

ALLEGATION LETTER

UNITED NATIONS SPECIAL RAPPORTEUR ON THE RIGHT TO HEALTH

IN THE MATTER OF
USE OF THE “SPECIAL 301” PROGRAM, SECTION 182 OF THE TRADE ACT OF 1974,
TO LIMIT ACCESS TO MEDICINES IN VIOLATION OF THE INTERNATIONAL RIGHT
TO HEALTH

SUBMISSION OF

**Mr. Apiwat Kwangkaew (Chairperson, Thai Network of People Living with HIV/AIDS);
Mr. Nimit Tienudom (Director, AIDS Access Foundation); Ms. Supatra Nacapew
(Director, Foundation for AIDS Rights)**

Thai Network of People Living with HIV/AIDS; AIDS Access Foundation; Foundation for
AIDS Rights; Thai NGO Coalition on AIDS; Friends of Kidney-failure Patients Club; Cancer
Patient Network; Foundation for Consumers; The Rural Pharmacist Foundation; The Rural
doctor foundation; Drug Study Group; Health Consumer Protection program, Chulalongkorn
University; Social Pharmacy Research Unit, Chulalongkorn University; Drug System Monitoring
and Development Program, Chulalongkorn University; Thai Holistic Health Foundation; FTA
Watch

1. In accordance with resolution 2002/31, we, the undersigned Thai organizations, submit this allegation letter to request that the Special Rapporteur respond to the enclosed information documenting violations of the international right to health by the United States through the operation of its “Special 301” program and related trade policies with Thailand.
2. The alleged victims in this matter are the Thai people in need of medicines. This allegation letter is submitted by Thai Network of People Living with HIV/AIDS, AIDS Access Foundation, and Foundation for AIDS Rights, organizations of Thai-based AIDS and human rights activists, people living with HIV/AIDS, public health experts, fair trade advocates and concerned individuals who campaign against policies that deny treatment for HIV.
3. By listing Thailand on its Special 301 Priority Watch List, the United States has used this report and other trade negotiations, Generalized System of Preferences, foreign aid, technical assistance and diplomatic pressure to promote intellectual property and pharmaceutical regulations that restrict access to affordable medications in Thailand. These policies are continuing in the present administration, and cause grave and needless suffering in Thailand. UN Human Rights officials have frequently affirmed that promoting access to medicines in poor countries is a human rights duty of all countries, including of donors and trade partners, and have reviewed country compliance with these mandates in human rights review proceedings.

THE U.S. LISTS THAILAND ON ITS SPECIAL 301 PRIORITY WATCH LIST

4. Despite the Doha declaration, clear human rights duties and the demands of global health, the U.S. has used, and continues to use, its “Special 301” program to pressure Thailand to give up TRIPS flexibilities.
5. One of the central tools used by the U.S. to promote “TRIPS-plus” policies on access to medicines has been the “Special 301” program. The program requires USTR to publish a list of countries that deny “adequate and effective protection of

intellectual property” and permits the unilateral imposition of trade sanctions against such countries, even in the absence of violation of any trade agreement. The USTR has listed Thailand on its “Special 301” program Watch List since 2001, and Thailand was elevated to the Priority Watch List starting in 2007 because it lawfully exercised its right to issue compulsory licenses.

6. On November 29, 2006, the Thai Ministry of Health issued a non-commercial, government use compulsory license for the first-line HIV/AIDS antiretroviral (ARV) efavirenz. In January 2007, the Thai government issued two more government use compulsory licenses for the ARV lopinavir/ritonavir, and for the heart medication clopidogrel. Finally, in January 2008, the Thai government issued government use compulsory licenses for four cancer medications: docetaxel, letrozole, erlotinib, and imatinib.
7. On March 20, 2007, The USTR downgraded Thailand to its “Special 301” Report Priority Watch List. The USTR cited the following reasons for the downgrade: “In addition to these longstanding concerns with deficient IPR protection in Thailand, in late 2006 and early 2007, there were further indications of a weakening respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country’s ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern.”¹
8. In March 2007, Abbott Laboratories Ltd., the patent owner of AIDS drug Kaletra (generic name: lopinavir/ritonavir), reacted to the Thai government’s compulsory licensing policy by withdrawing their drug registration application in Thailand for seven drugs, including Aluvia (a new heat-resistant version of Kaletra), and medicines for treating hypertension, kidney disease, etc. Ralph L. Boyce, who was later the U.S. Ambassador to Thailand, wrote a cable to support Abbott’s action, even he was aware of the adverse health consequences of the drug registration withdrawal².
9. On July 20, 2007, Ralph L Boyce, the U.S. Ambassador to Thailand, authored a letter to GEN Surayud Chulanont, the Prime Minister of Thailand, opposing the

legal and legitimate action taken by the Thai Ministry of Public Health to issue compulsory licenses to address the country's public health threats. In the letter, the Ambassador claimed that "While all WTO members have the ability to make appropriate use of flexibilities to address urgent situations, these decisions should not be made lightly and only as a last resort." In this letter, Ambassador Boyce also requested the Thai Ministry of Public Health to involve the patent-owner companies in the decision-making process in an open and transparent manner.³

