fails, then the Director General of

the Department of Intellectual Properties will determine the fees according to several criteria as established in section 51 of the Thai Patent Act (Document No. 3).

The decision on whether to implement the Government Use on other patented essential drugs depends on the work of the Subcommittee and the evidences that they produce according to the above-mentioned criteria. The proposal from the Subcommittee of the National Health Security Board will be submitted to the Ministry of Public Health for consideration to announce the Government Use, on a case by case basis. This is because the National Health Security Office is not a ministry, or a bureau or a department of the government; it is an independent public agency established under the National Health Security Act. The Ministry of Public Health will consider announcing the Government Use of patent only in the case of real necessity to achieve the universal access to essential medicines. The proposals from the Subcommittee have to be supplemented by clear evidence to support the decision by the Ministry. So if there is a real need and enough evidences proposed by the Subcommittee in the future, the Ministry will consider implementing the Government Use of patent on a case by case basis.

From the Thai experience, compulsory licensing or Government Use may be applied successfully in only less than 15 percent of all patented drugs. The Thai figures showed that majority of the non-patented drugs remains monopolized due mainly to the complexities of production. In addition, around majority of the patented drugs do not justify applying Government Use. Some of them do not meet the criteria, for examples drugs for Erectile Dysfunction Syndrome, drugs for baldness, and drugs for acne. In addition, most of the new patented drugs are just "me-too" products and do not have any significant benefit over those existing low price non-patented drugs. Besides, with Government Use, the patent holders still retain their rights and previous monopolized market (as described in Issue No.2). So, there is no need to worry that the Government Use and Compulsory Licensing will lead to the failure of the intellectual property systems.

Issue No. 5: The Government Use of Patents will save the government some funds but what are the benefits to the people?

The main objective of announcing and implementing the Government Use of patent is to *increase the access to essential medicines among the Thai people.* The government does not save any budget and in some cases has to spend more. For those ARVs which have limited coverage, like Efavirenz and Lopinavir+Ritonavir, many more people will have access to the drugs with the same budget level. In the case of Clopidogrel, the patients under the National Public Health Insurance Plan had no or very little access before, and the government had to pay an additional amount to allow access to the lower priced generic version of Clopidogrel. It should be reiterated that drugs derived from the implementation of the three Government Use of patent will be distributed only to those patients under any of the three public health insurance plans paid by the government. *The drugs can not be sold to the private sector or to those who are willing to pay out of pocket for their drugs.*

The benefits to the Thai people from the Government Use of patent on each drug are:

1. The case of Efavirenz patented by Merck Sharp and Dohme (Thailand) Limited

Efavirenz is an effective first line ARVs. It is less toxic than Nevirapine which is used in the locally produced Nevirapine based triple ARV formula, GPO-VIR . Around 20 per cent of patients using GPO-VIR will develop adverse drug reactions, from mild to severe, which can be life threatening. Patients in developed countries use Efavirenz based triple ARVs as their first line treatment, including developing countries that purchase drugs through external aid budgets. In Thailand, due to the high price of Efavirenz, all new cases of AIDS patients will have to be put on the more toxic Nevirapine based triple ARVs as their first line treatment. Around 20 per cent of them develop adverse reactions to the GPO-VIR. Only when they develop severe adverse drug reactions will they be switched to the Efavirenz based one, which is more than twice the price of GPO-VIR . With the Government Use of Patent, the Efavirenz price dropped from 1,400 Baht per month to 650 Baht per month. This will allow 20,000 more new patients to be put on to this Efavirenz based triple ARVs and reduce the risks from the toxicity of the Nevirapine based triple ARVs. If we allow competition to continue under the Government Use of Patent, it is expected that the price may go down further. If the price goes down to 20 per cent of the original price, then we will be able to support up to 100,000 patients with the same budget. This will allow all new patients to be treated with Efavirenz based triple ARVs in the next 5 years. There will be no need to subject the new AIDs patients with the more toxic Nevirapine based ARVs anymore.

2. The case of Lopinavir+Ritonavir patented by the Abbott Laboratories Limited

The Department of Disease Control has done a study on drug resistance among patients taking the first line ARVs. They found that around 10 per cent will develop drug resistance and will require second line ARVs, in the first few years. This depends mainly on the compliance of the patient and the virus itself. There are now around 500,000 people living with HIV/AIDS in Thailand. In the near future, at least 50,000 of them will require second line ARVs. One of the good second line drugs is the combination between Lopinavir and Ritonavir, patented by Abbott Laboratories Limited, under the trade name of Kaletra. The monthly price for the patented product is around 6,000 Baht in 2007. This means 72,000 Baht per patient per year. The budget required for 50,000 patients will amount to 3,600 million Baht. This is more than 100 per cent of the budget for ARVs in 2007. There is still the need to pay for the more than 100,000 patients on first line ARVs. If they do not receive second line ARVs, they will soon develop opportunistic infections and die. These are deaths occurring in the midst of the availability of the appropriate treatment. The high price of the second line ARVs are the major factors that hinders the attempt to save their lives. At the moment, we are able to support less than 2,000 cases of drug resistant patients. With the Government Use of Patent, we expect the drug price to go down at least to around 20 percent of the current price, which will allow us to save an additional 8,000 lives. With more competition and increased budget, we will be able to save more lives in the near future.

