

Congress of the United States

Washington, DC 20515

June 20, 2007

Ambassador Susan C. Schwab
United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Dear Ambassador Schwab:

As you are aware, Thailand recently issued compulsory licenses to purchase generic versions of several medications that were too costly for the government to purchase for its citizens. In doing so, it was acting within its international rights and obligations under the Agreement on Trade-Related Aspects of Intellectual Property, as specifically affirmed by the United States and other nations in the Doha Declaration.

In fact, your office specifically refrained from suggesting otherwise, despite complaints from pharmaceutical patentholders. Yet Thailand was added to the "Priority Watch List" in the annual USTR Special 301 trade report, which cited "a weakening of respect for patents" in Thailand, and a "lack of transparency and due process" in the issuance of the compulsory licenses.¹

It is difficult to interpret this decision as anything other than retaliation for Thailand's recent actions. It sends a troubling message, not only to Thailand but to the whole world, that the exercise of recognized public health flexibilities in trade obligations is frowned upon by the United States.

This response runs counter to the United States' obligation to respect the rights of all nations to implement their intellectual property rules in a way that is supportive of public health. We urge you to adhere to this principle and reassess U.S. policy toward Thailand to reflect this commitment.

Our concerns are detailed below.

Thailand's Actions

Thailand has a model program for HIV/AIDS treatment. Since 2003, the national health program, which covers all Thai citizens including nearly 600,000 living with HIV/AIDS, has provided broad access to anti-retroviral (ARV) drugs.² But an increasing number of patients have become resistant to first-line ARV therapies or experience serious side effects, and the newer ARV drugs that they must switch to generally cost much more.

¹ *USTR Special 301 Report 2007* (Apr. 30, 2007) 27.

² Bureau of AIDS, TB, and STI, Department of Disease Control, Thailand Ministry of Public Health, www.aidsthai.org.

To cope with the high prices and growing need, Thailand recently moved to safeguard the sustainable growth of its treatment efforts by issuing compulsory licenses for the ARVs efavirenz and lopinavir/r. It also issued a compulsory license for clopidogrel, a heart medication.³

The use of compulsory licenses, with “adequate remuneration” paid to the patentholder, is permitted by the WTO Agreement on Trade-Related Aspects of Intellectual Property, or TRIPS.⁴ While in certain cases a country must first make reasonable efforts to negotiate with the patentholder, no prior consultation is required in cases of extreme urgency or public non-commercial use.⁵

Each of the compulsory licenses issued only applies to non-commercial government use; those who buy the drugs in the private market must still purchase the patentholder’s branded versions.⁶ Thus, Thailand was under no obligation to consult with the patent holders. However, Thailand did in fact make concerted efforts to negotiate lower prices for these and other medicines during 2005 and 2006, even establishing an interagency working group to have informal and formal discussions with pharmaceutical companies.⁷

In some instances these negotiations resulted in a company offering an acceptable price for a patented drug. For example, we understand that Gilead Sciences wrote to your office about its positive experience dealing with Thai authorities on its proposal to offer \$1 per day pricing for the HIV/AIDS drug Viread (tenofovir).⁸

³ Text of the compulsory license decrees are available in English online at <http://www.cptech.org/ip/health/c/thailand/>.

⁴ World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) (TRIPS) Article 31(b).

⁵ *Id.*

⁶ The Ministry of Public Health And The National Health Security Office of Thailand, *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Drugs in Thailand* (Feb. 2007) 3.

⁷ *Id.* pp. 5-6.

⁸ Letter from Gilead Sciences Senior Vice President and General Counsel Gregg H. Alton to USTR Susan Schwab, March 16, 2007.

Abbott Laboratories had priced Kaletra, the patented version of lopinavir/r, at \$2200 per patient annually.⁹ Because Abbott would not offer a price affordable for the government's AIDS treatment program and the country was approaching a stock-out of the drug, Thailand decided to issue a compulsory license that would permit it to purchase generic versions of the drug. Compulsory licenses not only offer access to more affordable generics but also can impact patentholder's pricing. For example, faced with the prospect of generic competition, Abbott lowered the price of Kaletra to \$1000 for Thailand and 40 other low-income and lower-middle income countries.¹⁰

Thai AIDS patients now stand to benefit further from the recently-announced discounts that the Clinton Foundation has negotiated for generic versions of both lopinavir/r and efavirenz.¹¹ It is important to note that without the compulsory licenses, Thailand would not have been able to join other low- and middle-income countries in using this important opportunity to maintain and expand its AIDS treatment campaign.

