Gilead Loses Latest Battle Over PrEP Patents, but the Fight Goes On

Who owns the rights to PrEP? The U.S. government or the pharma giant?

February 10, 2020 By Trent Straube

A federal panel refused a request by pharmaceutical company Gilead Sciences to invalidate a pair of patents owned by the federal government to use Truvada as PrEP, or pre-exposure prophylaxis, to prevent HIV.

As STAT News reports, the ruling from the Patent Trial and Appeals Board is a setback for Gilead but other challenges and rulings remain in the ongoing legal battle over PrEP.

Last year, the Department of Health and Human Services (HHS) sued Gilead, saying the drugmaker infringed on the government's patents on a pair of meds. Basically, the federal government and the pharma company are battling over the rights to the discovery that HIV treatment can also be used as HIV prevention.

Currently, only two combo tablets are approved as PrEP. Both are manufactured by Gilead. They are Truvada (tenofovir disoproxil fumarate/emtricitabine) and Descovy (tenofovir alafenamide/emtricitabine). Descovy includes a new version of tenofovir that is linked to better markers of kidney and bone health. (To learn more about the differences in the two PrEP tablets, read this POZ article.)

In a statement to Stat News, Gilead said the latest ruling "does not mean that the HHS patents are valid" but simply that the patent board "did not find the limited evidence we were permitted to introduce…was sufficient to justify a full hearing on the merits using its expedited procedure.… Gilead continues to believe all four HHS PrEP patents are invalid and should not have been granted.… There is compelling evidence demonstrating that the HHS patents are invalid."

AIDS activists, however, lauded the recent ruling.

"This is a major victory for activists and the U.S. government," James Krellenstein, a member of the PrEP4All Collaboration told STAT. "This reinforces the position that the [federal government] patents are fully valid and enforceable and that Gilead willfully and recklessly infringed on valid patents that form a major revenue center in their product pipeline."

In a related but separate issue, PrEP4All claimed that the Truvada maker delayed a safer version of tenofovir. For details, see the December 2019 article "Activists Urge U.S. Agency to Reject Patent Extension on a Gilead HIV Med."

For more background on the patent battle, start with these articles:

- "CDC Has Patents on PrEP, Advocates Find"
- "Federal Government Sues Gilead Over PrEP"
- "It's Big Pharma vs. AIDS Activists at House Oversight Hearing on PrEP Pricing"
- "Here's How We Can Get Universal Access to PrEP"

To learn more about PrEP, see "How Well Do U=U and PrEP Work? The CDC Updates Its Answers" and visit the POZ Basics on HIV Prevention: PEP and PrEP.