THE U.S. PRESSES THAILAND TO RESTRICT ACCESS TO MEDICINES THROUGH "TRIPS-PLUS" TRADE PRESSURE

10. In reaction to the listing of Thailand on the Priority Watch List, the new Thai Public Health Minister Chaiya Sasomsab in February 2008 called for a review of the policy that led to the granting of compulsory licenses for the four cancer medications issued in January 2008. Minister Sasomsab cited Thailand's listing on the USTR Priority Watch List as a main reason for the review of the compulsory licensing review.⁴
11. Minister Sasomsab also cited concerns that the US would further downgrade Thailand by listing it as a Priority Foreign Country when calling for a review of the cancer drug compulsory licenses. The Priority Foreign Country listing is the last and most severe category under the "Special 301" program, with the US subjecting countries in this category to trade sanctions. The Pharmaceutical Research and Manufacturers of America (PhRMA) called for Thailand to be labeled a Priority Foreign Country in its submission on Thailand's intellectual property rights protection and enforcement to the USTR in February 2009.
12. The compulsory license review order by Minister Sasomsab caused a postponement in the delivery of two million tablets of clopidogrel.⁵ The compulsory license for clopidogrel was issued on January 25, 2007, and the Ministry of Public Health delegated the Government Pharmaceutical Organization to commence the importation process on February 12, 2007. In June 2007 the Thai Government Pharmaceutical Organization (GPO) Board approved the importation of two million tablets of clopidogrel from the generic drug manufacturer Kalida. With the review initiated by Minister Sasomsab, Kalida

postponed delivery to the GPO because it feared that the original drug maker might sue it if it exported clopidogrel to Thailand. The GPO did not receive this shipment of clopidogrel from Kalida until June 18, 2008 -- when the first consignment of 575,000 tablets arrived in Thailand.

13. Minister Sasomsab's compulsory license review caused a one-year delay in the receipt of the two million tablets of clopidogrel from Kalida, resulting in damages around 248,378,550 baht per month as calculated based on the number of patients who need clopidogrel and the difference in the costs between original and generic clopidogrel. A recent study revealed that clopidogrel increased life expectancy by 0.55 QALYs as compared with aspirin. In addition, in post-stroke patients, clopidogrel increased life expectancy by 0.17 QALYs as compared with aspirin.⁶ Clopidogrel provides a substantial increase in quality-adjusted life expectancy, with the delay in receiving clopidogrel also affecting the life expectancy of the patients along with their quality of life.
14. The Thai Ministry of Commerce also made several internal policy suggestions about how to get Thailand off the Priority Watch List. The Commerce Ministry suggested that no new compulsory licenses should be issued, that efforts to amend intellectual property laws (including the Thai Patent Act) should be sped up, and that more punitive measures and actions should be taken against IP infringing activities.⁷ These efforts by the Thai government to get off the Priority Watch List will lead to greater barriers to accessing medicines.

CONCLUSION

15. The Special Rapporteur for the Right to Health should call on the U.S. to account for its use of Special 301 program and other elements of its foreign policy that encourage and coerce Thailand to adopt intellectual property norms that restrict access to medicines, including access to antiretroviral medicines for people living with HIV/AIDS. The Special Rapporteur should encourage the U.S. to use its trade and foreign assistance programs to promote *full* use of TRIPS flexibilities and to otherwise revise its foreign policies to promote access to medicines. The Special Rapporteur should call on the U.S. to provide a procedure for the appeal of human rights issues within the Special 301 report, to reverse its unlawful

unilateral threats of trade sanctions via Special 301, and to reconsider and reverse the many decisions it has made that violate the right to health of Thai poor people and poor people around the world.

¹ USTR, 2007“Special 301” Report Executive Summary, USTR Reports and Publications (2007), Available at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf.

² Ralph L. Boyce’s cable

³ Letter of Ralph L. Boyce to the Thai Prime Minister

⁴ Treerutkuarkul, Apiradee. “Stop the Review,” in *The Bangkok Post*, 11 February 2008

⁵ Complaint letter by Saree Aongsomwang

⁶ Mark D Schleinitz, J Peter Weiss, Douglas K Owens. Clopidogrel versus aspirin for secondary prophylaxis of vascular events: a cost-effectiveness analysis. *Journal of medicine*. 2004; 116: 797-806.

⁷ Letter from Phuangrat Aswaphisit, Department of Intellectual Property, to all agencies in the Ministry of Commerce.

