February 19, 2008

Mr.Samak Sundaravej
Thai Prime Minister
Government House
Nakornpratom Rd.
Dusit, Bangkok
Thailand 10300

Mr.Chaiya Sasomsap
Minister of Public Health
Tiwanont Rd.
Talad Kwan District
Nontaburi Province 11000

Re: The Legality and Propriety of Thailand's Public Non-Commercial Use Licenses for AIDS, Heart-Disease, and Cancer Medicines

Dear Prime Minister Sundaravei and Minister Sasomsap:

We are a group of international legal experts who understand that the Government of Thailand is reviewing the legality and adverse trade impacts of seven compulsory licenses on AIDS, heart disease, and cancer medicines issued in Thailand since November 2006. We are writing to assure you that the licenses are fully lawful not only under Thai law but also under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS Agreement], and that it would be erroneous to use unsupportable allegations of illegality to revoke, suspend, or fail to implement the challenged licenses. Similarly, we believe that the full legality of the licenses greatly diminishes the likelihood of trade retaliation by the United States or the European Union. Although Thailand is gradually losing some of its advantages under the U.S.' Generalized System of Preferences (GSP) as it becomes more prosperous, this is an ordinary result of its growing economic prowess and is not directly related to Thailand's prior use of compulsory licenses.

THE THAI COMPULSORY LICENSES ARE FULLY LAWFUL UNDER INTERNATIONAL AND THAI LAW

Thailand's compulsory licenses on the AIDS medicines efavirenz and lopinavir/ritonavir, the blood thinner clopidogrel, and cancer medicines letrozole, docetaxel, and erlotinib, are lawful in every respect:

- they are fully compliant with Article 31(b) of the TRIPS Agreement, having been issued through proper procedures and on valid public health grounds;
- they have been issued for permissible, public non-commercial uses, and under both the TRIPS Agreement and the Thai Patent Act, such licenses require no advance negotiation with the patent holder (though Thailand did in fact negotiate unsuccessfully over an extended period of time);
- they set a proposed royalty of .5% to 5% of the sale price, which royalty is negotiable and appealable by the affected patent holder; and
- there are not so many licenses that Thailand can be accused of illegally discriminating against a field of technology.

(1) Under the WTO TRIPS Agreement, compulsory licenses can be granted on any grounds whatsoever, and Thailand is free to determine the grounds upon which licenses are granted.[1]

Article 31 of the TRIPS Agreement places no limitation upon a country's sovereign right to determine the grounds upon which licenses may be granted. Accordingly, compulsory licenses may be granted on any grounds whatsoever, including public health, with special, expedited provisions for emergencies or public non-commercial use, as well as for licenses issued to remedy anti-competitive practices. This freedom is reiterated in Paragraph 5b of the Doha Declaration on the TRIPS Agreement and Public Health (2001), which clearly and unequivocally states: "Each Member has the right to grant compulsory licences and *the freedom to determine the grounds upon which such licences are granted*." (Emphasis added.)

- **Compulsory licenses are not limited to emergencies only.**

The assertion that compulsory licenses are only available for "emergencies" is the most widely circulated and most common misunderstanding. Although there are special rules for emergencies that permit expedited procedures, the right to issue compulsory licenses in not limited to public health emergencies or other circumstances of extreme urgency.

- **Compulsory licenses are not limited to certain diseases.**

The assertion that compulsory licenses should be available for certain diseases only, primarily infectious diseases like HIV/AIDS or avian influenza, is another common misperception. The text of the TRIPS Agreement contains no limitation whatsoever on covered diseases. The E.U. and U.S. tried to create special disease categories in certain negotiations, but they were unsuccessful as developing countries, including Thailand, opposed pre-defining which category of patients would have access to affordable life-saving medicines and which ones would not.

- **Compulsory licenses are not limited to certain countries.**

There are no restrictions in Article 31 of the TRIPS Agreement or in the Doha Declaration on the Member States that can use compulsory licenses. There is no list of preferred countries and no prohibition on lower-middle-income countries such as Thailand issuing licenses. Although 45 countries bowed to U.S. pressure and temporarily relinquished their rights to import medicines pursuant to the Paragraph 6 Decision mechanism (now codified in Art. 31bis), even those countries retain their pre-existing right to issue compulsory licenses for domestic manufacture and/or to import non-predominant quantities from a producer country that has likewise issued an ordinary compulsory license. In this regard, the U.S. is the country that has granted the largest number of compulsory licenses and government use orders to remedy anti-competitive practices and to address government defined needs. In addition, recently several other countries, including Indonesia, Malaysia, Zimbabwe, Brazil, have granted compulsory licenses on patented medicines.

