Consumer Project on Technology

1621 Connecticut Avenue, NW, Suite 500, Washington, DC 20009

December 12, 2006

Ambassador Susan C. Schwab
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508
United States of America

Dear Ambassador Schwab:

We ask that the United States government not interfere with the Thai government decision to issue a government-use license on patents covering the AIDS drug efavirenz.

There is a concern that the USTR may have suggested to the Thai government that the WTO TRIPS agreement requires prior negotiations with patent owners before a compulsory license is issued. If so, the assertion was wrong. Article 31 of the TRIPS does not require prior negotiation before authorizing non-voluntary use of a patent, in *any* of the following cases:

(1) a national emergency or other circumstances of extreme urgency,
(2) cases of public non-commercial use, or
(3) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

In this particular case, the non-voluntary use was for a government owned entity that will provide medicines for a national program to treat AIDS. Under the WTO rules, there is no obligation for prior negotiation with patent owners in such cases.

There is also no requirement for prior negotiation with patent owners under the various US bilateral (and regional) trade agreements the United States has recently negotiated. The reason for this is obvious. In the TRIPS and the bilateral or regional trade agreements, these sections on prior negotiation were written to accommodate US law and practice. Our own government is not required to negotiate with patent owners or copyright owners before authorizing use by or for the government.

The main United States statute regarding use of a patent in such circumstances is 28 USC 1498. There is no obligation for prior negotiation or prior notice with the patent owner under 28 USC 1498, when a non-voluntary authorization is for the government.[1] This includes uses by third parties:

[1] TRIPS Article 31.b states "In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly." There is a similar

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

As trade officials charged with promoting US norms for intellectual property protection, it is useful to review what those norms actually are. The United State has a number of mechanisms to issue compulsory licenses on patents. These include, in addition to 28 USC 1498, the following:

- Mandatory patent licenses under Section 308 of the Clean Air Act (see: http://www.epa.gov/docs/fedrgstr/EPA-AIR/1994/December/Day-30/pr-251.html). *This statute is unfortunately not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).*

- Compulsory licenses for patents "affected with the public interest" that are of primary importance in the production or utilization of special nuclear material or atomic energy, for non-military purposes (See 42 USC 2183). *This statute is unfortunately not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).*

- The Bayh-Dole Act march-in rights for patents on inventions conceived with federal funding,

- Remedies to anticompetitive practices.

- Compulsory licenses issued under the procedures set out by the US Supreme Court in the recent eBay decision. *This approach is arguably not consistent with the provisions of the US FTA agreements negotiated with Jordan (2000), Singapore (2003), and Australia (2004).*

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provision in NAFTA. NAFTA Article 1709(10)(b) also requires that patent owners be notified "promptly," but *not* before a compulsory license is issued. See also: Executive Order 12889, Implementation Of The North American Free Trade Agreement, December 28, 1993:
Sec. 6. Government Use of Patented Technology. (a) Each agency shall, within 30 days from the date this order is issued, modify or adopt procedures to ensure compliance with Article 1709(10) of the NAFTA regarding notice when patented technology is used by or for the Federal Government without a license from the owner, except that the requirement of Article 1709(10)(b) regarding reasonable efforts to obtain advance authorization from the patent owner:
(1) is hereby waived for an invention used or manufactured by or for the Federal Government, except that the patent owner must be notified whenever the agency or its contractor, without making a patent search, knows or has demonstrable reasonable grounds to know that an invention described in and covered by a valid United States patent is or will be used or manufactured without a license; and
(2) is waived whenever a national emergency or other circumstances of extreme urgency exists, except that the patent owner must be notified as soon as it is reasonably practicable to do so.

The following are a just few recent examples of the use of compulsory licenses by the United States:

- In 2001, DHHS Secretary Tommy Thompson used the threat to use 28 USC 1498 to authorize imports of generic ciprofloxacin, for stockpiles against a possible anthrax attack.

- In 2001, the Department of Health and Human Services used its authority to exercise March-In rights for patents on stem cell lines held by the Wisconsin Alumni Foundation as leverage to secure an open license on those patents.[2]

- In 2002, the US FTC ordered a compulsory cross-license of the Immunex tumor necrosis factor ("TNF") patent, to Serono, including the "freedom to practice in the research, development, manufacture, use, import, export, distribution and sale of TNFbp-I Products and certain glycosylated and nonglycosylated fragments, derivatives and analogs thereof in the United States."

- In 2002, the US Department of Justice required Microsoft to license on reasonable and non-discriminatory terms intellectual property rights in a number of different protocols needed to create products that were interoperable with Microsoft Windows.[3]

- In 2005, the FTC ordered a compulsory license of Guidant's intellectual property surrounding the RX delivery system for Drug-Eluting Stents.

