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Drugmaker Gilead and U.S. Government Settle Patent Case Over PrEP to Prevent HIV

The billion-dollar lawsuit involved patents and research collaboration on Gilead Sciences' HIV pills Truvada and Descovy as PrEP.

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HIV drugmaker Gilead Sciences and the U.S. government reached a settlement last week in a long-running lawsuit over the patents for Truvada and Descovy as pre-exposure prophylaxis (PrEP) to prevent HIV.

The billion-dollar lawsuit stems from a 2019 case in which the government sued Gilead Sciences over patents and contracts related to their collaborative research. Details of the settlement were not disclosed, but in a statement Gilead said it "will receive a license to certain current and future government PrEP patents that will protect Gilead's freedom to operate for years to come."

The case involved the Department of Justice and the Department of Health and Human Services, which sued Gilead on behalf of the Centers for Disease Control and Prevention (CDC). The government 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.)

In 2022, according to Reuters, Gilead reported over $2 billion in global sales from Truvada and Descovy. The CDC claimed it was entitled to up to $691 million in damages from Truvada for PrEP and $311 million from Descovy for PrEP.

In May 2023, 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. The following month, the government asked a federal judge to overturn that verdict, claiming that the jury was misled and confused by Gilead.

For more background see, "UPDATE: U.S. Government Seeks New Trial in HIV PrEP Patent Lawsuit."

The Food and Drug Administration (FDA) 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.

To date, the FDA has approved three forms of PrEP: Truvada and Descovy are daily pills; Apretude is a shot given every two months. Generic (and much cheaper) versions of Truvada are available. A twice-yearly injectable, lenacapavir as PrEP, may be added to prevention options in the near future, as clinical trial results have shown it to be highly effective in women, gay men and gender-diverse populations. To learn more about PrEP, see the POZ Basics on HIV Prevention: Pre-Exposure Prophylaxis (PrEP).

In related news, health insurance is required to cover certain preventive care, such as cancer screenings, heart statins and PrEP for HIV. But will the mandate stand? For more, see the recent headline "Supreme Court to Hear Health Care Case on No-Cost Access to Preventive Services."