- **Thailand has valid public health grounds for each of the licenses issued.**

Although Thailand does not have an HIV/AIDS crisis on the scale of sub-Saharan Africa, HIV is still a major issue in Thailand and fully warrants the issuance of a compulsory license. Over 560,000 people in Thailand are infected with HIV, and AIDS has become a leading cause of death. Likewise, there is a growing crisis of chronic diseases in Thailand, including heart disease, diabetes, hypertension, and cancer. Thailand is wholly justified under international law to grant a license for accessing an important blood thinner such as clopidogrel that costs approximately seventy times more as a brand-name product (Plavix) than as a generic. Similarly, Thailand is justified in issuing compulsory licenses for medicines for cancer, the leading cause of death in Thailand. However, the main point is that Thailand is completely justified in deciding which public health needs it intends to address through compulsory licenses.

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[1] *See* WTO, *Frequently Asked Questions Compulsory Licensing of Pharmaceuticals and TRIPS*, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm.

(2) Under the WTO TRIPS Agreement, Thailand has issued a license for a permissible public non-commercial use.

Article 31 of the TRIPS Agreement specifically addresses licenses for public non-commercial use. The phrase "public non-commercial use" is not expressly defined in the TRIPS Agreement, but both its plain meaning and long-established government practice support the interpretation that government purchase of licensed medicines for the purpose of distribution within the public sector health system and to the beneficiaries of social insurance programs or to government employees is well within the ambit of this provision.

There is nothing in the text of Article 31 suggesting that public or government use of patented inventions is limited to only specific categories of subject-matter.. To the contrary, the U.K. Patent Act, for example, states specifically in section 56.2 that service of the Crown – otherwise known as government use or public non-commercial use – includes "the production or supply of specified drugs and medicines." A use is not rendered "commercial" simply because there is for-profit manufacture and sale, whether by a government-owned pharmaceutical company or more commonly by a private company. The "public non-commercial use" category regulates the "use," not the commercial nature of the economic activity by the licensee. Thus, it does not matter whether that licensee is a for-profit generic manufacturer such as Cipla in India, a major multinational originator company such as Pfizer, or a government-owned lab such as Thailand's Government Pharmaceutical Organization (GPO).

Instead, what is important is the "use" of the licensed product or process, namely that it be for a "public" purpose and that its use by the government be "non-commercial", meaning that the government itself is not engaging in a for-profit enterprise. Thus, in Thailand, even though a commercial transaction takes place pursuant to the Thai compulsory licenses – namely the manufacture, sale, importation, and distribution of a medicine – the actual purchaser of the medicines is the Royal Government of Thailand which is thereby fulfilling its mandate to directly provide medicine to the vast majority of Thai citizens through its public sector social insurance and public employee benefit program. Thailand will pay for and procures medicines pursuant to its compulsory licenses in order to supply medicines to Thai beneficiaries under three different government-sponsored insurance programs (the National Health Security System Act, the Social Security Act, and the Civil Servants and Government Employee Medical Benefit scheme). These public programs entitle 62 million Thais to access to some 900 different medicines, including antiretrovirals to treat HIV/AIDS. Ninety-eight percent of Thais are covered by these three government-sponsored insurance schemes, and 80% of Thais actually access their medical treatment and medicines through these public programs.

