

Congress of the United States
Washington, DC 20510

December 6, 2019

The Honorable Andrei Iancu
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Director Iancu:

We write to strongly urge you to reject Gilead Science, Inc.’s pending requests to extend two patents covering tenofovir alafenamide (TAF), a life-saving chemical compound used to treat and prevent HIV, known by the trade names Descovy, Genvoya, and Biktarvy, among others. Gilead delayed the development of TAF for nearly a decade in order to squeeze as much profit out of another compound for HIV, tenofovir disoproxil fumarate (TDF)—widely known under the trade names Viread and Truvada—during that drug’s period of patent exclusivity, despite knowing TAF was likely to be safer.¹ Gilead has made an obscene \$36 billion off of Truvada since 2004,² even though thousands of Americans could have been spared injury and even death had TAF been used instead.

In 2001, Gilead scientists knew TAF was a superior treatment.³ But in 2004, Gilead misled the public about why it stopped developing TAF, claiming that TAF was unlikely to be differentiated from existing drugs.⁴ Then Gilead withheld information on its true motives for halting the development of TAF from the U.S. Patent and Trademark Office (USPTO) and the Food and Drug Administration in the process of applying for patent extension. Under your agency’s regulations, patent owners have a duty to act in good faith and disclose all information that is potentially adverse to patent extension determinations if “there is a substantial likelihood” that the agency “would consider it important.”⁵

In 2011, Gilead executive John Milligan admitted to investors that “one of the reasons why we were concerned about developing” TAF was “our own study suggesting” TDF “wasn’t the safest thing on the market.” He concluded, “It seemed like we would have a mixed message.”⁶

¹ PrEP4All Collaboration Petition regarding Gilead Sciences, Inc.’s Patent Term Extension on U.S. Patent Nos. 7,390,791 and 7,803,788. (Dec. 4, 2019)

² Rowland, Christopher. “An HIV treatment cost taxpayers millions. The government patented it. But a pharma giant is making billions.” *Washington Post* (Mar. 26, 2019), available online at https://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

³ Gilead scientists Eisenberg, He, and Lee published research detailing the “greater clinical efficacy of GS-7340” (TAF). EJ Eisenberg, GX He, and WA Lee, “Metabolism of GS-7340, a novel phenyl monophosphoramidate intracellular prodrug of PMPA, in blood,” *Nucleosides Nucleotides Nucleic Acids* (Apr.-Jul. 2001), available online at: <https://www.ncbi.nlm.nih.gov/pubmed/11562963>

⁴ In a press release announcing the end of development for GS-7340 (TAF/Descovy), Gilead wrote “Based on the safety, tolerability and efficacy of Gilead’s HIV products established in clinical studies and commercial use, Gilead does not believe that GS 7340 has a profile that differentiates it to an extent that supports its continued development.” Gilead Sciences, Inc. (Oct. 21, 2004) <https://www.gilead.com/news-and-press/press-room/press-releases/2004/10/gilead-discontinues-development-of-gs-9005-and-gs-7340-company-continues-commitment-to-research-efforts-in-hiv>

⁵ 35 U.S. Code § 156; 37 CFR § 1.765(a)

⁶ PrEP4All Collaboration Petition regarding Gilead Sciences, Inc.’s Patent Term Extension on U.S. Patent Nos. 7,390,791 and 7,803,788. (Dec. 4, 2019); In May 2005, seven scientists, six of them from Gilead, published research which concluded that GS-7340 (TAF) is “expected to result in

As you know, the USPTO has very clear existing rules requiring the disclosure of any and all information during the patent-extension process.⁷ Based on statements made by executives, it appears Gilead failed to fulfill its legal obligation to disclose its true reason for halting the development of TAF to the USPTO.

The USPTO should reject Gilead's patent extension request on the grounds that Gilead concealed information. Additionally, we urge the agency to reject Gilead's patent extension request by invoking any existing discretion, such as the Director's discretion to waive UPSTO regulations "when justice requires."⁸ The United States is dealing with a massive public health crisis. Thousands of people are unnecessarily dying from a preventable disease. If the Administration is indeed serious about ending the HIV epidemic within ten years, the USPTO must use all existing authorities to achieve this goal.

TAF, if manufactured generically, could quickly and affordably reach hundreds of thousands of Americans who are in desperate need of HIV treatment and prevention. If Gilead's monopoly is allowed to continue, it will reap a profit while Americans suffer needlessly. Gilead's behavior was deceitful and immoral.

Corporate misconduct must not be rewarded by the U.S. government through extending a government-granted monopoly on this medicine that is likely worth tens of billions of dollars. We call on the USPTO to deny Gilead's patent extension request and offer urgent relief to countless Americans confronting HIV who were denied this medicine for nearly a decade due to the greed of Gilead. We also urge you to avoid setting a very dangerous precedent for other wealthy and powerful corporations that will look to be rewarded for deception and misconduct should Gilead obtain this patent extension.

We thank you for your prompt attention to this matter.

Sincerely,



Bernard Sanders
United States Senator



Alexandria Ocasio-Cortez
United States Representative

increased clinical potency relative to tenofovir DF". Furthermore, they found that a smaller dose of GS-7340 provided increased antiviral activity and decreased systemic exposure to the damaging effects of tenofovir. William Lee et. al, "Selective Intracellular Activation of a Novel Prodrug of the Human Immunodeficiency Virus Reverse Transcriptase Inhibitor Tenofovir Leads to Preferential Distribution and Accumulation in Lymphatic Tissue," *Antimicrob Agents Chemother.* (May 2005), available online at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1087627/>

⁷ 37 CFR § 1.765(a)

⁸ 37 CFR § 1.183