New Twist in the Gilead Patent Lawsuit Over Truvada and Descovy to Prevent HIV

The U.S. government and HIV drugmaker Gilead Sciences continue to fight over patents for Truvada and Descovy as PrEP.

January 7, 2021 By Trent Straube

Who holds the patents on the meds Truvada and Descovy when they're used as pre-exposure prophylaxis (PrEP) for the prevention of HIV? Is it the federal government or the drugs' manufacturer, Gilead Sciences? That's been the subject of heated discussion and lawsuits since early 2019. In the latest development, a federal judge ruled last week that the government cannot ignore Gilead's claims that the government breached its contracts when it asserted patents on Truvada as PrEP. As Westlaw Today reports, the judge said a statute of limitations did not negate Gilead's claims, nor did a pending lawsuit with overlapping issues.

The ruling was handed down by a judge on the U.S. Court of Federal Claims, which focuses on cases involving money damages alleged by companies contracted by the government. The case is Gilead Sciences Inc. v. USA.

The Food and Drug Administration (FDA) approved Truvada as PrEP in 2012. Truvada, which consists of two meds—tenofovir disoproxil fumarate and emtricitabine—was initially approved in 2004 as treatment for people living with HIV. So why is legal action ongoing in 2021?

In March 2019, a group of activists called PrEP4All claimed that the government—via the Centers for Disease Control and Prevention—held the patent on Truvada's use as PrEP because researchers with federal grants (and additional funding from the Bill & Melinda Gates Foundation) were the first to prove that the drug worked very well as prevention. The advocates wanted royalties from Gilead to fund a national PrEP program to make the med accessible to everyone, not just those who could afford it. (For background, see this POZ article.)

In November 2019, the government filed a patent lawsuit against Gilead regarding Truvada as PrEP, including the updated version of Truvada called Descovy. (You can read the Department of Health and Human Services press release here.)

In April 2020, Gilead fired back with a breach-of-contract lawsuit, alleging that the government

secured its patents by breaching five contracts with the pharmaceutical manufacturer. (Read Gilead's statement about that here.)

In last week's ruling, the judge said the government cannot dismiss Gilead's claims. The drugmaker also alleges that it suffered damages in the form of harm to its reputation and the likelihood that it would receive less favorable license terms.

In the United States, PrEP is available only as the daily tablets Truvada and Descovy; both consist of two meds. A generic version of Truvada became available last fall. To learn more, see "What's the Difference Between Truvada and Descovy for PrEP?" and "Prevention: Generic Truvada." For more general information, see the POZ Basics on HIV Prevention.

Scientists estimate PrEP to be about 99% effective among men who have sex with men and 88% to 90% among heterosexual men and women (though researchers believe this latter number is likely higher). For more details, see "How Well Do U=U and PrEP Work? The CDC Updates Its Answers."

In related news, see this recent blog post by activist Peter Staley: "My 60th (OMG!) Birthday Fundraiser for PrEP4All."

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