



A Non-parliamentary debate  
on the Rights to  
Compulsory Licensing

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I am not a member of the National Legislative Assembly. The following debate on the rights to compulsory licensing is a “non-parliamentary debate” delivered in response to the Prime Minister Gen. Surayud Chulanont’s report on his government’s work, presented to the National Legislative Assembly on 24 May 2007.



Dear Mr Speaker,

Since early May 2007, the Ministry of Public Health's use of compulsory licensing has been noted not only within Thailand but also all over the world. It seemed that because of the Ministry's use of compulsory licensing, the United States elevated Thailand from the "Watch List" to the "Priority Watch List". At the same time, an organization called USA for Innovation launched its diabolical attacks on Thailand on the websites and in the newspapers.

The Ministry of Public Health issued its first compulsory license on an AIDS drug on 29 November 2006 and two compulsory licenses were issued on AIDS and heart disease drugs later on. It should be noted that the issuance of the latter two compulsory licenses was made on 25 January 2007. I'm not sure if the date was intended to signify something. According to the Thai history that has been deeply embedded in the memory of my generation, 25 January was the date King Naresuan won his fight on elephant back with the Crown Prince of Burma. His victory at the time kept the country independent for 175 years from 1592 to 1767, when the country lost its independence again. The Royal Thai Army has regarded 25 January as its birthday for a long time until it was recently found that the date had been one week off the mark because of the wrong check of the year. So the Royal Thai Army Day has been changed accordingly.

Mr Speaker, whether it was intentional of the Ministry of Public Health to issue its compulsory licenses on that particular day or not, the fact is our use of compulsory licensing has been done as a sovereign state and in a genuine civilized manner. Thailand's action was legally supported by the Patent Act B.E. 2522 (1979) as amended by the Patent Act (No. 2) B.E 2535





(1992) and the Patent Act (No. 3) B.E. 2542 (1999). Such Act is consistent with the global rules known as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization and the Doha Declaration that had been approved by the ministers of public health of the WTO members, who met in Qatar on 14 November 2001. The United States also approved of this Declaration and even clearly stated in its 2002 Trade Promotion Authority Act that the United States trade policy respect other nations' public health initiatives under Doha. And the US legal principles are in line with our Patent Act and specified in the statute called 28 USC 1498. This Doha Declaration mainly focuses on intellectual property and public health. It is officially known as the Declaration on the TRIPS Agreement and Public Health.

Mr Speaker, although I'm not a lawyer, I can assure you that what the Ministry of Public Health has done was, in every respect, reasonable and legally permitted by the Thai laws and international rules.

Apart from studying the issue on my own and consulting with several lawyers, I beg to inform Mr Speaker that many foreign lawyers, particularly those in the United States, have

analyzed and pointed out that Thailand's exercise of compulsory licensing was legally implemented in every way.

Allow me to give Sean Flynn of the American University's Washington College of Law as an example. This academic is a law expert, specializing in intellectual property laws and works for the Program on Information Justice and Intellectual Property. His article, analyzing Thailand's compulsory licensing and being disseminated on 18 December 2006, concluded that Thailand's action had been taken in compliance with the Thai laws as well as those of the US.

This article appeared in the Ministry of Public Health's English-language White Paper (pp. 31-37), which had been published to explain this matter.

Another person is James Love, who specializes in law and economics. He is Director of the Consumer Project on Technology (CPTech), which is one of the programs founded by Ralph Nader, the globally well-known and experienced consumer protection advocate of the US. James Love wrote an analysis stating that compulsory licensing was a regular measure undertaken everywhere around the world, including in rich countries such as the US and UK as well as in developing





countries. He also cited tens of concrete examples to support his analysis, which appeared in the Ministry's White Paper of English and Thai languages (see pp. 44–50 for the Thai version). In addition, he also sent a letter dated 11 December 2006 to the US Trade Representative Susan Schwab explicitly explaining that Thailand's action had been entirely in line with international rules and consistent with the US laws. He asked the USTR not to interfere in the Thai government's decision, as the reports had it (see the Thai-language White Paper, pp. 70–76).