The U.S. Response

The Thai government's action is consistent with its obligations under the World Trade Organization (WTO) agreement on Trade Related Aspects of Intellectual Property (TRIPS). In response to a letter from Congress, your office specifically noted that the United States had "not suggested that Thailand has failed to comply with particular national or international rules."¹²

That statement was consistent with the Doha Declaration, in which the United States and 142 other countries specifically committed to respecting countries' rights to issue compulsory licenses on medicines. The Doha Declaration expressly affirms this flexibility under TRIPS, and states that "Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."¹³

⁹ *Abbott Statement Regarding New Initiatives to Expand Access and Affordability to lopinavir/ritonavir in the Developing World* (Aug. 13, 2006) (online at http://abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0341.htm).

¹⁰ Reuters, *Abbott makes AIDS drug offer to Thailand* (Apr. 23, 2007)

¹¹ Clinton Foundation, *Clinton Foundation and UNITAID Announce Price Reductions on 16 AIDS Medicines for 66 Developing Countries* (May 8, 2007) (online at <http://www.clintonfoundation.org/050807-nr-cf-hs-ai-pr-clinton-foundation-and-unitaid-announce-price-reductions-on-16-aids-medicines-for-66-developing-countries.htm>).

¹² Letter from USTR Susan Schwab to Representative Henry A. Waxman and 21 members of Congress (Jan. 17, 2007) (online at <http://www.house.gov/waxman/pdfs/thai%20ustr%20response.pdf>).

¹³ Paragraph 5, 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference — Fourth Session, WT/MIN(01)/DEC/2, adopted 14 November 2001. ("Doha Declaration"). The Doha Declaration also affirms that each country "has the right to

Yet now, the United States appears to have acted on the complaints of Abbott and others. In the Special 301 Report, which outlines the United States' concerns about other nations' violations of intellectual property standards, you elevated Thailand to the "Priority Watch List":

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 of 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. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval.¹⁴

Considering that Thailand has not been on the Priority Watch List since 1992, the move is being viewed in the public health community as a warning and a threat to other countries that might consider similar action.

Our concerns about the U.S. response to Thailand are compounded by the possibility that Thailand's presence on the Priority Watch List could result in the elimination of duty-free access Thailand receives under the Generalized System of Preferences (GSP) for gold jewelry and other exports to the United States. One of the criteria for eligibility under the GSP program is that the recipient country provides adequate and effective intellectual property protection.

Conclusion

USTR's treatment of Thailand in the Special 301 calls into question the United States' commitment to the Doha Declaration. In addition to specifically affirming countries' right to issue compulsory licenses and to determine the grounds upon which they are granted, the Declaration states that intellectual property obligations should be "interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicine for all."¹⁵ Yet the U.S. treatment of Thailand in the Special 301 report, and the prospect of retaliatory changes to Thailand's GSP status, would appear to penalize the legitimate exercise of these rights.

determine what constitutes a national emergency or other circumstances of extreme urgency." However, this determination is only relevant to compulsory issues that are issued without prior consultation because of such an emergent or urgent situation (see text accompanying note 7, *supra*). For public non-commercial use, or for situations in which reasonable prior consultation has occurred, these narrow grounds do not apply.


¹⁴ *Supra* note 1.


¹⁵ Doha Declaration, Paragraph 4.

We call on you to take steps to remove Thailand from the Special 301 Priority Watch List and to abandon any further retaliation for Thailand's public health efforts. We also ask you to commit to respecting the rights of WTO members to freely exercise public health flexibilities under TRIPS and the Doha Declaration, including compulsory licensing.

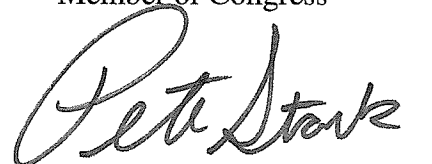
We request a response by July 9, 2007.


