UPDATE: U.S. Government Seeks New Trial in HIV PrEP Patent Lawsuit

A jury in May ruled in favor of Gilead Sciences, maker of HIV prevention pills. Now the government wants a judge to overturn the verdict.

June 23, 2023 By Trent Straube

UPDATE JUNE 23, 2023: The U.S. government wants a federal judge to overturn a recent verdict in an PrEP patent lawsuit that ruled in favor of HIV drugmaker Gilead Sciences, reports STAT News. In asserting that the jury was misled and confused by Gilead, the government also seeks a new trial regarding pre-exposure prophylaxis, or PrEP, pills to prevent HIV, according to Bloomberg Law.

In its complaint, the government asserts that Gilead "failed to show sufficient proof that the patents were invalid and, in fact, had been infringed," adding that "Gilead has repeatedly refused to obtain a license from CDC to use the patented regimens."

A June 23 statement from advocacy group PrEP4All and Public Interest Patent Law Institute read in part:

> "PrEP4All commends the Department of Justice (DOJ) for taking action and urging a Delaware federal judge to overturn the recent verdict in US v. Gilead, which, should it stand, would let Gilead off the hook for infringing on patents held by the federal government.... We call on Judge Noreika to heed the government's request. Much is at stake for communities affected by HIV/AIDS. In January 2022, PrEP4All and other advocacy organizations released a letter demanding that the U.S. government publicly commit to using royalties from U.S. v. Gilead to increase access to PrEP through a national PrEP program. Hundreds of thousands of new HIV infections have occurred in our communities since PrEP was approved in 2012; it is time for Gilead to be held accountable for its central role in undercutting PrEP access to marginalized communities, and for funds to be reinvested in ending HIV as an epidemic for all communities in America."

Below is our original article, "Gilead 'Won on All Counts' in Billion-Dollar HIV PrEP Patent Lawsuit," about the ruling.

MAY 9, 2023: HIV drugmaker Gilead Sciences won a patent lawsuit brought by the federal government regarding Truvada and Descovy used as pre-exposure prophylaxis (PrEP) to prevent HIV, Reuters reports.

Specifically, a federal court jury in Delaware ruled that the HIV drugmaker Gilead Sciences did not infringe on patents and that the government's patent claims were invalid.

"We are pleased with today's favorable jury verdict in the Delaware District Court, in which Gilead won on all counts," stated Deb Telman, Gilead executive vice president of corporate affairs and general counsel, in a released statement. "The jury determined that Gilead has not infringed the U.S. government's patents and that the patents are invalid."

Telman continued, "Today's decision confirms our longstanding belief that we have always had the rights to make Truvada and Descovy for PrEP available to all who need it. Gilead will continue to champion collaborations, including our efforts with the U.S. Health and Human Services Department (HHS) and CDC [Centers for Disease Control and Prevention] that span more than 15 years, as we all work together toward our common goal to end the HIV epidemic for everyone, everywhere."

In November 2019, the federal government—on behalf of the CDC—filed a complaint regarding the PrEP patents. Earlier that year, the activist group PrEP4All claimed that the CDC held the patent for 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 regardless of their ability to pay. (For background, see this POZ article.)

For more details about the court case, see "Billion-Dollar HIV PrEP Patent Lawsuit—U.S. v. Gilead—Goes to Trial."

Last year, according to Reuters, Gilead reported over $2 billion in global sales from Truvada and Descovy (both tablets contain two different meds, and both are also used in some treatment regimens for people living with HIV). The CDC claimed it was entitled to up to $691 million in damages from Truvada for PrEP and $311 million from Descovy for PrEP.

The Food and Drug Administration approved Truvada as treatment in 2004 and as PrEP in 2012; the FDA approved Descovy (an updated version of Truvada) as treatment in 2016 and as PrEP in 2019.

The court case between the U.S. government and Gilead is one of several lawsuits involving HIV drugs. For other examples, all from last year, see:

- "Buckle Up! The 'Staley v. Gilead' lawsuit could cost Big Pharma billions,"

- “Another Drugmaker Sues to Stop the Sale of Fake HIV Meds” and
- “HIV Drugmaker Settles Lawsuit Alleging Deals to Keep Prices High.”

PrEP has made other national headlines lately. In September 2022, a district judge in Texas ruled that requiring health insurance to cover PrEP as HIV prevention violates the religious beliefs of a Christian-owned company. In March 2023, a federal judge in Texas struck down the mandate that health insurance must cover many preventive health care services, including some cancer and diabetes screenings, HIV tests and PrEP. The ongoing case could jeopardize access to preventive care.

Meanwhile, PrEP4All and other advocates continue to urge lawmakers and the White House to create a national PrEP program.

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http://beta.docker.realhealthmag.com/article/gilead-won-counts-billiondollar-hiv-prep-patent-lawsuit