

Gilead Releases HIV Regimen Biktarvy, ViiV Sues for Patent Infringement

ViiV alleges that the bicitegravir component of the tablet infringes on its own patent for Tivicay (dolutegravir).

February 8, 2018

Just after the Food and Drug Administration (FDA) [approved](#) Gilead Sciences' new single-tablet HIV treatment regimen Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), ViiV Healthcare announced that it had filed suit against the company in both the United States and Canada, alleging patent infringement.

ViiV, which is majority-owned by GSK (GlaxoSmithKline) and has Pfizer and Shionogi as shareholders, says it will seek to prove that the bictegravir component of Biktarvy infringes on ViiV's patent for Tivicay (dolutegravir) as well as other compounds that include the latter drug's "unique chemical scaffold."

Both bictegravir and Tivicay belong to the integrase inhibitor class of antiretroviral (ARV) treatments for HIV. The FDA's approval of Biktarvy on February 7 ushered bictegravir into the open pharmaceutical market for the first time.

The same day, ViiV announced it had filed suit against Gilead in the U.S. District Court for the District of Delaware regarding patent No. 8,129,385 and in the Canadian Federal Court in Toronto regarding Canadian patent No. 2,606,282. Rather than seeking to block Gilead's production of bictegravir, ViiV is seeking financial redress for the alleged patent infringement.

ViiV's legal counsel in these cases includes Desmarais LLP for the U.S. litigation and Bereskin Parr for the Canadian case.

Biktarvy's three ARV components include bictegravir plus the two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) found in Gilead's Descovy (emtricitabine/tenofovir alafenamide), a tablet that was [approved](#) in April 2016.

Tivicay, which was [approved](#) in August 2013, is included in the combination pill Juluca (dolutegravir/rilpivirine), the first two-drug, complete HIV regimen, which was [approved](#) in November 2017, and in Triumeq (dolutegravir/abacavir/lamivudine), which was [approved](#) in August 2014.

The financial stakes are considerable in the battle for market share in the HIV treatment field. According to ViiV, more than half a million people worldwide take Tivicay in some form—as [Reuters reports](#), this brought in about \$5.6 billion for the company in 2017. Gilead, Reuters states, is expected to reap a peak of \$5 billion in annual sales for Biktarvy by 2024, although the drug will surely cannibalize sales of other ARVs produced by the company.

Biktarvy’s list price is \$36,000 per year.

Gilead spokesperson Ryan McKeel, reacting to ViiV’s lawsuit, released the following statement: “We remain steadfast in our opinion that Biktarvy does not infringe ViiV’s U.S. patent. ViiV’s challenge does not impact our ability to make Biktarvy available to patients in the U.S.”

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