- In 2005, the US Department of Justice cited its right to use patents in 28 USC 1498 when it opposed injunctive relief for infringement of the patents relating to the Blackberry email services supplied to both the government and private firms that used the Blackberry device to communicate with the government.[4]

- In a November 2005 Congressional hearing, DHHS Secretary Michael Levitt testified before the House of Representatives that he had threatened to override the patents on treatments for Avian Flu if companies had not expanded US production facilities.[5] More recently, the Centers for Disease Control threatened to use US Bayh-Dole "march-in" rights to issue compulsory licenses on patents on reverse genetics, which are needed to manufacture vaccines for avian flu.

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[2] September 5, 2001, "National Institutes of Health and WiCell Research Institute, Inc., Sign Stem Cell Research Agreement," http://www.nih.gov/news/pr/sep2001/od-05.htm.

[3] United States Of America, Plaintiff V. Microsoft Corporation, Defendant. Civil Action No. 98-1232 (CKK), FINAL JUDGMENT, (November 12, 2002). For a detailed account of work to implement the order, see: INTERIM JOINT STATUS REPORT ON MICROSOFT'S COMPLIANCE WITH THE FINAL JUDGMENTS, http://www.usdoj.gov/atr/cases/f201300/201386.htm

[4] The United States' Statement Of Interest, November 2005., NTP, INC., Plaintiffs, V. RESEARCH IN MOTION, LTD., Defendant., Civil Action No. 3:01CV767.

[5] See video excerpts from November 8, 2005 Hearings of the Subcommittee on Health of the House Committee on Energy and Commerce, http://www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html

- In June 2006, a court granted Microsoft a compulsory license to use two patents owned by z4 Technologies that relate to digital rights management systems used by Microsoft for its Windows and MS Office software programs.[6]

- In July 2006, a court granted DirectTV a compulsory license to use the Finisar patent on integrated receiver decoders (satellite set top boxes), for a royalty of $1.60 per device.[7]

- In August 2006, a court granted Toyota a compulsory license on three Paice patents for hybrid transmissions, for a royalty of $25 per automobile.[8]

- In September 2006, a court granted Johnson and Johnson a compulsory license to use three of Jan Voda's patents on guiding-catheters for performing angioplasty.[9]

The point of this history lesson is to emphasize a point that some USTR officials seem to overlook. The flexibilities in the TRIPS agreement are there for good reasons. As evidenced by the many cases described above, there are many situations where *any* country will want to limit or create exceptions to the exclusive rights of a patent.

In the case of efavirenz patents, Thailand is clearly seeking to create a policy that will strengthen competition among generic suppliers, and enhance it's own capacity to manufacture AIDS medicines. The benefits of this policy will be more pronounced over time, as competition, economies of scale and learning by doing lead to more efficient production by generic producers.

Looking more closely at Thailand, one can see why this is so important. The United States has a much higher national income than Thailand, but a much lower rate of HIV infection. When compared to Thailand, the US has thirty-five times the income per HIV patient.[10]

	United States	Thailand
Population (2005)	297 million	64 Million
GNI (2005)	13 trillion	177 billion
GNI per capita (2005)	$ 43,740	$ 2,750
HIV+ population	1,200,000	580,000
Rate of HIV infection (per 100,000)	404	906
GNI per HIV+ person	$10.8 million	$ .3 million

[6] This case was decided under the new US Supreme Court standard for granting injunctions on patents. See eBay Inc. v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839-1841 (U.S. 2006)).
[7] Ibid.
[8] Ibid.
[9] Ibid.
[10] Assuming that the ability to pay is linear in terms of income, a second line AIDS drug that is sold for $1,000 in Thailand would be equivalent to a product selling for $70,000 in the United States. With health care budgets rising faster than incomes, the impact is even worst for the lower income country.

Because of US trade policies, including the 1993 agreement negotiated by former USTR Mickey Kantor,[11] Thailand has been slow to provide treatment to its very large population of AIDS patients. Until November 2006, Thailand had not used the compulsory licensing provisions that are permitted in the TRIPS. Thailand started its treatment program by relying extensively on a handful of older AIDS drugs that were off patent in Thailand. These products are not the best that modern science offers. Many Thai AIDS patients suffer from the predictable side effects associated with the older medicines. In any case, over time, AIDS patients everywhere develop resistance, and cannot be treated without access to new medicines.

Thailand will need sustainable access to second line AIDS drugs at affordable prices. If Thailand does not issue compulsory licenses on the patents for these medicines, it will have to limit access to treatment. This will mean much suffering and death, an outcome that is avoidable.

