



October 25, 2012

Dr. Francis Collins
Director
National Institutes of Health
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Bethesda, MD 20892
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Dear Dr. Collins,

The American Medical Students Association (AMSA), Knowledge Ecology International (KEI), U.S. Public Interest Research Group (PIRG) and the Universities Allied for Essential Medicines (UAEM) are filing the attached petition requesting that the National Institutes of Health (NIH) grant Bayh-Dole Act march-in rights for the patents held by Abbott Laboratories relevant to the manufacture and sale of ritonavir, a federally funded invention that is much more expensive in the United States than in Canada, Europe or other high-income countries.

In the more than 31 years of the history of the Bayh-Dole Act, the NIH has never granted a march-in request. This reluctance to protect the public in cases of abuses of patent rights has led to increasingly aggressive and abusive practices by holders of rights in NIH funded patented inventions. It is our expectation that the past unwillingness to grant march-in petitions will not prejudice the opportunity for a serious review of this petition.

The organizations are asking the NIH to grant open licenses on patents held by Abbott for the manufacture and sale of the HIV drug ritonavir. The petition also requests the NIH adapt two rules that will create standards for future march-in requests, making NIH policy more predictable as well as effective in protecting the public's interest in federally funded inventions.

At the center of the petition is an important policy issue for the NIH. Can a holder of an NIH funded patented medical invention expect to maintain its monopoly when U.S. residents pay more than consumers in other high income countries? The petitioners are asking the NIH to set a policy that would grant march-in requests when U.S. residents face substantially higher prices than the patent owners charge in other countries with comparable incomes. The petition also asks the NIH to adopt a clear policy on march-in petitions in cases where patents on medical inventions are "necessary to effect significant health benefits" of a second product "used or is potentially useful to prevent, treat or diagnose medical conditions or diseases involving humans."

Respectfully submitted,

A handwritten signature in black ink that reads "Krista L. Cox".

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