- **Thailand was not obligated to engage in prior negotiations with the patent holders, either for price reductions or for voluntary licenses.**

Article 31 of the TRIPS Agreement ordinarily requires that "the proposed user has made *efforts to obtain authorization* from the right holder on *reasonable commercial terms* and conditions and that such efforts have not been successful within a *reasonable period of time*." However, under this same provision, the requirement of prior negotiation "may be waived by a Member in the case of a national emergency or other circumstance of extreme urgency or in cases of *public non-commercial use*." In these cases, the only obligation is notice to the patentee: "In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable ground to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly."[2]

- **Despite not being required to do so, the Thai government did negotiate with patent holders.**

[2] Not only does the TRIPS Agreement expressly allow Thailand to bypass prior negotiations with patent holders, Section 51 of the Thai Patent Act permits any ministry, bureau or department of the Government to issue a license for "public consumption" of generic medicines without prior negotiations, subject only to an obligation to a set a royalty rate which is thereafter reviewable by the patent owner. Comparable U.S. law permits the same kind of no-prior-negotiation government use by the federal government and its contractors: 28 U.S.C. § 1498(a) and U.S. Executive Order 12899 § 6.

Despite not being required to, the Thai government tried to negotiate price discounts with ARV patent holders between 2004 and 2006. The record shows that Thailand has engaged in protracted price negotiations with the drug industry for at least two years.

History of Thai Price Negotiations with Abbott and Merck

Price negotiations	Results
16 Nov. 2004, formal letters	• No price reductions
10 Aug. 2005, face-to-face negotiations	• Abbott reduced the price of LPN/r from US$6000 to US$4000/pppy • Merck no price reductions
28 Dec. 2005, face-to-face negotiations	• Abbott reduced the price of LPN/r from US$4000 to US$3000/pppy
Mid 2006	• Abbott reduced the price of LPN/r from US$3000 to US$2200/pppy • Merck reduced the price of efavirenz from US$300 to US$250/pppy
Late 2006	• Abbott claims to have offered LPN/r for $1700/pppy (Brazil had negotiated a price in this range from Abbott in 2005)

Similarly, the Thai government has engaged in extensive negotiations over several months with the patent-holders of the cancer medicines newly subject to a compulsory license. In fact, it reached agreement with one patent holder, Novartis, resulting in revocation of an immediate government use license on Glivec.

(3) Thailand has offered adequate remuneration and remains open to negotiation or appeals of royalty rates.

Under Article 31 of the TRIPS Agreement, when compulsory licenses are granted, patent holders are entitled to individualized determinations and adequate remuneration taking into account the economic value of the authorization; they are also entitled to certain rights of review. Thailand initially set its royalty rate at .5% to 5% and has repeatedly stated that it is willing to negotiate those rates and in fact has engaged in direct royalty rate discussions with the patent holders. In addition, the patent holders have rights of appeal pursuant to Section 50 of the Thai Patent Act so long as they do so within sixty days. None of the patent holders have in fact appealed the royalty rate that was set.

(4) Thailand has not issued so many pharmaceutical licenses that it is discriminating against a field of technology or otherwise abusing its right to issue compulsory licenses

Thailand has issued only six compulsory licenses, each according to a very strict set of criteria set forth in its White Paper.[3] Although Article 27.1 of the TRIPS Agreement does prohibit absolute discrimination against a field of technology, such as wholesale or automatic licenses for a whole field of technology, it does allow differentiation and different rates of compulsory license utilization between fields of technology. There are, of course, over two hundred patented medicines in Thailand, and the Department of Public Health has been extremely selective in choosing licenses that address life-threatening diseases. Worldwide, there are significant variations in country practices with respect to compulsory licenses. For example, in the U.S., the government has special compulsory license rules for technologies in the fields of aerospace, atomic energy, pollution controls, and for insecticides, fungicides, and rodenticides; and it has

[3] The Ministry of Public Health and the National Health Security Office, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of patents on Three Essential Drugs in Thailand* (Feb. 2007) , http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf.

has taken a government use license on Blackberries for use by government officials and contractors. Although Thailand should continue to take care in selecting medicines upon which compulsory licenses will be granted, it is not even close to running afoul of the prohibition against discrimination and continues to have discretion to issue compulsory licenses on many other essential and life-saving drugs.

