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Activists to PrEP-maker Gilead: Stop Blocking Progress on HIV

ACT UP Dublin has renewed the call for pharma giant Gilead Sciences to stop blocking access to its anti-HIV medication, Truvada. ACT UP demands that Gilead end its efforts to extend its expired patent and significantly drop the price where the patent is still in effect.

Members of ACT UP Dublin gathered outside the High Court in Dublin this morning as Gilead's legal team arrived for the first day of a trial on the validity of the Supplementary Protection Certificate (SPC) for Truvada. The original patent expired in 2017, but the disputed SPC would extend Gilead's monopoly on Truvada until 2020 in Ireland.

ACT UP Dublin member Andrew Leavitt said:

“Gilead has earned an international reputation for price gouging and dodging taxes.¹ Here in Ireland, Gilead has done nothing but obstruct access to PrEP. They rebuffed HSE efforts to create a PrEP demonstration project in 2016,² then refused to engage with the NCPE in the HSE's pharmaco-economic review process in 2017, forcing the Government to take exceptional measures by requesting a review from HIQA.”³

“A victory in this suit might bring a windfall for Gilead, but it would be a disaster for Ireland's HIV prevention efforts,” Leavitt warned.

While it is widely anticipated that the Irish court will find the SPC invalid, a ruling in Gilead's favour could upend plans for provision of PrEP by the State. A draft Health Technology Assessment report from HIQA found that PrEP is safe and highly effective, and—based on the lower prices charged by generic companies—that a PrEP programme would be cost saving for Ireland, noting that “providing PrEP is less costly... than not providing PrEP.”⁴

Scheduled to run for three weeks, the trial is the latest round in a dispute which began in July 2017. In November 2017 the court denied an injunction sought by Gilead to prevent the sale of generic versions of Truvada in Irish pharmacies prior to a ruling on the validity of the SPC.

¹ See, e.g.: “The drug company that shocked the world with its prices dodged \$10 billion in taxes, report says” *Washington Post*, 13 July 2016. Available at: www.washingtonpost.com/news/wonk/wp/2016/07/13/maker-of-84000-drug-avoided-10-billion-in-u-s-taxes-report-says and “US pharma giant Gilead uses ‘Double Irish’ tax loophole” *The Times* (UK), 26 December 2018. Available at: www.thetimes.co.uk/article/us-pharma-giant-gilead-uses-double-irish-tax-loophole-j9gq5rdb7

² “Getting PrEP-ed for HIV prevention” *Medical Independent*, 18 July 2017. Available at: www.medicalindependent.ie/getting-prep-ed-for-hiv-prevention/

³ “There are few drugs, since Viagra, that have captured the global imagination more than Truvada” *Irish Examiner*, 30 July 2018. Available at: <https://www.irishexaminer.com/breakingnews/lifestyle/features/there-are-few-drugs-since-viagra-that-have-captured-the-global-imagination-more-than-truvada-858541.html>

⁴ “HIQA launches public consultation on a PrEP programme to prevent HIV” HIQA, 23 April 2019. Available at: www.hiqa.ie/hiqa-news-updates/hiqa-launches-public-consultation-prep-programme-prevent-hiv

Truvada—a combination of anti-HIV drugs tenofovir and emtricitabine—is widely used in combination with additional drugs in the treatment of HIV. It is also the only medication approved for use in the prevention method known as pre-exposure prophylaxis (PrEP).

Two generic versions of Truvada—marketed by Mylan and Teva, the defendants in the current litigation—are currently available in Irish community pharmacies, retailing for as little as €50 for a month’s supply. Before the launch of generics in December 2017, PrEP users in Ireland would have had to pay over €400 per month for branded Truvada.

The Irish case goes to trial as Gilead Sciences faces increasing criticism around patent claims for Truvada in the United States. Since last year a coalition of activists has called on the US National Institutes of Health to break Gilead’s patent on Truvada in the US to allow generic manufacturers to enter the market there.⁵

Following revelations in March of unenforced patents held by the US Centers for Disease Control on the use of Truvada as PrEP, US activists have called for the CDC to enforce the patents or use them as leverage to force Gilead to drop the exorbitant price it charges for Truvada in the US.⁶

A group of US senators has also called on the Dept. of Health and Human Services to enforce its patents, decrying multinational companies who reap “billions of dollars in profits without properly compensating the government for its investments.” And last week it was reported that the US Justice Department is reviewing the unenforced CDC patents.⁷

ACT UP’s Andrew Leavitt said, “Gilead’s behaviour has been disgraceful. The high price Gilead demands for Truvada has delayed PrEP access across Europe—including here in Ireland—and continues to be a huge obstacle to access in the US. This is not how a responsible, community-minded company—especially one supposedly concerned about health—should act.”

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About ACT UP Dublin:

ACT UP Dublin is a local chapter of ACT UP, The AIDS Coalition To Unleash Power, an international HIV activist organisation. ACT UP Dublin was founded in July 2016 to take action on Ireland’s HIV crisis. We seek a more urgent and effective response to HIV from government, community organisations, and the public at large.

⁵ “#BreakThePatent: How HIV activists are going after Gilead’s PrEP patent” *NBC News*, 19 July 2018. Available at: www.nbcnews.com/feature/nbc-out/breakthepatent-how-hiv-activists-are-going-after-gilead-s-prep-n892891

⁶ “An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions.” *Washington Post*, 26 March 2019. Available at: www.washingtonpost.com/business/economy/pharma-giant-profits-from-hiv-treatment-funded-by-taxpayers-and-patented-by-the-government/2019/03/26/cee5afb4-40fc-11e9-9361-301ffb5bd5e6_story.html

⁷ “Gilead defied a government HIV patent. The Justice Department has opened a review.” *Washington Post*, 24 April 2019. Available at: www.washingtonpost.com/business/economy/gilead-defied-a-government-hiv-patent-the-justice-department-has-opened-a-review/2019/04/24/16e4e20e-62bc-11e9-bfad-36a7eb36cb60_story.html