

Essential Inventions, Inc.
P.O. Box 19367, Washington D.C. 20036

January 29, 2004

The Honorable Tommy Thompson
Secretary
Department of Health and Human Services
200 Independence Ave., S.W.
Washington D.C. 20201

**RE: Petition to use authority under Bayh-Dole Act to promote access to
ritonavir, supported by National Institute of Allergy and Infectious
Diseases contract No. AI27220**

Dear Secretary Thompson:

The enclosed petition formally requests that you use authority under the Bayh-Dole Act, 35 U.S.C. § 200 et seq., to authorize third parties to use patents necessary for the manufacture and sale of ritonavir, an antiretroviral protease inhibitor used to treat HIV/AIDS.

Federal Rights in Ritonavir

Ritonavir was conceived or first actually reduced to practice in the performance of National Institute of Allergy and Infectious Diseases contract number AI27220, as is reflected on each patent. Thus, under the Bayh-Dole Act the Federal government has “march-in” rights allowing it to order the patent holder or assignee to license the patent to any person if the invention is not made available to the public on reasonable terms or if necessary to alleviate health and safety concerns.

Abbott’s Abusive Pricing

Abbott’s pricing of ritonavir has been unreasonable, anticompetitive and threatens the health and safety of people with AIDS. As a standalone protease inhibitor, Abbott has consistently priced ritonavir higher than many other protease inhibitors that were not created with government funding. Recently, it increased the ritonavir price five-fold. A full treatment of ritonavir is now priced at over \$45,000 a year; 3-5 times higher than most other standalone protease inhibitors.

Ritonavir is used in a low dose to “boost” the effectiveness of six (of seven) protease inhibitors marketed by other companies. There is no other medicine with ritonavir’s boosting properties. Abbott insulated its own boosted protease inhibitor, Kaletra, from the price increase. Thus, Abbott’s price increase has effectively raised the price of its rivals’ products by \$3,129 - \$6,258 a year, giving patients, insurance companies and other payers a compelling reason to switch patients to Kaletra, even if it is not the best choice from a medical point of view. Abbott has also created a huge disincentive for firms to develop new

protease inhibitors (such as Boehringer-Ingelheim's tipranavir) that work best with Norvir boosters.

Request for an Open License

To remedy Abbott's abusive practices, we request that you issue an "open license" for all ritonavir patents that are subject to federal rights. An open license is a non-exclusive license that grants authority to use the subject invention to any qualified supplier on the same non-discriminatory terms.

Royalty and Research and Development Contribution

We anticipate and share concerns that efforts to reduce prices for this government-funded invention will reduce profits to Abbott and consequently reduce somewhat private sector incentives to invest in research and development. To address these concerns we propose terms that include both a 5% royalty to the patent holder on each generic sale and a special obligation for manufacturers of ritonavir to finance research and development for AIDS. We recommend a required research and development contribution of \$.004 per mg of generic ritonavir sold. This would provide R&D funding of \$29 million annually for every 10,000 patients that use generic ritonavir.

Procedural Requests and Guidelines

The procedures for this application are defined in 37 C.F.R. § 401.6. Pursuant to those regulations, we request that the Department of Health and Human Services (DHHS):

- Notify Abbott in writing of the information presented in this petition and request a written reply from Abbott to DHHS and Essential Inventions;
- Request from Abbott all information relevant to the matter. Proposals for information requests from Essential Inventions, Inc., will be forthcoming;
- Within 30 days of the date of this letter, or within 60 days of the receipt of comments from Abbott, notify Abbott of the Secretary's determination to consider the exercise of march-in rights for each of the patents subject to the enclosed petition;
- Within 30 days of notifying Abbott of that DHHS will consider using its march-in rights, hold a hearing with representatives from Essential Inventions, Inc. and Abbott to resolve any disputed issues of material fact raised by Abbott;
- Within 90 days after the completion of fact finding, issue a written determination on Essential Invention's petition identifying the facts and reasons on which the decision is based, including discussion of how the decision is consistent with the purposes and policy objectives of the Bayh-Dole Act.

Essential Inventions, Inc. requests copies of all correspondence between Abbott and DHHS and requests to have a representative present at any meeting in person or on the telephone. We request that no ex-parte communication take place between DHHS and either party.

We look forward to your prompt consideration of this urgent matter.

Sincerely,

James Love
President
Essential Inventions, Inc.

Sean Flynn
Counsel
Essential Inventions, Inc.