

January 31, 2020

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

Dear Director Iancu,

We, the undersigned organizations, write to urge the USPTO to reject the three-year patent term extension (PTE) requests made by Gilead Sciences, Inc. (Gilead) for tenofovir alafenamide (TAF). We strongly support the petition submitted by the PrEP4All Collaboration (PrEP4All)¹ on December 4th, 2019,^{2, 3} and their request to reject the PTE request outright or, alternatively, hold a public hearing to further investigate the circumstances around the delayed development of TAF by Gilead.

PrEP4All's petition filed with the USPTO presents evidence that Gilead voluntarily delayed development of TAF for approximately six years. As early as 2002, the company suspected TAF may lead to improved clinical outcomes for kidney and bone health in people on treatment for HIV infection compared to an older compound called tenofovir disoproxil fumarate (TDF).⁴

Evidence in PrEP4All's petition indicates that this intentional delay strategy was implemented by Gilead to avoid competition with their existing TDF-based products and to artificially increase TAF's eligibility for PTE. At present, TAF is set to go off-patent in 2022, but by intentionally delaying development of TAF for six years, Gilead cleverly rendered its patents eligible for PTE until 2025. Gilead did not disclose this gamesmanship to the USPTO. Granting a patent term extension under these circumstances would be an abuse of the PTE program--a program that is meant to compensate innovators for delays caused by the FDA, not reward or incentivize unethical decisions by corporate executives to withhold innovative and, in the company's

¹ The petition was filed on behalf of PrEP4All by the Technology Law & Policy Clinic of New York University School of Law.

²Rowland C. "Gilead delayed safer HIV drug to extend monopoly profits, advocates allege." Washington Post [Internet]. 2019 December 5. Available from: https://www.washingtonpost.com/business/economy/gilead-delayed-safer-hiv-drug-to-extend-monopoly-profits-advocates-allege/2019/12/05/71d4d6ac-1538-11ea-8406-df3c54b3253e_story.html

³ A copy of the full petition is available here: <https://breakthepatent.org/wp-content/uploads/2019/12/PrEP4All-petition-re-PTE-December-4-2019-FINAL-with-active-URLs-reduced33227.pdf>

⁴Markowitz M, Zolopa A, Squires K, et al. Phase I/II study of the pharmacokinetics, safety and antiretroviral activity of tenofovir alafenamide, a new prodrug of the HIV reverse transcriptase inhibitor tenofovir, in HIV-infected adults. *J Antimicrob Chemother.* 2014 May;69(5):1362-9. doi: 10.1093/jac/dkt532. NOTE: While this study was not published in the medical literature until 2014, its results were collected in 2003.

estimation, potentially safer medications from vulnerable communities in order to maximize profits.

As outlined in the petition filed by PrEP4All, Gilead's PTE requests to the USPTO withheld material facts about why and when it delayed development of TAF. Such corporate dishonesty warrants further investigation and scrutiny by USPTO, before granting of any extension, and likely merits complete dismissal of Gilead's petitions.

Additionally, the USPTO should consider the public health consequences of Gilead's behavior. While the safety benefits of TAF are at present debatable for HIV patients on *unboosted* treatment regimens (i.e., regimens not containing ritonavir or cobicistat) and in the case of HIV pre-exposure prophylaxis (PrEP), there is evidence of clinically significant reductions in bone and kidney toxicity in *boosted* TAF regimens compared to *boosted* TDF regimens.⁵

We find it alarming that a 2018 modeling study funded by Gilead itself estimated that **delaying access to TAF and another TDF sparing regimen by nine years** among people living with HIV in the U.S. **could lead to 16,200 more deaths and over 150,000 injuries.**⁶ If such modeling is accurate, then the company's years-long intentional delay in TAF development may have led to thousands of excess deaths, and certainly should not be rewarded by the USPTO by granting a PTE. Many HIV patients on boosted regimens currently suffer from lack of access to TAF because of its high price. Granting Gilead's request for an extended patent monopoly on TAF could mean that those patients will have to continue to wait beyond 2022 for access to low-cost generic TAF, potentially inflicting further harm. The USPTO now has an opportunity to prevent this future harm by denying Gilead's requests for PTE.

We look forward to your urgent attention to this letter. We are members of marginalized communities, as AIDS and public health advocates, and as advocates for a transparent, publicly accountable government. We depend on the USPTO and other federal agencies to enforce industry compliance with governing ethical standards. Gilead's actions around TAF and unjustified PTE requests clearly run counter to current federal and community efforts to end the HIV epidemic, and set a worrisome precedent for ethical pharmaceutical product development in America.

⁵ Hill A, Hughes SL, Gotham D, Pozniak AL. Tenofovir alafenamide versus tenofovir disoproxil fumarate: is there a true difference in efficacy and safety? J Virus Erad. 2018 Apr 1;4(2):72-79.

⁶ James Baumgardner et. al, Modeling the Impacts of Restrictive Formularies on Patients with HIV, PubMed.gov (July 24, 2018), <https://www.ajmc.com/journals/issue/2018/2018-vol24-sp8/modeling-the-impacts-ofrestrictive-formularies-on-patients-with-hiv>. (Exhibit 3) (The publication discloses that "Funding for this study was provided by Gilead Sciences to Precision Health Economics.").

Sincerely,

ACT UP

ACT UP NY

African Alliance for HIV Prevention

AIDS Action Baltimore

Alliance for Retired Americans

Black AIDS Institute

CARES of Southwest Michigan

Center for Law, Innovation and Creativity, Northeastern U. School of Law

Cero VIH PUerto .Rico

Chicago Women's AIDS Project

CrescentCare

Delaware HIV Services

Doctors for America

Health GAP (Global Access Project)

HIV AIDS Alliance of Michigan

Housing Works, Inc.

Independent Activist

Indivisible

Initiative for Medicines, Access, & Knowledge (I-MAK)

Los Angeles LGBT Center

my self has a woman living with HIV

myPLUS Malaysia

National Working Positive Coalition

NETWORK Lobby for Catholic Social Justice

Positive Malaysia Treatment Access and Advocacy Group (MTAAG+)

Positive Women's Network-USA

Prevention Access Campaign

Public Citizen

R Street Institute

SERO Project

SIECUS: Sex Ed for Social Change

SWOP Behind Bars

TCOI (Tennessee Community Outreach Initiative) formerly TAPWA (Tennessee Assoc. of People With AIDS)

The Cranky Queer Guide to Chronic Illness

Treatment Action Group (TAG)

Vaccine Advocacy Resource Group

Yale Global Health Justice Partnership