In fact, there are many prominent persons clearly expressing their support for Thailand's use of compulsory licenses, pointing out that such action was reasonable and entirely lawful according to international rules and regulations.

Allow me to refer to another case of 22 members of the US Congress, sending their letter to the US Trade Representative Susan Schwab clearly elaborating how lawful and reasonable Thailand's exercise of compulsory licensing had been and asked the USTR not to interfere, as the reports had it. That letter—dated 10 January 2007 and appeared in the White Paper (Thai version, pp. 78–80)—clearly described how Thailand had followed the procedures by first providing AIDS drugs to AIDS patients in 2003

after the country's Government Pharmaceutical Organization could produce generic antiretroviral therapies—GPO–vir.

Mr Speaker, I'd like to further add that Thailand was the first country in Asia that had the fastest and most widespread of AIDS epidemic. I won't say what caused it but would like to inform you that AIDS patients in Thailand had to die in droves. Most of them died quietly because doctors often diagnosed them as dying of other diseases to help prevent their surviving relatives from suffering discrimination. But field studies found that AIDS became number one killer disease in many provinces, especially in the upper northern region, where cancer, heart disease and accident had claimed top rankings for a long time. This was because AIDS drugs at that time were so expensive, costing an average expense of 25,000 baht per month. When we could produce GPO–vir, the expense was 20 times reduced to only 1,200 baht per month. Now, the price can be 10% lowered to only 1,080 baht per month. And the GPO announced that the price would be 10% further reduced from 1 October 2007.

Mr Speaker, AIDS drugs are expensive because they are patented. But the price of GPO–vir can be tremendously lowered because its three therapies are no longer patented.





Mr Speaker, the letter of the 22 US Congressmen explained with profound understanding of Thailand that because a number of the AIDS patients had developed severe side effects from one of the first-line regimens, they needed to take the patented therapies.

The Ministry of Public Health's academics and executives were fully aware of the need to provide replacement therapies. Because those drugs were under patent, attempts were made to negotiate their prices, but to no avail. An explicit evidence of such negotiation appeared in the forms of the letter dated 27 November 2004 from the director general of the Department of Disease Control to the company and the refusing letter of the company dated 27 January 2005. These two letters were also included in the White Paper (Thai version, pp. 56–57). The Ministry of Public Health tried again by setting up a working committee consisting of representatives of concerned offices such as the Departments of Internal Trade and Intellectual Property to negotiate the price reduction, but did not succeed. Such attempt was also documented in the White Paper (pp. 51–54).

Mr Speaker, in such case the Ministry had three choices. First, continuing to buy expensive drugs, but this would bring on a

major problem. In the past, the government's allocated budget to the Ministry's Health Security for All Programme was always inadequately lower than expected. Since the Programme started in 2001, every state hospital had to carefully economize on its funding and use its earned donations to contribute to the budget. So far, over 10,000 million baht have been used. This choice was rather bumpy and constricted, as hundreds of hospitals have been nearly bankrupt. Second, allowing the patients to shoulder the burden, this would of course kill most of them that were poor. All of us, who were doctors, pharmacists, nurses, and health officials, didn't want to make that choice. So we needed to use the remaining choice of exercising compulsory licensing to provide cheaper medicines.

Mr Speaker, it was evident that this had not been a rash decision. We had been aware that we might have to do this since we decided to take good care of our people. And we did follow the required procedures. Thus, all the accusations leveled against us were false. Our necessity had evidently been described in the letter signed by 22 US Congressmen. Finally, the USTR chief sent her official letter dated 17 January 2007 replying that the agency has respected Thailand's exercise of compulsory licensing and





never suggested that Thailand has violated national and international rules (Thai-language White Paper, p.40).

But then on 30 April 2007, the USTR decided to blacklist Thailand, pointing out reasons relevant to Thailand's compulsory licenses and citing its lack of transparency in doing so.

A lot of people must have been surprised and puzzled. So was I. Thailand has not been blacklisted for 15 years since 1992.

