

Congress of the United States  
Washington, DC 20510

December 12, 2019

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

Dear Director Iancu,

We write today to express our concerns with the alleged conduct of Gilead Sciences related to its request for patent term extensions (PTEs) for patents relevant to the company's HIV prevention medication, Descovy. We are particularly troubled by the allegation that Gilead may have intentionally delayed development of Descovy in order to maximize profits from its existing drug Truvada, despite taking the position that Descovy is a safer formulation with fewer potential harmful side effects. Given the nature of the allegations against Gilead, we request that the U.S. Patent and Trademark Office (USPTO) conduct a thorough review of Gilead's conduct in order to determine if the company has been candid and acted in good faith with regards to their request for PTEs.

Gilead is currently in the process of requesting PTEs for a pair of patents related to the drug combination tenofovir alafenamide, known as TAF. TAF, under its brand name of Descovy, recently became the second ever drug approved by the FDA for use as pre-exposure prophylaxis for HIV (PrEP). PrEP can reduce the risk of acquiring HIV by more than 90 percent.<sup>1</sup> In 2018, the Centers for Disease Control and Prevention estimated that 1.1 million Americans could benefit from PrEP.<sup>2</sup> The only other drug for PrEP currently on the market is Gilead's Truvada, which is a combination of the drugs emtricitabine and tenofovir disoproxil fumarate (TDF).

Now that Descovy has been approved for PrEP, Gilead has begun marketing it as a safer alternative to Truvada with a less toxic formulation and fewer potential adverse side effects.<sup>3</sup> Because TAF is effective in smaller doses than TDF, Gilead has taken the position that patients can take less of the drug, leading to lower levels of kidney and bone toxicity. If USPTO grants the PTEs requested by Gilead, Descovy will remain under patent until 2025, rather than 2022. Gilead sells more than \$11 billion of HIV-related products in the US every year. Based on those

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<sup>1</sup> Centers for Disease Control and Prevention, *HIV prevention pill not reaching most Americans who could benefit – especially people of color* (Mar. 6 2018) (available at <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html>).

<sup>2</sup> *Id.*

<sup>3</sup> Gilead Sciences, *Gilead Presents 96-week Discover Trial Data Supporting Non-inferior Efficacy and Key Safety Differences of Descovy For PrEP Compared With Truvada For PrEP* (Nov. 6, 2019) (available at <https://www.gilead.com/news-and-press/press-room/press-releases/2019/11/gilead-presents-96-week-discover-trial-data-supporting-non-inferior-efficacy-and-key-safety-differences-of-descovy-for-prep-compared-with-truvada-for>).

numbers, maintaining patent protection for Descovy for an additional three years alone could be worth over \$30 billion.<sup>4</sup>

Bringing a safer version of a drug that could potentially save thousands of lives to market is in the public interest. However, intentionally keeping safer versions of drugs off the market in order to maximize corporate profits is clearly not. At the heart of the allegations against Gilead is the claim that Gilead may have deliberately delayed development of the safer drugs used in Descovy by over a decade in order to maximize profits from its blockbuster drug Truvada. Indeed, Gilead initially patented the TAF formulation used in Descovy in 2000, only to allegedly abruptly cut off research and development in 2004. Since 2004, Gilead has earned over \$36 billion from sales of Truvada.<sup>5</sup>

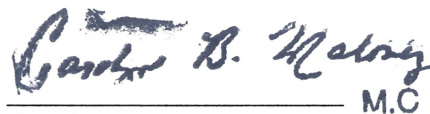
Gilead, like other pharmaceutical companies, has long argued that the billions of dollars in profits reaped from sales of prescription drugs protected by government-issued patents allow companies to “continue to innovate.”<sup>6</sup> However, if the allegations against Gilead are true, then Gilead has been incentivized to keep innovative, potentially safer drugs off the market in order to maximize profits by gaming the patent system.

Included in the allegations against Gilead is the accusation that they have acted in bad faith in requesting PTEs for Descovy and have not been candid with USPTO. Given that the extension of the patents could mean high long-term costs to both taxpayers and consumers, these serious allegations require thorough investigation by USPTO. If these allegations are found to have merit, it is hard to see how justice or the public interest would be served by extending patent protection for TAF beyond 2022. We urge you to conduct a thorough review of these allegations when determining whether or not it is appropriate to grant Gilead the requested PTEs.

Sincerely,



Debbie Stabenow  
United States Senator




Carolyn B. Maloney  
Chairwoman  
House Committee on Oversight and Reform

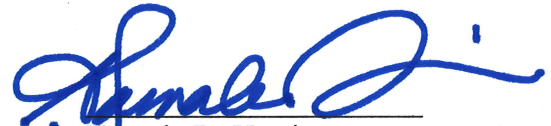
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<sup>4</sup> NASDAQ: GILD Investor Notice: Lawsuit by Consumers Against Gilead Sciences, Inc. Announced by Shareholders Foundation, Yahoo! Finance (Sept. 11, 2019) (available at <https://finance.yahoo.com/news/nasdaq-gild-investornotice-lawsuit-111500674.html>).

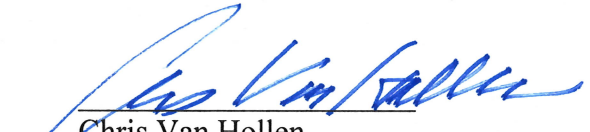
<sup>5</sup> *Petition seeking review from the U.S. Patent and Trademark Office of the Requests for Patent Term Extension on U.S. Patent Nos. 7,390,791 and 7,803,788, assigned to Gilead Sciences, Inc.*, submitted by PrEP4All Collaboration (Dec. 4, 2019).


<sup>6</sup> *The Business of Saving Lives*, Wall St. Jn. (Oct. 20, 2017) (available at <https://www.wsj.com/articles/the-business-of-saving-lives-1508538402>).


  
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United States Senator


  
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United States Senator

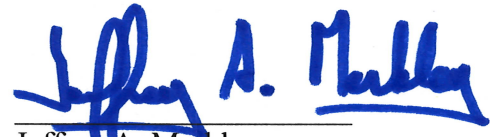
  
Richard Blumenthal  
United States Senator


  
Chris Van Hollen  
United States Senator

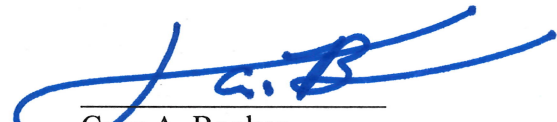
  
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