Sincerely,

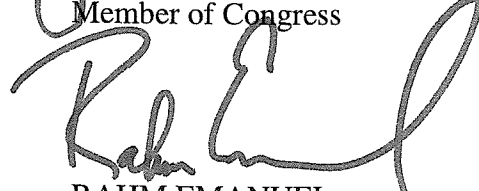

HENRY A. WAXMAN
Member of Congress

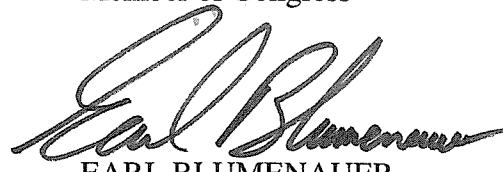

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Member of Congress

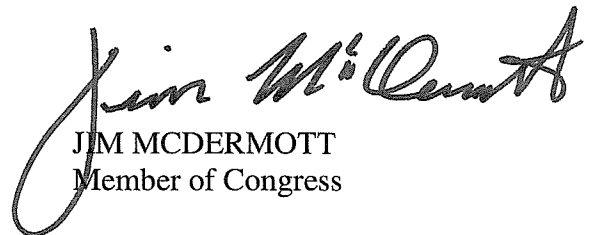

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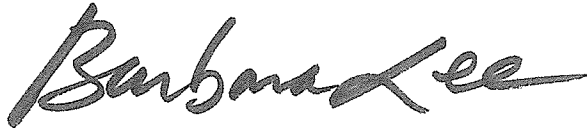

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JAMES P. MORAN
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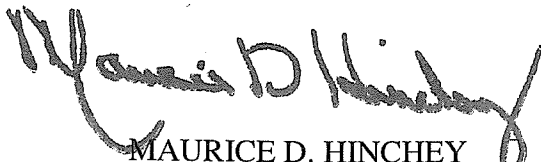

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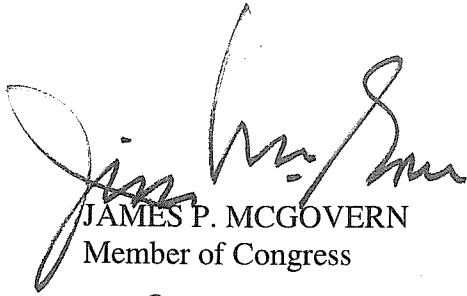

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RAÚL M. GRIJALVA
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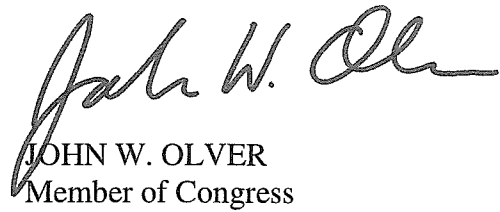

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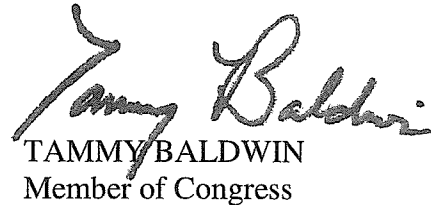
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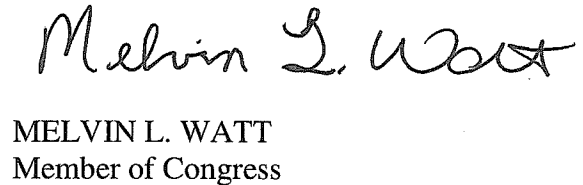
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TAMMY BALDWIN
Member of Congress



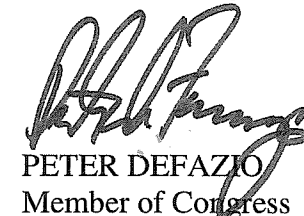
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Member of Congress



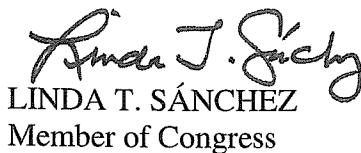
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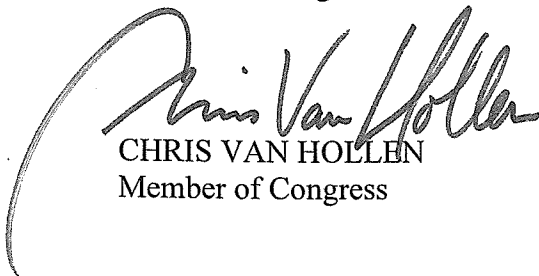
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