Who Owns the Rights to PrEP?

The courts will be the judge of that. And AIDS United welcomes the lawsuit over Truvada as HIV prevention.

November 29, 2019 By AIDS United

For well over a year HIV advocates, the federal government, and the pharmaceutical industry have been engaged in intense debate around a set of arcane and complicated issues concerning the U.S. patent system and the development of medications for preventing the transmission of HIV. However, while the ins and outs of U.S. patent law are extensive, the central issue being discussed has always been fairly straightforward: Does the federal government properly own the patent rights for use of Truvada for Pre-Exposure Prophylaxis (PrEP) because taxpayer funded research proved it could be used as a vital HIV prevention strategy?

This month, the Department of Health and Human Services (HHS) made it clear where it stood on the issue by suing Gilead Sciences in U.S. District Court, alleging that the pharmaceutical company has, "willfully and deliberately induced infringement of CDC's (Centers for Disease Control's) patents" to varying extents concerning the use of their drugs Truvada and Descovy for PrEP. As a result, HHS is asking the courts to award them with financial compensation for Gilead's continued marketing and use of Truvada for PrEP without paying the federal government royalties for their patent ownership.

Truvada was originally sold by Gilead beginning in 2004 as an antiretroviral therapy for people already living with HIV. In subsequent years, CDC research showed that Truvada was effective in preventing the transmission of HIV when given to individuals who were not living with HIV; soon thereafter it filed a series of patent applications, which were granted in 2015. For their part, Gilead received FDA approval to sell Truvada as a PrEP regimen in 2012, three years before the federal government were awarded their patents.

A statement from Gilead was released shortly after news of the HHS lawsuit broke, saying that they "strongly believe that the patents granted to HHS since 2015 for PrEP and PEP (Post-Exposure Prophylaxis) are not valid and reject any notion of willful infringement." Absent a settlement between Gilead and HHS, the lawsuit could drag on for years.

In response to the news of the filing of this legal case by HHS against Gilead concerning the patent rights around PrEP, AIDS United would like to state the following:

The community we represent at AIDS United is concerned about access and price for HIV prescription drugs, including drugs for prevention. Getting PrEP into the hands of those who want

or could benefit from it—regardless of whether they can afford it—is among the most pressing of our many policy and advocacy priorities. We are clear that high prices are an issue for the HIV field for both prevention and treatment, and we appreciate the activism that focuses on this issue.

AIDS United welcomes the lawsuit as the opportunity to bring resolution to this issue. The outcome could ultimately help to ensure equal and affordable access to life saving medications that is central to the advocacy of the HIV community.

AIDS United has always supported access to the most expansive prevention tools, including PrEP. And whatever the legal outcome, we will continue fighting to scale up those tools." Just like when we fought for stronger federal resources and investments, drafted an early version of the "Roadmap to Ending the HIV Epidemic," called for a robust expansion of Medicaid, and outlined a broad platform of effective legislative proposals to address the epidemic, including Senator Kamala Harris' PrEP Access and Coverage Act, which would dramatically expand access to the critical antiviral drug. We will also work with the Administration and Congress to ensure that any monetary award or settlement received by the government as a result of this lawsuit goes directly towards ending the HIV epidemic and will not revert to the general treasury.

We look forward to continuing our engagement in this important work with our partners to end the epidemic and ensure universal access to PrEP for all who want it.

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