3. The case of Clopidogrel patented by Sanofi-Aventis Limited

This is an anti-platelet drug which is at least as effective as or more effective than Aspirin in preventing coronary obstruction. It is commonly used in patients with coronary heart diseases which are estimated to be around 300,000 patients in

Thailand. It is almost the only drug that can be used in the case of applying coronary artery stent. However, due to the very high price of 73 Baht per day, only around 30,000 patients can afford it,based mainly on out of pocket payment. So, the rest of the poor people who cannot afford to pay have to live with only Acetyl Salicylic Acid. The Permanent Secretary announcement of the Government Use of its patent will reduce the price at least 10 times to less than 7 Baht and allow patients under the universal health insurance scheme to also have access to the drugs. In this case the government and especially the contracted hospitals have to pay additional budget to support access to these generics. However, the lower price generics make it affordable by the government.

From the three examples above, it is clear that the Thai government's goal in implementing the Government Use of patent is to increase the access to the patented essential drugs, *rather than to save budget.* In the case of Clopidogrel, it is clear that more funds will be needed, but is within affordable limit.

Issue No. 6: What will the implications on the Thai export and economy and multinational industries be in Thailand?

The first thing to consider in addressing this question is that Thailand is implementing the Government Use of patent in compliance with national and international legal frameworks, based on solid evidences of the need to allow the Thai citizens to have more access to patented essential drugs. Furthermore, we are happy to negotiate and discuss with all the patent holders in a constructive manner for the benefits of all stakeholders. Thus there should not be inappropriate reactions and trade retaliation from our trade partners.

The Ministry of Public Health is fully aware that at least two-thirds of our economy depends on exporting of our goods and services. Furthermore, 15 to 18 per cent of our exports go to the USA, the country of origin of two of the patent holders that we have implemented the Government Use. If the US government applies retaliation measures on our exports which results in 10 per cent reduction of exports to the US market, it will mean a one to 1.2 per cent loss of economy and several hundred thousands job losses. So this is a very sensitive issue. Unless there is very important need for the people supported by solid evidences, we will not make these decisions. So the decision on the Government Use of Patent for the three drugs has been made very carefully based on solid legal and social grounds.

It should be noted that a few daily newspapers in Thailand had reported in mid February that the Trade Counselor of the US Embassy in Thailand has informed the senior official of the Thai Ministry of Commerce that the US will not use this case in their consideration of the status of Thailand in their list of countries trade relation. This is good news and it provides evidence of the US fair trade policy. However, there has been no official confirmation on both sides, so far. Nevertheless, if there is unfair trade retaliation against Thai products/services which is not in compliance with the WTO trade rules, we will have the right to bring the case to the Dispute Settlement Body of the WTO.

Furthermore, it should be reiterated that the Government Use of Patent does not touch on the out of pocket payment market, the current market of the patented drugs. The Government Use only opens new market for those who never have access to these drugs before. The patent holders have the full right to reduce their price to compete with the generics in this new market. So after the Government Use of Patent, there will be two drug markets in Thailand. One for those well off people and the two million foreign patients who pay out of pocket for the high price monopolized patented drugs. This market covers around 15-20 per cent of the population. The other is for those who are paid by the government for the lower priced competitive drugs. This is the majority of the Thai people who use their rights under the universal health insurance schemes.

In addition, the size of the Thai drug market is less than 0.5 per cent of the global drug market. It is even less for the market of patented drugs. So there should not be significant effect on the market and return of the research based drug companies.

On the contrary, the Government Use will allow the local pharmaceutical manufacturers, especially the Government Pharmaceutical Organization, to develop their capacities and products. In case that the discussion and negotiation leads to the agreement on voluntary licensing, there will also be technology transfer to further strengthen the local manufacturing capacity in Thailand.

Issue No. 7: Has the Ministry of Public Health consulted with other ministries and why not bring it to the decision of the Cabinet?