ATTACHMENTS:

Ambassador Ralph Boyce's Cable

Letter of Ralph Boyce to Thai Prime Minister

Treerutkuarkul, Apiradee. "Stop the Review," *Bangkok Post*, 11 February 2008

Complaint Letter by Saree Aongsomwang

Letter from Phuangrat Aswaphisit, Department of Intellectual Property, to Ministry of Commerce

ACTION EAP-00

RELEASED IN FULL

INFO	LOG-00	EEB-00	AID-00	CEA-01	CIAE-00	CTME-00	INL-00
	C-00	DNI-00	DODE-00	ITCE-00	DOIE-00	EXME-00	E-00
	FAAE-00	UTED-00	VCI-00	FRB-00	H-00	TEDE-00	INR-00
	IO-00	LOC-01	L-00	VCIE-00	NSAE-00	ISN-00	NSCE-00
	OES-00	OIC-00	OMB-00	NIMA-00	EPAU-00	ISNE-00	SP-00
	STR-00	NCTC-00	FMP-00	CBP-00	BBG-00	EPAE-00	IIP-00
	DRL-00	G-00	NFAT-00	SAS-00	FA-00	/002W	

-----914790 142335Z /38

R 142323Z MAR 07

FM AMEMBASSY BANGKOK

TO SECSTATE WASHDC 5544

ASEAN MEMBER COLLECTIVE

USMISSION GENEVA

USDOC WASHINGTON DC

DEPT OF HHS WASHINGTON DC

UNCLAS BANGKOK 001524

SIPDIS

STATE PASS USTR FOR B. WEISEL, C. WILSON

STATE PASS USPTO

HHS/OHGA FOR AMAR BHAT

USDOC FOR JKELLY

E.O. 12958:N/A

TAGS: ECON, ETRD, KIPR, TH

SUBJECT: ABBOTT LABS HALTS NEW DRUG REGISTRATIONS

1. Abbott Labs, the recent target of a compulsory license on their patented antiretroviral Kaletra, confirmed to Embassy that the company had withdrawn applications for registration of seven new pharmaceutical products in Thailand, and had no plans to introduce new products until its intellectual property was properly respected.

The seven drugs include Aluvia, a new heat-stable version of Kaletra. Although the two drugs are identical in effect, the new version is considered ideal for tropical environments such as Thailand. Other drug applications pulled include treatments for hypertension, kidney disease, auto-immune disease and congestive heart failure. The applications had been on file with the Thai FDA for up to ten months awaiting approval.

2. Abbott said they had notified the FDA's Drug Control Division (DCD), but RTG officials interviewed by press said they were unaware of Abbott's actions (Embassy's calls to FDA officials were not returned today). The DCD's Senior Pharmacist Dr. Suchart Chongprasert told a Wall Street Journal reporter that he was

UNITED STATES DEPARTMENT OF STATE
 REVIEW AUTHORITY: CHARLES E LAHIGUERA
 DATE/CASE ID: 08 MAY 2009 200804019

UNCLASSIFIED

UNCLASSIFIED

surprised that Abbott would choose to unilaterally restrict its sales in Thailand and was waiting to see the actual documentation withdrawing the applications. Asked if the RTG would respond with further CLs, Dr. Suchart said the process of identifying drugs to license was lengthy and no more CLs were in the pipeline.

3. Matichon newspaper quoted Dr. Siriwat Tiptaradol, Secretary General of the Thai FDA, that the Ministry of Public Health planned to invite relevant parties, especially the three companies whose patents were broken, to meet on March 26 to negotiate. However, none of the three had yet to receive an invitation.

4. Comment: Abbott's actions will certainly be controversial. However, the action may strengthen the hand of Abbott and the rest of industry in future dealings with the RTG. Abbott's move puts the RTG on notice that there are visible consequences for its actions, rather than solely a vague weakening of the investment environment. Whether this focuses the minds of RTG officials at upcoming negotiations remains to be seen. End Comment.

BOYCE

NNNN

UNCLASSIFIED



EMBASSY OF THE
UNITED STATES OF AMERICA
BANGKOK

THE AMBASSADOR

July 20, 2007

Your Excellency:

When we spoke in late March, before my trip to the United States, I welcomed your assurance that no new compulsory licenses on pharmaceuticals would be issued. I reported this news to my Government and to U.S. industry on my subsequent travels back to Washington, which greatly eased the tension. I now fear that the compulsory licensing issue will soon reemerge.

A number of U.S. pharmaceutical manufacturers are closely following the deliberations of the Ministry of Public Health ad hoc committee formed to consider pharmaceutical compulsory licenses. The Ministry of Public Health has confirmed that it is actively considering a list of additional drugs for compulsory licensing. My staff has consulted with officials from the Ministry of Foreign Affairs and Ministry of Commerce, who have not been able to reassure us that no additional compulsory licenses are forthcoming.

My Government thinks it is important for all countries, including Thailand, to play a role in, and benefit fully from, the development of new and more advanced medical treatments. Strong protection of intellectual property rights, including through patents, remains a vital part of that process. While all WTO members have the ability to make appropriate use of flexibilities to address urgent situations, these decisions should not be made lightly and only as a last resort.

We strongly urge the Ministry of Public Health to engage openly and transparently with the companies that developed the drugs that are at issue. I look forward to your continued leadership on this issue.

