



Press Release, 15 Feb 07

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FTC ASKED TO INVESTIGATE GILEAD EFFORT TO CONTROL MARKET FOR AIDS DRUGS INGREDIENTS

[Complaint available here:

<http://www.keionline.org/misc-docs/ftcgilead12feb07.pdf>]

Washington, D.C. February 15, 2007. Knowledge Ecology International (KEI) has petitioned the U.S. Federal Trade Commission to seek remedies for anticompetitive practices by the pharmaceutical company Gilead. The advocacy group claims that Gilead is using patents on a government funded AIDS drug invented at Emory University to cut-off low cost supplies of ingredients for two AIDS drugs.

KEI charges Gilead with using licenses to patents on the AIDS drug emtricitabine in 45 countries to control the supply of the "active pharmaceutical ingredients" (APIs) to more than 100 other countries, and control the market for a second AIDS drug (tenofovir) that is generally off-patent in developing countries.

Northeastern University School of Law Professor Brook Baker notes Gilead's licenses "(1) split and tie-up the market for active pharmaceutical ingredients, (2) seek royalties on approved sales even when patents are not in force, and (3) prevent additional sales in unapproved markets even where tenofovir and emtricitabine and their combinations are not patented."

According to the KEI complaint, "This action imposes higher costs for AIDS drugs in more than 150 developing country markets. The United States government is the largest purchaser of AIDS drugs in the developing world, and is harmed by this anticompetitive practice."

According to Ellen 't Hoen from the humanitarian group MSF, "In the case of tenofovir (TDF) the cost of the API may account for 80% of the total cost of production. Limiting access to API for the production of TDF will inevitably keep the price artificially high."

Announced in 2003, the President's Emergency Plan for AIDS Relief (PEPFAR) is the largest commitment ever by any nation for an international health initiative dedicated to a single disease – initially \$15 billion over five years. Fifty-five percent of the PEPFAR budget is for the treatment of individuals with HIV/AIDS, and in FYs 2006 through 2008, 75 percent of those outlays will be spent on the purchase and distribution of antiretroviral drugs. PEPFAR supports programs in **120 developing countries**.

The KEI complaint details a scheme by Gilead to partition the developing world in half, and license certain companies to sell tenofovir and emtricitabine in one part of the world on the condition that companies restrict the buying or selling of APIs with companies who sell in the other part of the world.



“The patent landscape on the two drugs is very different. Gilead has used the patents on emtricitabine in 45 countries to control the market for APIs in the entire developing world, not only for this drug, but also for tenofovir, a drug that is actually off patent in most countries,” said KEI Director James Love.

The main focus of the Gilead licensing strategy is to co-op the generic manufactures, so that they only sell or buy APIs with companies approved by Gilead. For receiving a license to use the Emory patents in 45 countries, the license requires payment of royalties in countries where Gilead does not hold a patent, and to not compete in countries that collectively have 2.5 billion residents.

By partitioning the market in this way, Gilead has made generic suppliers of APIs less efficient, and reduced the number of competitive suppliers in all markets, leading to higher prices for AIDS drugs purchased by US government funded health programs.

KEI told the FTC that the patents on emtricitabine were based upon publicly funded research grants to Emory University, and that as a consequence, the US government can easily demand changes in the Gilead licensing practices, by threatening to exercise its royalty free rights in the patents.

“It is particularly troubling that some of the drugs were developed with federal government funding, and that the costs of any such anticompetitive licensing would be paid by American taxpayers who subsidize developing country purchases through the PEPFAR program,” said Joshua D. Sarnoff, from the Glushko-Samuelson Intellectual Property Law Clinic at American University.

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COMMENTS BY PUBLIC GROUPS AND PATENT EXPERTS

Ellen 't Hoen Policy Advocacy director MSF Access to Essential Medicines Campaign
"TDF is part of the standard 1st line treatment in the West, but it is largely out of reach of people in developing countries despite the fact that WHO recommends its use for 1st line. In the case of TDF the cost of the API may account for 80% of the total cost of production. Limiting access to API for the production of TDF will inevitably keep the price artificially high."

Joshua D. Sarnoff Glushko-Samuelson Intellectual Property Law Clinic, Washington College of Law, American University

“The potential for these critically important AIDS drugs to be licensed in an anticompetitive fashion is a very serious concern, and one that definitely warrants investigation by the FTC. We should be finding ways to make such drugs more affordable in developing countries where they are needed and where the ability to pay for the drugs is severely limited. It is particularly troubling that some of the drugs were developed with federal government funding, and that the costs of any such anticompetitive licensing would be paid by American taxpayers who subsidize developing country purchases through the PEPFAR program.”

Professor Brook Baker, Northeastern University School of Law

"We need new standards to assure that rich drug companies like Gilead don't over-reach when they are forced to grant licenses for accessing essential medicines in developing countries. These



so-called voluntary licenses are usually granted as a result of pressure by AIDS and public health activists who seek to ensure that robust generic competition results in sustainable supplies of low-cost and good quality medicines. This is what happened in the Gilead case, but when the actual details of the licenses are revealed, we find that profit-maximization still reigns supreme through terms that: (1) split and tie-up the market for active pharmaceutical ingredients, (2) seek royalties on approved sales even when patents are not in force, and (3) prevent additional sales in unapproved markets even where tenofovir and emtricitabine and their combinations are not patented. All of these illegal terms increase profits for Gilead and simultaneously raise prices in fractured developing country markets. Under the cover of good deeds, Gilead has engaged in some sharp and anti-competitive practices that must be and can be addressed by the U.S. government, which retains rights to correct the anti-competitive terms and to issue its own licenses to inventions it helped finance. The Knowledge Ecology International request for an FTC investigation is public citizenship at its finest."

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