The Ministry of Public Health has long built up close and constructive relationship with all concern ministries, not only on this issue but also on other health development issues. Representatives from the Ministry of Commerce are involved in the work of the Ad Hoc Working Group to negotiate the price of the patented drugs and the work of the Subcommittee to implement the Government Use of patented drugs. Furthermore, before announcing the Government Use of patent, the Ministry of Public Health held another consultative meeting to have a final analysis of the legal aspect of the announcement. The representative of the Ministry of Commerce, the Office of the Council of State, the Lawyer Council, and other concerned parties were invited and actively participated.

In the subsequent negotiation with the drug companies, we also invited the representative from the Ministry of Foreign Affairs. The new Committee to negotiate the patented drug price, chaired by the Secretary General of the Thai FDA also consists of representatives from all concerned departments as well as consumer groups and specialists.

Lastly, the Ministry of Public Health also played active role in working closely with the Department of Trade Negotiation, Department of Intellectual Properties of the Ministry of Commerce and the Department of International Economic Affairs and Department of America and South Pacific Affairs of the Ministry of Foreign Affairs in preparing common guidelines for explaining the situation on Government Use of Patent in Thailand.

It should be reiterated here that according to section 51 of the Thai Patent Act, *it is the authority of any ministry, bureau or department of the government, to issue the Government* Use of patent. There is no need to get prior approval from the Ministry of Commerce and the Cabinet. This is different from section 52, which applies in the situation of war and extreme emergency; the Prime Minister with the approval of the cabinet, can issue order for the Government Use of patent.

Finally, with so many unclear questions related to the implementation of the Government Use of patent, the Public Health Minister submitted an explanatory note to the Prime Minister as well as a copy to the Minister of Commerce, the Minister of Foreign Affairs and the Minister of Science and Technology.

An 80 page white paper to explain and provide evidence related to the Government Use of patent was also published and distributed on February 16th 2007. It is also available on the website at www.moph.go.th and www.nhso.go.th .Finally, this English version of the white paper was prepared and published on March 6th 2007. It is also available on the two websites.

Issue No. 8: Will the issuing of Government Use result in a step backward for development of Drug Research and Development in Thailand?

Most research based drug companies invest only in some clinical and market research in Thailand. The purpose is mainly to obtain appropriate information for marketing of their products. The Thai drug market, although still very small, is growing and bigger than most ASEAN countries. So it is the interest of the research based drug companies to continue their businesses here. Thus they still have to invest in the clinical and marketing researches as mentioned above.

Thailand is developing its capacity and standard to support drug research and development, including the Good Laboratory Practice, the Good Clinical Practice, and the Good Manufacturing Practice. These capacities together with good research facilities and an adequate mix of good compliance patients will attract more researches from the drug industries. In the future if these capacities are up to international standards and cost-effective, they will automatically attract drug industries to invest in research in Thailand. If our quality is not up to the standard and too costly, drug industries will definitely carry out their research somewhere else. This has nothing to do with the Government Use of Patent or the level of protection of Intellectual Property Rights at all.

At the moment, most basic biomedical research is supported by the public budget, both nationally and from international organizations. The pharmaceutical industry puts very little effort to support this kind of research in Thailand, and there is no clear evidence of increasing efforts.

In the early 1990s when we were pressured to strengthen our patent act and to include product patents, we were also told that if we agreed to do so, there would be more investment in drug research and also technology transfer from the industries. We did revise our patent act to comply with the TRIPS since 1992, eight years before the 2000 WTO deadline. However, there has been no significant increase in drug

research and development from the industries. For technology transfer, we only witnessed the transfer of their drug factories from Thailand to countries with lower wages and cost. The number of drug factories in Thailand declined from 188 in 1992 to 166 in 2006.

Issue No. 9: What are the views of the World Health Organization and other international organizations on this movement in Thailand? Dose the Thai public support this decision?

The Director General of WHO, Dr. Margaret Chan, sent a letter, dated 7 February 2007 (Document No. 13), to the Public Health Minister of Thailand confirming that WHO unequivocally supports the use of TRIPS flexibilities, including compulsory licensing. She also confirmed that
Thailand's actions fully complied with TRIPS and there was no need for prior negotiation with the drug companies. She also supports the constructive discussion with the companies, which is the same view as Thailand, as described in Issue No. 3.

In addition, the letter from the 22 US Congressmen to the US Trade Representative and the reply from the US Trade Representative also confirm the legal and social ground as that of the WHO DG.

Furthermore, there has been overwhelming support from various international organizations, for example UNAIDS (Document No. 23), Medecins Sans Frontieres (MSF-Document No. 24), the Third World Network (Document No. 25), the Consumer Project on Technology (Document No.26), and the Clinton Foundation (Document No. 27).