Sincerely,



Ralph L. Boyce

His Excellency
GEN Surayud Chulanont,
Prime Minister of the Kingdom of Thailand,
Government House,
Pitsanulok Road,
Bangkok 10300.

'Stop the review'

Bangkok Post - February 11, 2008

Apiradee Treerutkuarkul

Health activists, cancer and Aids patients yesterday urged Public Health Minister Chaiya Sasomsab to stick with the compulsory licences on cancer and Aids drugs announced by the previous government.

About 50 protesters from a network of people living with HIV/Aids and cancer patients gathered at the Public Health Ministry to hand a protest letter to Mr Chaiya who is under public criticism after announcing that he plans to immediately review the CL policy on patented lung and breast cancer drugs Docetaxel, Erlotinib and Letrozole.

The minister was of the view that the CL policy was politically correct but "legally incorrect." The activists expressed concern over Mr Chaiya's position, arguing that there was no better choice to extend public access to cheap life-saving medicines at this time.

They also asked him to listen to public views, not just the pharmaceutical industry and the Commerce Ministry, before revoking the licences.

"He doesn't know in what difficulty poor cancer patients and their families are. Most of them die because they can't afford the costly patented drugs," said Saichon sae Lim, a patient who has been suffering from ovarian cancer for five years.

"If the new minister really wants to help the poor at the grassroot level who elected him, he will not terminate the licences of cancer medicines," she said.

Mrs Saichon said many cancer patients were dying simply because they found the life-saving drugs unaffordable.

She has decided to put her survival hopes on a strict and healthy diet and exercise, instead of modern medication, because she too can't afford the cancer medicines. Her condition is now too serious and considered incurable by any of the available drugs.

Nimit Thien U-dom, the director of Aids Access Foundation, said the network of people living with HIV/Aids and consumer groups were closely monitoring the new minister's performance, particularly on the licences policy, as any CL termination would seriously hurt the poor. "It will be a shame if he does, as the country would lose so much and the poor would be deprived of life-saving drugs. They will die a premature death," he said.

Mr Chaiya has, however, made it clear he would stand firmly by his decision to review the compulsory licences imposed against four cancer-fighting drugs even though he insists there was no plan to revoke the policy for the time being.

"Saving 500 million baht through the CL policy would mean nothing compared to the damages we could suffer if billions of baht worth of our exports are boycotted," he told the health activists.

He said it was all so clear that the CL policy was the reason why the US Trade Representative had penalised [Thailand](#) by putting it on the Special 301 Priority Watch List (PWL). Being put on the PWL has led to the elimination of the duty-free access Thailand enjoyed under the Generalised System of Preferences (GSP) for gold jewellery and other exports to the US since July 1, 2007.

Mr Chaiya said he received a confidential letter signed by former commerce minister Krirk-krai Jirapaet asking the new government to review the policy on compulsory licensing. The letter was sent through permanent secretary for health Prat Boonyawongwirote on Feb 4, the day Mongkol na Songkhla ended his term as health minister.

According to the letter, commerce officials are worried about the policy's impact on the country's relations with its key trading partners, the European Union and the [United States](#), home to several pharmaceutical giants.

The concern is now greater about the possibility Thailand would be downgraded further and put on the Priority Foreign Country (PFC) list, which is the last and most severe US copyright protection category and subject to trade sanctions. The Pharmaceutical Research and Manufacturers of America (PhRMA) has threatened to press Washington for tougher action against Thailand.

Drug firms and have continuously accused Thailand of stealing their intellectual property.

But under World Trade Organisation rules, it is legitimate for member countries, including Thailand, to use the Trade-Related Aspects of Intellectual Property Rights (TRIPS) to issue compulsory licences to make or buy generic versions of patented drugs deemed critical to public health as long as the medicines are meant for domestic and emergency use. Cancer is a leading cause of death among the Thai population. Around 15,000 Thais die each year due to lung and liver cancer alone.

Dr Mongkol on Jan 4 signed four ministerial announcements to license Letrozole, a breast cancer medicine being produced by Novartis, the breast and lung cancer drug Docetaxel by Sanofi-Aventis and Roche's Erlotinib, used for treating lung, pancreatic and ovarian cancer. However a licence issued on a leukaemia drug, Glivec, was eventually cancelled after its maker, Novartis, agreed to supply it free to hundreds of Thai patients under its philanthropic programme.

Dr Mongkol earlier overrode Merck's Aids drug Efavirenz in Nov 2006 and later Abbott Laboratory's Kaletra and Sanofi Aventis' heart drug Plavix in Jan 2007, saying the country could not afford patented drugs to cover 48 million of the 63 million Thais under the universal healthcare scheme.

Mr Prat said he and the minister would discuss and review the CL policy with commerce officials on Feb12.

Dr Vitit Artavakun, director of the Government Pharmaceutical Organisation, said the purchase of the generic version of Docetaxel might have to be delayed if the Public Health Ministry goes ahead with the CL policy review.



