

ESSENTIAL INVENTIONS, INC

1621 Connecticut Avenue, Suite 550, Washington, DC 20009

Voice +1.202.332.2670, fax +1.202.332.2673

<http://www.essentialinventions.org>

5 January 2007

Robert Portman, Director
The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Via fax 1.202.395.1005

Re: Federal Procurement of Patented Drugs under Statutory Licenses

Dear Director Portman:

We are writing to request that your Office take steps to develop and accept alternative competitive sources of supply for federal procurement of two medicines the patents for which the government has statutory licenses. This action can save the federal government (and taxpayers) hundreds of millions of dollars.

Under U.S. Code tit. 35, §§ 202(c)(4) and 209(d)(1), the federal government retains worldwide, non-transferable, irrevocable, paid-up licenses to practice, or to have practiced for or on its behalf, patents resulting from sponsored research or patents owned directly by the government, respectively.

To demonstrate the importance and practical benefit of the statutory licenses, Essential Inventions is willing to manufacture, import, and sell to the federal government inexpensive generic versions of two drugs used for the treatment of HIV/AIDS. Stavudine, or d4T, is marketed in the U.S. by Bristol Myers Squibb under the trade name Zerit™. Ritonavir is marketed in the U.S. by Abbott Laboratories under the trade name Norvir™. Patents on these two drugs in which the federal government has statutory licenses under the aforementioned § 202(c)(4) are listed in Attachment A.

The federal government procures these drugs for distribution by the Department of Defense, the Public Health Service, the Federal Bureau of Prisons, the National Institutes of Health, and the Department of Veterans Affairs. Both drugs are listed on the Federal Supply Schedule. The President's Emergency Plan for AIDS Relief (PEPFAR) also directly procures drugs for distribution in developing countries, and, with an eye to maximizing access, already procures FDA-approved generic versions of d4T. Furthermore, the federal government pays for these drugs under various reimbursement

programs, such as Medicaid, the AIDS Drug Assistance Program (ADAP), and the federal Office of Personnel Management health insurance programs.

Specifically, we request that OMB do the following:

- 1) Provide Essential Inventions and any other qualified supplier with an agreement to use the patents listed below for the purposes of supplying the federal government with d4T and ritonavir.
- 2) Support any changes in rules or legislation that may be necessary to expand the authority of third parties that administer federally supported health programs to procure generic copies of d4T, ritonavir, and other federally funded pharmaceutical inventions directly for distribution to patients.

If the federal government should exercise its statutory patent licenses for drugs resulting from research paid for by the U.S. taxpayer it can obtain medicines at significant savings to U.S. taxpayers. For example, d4T from BMS is now priced at more than \$3,600 per year on the Federal Supply Schedule, but generic d4T costs less than \$50 per year in countries where generic competition is legal.

In the case of ritonavir, the federal government can address another serious problem. Abbott Laboratories increased the price of ritonavir 400 percent in December of 2003, but only applied the price increase in the United States, if one used ritonavir with a non-Abbott supplied protease inhibitor. The price hike for ritonavir did not apply to some federally supported health programs, but did for others.

Far lower prices exist for ritonavir outside of the United States, where Abbott sells the product at one-fifth to one-tenth the U.S. prices, or when ritonavir is purchased in a co-formulated version with lopinavir, as Kaletra™.

Abbott's 400 percent price hike for the standalone price of ritonavir was designed to make it prohibitively expensive for AIDS patients to use ritonavir with non-Abbott protease inhibitors, an anticompetitive strategy that is at the center of a January 3, 2006 report in the Wall Street Journal (see: John Carreyrou, "Inside Abbott's Tactics To Protect AIDS Drug: Older Pill's Price Hike Helps Sales of Flagship; A Probe in Illinois," *Wall Street Journal*, January 3, 2007; Page A1.)

Abbott has also refused to license the ritonavir patents to other U.S. manufacturers of protease inhibitors, which has decreased the choice and quality of medicines available to AIDS patients. We therefore additionally request OMB to permit other manufacturers of AIDS drugs to use the patents on ritonavir to provide co-formulated AIDS drugs for federal uses.

By lowering the cost of these HIV/AIDS drugs it will be possible to expand other services to persons living with HIV.

We look forward to your reply.

Very truly yours,

James Love
Chairman of the Board of Directors
Essential Inventions, Inc

Cc: Senators Sherrod Brown, Ted Kennedy, Bernard Sanders, Hillary Clinton, Barack Obama. Representatives Henry Waxman, Tom Allen, Dave Obey, Janice Schakowsky, Rahm Emanuel.

Attachment A

List of U.S. Patents in which the federal government retains statutory licenses under 35 U.S. Code § 202(c)(4).

Stavudine (d4T)

U.S. Patent No. 4,978,655

Ritonavir

U.S. Patent No. 5,541,206

U.S. Patent No. 5,635,523

U.S. Patent No. 5,648,497

U.S. Patent No. 5,674,882

U.S. Patent No. 5,846,987

U.S. Patent No. 5,886,036