THAILAND IS NOT SUBJECT TO PLACEMENT ON THE U.S. SPECIAL 301 WATCH LIST AS A PRIORITY FOREIGN COUNTRY, NOR IS IT LIKELY TO BE SUBJECTED TO TRADE RETALIATION AND REDUCTION OF GSP PRIVILEGES BECAUSE OF ITS LAWFULLY ISSUED COMPULSORY LICENSES

Although there is no legitimate concern that the Thai compulsory licenses are unlawful in any respect, some officials in the new government are on record expressing concern about the impact of compulsory licenses on Thailand's exports and the risk of retaliation from its biggest trading partners including the U.S. and E.U. These concerns arise because the biotech and pharmaceutical industries in the United States are reported to be requesting that Thailand be designated a "Priority Foreign Country" by the U.S. Government in its 2008 Special 301 Watch List and because Thailand did lose some no-tariff trade preferences under the U.S. GSP system last year on polyethylene pellets; large flat-panel, color TVs with VCRs; and gold jewelry.

Placement on the 301 Watch List as a Priority Foreign Country is reserved only for "the most onerous and egregious acts, policies, and practices which have the greatest adverse impact (actual or potential) on the relevant U.S. products."[4] Since Thailand's licenses are fully lawful, since it in fact negotiated transparently and with due process with the affected pharmaceutical patent holders, and since the U.S. has never claimed that Thailand's compulsory licenses were egregious or illegal,[5] it is virtually inconceivable the U.S. would designate Thailand as a Priority Foreign Country or that it would reduce GSP privileges because of Thailand's handful of licenses. It is equally clear that the removal of some GSP preferences last year was part of the normal process of reducing privileges for growing and competitive economies such as Thailand's.

This analysis that the risk of retaliation is minimal is strengthened by the emergence of a New Trade Policy in the U.S. Congress that is more supportive of measures to improve access to medicines,[6] by pending resolutions in both the Senate and the House of Representatives calling on the U.S. to respect the 2001 Doha Declaration and to refrain from using the Special 301 Watch List to punish countries for using TRIPS-compliant flexibilities,[7] and by a shared sentiment by U.S. presidential candidates and the public at large about over-reaching by the U.S. pharmaceutical industry.

IN CONCLUSION, THE THAI COMPULSORY LICENSES ARE LEGAL IN ALL RESPECTS AND THAILAND FACES NO CREDIBLE THREAT OF TRADE RETALIATION FOR HAVING ISSUED LAWFUL LICENSES.

The new Government of Thailand is of course free to reassess the policies of the prior government, but it should not do so based on a legally incorrect analysis of the legality of the previously issued licenses nor based on an inaccurate assessment of the risk of punishing trade sanctions by its largest trading partners. In the past, the Thai government, including predecessors of the current government, has made wise decisions to provide low-cost, and subsequently free, medicines to the Thai people. The government has increasingly recognized the importance of promoting and preserving health and of ensuring a present and future supply of affordable life-saving and life-enhancing medicines. Patent holders would like to have

[4] 19 U.S.C. § 2242(b).
[5] "We have not suggested that Thailand has failed to comply with particular national or international rules." USTR Schwab's letter to Members of Congress, January 17, 2007.
[6] Congress and Administration Announce New Trade Policy, U.S. House of Representatives Way & Means Committee (news release), May 11, 2007, available at: <http://waysandmeans.house.gov/news.asp>. Pursuant to the New Trade Policy, data-exclusivity, patent-registration linkage, and patent-term-extension provisions in U.S. trade agreements with Peru, Panama, and Columbia have been liberalized or eliminated, and the text of the Agreements now expressly references countries' rights to use TRIPS and Doha Declaration flexibilities to prioritize public health and access to medicine for all.
[7] House Resolution 525 and Senate Resolution 241 that expressly state that the U.S. "should ... not place countries on the Special 3021 Priority Watch List under section 182 of the Trade Act of 1974 for exercising the flexibilities on public health provided for in the TRIPS Agreement, such as issuing compulsory licenses to obtain access to generic medicines in accordance with the Doha Declaration."

holders would like to have complete freedom to charge whatever they like, but their desire for unrestricted profits is at variance with the government's interest in spending money wisely, in building a more competitive market for medicines, and in promoting pharmaceutical capacity in Thailand.

Taking all of these factors into account, we respectfully submit that not only should Thailand maintain its existing compulsory licenses, but it should implement them as well. Likewise, it should preserve its sovereign right to issue such licenses in the future and it should maintain a credible threat of licenses when it negotiates prices with drug companies. Above all, it should continue to prioritize public health and access to medicine for all.

Very truly yours,

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