EMBASSY OF THE
UNITED STATES OF AMERICA
BANGKOK

THE AMBASSADOR

July 20, 2007

Your Excellency:

When we spoke in late March, before my trip to the United States, I welcomed your assurance that no new compulsory licenses on pharmaceuticals would be issued. I reported this news to my Government and to U.S. industry on my subsequent travels back to Washington, which greatly eased the tension. I now fear that the compulsory licensing issue will soon reemerge.

A number of U.S. pharmaceutical manufacturers are closely following the deliberations of the Ministry of Public Health ad hoc committee formed to consider pharmaceutical compulsory licenses. The Ministry of Public Health has confirmed that it is actively considering a list of additional drugs for compulsory licensing. My staff has consulted with officials from the Ministry of Foreign Affairs and Ministry of Commerce, who have not been able to reassure us that no additional compulsory licenses are forthcoming.

My Government thinks it is important for all countries, including Thailand, to play a role in, and benefit fully from, the development of new and more advanced medical treatments. Strong protection of intellectual property rights, including through patents, remains a vital part of that process. While all WTO members have the ability to make appropriate use of flexibilities to address urgent situations, these decisions should not be made lightly and only as a last resort.

We strongly urge the Ministry of Public Health to engage openly and transparently with the companies that developed the drugs that are at issue. I look forward to your continued leadership on this issue.

Sincerely,



Ralph L. Boyce

His Excellency
GEN Surayud Chulanont,
Prime Minister of the Kingdom of Thailand,
Government House,
Pitsanulok Road,
Bangkok 10300.



เครือข่ายผู้ติดเชื้อเอชไอวี/เอดส์ ประเทศไทย
Thai Network of People Living with HIV/AIDS

๔๙๔ ซอยนครไทย ๑๑ ลาดพร้าว ๑๐๑ คลองจั่น กทม. ๑๐๒๔๐ โทรศัพท์ ๐๒-๓๗๗-๕๐๖๕ โทรสาร ๐๒-๓๗๗-๙๗๑๙ อีเมล: tnph@thaiplus.net
494 Soi Nakonthai 11 (Ladproaw 101) Klongjun Bangkok, Thailand 10240 Tel. 02-377-5065 Fax 02-377-9719 e-mail: tnph@thaiplus.net

No. Special TNP+ 002/2008

15 May 2008

Subject: Request for the removal of Mr Chaiya Sasomsap from the Minister of Public Health post

To: Speaker of the Senate

Attachments: 1. Documents signed by 23,967 eligible voters;
2. Attachment No. 1, 9 pages;
3. Attachment No. 2, 2 pages;
4. Attachment No. 3, 5 pages;
5. Attachment No. 4;
6. Attachment No. 5, 8 pages;
7. Attachment No. 6, 7 pages;
8. Document on the Facts and Evidences on the 10 Burning Issues, 1 copy; and
9. Document on the Answers to 10 Important Issues about the Government Use of CL, 1 copy.

As my colleagues and I, 16 people in total, have initiated a collection of at least 20,000 signatures of eligible voters in an attempt to request through the Speaker of the Senate for the Senate's removal of Mr Chaiya Sasomsap from the Minister of Public Health post, we can now collect a total of 23,967 (twenty-three thousand nine hundred and sixty-seven) signatures.

Therefore, we would like to submit the name list of the abovementioned eligible voters to the Speaker of the Senate and members of the Senate to proceed with the removal of Public Health Minister Chaiya Sasomsap, based on the following accusations that are indicative of:

1. Administrative malpractice: In his capacity as Public Health Minister, Mr Chaiya Sasomsap took an action that could inflict potential damage upon national budget by calling for a review of the government use of compulsory licenses on four patented cancer medicines, whose CL use had already been announced since 4 January 2008 by the former Public Health Minister Dr Mongkol na Songkhla. Such announcement appeared in all types of media reports (see Attachment No. 1). The review, ordered by the ministry's highest-ranking official, did affect the import of coronary heart disease drug (Clopidogrel), whose patent right had been used by the government's compulsory licensing since 12 February 2007. The Government Pharmaceutical



เครือข่ายผู้ติดเชื้อเอชไอวี/เอดส์ ประเทศไทย
Thai Network of People Living with HIV/AIDS

๔๙๔ ซอยนครไทย ๑๑ ลาดพร้าว ๑๐๑ คลองจั่น กทม. ๑๐๒๔๐ โทรศัพท์ ๐๒-๓๗๗-๕๐๖๕ โทรสาร ๐๒-๓๗๗-๙๗๑๙ อีเมล: tnph@thaiplus.net
494 Soi Nakonthai 11 (Ladproaw 101) Klongjun Bangkok, Thailand 10240 Tel. 02-377-5065 Fax 02-377-9719 e-mail: tnph@thaiplus.net

Organization (GPO) Board has approved a resolution to import two million tablets of the generic version of the drug since June 2007 and is in the process of taking delivery of the medicine. But Mr Chaiya's calling for a review on 6 February 2008 made Kalida, the generic drug maker commissioned to supply the medicine, inform the GPO of its decision to postpone delivery of the 2-million-tablet drug until the company has consulted with its legal advisors to assure that it will not be sued by the original-drug maker. Previously, Kalida had insisted that it would deliver the medicine on the scheduled date despite being threatened by a letter from the representative of Sanofi Pasteur (Thailand) Ltd., dated 16 January 2008 (see Attachment No.2).