The United States should not pressure Thailand on the issue of issuing compulsory licenses on patents for AIDS drugs. It should accept the fact that Thailand, like all WTO members, has an obligation to take measures to "promote access to medicines for all."[12]

The United States and other high-income countries are increasingly realizing that they too have to consider using compulsory licenses on patents for medical inventions. For example, Canada and several European countries have threatened to use compulsory licenses on the Myriad patents for tests used to identify the risks of breast cancer -- tests that are not widely available in the United States, because of the high price.[13] It is increasingly difficult for high-income countries to afford the prices for new treatments for cancer or other severe illnesses. With our own aging population, we cannot have a sustainable program of access to the latest medical discoveries, without having the ability to at least threaten to override the exclusive rights of a patent.

The tough USTR positions on patents, pharmaceutical test data and drug prices in trade negotiations are an attempt to deal with the global problem of funding medical R&D. They focus entirely on measures that raise drug prices. In our opinion, this is a mistake. We believe the United States would be better off embracing a new approach, one that focuses on sharing the costs of medical R&D -- not just through high drug prices, but through any mechanism that supports relevant R&D efforts. For example, we would benefit if our trading partners would engage with the NIH to share the costs of medical R&D for global health problems, provide sustainable funding for the many new non-profit product development ventures, or if they would fund new mechanisms to stimulate

[11] http://www.cptech.org/ip/health/c/agreements/thai-1994-ip.html. See also: Susannah Markandya, Timeline of Trade Disputes involving Thailand and access to medicines, July 23, 2001. http://www.cptech.org/ip/health/c/thailand/thailand.html.

[12] Paragraph four of the 2001 Doha Declaration on TRIPS and Public Health.

[13] The tests are more widely available in countries that have shipped patient tests to offshore testing labs where patents are not in effect.

R&D, such as advanced marketing commitments for new vaccines, or "prize funds" that reward medical innovations that improve health outcomes.[14]

Last week the World Health Organization (WHO) convened the first meeting of it's new Intergovernmental Working Group on Intellectual Property Rights, Innovation and Public Health. At this first meeting, thirty-three countries, including Thailand, supported work on a new treaty or agreement to provide sustainable sources of R&D for global health priority projects. It is in the interest of the United States that other countries, rich and poor, do more to pay the costs of such research. But for many of our trading partners, an agreement to support medical R&D would be more appropriate and acceptable than a trade framework that only seeks to raise drug prices.

As the new head of USTR, you have the opportunity to reframe our trade policy so that it provides a rational, effective and ethical solution to the global free rider problem. We need to ensure that everyone contributes fairly to the costs of medical R&D, but in a framework that ensures people can have access to new inventions.

I would like to meet with you and your staff to discuss these matters.

Sincerely,

James Love
Director
Consumer Project on Technology

Cc:

Karan K. Bhatia, Ambassador, Deputy U.S. Trade Representative

Victoria A. Espinel, Assistant U.S. Trade Representative for Intellectual Property Rights

Barbara Weisel, Assistant U. S. Trade Representative for Southeast Asia-Pacific and Pharmaceutical Policy

Senators Edward Kennedy, Hilary Clinton, Barack Obama, Sherrod Brown, Bernie Sanders, Chuck Schumer, Diane Feinstein, Barbara Boxer, Trent Lott, Chuck Grassley, Byron Dorgan, Richard Durbin, Ron Wyden, Patrick Leahy

[14] Aidan Hollis. An Optional Reward System for Neglected Disease Drugs, 2005; Joseph Stiglitz, Give Prizes not Patents. *New Scientist*, September 16, 2006; Thomas Pogge on Online Opinion. "A New Approach to Pharmaceutical Innovations," June 21, 2005; James Love. "Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D." Paper for the WIPO Open Forum on the draft Substantive Patent Law Treaty (SPLT), March 2006.

Speaker Nancy Pelosi, Representatives Charles Rangel, Henry Waxman, John Dingell, Tom Allen, Janice Schakowsky, Rahm Emanuel, Dan Burton, Rosa DeLauro, Jo Ann Emerson, Dennis Kucinich, Barbara Lee, Sander Levin, Jim McDermott, Maxine Waters, Peter Stark, Charles Gonzalez, John Lewis, Xavier Becerra, John Larson, Linda Sanchez, Lloyd Dogget, Howard Berman, Lois Capps, Joe Crowley, Mark Udall, Betty McCollum, Raul Grijalva, Hilda Solis

Dr. Margaret Chan, Director-General Elect, World Health Organization

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Dr Suwit Wibulpolprasert, Senior Advisor on Health Economics, Ministry of Public Health, Thailand

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