This decision of the Ministry of Public Health has contributed to its being voted as the top appreciated ministry of the new government, according to public poll from the National Statistical Office in February 2007. This is the best evidence of the support from the Thai public in addition to many supportive articles and editorials in the popular local newspapers.

Issue No. 10: How can we be sure that the drugs derived from the Government Use of Patents will be equivalent in quality to the patented products?

At least five mechanisms can ensure the equivalence of the drugs to those patented products:

1. For those drugs that WHO has a system for prequalification, especially ARVs, the anti- TB and the anti-malarial drugs, only WHO pre-qualified products will be imported under the Government Use of Patent system.

2. For all drugs, the quality of the product has to be approved by the Department of Medical Science, the Ministry of Public Health.

3. All drugs have to be registered by the Thai FDA and a bioequivalence study is needed in the registration process.

4. Before distribution to the public, the Government Pharmaceutical Organization, the designated body to implement the Government Use of patent, will have to carry out quality assurance of the products.

5. The Thai FDA, the Disease Control Department and the National Health Security Office will jointly carry out post-marketing surveillance of these drugs to ensure the quality.

译者后记

《生命的权利》是一本生动的书。

随着相关知识在中国的普及，“强制许可”逐渐成为一个时髦的词汇，可是这条路究竟怎么走，绝大多数人却是心中无数。就仿佛是远处的一座大山，看得见，摸不着，更不知道如何去接近去攀登。枯燥空洞的理论，好比是繁冗复杂的地形图，充斥着GPS节点，很容易让人困惑乃至泄气。而这本小册子能为大家提供的，是一段娓娓道来的攻略，用平实清新的语言，缓缓地告诉你该如何做好出发前的准备，路上会有哪些困难，曾经走过的弯路，当然还有最重要的：成功登顶后的喜悦，以及向下一座更高的山头发起冲击的新起点。

本书所描述的波澜壮阔的舞台，就在我们的邻邦泰国。正如本书开头所说的这段话：“一个国际社会中小小的、柔顺的发展中国家，是如何象恐怖杀手杰克般成为全球谈资的呢”？当一个在国际世界上并不起眼的国家，拿出可能被很多人嘲笑为自不量力的勇气，不屈地发动起一场堂吉诃德般的斗争时，在不断的“探讨”和“倡导”中踯躅不前的我们，是否应该有一些更多的反思呢？

我们每一个译者都相信，这本书能够带给我们信念和力量。

原因很简单，它告诉我们，有无数的人在这条路上奋斗过，失败过，成功过。

于是我们就知道，在这条路上，我们都不再是孤单一人。

是的，只要我们都“在路上”……

王翔宇 执笔

2009年六月于北京

Postscript

The Right to Life is a lively book.

With the spreading of relevant knowledge in China, the compulsory license has become a fashionable concept, yet most of us fail to know how to find the way. Compulsory license is just like a huge mountain in front of us, we can see it, but we cannot touch it, cannot get closer and cannot climb up to the top. The boring theory is like a complicated map full of GPS point for professionals, which is really confusing and discouraging. This book, however, provide us with a roadmap by simple wording. It informs us on how to make preparations, on what kinds of difficulties will be ahead of us, on which wrong roads may puzzle us, and most of all, the great joy when we reach to top, as well as the new starting points for the next adventure to higher mountains.

The magnificent arena described in this book is located in Thailand, our neighboring country. As mentioned in the first page, "how did a small and submissive developing country in the global community become the 'Talk of the Globe' as Jack the Giant Killer"? When Thailand, this small country started this Don Quixote combat with great courage, which was ridiculed by many outsiders, shall we Chinese people, who are still wandering after so many "discussions" and "advocacy", have more introspection?

We translators are fully convinced that this book will bring us with faith and strength.

The reason is very simple, since the book tells us, countless people used to fight in this road. They failed and then they achieved a success.

So, we know that on this road, we are not alone.

Yes, as long as we are "on the road" ……

By Wang Xiangyu
June, 2009 Beijing

作者简介(Introduction of the Author)：

卡尼卡（陈妙裳）女士有着媒体从业的背景。在非政府组织领域中，她是无国界医生“病者有其药”项目与朱拉隆功大学消费者健康保护项目合作项目的协调人，同时也是泰国自由贸易协定观察的活跃成员。自由贸易协定观察是一个对自由贸易谈判所造成的严重社会影响进行监控和社会运动的联盟。在媒体界，她则是《路》杂志“全球报告”专栏的每周撰稿人。此外，她还主持着一档名为“国际评论晨报”的广播新闻节目（FM96.5)，对国际时事进行评论。没有医药背景的她将一些相当难以理解的议题，诸如全球性事件尤其是药物专利问题，快速地介绍给她的听众，并因此享有盛誉。

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China Global Fund Watch Initiative

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