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February 15, 2010

Dear USTR Commission,

Re: Comments of Thai Civil Society Organizations upon the USTR annual Special 301 Report

We are pleased to know that the USTR has set up an unprecedented process, requesting comments from the public and arranging public hearing. We hope that it will be a process to counterbalance the comments of the private sector, particularly the multinational pharmaceutical industry, in order that the USTR will take the aspect on right to health, rather than trade and economy, into account.

As a result of the constant trade-sanction threats that the USTR has been using to pressurize Thailand since 1985 through the unilateral-measure Special 301 Report and GSP, the Thai governments always compromised as they had a vain hope that our country would gain the economic wealth from the export market in the United States in return and such wealth would be distributed to all Thais, through employment and investment, and it would help improve basic social services. However, our governments were blinded to the harmful impacts and agreed to trade away the public health of Thai people for the economic benefits that went to a limited group of people only.

In Thailand, most of the essential medicines are patented and their prices are very expensive, comparing to the international prices.[1] While the public health of the country was at risk of the inaccessibility, it left no choice to Thailand, but to exercise its legitimate and legal rights to use the TRIPS public health safeguard, known as compulsory licensing, to address the public health threat due to the lack of affordable essential medicines. Similar to the United States, Thailand complied with the national and international legal frameworks in translating the compulsory licensing policy into practice. On the contrary, Thailand was heavily opposed by the U.S. government and harshly retaliated by the U.S. pharmaceutical industry. An U.S.-based drug company decided to withdraw the registrations of their new drugs in Thailand, and the USTR announced to downgrade Thailand to the PWL in 2007 and 2008.

> ***"While the United States** acknowledges a country's ability to issue such licenses* **(compulsory licenses)** *in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern.",* **USTR 2007 Special 301 Report.**
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> ***"The U.S. government strongly urges Thailand's authorities to take concrete actions to strengthen its IPR regime that include** continuous and sustained enforcement actions that get to the source of the infringing activity and issuance of deterrent penalties to IPR infringers, specific steps to improve inter-agency coordination.....**While the United States recognizes the importance of Thailand's public health challenges,** Thailand's recent policies and actions regarding the compulsory licensing of patented medicines have contributed to continuing concerns **regarding the adequate and effective protection of IPR in Thailand.",* **USTR 2008 Special 301 Report.**

In the 2007 and 2008 Special 301 Reports, Thailand has been categorized a PWL country by being accused of its compulsory licensing action, in addition to the inadequate and ineffective copyright and trademark

1 Cha-oncin Sooksriwong *et al* (2007), "Medicine Pricing, Availability, and Affordability in Thailand"

protection and the delay in the granting of patents. With such accusation, it reflected that the USTR did not take other aspects, particularly humanity and public health needs, into account and also turned its back on the international agreements (e.g. TRIPS Agreement and Doha Declaration on TRIPS Agreement and Public Health). The USTR is merely protecting economic benefits of the powerful multinational pharmaceutical industry who are a vital supporter of the U.S. political system, and the U.S. government is practicing a double-standard on the use of the TRIPS public health safeguards.

By compulsory licensing policy, Thailand can temporarily override drug patents registered in Thailand, with a requirement of paying royalty fees in return, and produce or import generic versions of the medicines to address public health concerns. It requires no negotiation with patent holders in advance. This is a legal mechanism in compliance with both the national patent law and the WTO TRIPS Agreement.

Due to the compulsory licenses, a great number of Thai patients can access to essential medicines for free through the national health insurance system and regain their life quality. As of March 2009, about 50,000 people living with HIV could take the generic AIDS-drug efavirenz, a threefold increase in the number of people living with HIV accessible to efavirenz. Over 3,000 could access to the generic lopinavir/ritonavir, three times greater than the number of the patients accessing to the patented medicines[2].

The U.S. requests of intellectual property rights for medicines, both in the Special 301 Reports and the suspended U.S.-Thai Free Trade Agreement (FTA) – which the Thai government is considering to re-open the negotiation, includes provisions excessive than Thailand's obligations under TRIPS, for example, restrictions on the grounds for compulsory licensing, limits to challenging potentially invalid patents, extension of patent terms, data exclusitivity, and linkage between marketing approval and patent status. Recently there is a potential that the additional provisions of border measure and IP enforcement to seize goods in transit and increase prosecution against IP violation will be included in the trade agreement negotiation or the action plan in response to the Special 301 Reports. The inclusion of these so-called "TRIPS-plus" rules into the requests with regard to the Special 301 Reports and the FTA could seriously hamper Thailand's HIV & AIDS programs and access to other essential medicines, thus depriving thousands of people of effective treatment.

It is considered an improvement sign that the USTR is slightly shifting their stance to listen to the comments from the pubic sector, particularly in developing countries. However, a concern remains if the USTR does not take the given comments into account seriously and continue overprotecting the U.S. multinational pharmaceutical corporations' benefits, without recognizing public health needs of the patients in the developing world and respecting the TRIPS Agreement and the Doha Declaration. If so, the comments and the public hearing are a waste of time and do not make any difference.

We also urge the USTR under the Obama Administration to stop pressurizing Thailand and other developing countries, by using the Special 301 Report or other trade sanction measures, for changes in policies in those countries that are excessive than TRIPS Agreement's obligations. The trade negotiations, including bilateral/regional trade agreements, should be transparent at all processes. The USTR should open up the plan of actions agreed between the Thai Ministry of Commerce and the USTR, with regard to the Special 301 Report, to the public. The U.S. government should also demonstrate their sincerity in making a balance between IPR protection and R&D promotion by actively urging the U.S. pharmaceutical industry to provide technology transfer to the developing countries in a sustainable and meaningful way.

Sincerely yours,

Nimit tienudom

Mr. Nimit Tienudom
Director
AIDS Access Foundation

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[2] National Health Security Office (Sub-committee for Benefits and Services Development)

On behalf of the following civil society organizations in Thailand

Thai Network of People Living with HIV/AIDS
Alternative Agriculture Network
Friends of Kidney-failure Patients Club
Cancer Patient Network
Foundation for Consumers
The Rural Pharmacist Foundation
Foundation for AIDS Rights
Thai NGO Coalition on AIDS
Drug Study Group
Thai Health Foundation
FTA Watch