Such delayed delivery caused at least a damage of about 248,378,550 million baht to Thailand within a period of one month. This estimated loss was based on the coronary heart disease incidence rate of approximately 350/100,000 at risk population. If only the 47-million patients under the Healthcare Security System were taken into account, 164,500 patients would be affected. Of these heart patients, 70% of them or 115,150 patients needed continuous medication of one tablet a day for at least one month. Thus, 3,454,500 tablets were needed and would cause a minimum loss of 248,378,550 to the government (calculation based on the prices of the original-drug and its generic version of 73 and 1.10 baht per tablet).

Therefore, it would not be plausible if the Minister of Public Health argued that he had not actually taken any action or sent any instruction to the GPO, or ordered the cancellation of the compulsory licensing on the heart disease drug. His interview with the press calling for a review of the government use compulsory licensing, an action which he had called gratifying but wrong, was as good as a verbal instruction that his subordinates would follow and implement. This was also consistent with an interview given by the president of the Pharmaceutical Researchers and Manufacturers of Thailand (see Attachment No. 3), despite the fact that the government use of CL is pursuant to Thailand's national laws and international rules.

This action, which has damaged the national budget, is deemed malpractice since it has prevented the importation of the generic drug and allowed Sanofi Pasteur (Thailand) Ltd to directly benefit from a monopoly on the production and sale of the drug in the country.

2. Intentional breach of constitutional and legal provisions: Evidently, patients, consumers and the public were clearly informed of Mr Chaiya's intention through his interview with the press on 6 February 2008 calling for a review of the government



เครือข่ายผู้ติดเชื้อเอชไอวี/เอดส์ ประเทศไทย
Thai Network of People Living with HIV/AIDS

๔๙๔ ซอยนครไทย ๑๑ ลาดพร้าว ๑๐๑ คลองจั่น กทม. ๑๐๒๔๐ โทรศัพท์ ๐๒-๓๗๗-๕๐๖๕ โทรสาร ๐๒-๓๗๗-๙๗๑๙ อีเมล: tnph@thaiplus.net
494 Soi Nakonthai 11 (Ladproaw 101) Klongjun Bangkok, Thailand 10240 Tel. 02-377-5065 Fax 02-377-9719 e-mail: tnph@thaiplus.net

policy on the use of CL on four patented drugs. That would be the implementation of administrative and political power before the government officially presented its policy to the Parliament on 18 February 2008. Moreover, his proposed policy would be in conflict with that of the government, which intended to provide equitable healthcare services to the people by using their ID cards. Again, this policy of the government will not work if the three existing healthcare schemes (Civil Servant Welfare Benefit, Social Security and Gold Card Schemes) still provide different benefits, particularly those related to medicines because of the high prices resulted from a monopoly on their production and sale.

3. Administrative and judicial malpractice and intentional breach of constitutional or legal provisions: He moved Dr Siriwat Thiptaradol from his post as the Food and Drug Administration secretary-general without being clearly charged with any misconduct, thus it was more like a punishment and the minister's lack of solid evidence made him change his reason for such decision on a daily basis when asked by the media. Though the minister argued that the transfer was suggested by the ministry's permanent secretary for the sake of the ministry's smooth, appropriate and more effective administration, his communication with the public on many occasions showed that the permanent secretary had been pressured to follow the minister's verbal instruction. And that could be deemed as judicial malpractice since Dr Siriwat Thiptaradol has been a good civil servant entrusted with an important role in the government use of compulsory licensing (see Attachment No. 4).

Moreover, Mr Chaiya's verbal instruction to have Dr Pongthep Wongwatcharapaiboon—president of the Rural Doctors Society—transferred was also witnessed by several persons and appeared in the press. Such action was an administrative interference and intentional removal of a practicing civil servant who was conscientiously performing his duties to prevent public damages (see Attachment No. 5).

4. Administrative malpractice: Since taking up the Public Health Minister's post, Mr Chaiya has never had any evident achievements in protecting the patients and consumers. On the contrary, his performance on several occasions has impeded the health system reform and public health promotion. Take for instance, calling for a review of the CL on four cancer drugs, as mentioned in the first accusation; giving interviews saying advertisement of alcoholic drinks in the general press would be permitted (see Attachment No.6); and stating that he would review the (Public Health



เครือข่ายผู้ติดเชื้อเอชไอวี/เอดส์ ประเทศไทย
Thai Network of People Living with HIV/AIDS

๔๙๔ ซอยนครไทย ๑๑ ลาดพร้าว ๑๐๑ คลองจั่น กทม. ๑๐๒๔๐ โทรศัพท์ ๐๒-๓๗๗-๕๐๖๕ โทรสาร ๐๒-๓๗๗-๙๗๑๙ อีเมล: tnph@thaiplus.net
494 Soi Nakonthai 11 (Ladproaw 101) Klongjun Bangkok, Thailand 10240 Tel. 02-377-5065 Fax 02-377-9719 e-mail: tnph@thaiplus.net

Ministry's) Notification No.18 on the designation or classification of public places where non-smokers' rights are protected, such as in food shops and air-conditioned business places.

