Lawsuit Claims Gilead Delayed the Release of a Less Toxic Version of Tenofovir

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Since its approval in 2001, the med tenofovir has become the most prescribed HIV drug in the world, earning about $11 billion each year for its manufacturer, Gilead Sciences. As the Los Angeles Times reports, a lawsuit against Gilead by AIDS Healthcare Foundation (AHF) claims that the pharmaceutical giant delayed the development of a newer and safer version of the med in an attempt to extend its patent.

The original version of the drug, tenofovir disoproxil fumarate (TDF), sold as the brand-name Viread, can be toxic to kidneys and bones. More than 10 years ago, Gilead developed a newer, less harmful version called tenofovir alafenamide (TAF), but after promising results from clinical trials, Gilead stopped research into the med. In 2010, research resumed.

In November 2015, the Food and Drug Administration (FDA) approved Genvoya, a new combo tablet that includes TAF, as an updated version of Stribild. However, TAF is not approved for use as pre-exposure prophylaxis (PrEP), the daily prevention pill taken by people who are HIV negative.

The lawsuit by AHF claims that Gilead could have developed the safer version sooner but failed to do so in order to increase its profits and patents. “That’s a decade of potentially avoidable kidney and bone toxicity,” AIDS advocate Tim Horn of Treatment Action Group, told the Times.

The article also points out that in the early 2000s, the FDA had sent warning letters to Gilead because the company’s sales reps were downplaying TDF’s risks to bone and kidney health.

POZ founder and long-term survivor Sean Strub is quoted in the Times story as a person whose bones deteriorated after taking the original tenofovir. He began taking the med while in his 40s and within a few years had the bones of an 85-year-old woman.

According to the newspaper, Gilead says it originally stopped research on TAF because it was focused on developing a new type of HIV med called an integrase inhibitor.

AHF, which operates HIV clinics across the globe, filed the lawsuit against Gilead on April 11, 2016.

You can read the entire document at an LA Times link here, but below is an excerpt from the lawsuit:

> "In a relentless effort to maximize its profits, Gilead manipulated the patent system and engaged in anticompetitive practices to prevent economical access to TAF—an antiviral agent used in the treatment of HIV. TAF is not a new compound. TAF is a prodrug of the compound Tenofovir, which was first synthesized over thirty years ago in the Czech Republic. Nor was TAF the first prodrug of Tenofovir. Several years before Gilead obtained a patent on TAF, Gilead had patented a similar prodrug called Tenofovir Disoproxil ("TDF"). Despite similarities between TAF and TDF and the weakness of the patents covering TAF, Gilead illegally seeks to extend the period of patent exclusivity for drugs incorporating Tenofovir by decades.
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> "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 expanding its licensing agreement with Johnson & Johnson subsidiary Janssen Sciences to block entry by potential competitors and prevent competition.…
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> "The delay in conducting clinical trials deprived those suffering from HIV of TAF for more than a decade. Those people suffering with HIV were forced to take TDF, which because of TDF's lower absorption rates had higher bone and kidney toxicities. It is possible that HIV patients suffered from 10 years of additional accumulated kidney and bone toxicity using TDF while TAF stayed on the shelf."

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