U.S. Sen. Baldwin: Joins colleagues to raise concerns about potential patent infringement by pharmaceutical company Gilead Sciences and high price of its HIV-prevention drug, Truvada

Posted on Thursday, Apr 25, 2019

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WASHINGTON, D.C. – U.S. Senator Tammy Baldwin joined her Senate colleagues to raise concerns about reports that pharmaceutical company Gilead Sciences is profiting from an HIV-prevention drug that infringes upon patents owned by the United States Government and selling it at a price that makes the drug unaffordable for many Americans.

The Senators, led by Senator Debbie Stabenow (D-MI), asked the Department of Health and Human Services (HHS) to detail what steps have been taken to make sure that government-held patents are properly licensed, to ensure that any potential patent infringements are acted upon, and to document how they take the affordability of drugs into consideration when licensing patents.

"Gilead charges between $1,600 to $2,000 for a month's supply of Truvada and generated $3 billion in revenue off of Truvada sales last year," **the Senators wrote.** *"Gilead's Truvada relies on the usage of...[processes that were] invented –*

and patented – by scientists working for the CDC. Those patents are held by the United States of America, as represented by the Secretary of the Department of Health and Human Services (HHS).”

“Although Secretary Azar has stated that negotiations are ongoing, Gilead has reportedly reached no agreement with the government that would allow them to make use of these patented methods,” **the Senators continued.** *“The government should also be willing to enforce its patents and take legal action against companies that appear to be infringing on their patents, in order to prevent multinational companies from reaping billions of dollars in profits without properly compensating the government for its investments.”*

Senators Richard Blumenthal (D-CT), Ben Cardin (D-MD), Tammy Duckworth (D-IL), Bernie Sanders (I-VT), and Chris Van Hollen (D-MD) joined Senators Baldwin and Stabenow in sending the letter.

The full letter is available below. An online version of this release is available here.

April 23, 2019

The Honorable Alex M. Azar II

Secretary

U.S. Department of Health and Human Services

200 Independence Avenue, S.W.

Washington, DC 20201

Dr. Robert Redfield, M.D.

Director

Centers for Disease Control and Prevention

1600 Clifton Road

Atlanta, GA 30333

Dear Secretary Azar and Director Redfield:

We write today regarding recent reports that the Centers for Disease Control and Prevention (CDC) has patented methods for the prevention of HIV infection that are relevant to Gilead Science's prescription drug Truvada. Gilead charges between $1,600 to $2,000 for a month's supply of Truvada and generated $3 billion in revenue off of Truvada sales last year. We are deeply concerned that a drug company is marketing a product that appears to potentially be infringing upon patents owned by the United States Government and selling it at a price that makes the drug unaffordable for many Americans. We would like to know what steps have been taken to ensure that any usages by private companies of government-held patents are properly licensed and that any potential infringements are acted upon.

The federal government is the major funder of basic research, much of which ultimately leads to the discovery and development of innovative drugs. According to the Government Accountability Office, in 2014 alone the National Institute of Health (NIH) obligated $13.6 billion to basic research; pharmaceutical companies in the U.S. contributed $6.3 billion towards basic research that year. Gilead's Truvada relies on the usage of the drugs emtricitabine and tenofovir for pre-exposure prophylaxis against HIV (PrEP). PrEP was invented – and patented – by scientists working for the CDC. Those patents are held by the United States of America, as represented by the Secretary of the Department of Health and Human Services (HHS).

Based on an analysis of these patents and the FDA-approved prescribing information for Truvada, Gilead appears to potentially be marketing a prescription drug for usages that are patented by the government. Although Secretary Azar has stated that negotiations are ongoing, Gilead has reportedly reached no agreement with the government that would allow them to make use of these patented methods. When the government holds a patent, licenses should be granted on terms that make it economically viable for industry to develop drugs, but allow the government to recoup its investment and fund further research as well as ensure that drugs developed using government-owned patents are affordable. The government should also be willing to enforce its patents and take legal action against companies that appear to be infringing on their patents, in order to prevent multinational companies from reaping billions of dollars in profits without properly compensating the government for its investments. For these reasons we ask that

you provide us with the following:

1. Please provide copies of any HHS or CDC policies, procedures, or guidance related to the filing for a patent, licensing patents held by the United States of America, and for identifying cases of potential infringement and enforcing patent rights that may be subject to such infringement.
2. Please provide us with the number of patents currently held by the United States of America, as represented by the Secretary of the Department of Health and Human Services, and of those, how many have currently been licensed for use by pharmaceutical companies.
3. Please document for us how HHS or CDC take into consideration the affordability of prescription drugs when licensing patents held by the United States of America.
4. Please provide a detailed summary of the status of negotiations between HHS or CDC and Gilead regarding any patents held by the United States of America related to the use of drugs emtricitabine and tenofovir for PrEP held by the United States of America. Please include a summary of communications between HHS or CDC and Gilead.
5. Please provide a detailed summary of the steps that HHS or CDC have taken to identify any specific instances of infringement upon the patents related to the drugs emtricitabine and tenofovir for PrEP held by the United States of America and the steps HHS or CDC have taken to enforce its patents and to hold infringers liable.

Please provide us with a complete response to these requests no later than May 7, 2019. Thank you for your prompt attention to this matter.