According to the four abovementioned accusations leveled against him: administrative malpractice, intentional breach of constitutional and legal provisions, and judicial malpractice, Public Health Minister Chaiya Sasomsap is therefore no longer qualified to hold the post of public health minister and should be removed from the post by the Senate.

I and 15 of my colleagues, as the originators of the collection of eligible voters' name list, will be pleased to provide additional evidence if you and the members of the Senate, National Anti-Corruption Commission, or concerned agencies should need it.

Please be thus informed and proceed with the matter. We are extremely grateful for your support for the people's direct political participation.

Yours truly,

(Miss Saree Ongsomwang)

Representative of the original collectors of the name list of eligible voters

Coordinator: Siriporn Raweekool 081 716 6269

MOST URGENT

No Pho No 0703/



Ministry of Commerce
44/100 Nonthaburi Road
Amphoe Muang
Nonthaburi 11000

February 2009

Subject: US private sector's comments on Thailand's IPR protection status

Attachment: Summary of the US private sector's comments on Thailand's IPR protection status

To:

Facts

According to the Special 301 mechanism, created by the US Omnibus Trade and Competitiveness Act, the United States Trade Representative (USTR) is responsible for designating the US trading partners' status based on their protection of intellectual property rights (IPR) every year. In 2007 and 2008, Thailand was placed on the Special 301 Priority Watch List because of the gross violation of IPR.

As for the 2009 designation procedure, the USTR asked concerned parties to submit their comments on Thailand's IPR protection and enforcement. The submissions from the US private sector must be received by 17 February 2009 while those from the Thai government must be within 2 March 2009. Based on the said submissions, the USTR would announce its decision on Thailand's categorized status in late April 2009.

Submissions of the US private sector

On 17 February 2009, the USTR received the private sector's submissions on Thailand's IPR protection and enforcement, which were as follows:

1. In the opinion of the International Intellectual Property Alliance (IIPA)—an association of industries whose main concern is the copyright protection of cable TV, books, software and movies—the government led by the prime minister (Abhisit Vejjajiva) has taken earnest action to address the IPR violations and it hoped that this policy would be carried on.

Nevertheless, the IIPA recommended to USTR that Thailand should remain on the PWL because of the high losses of USD 312.8 million due to the copyright piracy and rampant violations of IPR in 2008. The association also added that one of the causes contributing to Thailand's less successful deterrence of the IPR violations had been the court's refusal to issue search/arrest warrants. It demanded that the government make an earnest effort to prosecute and punish offenders, as well as making

amendments to relevant laws, such as a law to ban illegal camcording at movie theatres.

2. The Pharmaceutical Research and Manufacturers of America (PhRMA), a trade group of the US pharmaceutical companies, requested that Thailand be designated as a Priority Foreign Country, citing Thailand's exercise of compulsory licenses, counterfeit pharmaceuticals problems, lack of data exclusivity and patent linkage system.
 3. The Cable & Satellite Broadcasting Association of Asia (CASBAA), a trade association dedicating to the promotion of multi-channel pay-television via cable and satellite networks, requested the USTR to keep Thailand on its PWL, as had done in 2008. It pointed out that the piracy of the cable TV contents has continued in Thailand, where concerned laws could not effectively deter the intellectual property infringements.
 4. The American Apparel & Footwear Association (AAFA), a trade association of clothes and footwear industries, reported that in obtained more cooperation from Thailand's concerned agencies in deterring the infringement in the past year. The AAFA, however, did not suggest that the USTR place Thailand on any of its designations list.
 5. Levi Strauss & Co. reported that Thailand's concerned agencies, especially the police and Customs Department, provided their active cooperation in suppressing the IPR violations. But still, pirate goods had been found to be on sale in several areas in Bangkok and the provinces. Nevertheless, the company as it had done in 2008 did not recommend any designation for Thailand.
- All details can be found in the attachment.

Actions taken by the Ministry of Commerce

1. After due consideration, the Ministry of Commerce deems that the following actions might be necessary to remove Thailand from the PWL.
 - 1.1 Taking adequate and effective actions against infringing activities at all levels and imposing concrete punitive measures;
 - 1.2 No additional use of compulsory licenses for the time being and accelerating the meeting of the Joint Public-Private Sectors Commission to send a signal that a public-private dialogue, whereby all concerned with ways to solve the problems of access to medicines are engaged, is available;
 - 1.3 Accelerating amendments to IPR laws, such as the Trade Marks, Copyrights and Patent Acts, as well as appointing the Broadcasting and Television Business Operation Commission to perform the duties, prescribed by the Broadcasting and Television Business Operation Act B.E.2551 (2008) to revoke or suspend the operating licenses granted to the operators of cable and satellite television stations broadcasting pirate contents;
2. The Ministry of Commerce is coordinating with concerned agencies to present Thailand's arguments against the US private sector's accusations by 2 March 2009 and will discuss ways to address the IPR infringement in Thailand with the US.

