



## Yale *Global Health Justice Partnership*

A PROGRAM OF YALE LAW SCHOOL AND THE YALE SCHOOL OF PUBLIC HEALTH

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### Summary of Statement on CDC's Patents for PrEP

On March 12, 2019, the Yale Global Health Justice Partnership (“GHJP”) published a “Statement on CDC’s Patents for PrEP” by GHJP fellow and patent attorney Christopher Morten, which presents analysis of certain patents owned by the U.S. government that appear relevant to use of TRUVADA® tablets for pre-exposure prophylaxis (“PrEP”) against HIV infection.

The key conclusions of the Statement are these: The U.S. Patent and Trademark Office determined that U.S. government inventors affiliated with the Centers for Disease Control and Prevention were the first to determine that the drugs in Gilead’s TRUVADA® tablets can be used to prevent HIV transmission. Through patents that it owns, which we’ve termed “CDC’s Patents for PrEP,” the U.S. government appears to have a legal right to prevent anyone in the United States from using these drugs for this purpose without its permission.

This document provides a summary of relevant facts and conclusions in the Statement.

- **The U.S. government owns patents that cover HIV PrEP:** “CDC’s Patents for PrEP” are U.S. Patent Nos. [9,044,509](#), [9,579,333](#), and [9,937,191](#). Each patent is entitled “Inhibition of HIV Infection through Chemoprophylaxis.” Broadly speaking, each of the patents claims methods of protecting a person from infection by an immunodeficiency retrovirus, e.g., HIV-1, by administering to the person a combination of two drugs, (1) emtricitabine and (2) tenofovir or a chemical derivative of tenofovir known as an ester, such as the tenofovir ester tenofovir disoproxil fumarate, prior to exposure to the virus. In plainer terms, each of CDC’s Patents for PrEP covers HIV PrEP with a combination of emtricitabine and tenofovir disoproxil fumarate, the two drugs in TRUVADA® tablets sold by Gilead Sciences, Inc. (“Gilead”). Each patent is assigned to—that is, owned by—the United States of America, as represented by the Secretary of the Department of Health and Human Services. The research underlying the patents appears to have been performed at the Centers for Disease Control and Prevention (“CDC”).
- **The first patent issued in 2015 and is expected to remain in force until 2031:** The first of CDC’s Patents for PrEP, U.S. 9,044,509, issued—that is, was granted by the U.S. Patent and Trademark Office (“USPTO”) and became legally enforceable—on June 2, 2015 and is scheduled to remain in force until May 12, 2031. The other two patents issued later and are scheduled to remain in force until January 31, 2027.



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- CDC’s Patents for PrEP appear valid and enforceable:** Patents can be contested, and not all of them survive later challenge. But based on our preliminary review, CDC’s Patents for PrEP appear to be valid and enforceable. All three patents were reviewed by a patent examiner of the USPTO, who concluded that the patents’ claims are compliant with all requirements and conditions of patentability under U.S. law. Our research shows that the patent examiner, after conducting a search, did not identify any prior art—that is, prior public disclosure, such as a patent or a scientific article—that describes prevention of HIV infection in an uninfected patient by administering, by mouth, a combination of emtricitabine and tenofovir or a derivative of tenofovir. As such, the examiner concluded that the patents’ claims are novel. The examiner also concluded that the patents’ claims are nonobvious in view of significant differences between the claimed methods and what was known in the prior art and in view of certain beneficial, unexpected properties of the claimed methods. The apparent validity of CDC’s Patents for PrEP is corroborated by the fact that a counterpart patent in Europe, [European Patent No. 2,015,753](#), was challenged by the generic pharmaceutical company Mylan in an intensive, multi-year proceeding before the European Patent Office known as an opposition. The European patent survived the opposition.
- Use of Gilead’s TRUVADA® tablets appears to infringe CDC’s Patents for PrEP:** Gilead sells an emtricitabine and tenofovir disoproxil fumarate product under the brand name TRUVADA®. TRUVADA® tablets are indicated—that is, FDA-approved—for PrEP against infection by HIV-1. Comparison of an exemplary claim of CDC’s Patents for PrEP (claim 1 of U.S. 9,044,509) with [the prescribing information that Gilead provides with TRUVADA® tablets](#)—the drug “labeling” that instructs doctors on how to use TRUVADA® tablets—reveals that use of TRUVADA® tablets for PrEP according to these instructions appears to infringe at least this exemplary patent claim. (To “infringe” a patent claim is to violate the patent holder’s exclusive right to control the use of the patented invention.)
- The U.S. government could assert the patents and seek money damages:** Infringement of a patent claim can create liability, including potential money damages owed to the patent owner. Should the U.S. government decide to enforce claim 1 of U.S. 9,044,509, the exemplary claim noted above, or other, similar claims of CDC’s Patents for PrEP, the U.S. government could possibly be entitled to collect money damages.