AHF: Gilead Says it “Had No Duty to Develop” Less Harmful AIDS Drug in Legal Motion on Patent Lawsuit

Posted March 25, 2016

- Tweet
- Share

In January, AHF filed a federal lawsuit against Gilead Sciences, Inc. and two other defendants alleging drug patent manipulation and anti-trust claims regarding Genvoya, Gilead’s new four-in-one Fixed Dose Combination (FDC) to treat HIV/AIDS patients. Gilead unsuccessfully sought US patent extension on Stribild, its similar but earlier FDC that includes a form of Tenofovir, the drug at the heart of AHF’s lawsuit.

According to the legal news website, Law360, Gilead attorneys, in a motion to dismiss AHF’s lawsuit, wrote, “Just as Gilead was under no antitrust duty to bring a standalone TAF product to market, it likewise had no duty to develop, test, seek approval of or launch its new product on any particular timetable.”

LOS ANGELES (March 25, 2016) In a motion to dismiss the federal lawsuit filed by AIDS Healthcare Foundation (AHF) against Gilead Sciences Inc. seeking to invalidate patents on key AIDS drugs held by the Bay Area drug maker, lawyers for Gilead wrote that the company, *“… had no duty to develop …”* a less harmful HIV/AIDS drug.

AHF’s lawsuit was filed in January 2016 in U.S. District Court, Northern District of California, [Case #

3:16-cv-00443]. AHF's patent and anti-trust case centers on slightly different formulations of Tenofovir, a key HIV/AIDS drug which was first synthesized over thirty years ago in the Czech Republic. One formulation of Tenofovir (tenofovir alafenamide or TAF) is a component in Genvoya, Gilead's newest four-in-one Fixed Dose Combination (FDC) to treat HIV/AIDS patients, which was approved by the FDA in November 2015.

Gilead's similar predecessor four-in-one Fixed Dose Combination, Stribild, includes an earlier formulation of Tenofovir (tenofovir disoproxil fumarate or TDF, commercially branded as Viread). TDF has potentially harmful side effects including kidney damage and bone loss. The Tenofovir formulation known as TAF has far fewer side effects, a fact that Gilead is using in its marketing and promotion of Genvoya. TDF, the earlier formulation of Tenofovir, is also now nearing the end of its patent protection.

"The legal news website Law 360 reports that Gilead and its attorneys, in its motion to dismiss our lawsuit, actually say that they had no obligation whatsoever to develop this newer, less harmful form of Tenofovir. Despite the fact that Gilead is now widely touting its updated formulation of Tenofovir's reduced risk of causing kidney damage and bone loss, it doesn't matter one bit legally if they purposely delay bringing it to market. Instead, so they could continue to maximize profits—and run the patent clock—on its older, potentially more harmful Tenofovir formulation. Gilead delayed bringing TAF to market and has yet to do so for TAF as a standalone drug," said **Michael Weinstein**, President of AIDS Healthcare Foundation. "An indefensible excuse by Gilead on moral grounds as well as a brazen defense on legal grounds that we will continue to challenge."

According the Law 360 article (March 23, 2016, Stan Parker) "*AIDS Healthcare Foundation alleged in its complaint that Gilead intentionally postponed clinical studies of TAF until its exclusivity period for TDF was about to expire, putting its market position ahead of patients who need the treatments. It also alleged that patent protections relating to Genvoya must be nixed because TAF was an anticipated, not novel, improvement on TDF."*

Law 360 also noted, *"Just as Gilead was under no antitrust duty to bring a standalone TAF product to market, it likewise had no duty to develop, test, seek approval of or launch its new product on any particular timetable," the company wrote.*

AHF's lawsuit also names Japan Tobacco Inc. and Emory University and asserts anti-competitive violations of the Sherman Act,15 U.S.C. §§ 1 & 2.

AHF currently cares for over 605,000 HIV/AIDS patients in 36 countries and purchased millions of dollars of antiviral drugs from Gilead in 2015 alone. In its legal filing, AHF asserts that:

Gilead's attempt to extend the period of patent exclusivity for drugs incorporating Tenofovir arises from Gilead manipulating the patent system, entering into a licensing agreement with Japan Tobacco, and using a preexisting patent licensing agreement with Emory University to block entry by potential competitors and prevent competition. Gilead's actions have directly harmed AHF, which in 2015 alone

purchased millions of dollars of antiviral drugs from Gilead.

According to a New York Times article at the time of Genvoya's approval by the FDA in November 2015, Genvoya *"…contains the same four drugs as Stribild, but with the tenofovir disoproxil fumarate replaced by tenofovir alafenamide. The new form of the inhibitor, Gilead said, enters cells where H.I.V. replicates more efficiently, resulting in 91 percent less tenofovir in the bloodstream. That should make the pill less likely to cause kidney damage or loss of bone density…"*

In response to FDA approval of Gilead's Genvoya, the Indian online news site 'The Hindu' published a November 8, 2015 article titled, *"Magic Pill, or Just an Old Cocktail?"* The article noted:

"There are two things one needs to know about this drug. First, it is not a new drug. It is a combination of four old drugs — elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide (TAF). This is called a Fixed Dose Combination (FDC).And while FDCs are good for improving adherence among patients, this is no magic pill. 'Technically, this is simply not a breakthrough. No new drug has been discovered – older drugs have been brought together in the FDC form. This is important as it improves compliance, which is a great thing but to call it a breakthrough is a stretch,' said Dr Manish Kakkar, a public health specialist in communicable diseases at the Public Health Foundation of India (PHFI)."

In January 2013, shortly after the FDA approved Stribild, the Fixed Dose Combination on which Genvoya is now based, Gilead filed a citizen's petition with the FDA seeking an extension on its patent protection on the drug from three years to five years.

In October 2014, the FDA denied Gilead's petition for the patent extension.

AHF's lawsuit, which demands a jury trial, seeks "Declaratory Judgment of Patent Invalidity and Violation of the Sherman Act, 15 U.S.C. §§ 1 & 2.