Please be thus informed. In case your agency has any useful information that will contribute to Thailand's arguments against the US private sector's accusations, including the information that the Deputy Minister of Commerce can use in the discussion with the US during the visit to be made during 9-17 March 2009, we will be grateful if you will let the Ministry of Commerce know in the first instance.

Yours sincerely,

(Mrs Phuangrat Aswaphisit)

Director General

Department of Intellectual Property

Committee member and secretary of the

Prevention and Suppression of Intellectual Property Infringement Policy Committee

Department of Intellectual Property

Tel: 0 2547 4653

Fax: 0 2547 4665

Summary of the US private sector's comments on Thailand's intellectual property protection in 2009

Agency	Comments	Recommended designation	
		2008	2009
1. PhRMA	<ul style="list-style-type: none"> - Lack of a clear policy on the use of CL; - Reports have it that the Ministry of Public Health would issue additional CL without prior consultation with the private sector; - No calling of the meeting of the Joint Public-Private Sectors Commission to solve the problems of access to medicines; - Widespread availability of counterfeit medicines exists without any further investigation to arrest counterfeiters; also the penalties for the offenders are not severe enough; - There is no patent linkage system; - No data exclusivity protection is permitted; - The DIP's delayed patent examination and Thailand's not joining the Patent Cooperation Treaty (PCT); - Government procurement regulations require government hospitals to buy medicines from the GPO, thus preventing private companies from competing; - The Safety Monitoring Program prevents the newly approved medicines from being distributed outside of the hospitals for a period of 2-4 years since their chemical entities have been registered and approved; - The new draft Drug Act requires pharmaceutical companies to reveal the information related to the medicine's patent status and research cost, which may be used inappropriately; and - The draft Product Liability Act will make pharmaceutical companies liable to the impacts resulted from the medicines being used in clinical trials. 	PFC	PFC
2. IIPA	<ul style="list-style-type: none"> - The government led by the prime minister (Abhisit Vejjajiva) has taken earnest action to address the IP violations and it was welcome news that the Deputy Minister of commerce (Mr Alongkorn Polbutra) gave the private sector a chance to meet him in January 2009; - It is hoped that the WIPO Global Leaders Award presented to HM the King will encourage the government to seriously take further action against the 	PWL+out-of-cycle review	PWL

	<p>intellectual property infringement;</p> <ul style="list-style-type: none"> - The losses of copyright piracy in 2008 was as high as USD 312.8 million and the piracy of business software was as high as 76%, compared with that of the Asian region, which was at 66%; and pirate product was still widespread; and - IIPA recommended that Thailand take stricter measures to provide IP protection, such as taking enforcement activity in the Red and Yellow Zone areas, removing the websites selling pirate product or providing free download of pirated works, cracking down on the piracy of book copyright and illegal camcording in movie theatres, addressing court's refusal to issue search/arrest warrants, revoking the and screen time quotas on Thai and foreign films, and accelerating the appointment of Broadcasting and Television Business Operation Commission (BTBOC) to set the licensing criteria for the cable and satellite television broadcasting business operations. 		
3. CASBAA	<ul style="list-style-type: none"> - Thailand's piracy of broadcast cable-TV contents is rampant, particularly by provincial operators with unauthorized licenses; - The Broadcasting and Television Business Operation Act B.E.2551 (2008), authorizing the BTBOC to revoke or suspend the operating licenses granted to the operators of cable and satellite television stations that have been ruled liable for broadcasting pirate contents, is practically ineffective as the BTBOC is yet to be appointed and it takes a long time before final court decisions will be made; and - Delayed prosecutions and the penalties are not severe enough to deter the offences. 	PWL	PWL
4. AAFA	<ul style="list-style-type: none"> - Reception of better cooperation from Thailand's agencies responsible for IP infringement suppression; and - DIP accepted an application for registering a trademark that looked like that of a member of the AAFA. 	No recommendation	No recommendation
5. Levi Strauss & Co.	<ul style="list-style-type: none"> - Reception of close cooperation from Thailand's agencies responsible for IP infringement suppression, especially the police and Customs Department; - Pirated goods had been found to be sold in several areas, for instance, Bangkok, Chiang Mai, Chiang Rai, Nakhon Sawan, Samut Sakhon, Nakhon Ratchsim, Phatthalung, Nakhon Pathon, Chon Buri, Nonthaburi, Samut Prakan 	No recommendation	No recommendation

	and Pathum Thani; and - DIP accepted an application for registering a trademark that looked like that of Levi's.		
--	---	--	--