But Mr Speaker, digging deep into a recent history of the US and Thailand's patenting will help us figure out what has been going on.

Let me inform you that this is not the first time that we were treated in this manner. In fact, we have been treated this way since 1984-85, when we were compelled to amend our Patent Act and constantly pressured to give in to intellectual property demands.

Our Patent Act B.E. 2522 (1979) was in fact valid according to international rules. As a developing country, we therefore protected only the process patent, not the product patent.

So we could produce any drugs for our use if the production process was clearly different from that of the patent holders. The process patent protection term lasted 15 years, which I insist that it was in compliance with international rules of that time that accepted the different abilities of rich and developing countries. It was like giving a handicap to weaker golfers. But this advantage was constrained by the World Trade Organization's schedule that required developing member countries to develop and amend their laws to protect product patent, as well as extend protection term to 20 years by 2000 while the deadline could be extended for another five years till 2005 for underdeveloped member countries.

Mr Speaker, regarding this matter we've always been pressured and fought back relentlessly. Several times was the Bill submitted to Parliament in compliance with the US demands, but all failed. Once on 28 April 1988, the Bill won its first-reading votes. Thirty-two MPs affiliated to a coalition party decided to vote against it. That coalition party had to quit the government to demonstrate its responsibility. The then prime minister, who is president of the Privy Council and Statesman, announced the dissolution of Parliament the following day, resulting in the rejection of the Bill.





But eventually, we were forced to amend the Patent Act in 1992. The then Minister of Public Health Dr Pairoj Ningsanond and especially the Deputy Minister Dr Atthasit Vejajiva strongly objected to the amendment but could not withstand the US threats of cutting Thailand's GSP and employment of strict "Special 301" measures on us. It must be recorded in history that we amended our Patent Act eight years before the WTO required us to do so whereas India did so in 2005, 13 years after us.

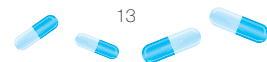
Mr Speaker, then was the time when the military-backed Peace-Keeping Council was in power. The US pushed very strong pressure on us by downgrading Thailand to the Priority Foreign Country, which was worse than the Priority Watch List status we are in now. We had to bitterly agree to amend the law for fear of losing the GSP privileges, which were solely subjected to the US's discretion to grant or withdraw whenever it liked. While these privileges were temporary our amendments of the law was a permanent granting of our rights that included the rights to all product including medicine, one of the four those necessities of life.

Mr Speaker, I was so impressed by many of our Thai fellows-whose free spirit that has been Thai people's uniqueness

for a long time—who must have been reminded by the country's bitter loss of territory during the reign of King Rama V and got together to fight this battle. Although we had to give in to providing product patent protection and extending the 15-year protection term to 20 years, we succeeded in laying a condition that a Drug Patent Board be established to control the medicine prices and see to it that the pharmaceutical technology was transferred to us. The US agreed to have these two issues incorporated in the amendments and would fulfill its obligations, but never kept its promise, particularly regarding the technology transfer.

On the contrary, the US continued to ask for more. At the end, the section on the Drug Patent Board was deleted in the amendments of the Patent Act, compelled to be made in 1999. Therefore, the only legal measure available to deal with patented drugs is the exercise of compulsory licensing, an international rule recognized by the WTO.

Mr Speaker, a patent is in fact not a property. It is a right that a state or global community grants to a patent holder to promote invention for human good. Such right must therefore be flexible, as it is internationally called flexibility by the WTO, so that it can be used on three conditions, provided by Thailand's Patent





Act, as follows:

- 1) That the patent holder has not produced the product or there is a shortage of such product, or the product is sold at unreasonably high prices; the Act allows an individual to apply for the use of compulsory right, but prior negotiations with the patent holder must be made (sections 46–50);
- 2) In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may exercise the right **without asking for prior permission from the patentee**, but shall notify the patentee of the use of right and the remuneration to be paid. The patentee is not entitled to veto the use of the right but is allowed to negotiate the remuneration. In case of disagreement, the director general of the Intellectual Property Department shall

decide. In the case that this is not satisfactory, an appeal can be made to the Intellectual Property Court (Section 51).

**Such content and principles of the use of compulsory licensing are in line with TRIPS' Article 31 (b) and Doha Declaration mentioned earlier (for details, see the Thai-language White Paper, pp. 22–24 and English version, pp. 23–25).**

- 3) 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 right without asking for permission from the patentee and a fair remuneration to the patentee shall be paid.

Mr Speaker, a lot of people may not understand why we have been pressured unabated to give in to patent demands, especially those relevant to drug patent. How powerful is the drug industry? Allow me to inform you that if you have a chance to read the book *The Truth About the Drug Companies: How They Deceive Us and What to Do About It*, you will understand. It was written by Dr Marcia Angell, a senior lecturer of the Department of Social Medicine, Harvard Medical School and former Editor-in-Chief of







the New England Journal of Medicine. In 1997 she was named by the Time magazine as one of the most influential Americans working on health. In that year, President Clinton was named the most influential politician while Tiger Woods was recognized as the most outstanding sports person. Dr Angell's book describes a large number of dubious incidents taking place in the pharmaceutical industry. Each of her case was supported by explicit evidences

This dubious influence has periodically compelled us to buy drugs at unreasonably high prices. Our effort to create legal measures to prevent high pricing of medicines was aborted. Our current attempt to resort to the only remaining legal means is being threatened by blacklisting us and severe attacks.

I don't really know how long we have to bear.

Mr Speaker, my update on the Thai-US FTA negotiations revealed that one of the US proposed demands put on Thailand was to change Section 51 of the Patent Act to specify that if compulsory licensing is to be used; prior permission from the patentee shall be required. This proposal is beyond the requirement of the WTO's TRIPS Agreement, not to mention the proposed extension of protection duration from 20 to 25 years. It is fortunate that the bilateral Thai-US FTA has not been signed; otherwise,

this would mean that had granted patent protection of all products to the US for another five years. Consequently, we would have to give similar patent protection to other countries.

Importantly, if we agreed to amend Section 51 to the effect that if compulsory licensing is to be used; prior permission from the patentee shall be required, it would mean that we had given our sovereignty to other countries. Thus, the TRIPS flexibility would be completely meaningless and we would no longer be able to exercise our compulsory licenses, as our long experiences have already taught us.

Many years ago, the Department of Disease Control—formerly known as the Department of Communicable Diseases Control—had to buy a particular medicine for treating opportunistic infection in AIDS patients. The drug company set its price at 270 baht per tablet. Not a cent would be discounted even if it was bought in bulk. This was because the firm had a monopoly right to the medicine. A few years later when the monopoly patent expired and domestic drug companies could produce its generic version at a competitive price, it cost only 10 baht per tablet. Now a tablet costs only six baht.





Mr Speaker, I was thankful that the Prime Minister clearly demonstrated his stance and understanding of the Ministry of Public Health's exercise of compulsory licensing. I believe that he has been severely pressured by the US and internal government agencies and the private sector. But I firmly believe in him even if I had no chance to work closely with him. But my studying of his work background and once being informed by the Ministry's spokesperson—who saw the incident of his imperturbable character when he handled the Ratchaburi Hospital occupation by the God's Army, I am convinced that his leadership will help Thailand get over these problems wisely and with dignity. History would not need to record that Thailand had to overwhelmingly give in to intimidation and wrongful coercion when he was in power.

Mr Speaker, allow me to inform that the USTR's black-listing of Thailand is a measure being employed periodically. Our submission does not mean that they will stop threatening and appreciate our docility. I agree that we must right all the wrongs, such as violations of copyrights and trademarks. But we have to stand firm on our national dignity and lawful right to compulsory licensing to protect our citizens and ensure that they will have sustainable access to the health security for all.

I am sure that as a great nation, the US respects what is right and legitimate and will not admire those who are weak and submissive. I believe that we can maintain our good understanding and relations with the US. Let me thank you again Mr Prime Minister. I'd like to reiterate that I believe in you.

Thank you.

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