United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

September 18, 2024

Daniel O'Day
Chairman and Chief Executive Officer
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Mr. O'Day:

Recent research published in the journal *Nature Biotechnology* identified errors in the calculation of patent term adjustment (PTA) by the U.S. Patent and Trademark Office (USPTO) that appear to have extended the duration of patents held by certain pharmaceutical companies beyond the statutorily prescribed expiration dates.

According to the researchers, Gilead Sciences received 108 days of excess patent protection for U.S. Patent No. 7,390,791, which claims the active ingredient of Gilead's HIV medicine, Genvoya. The researchers estimate that this additional patent period—based upon an error by the USPTO—could result in approximately $520 million in additional revenue for Gilead. Taxpayers already spend a significant amount on Genvoya—including more than $7.4 billion in Medicare and Medicaid expenditures for the medication between 2018 and 2022.

While USPTO regulations do not require patent holders to report errors in PTA, pharmaceutical companies regularly petition the USPTO to correct errors that result in less PTA than that to which the companies were entitled. Pharmaceutical companies should likewise report errors that result in excess PTA. Yet, a review of the USPTO's Patent Center database suggests that Gilead has not reported any errors regarding potential excess PTA for U.S. Patent No. 7,390,791. If this error is not corrected, we fear Gilead will receive millions of dollars in gains at taxpayer expense.

To understand Gilead's position and intentions with respect to U.S. Patent No. 7,390,791, we ask that you respond to the following questions no later than October 11, 2024:

1. Does Gilead dispute that its U.S. Patent No. 7,390,791 received 108 days of excess PTA? If so, please provide Gilead's calculation of the proper amount of PTA for the patent.
2. When did Gilead become aware of the excess PTA granted to U.S. Patent No. 7,390,791?
3. Does Gilead commit to reporting the excess PTA granted to U.S. Patent No. 7,390,791 to the USPTO and asking for a correction? If not, why not?
4. The U.S. Food and Drug Administration's (FDA's) *Approved Drug Products with Therapeutic Equivalence Evaluations*, or "Orange Book," lists the expiration date for U.S. Patent No. 7,390,791 as April 17, 2025—a date the includes the erroneously

calculated PTA. Does Gilead commit to correcting the patent's expiration date in the Orange Book? We remind you that patent information included in the Orange Book is submitted to the FDA under penalty of perjury.

Thank you for your attention to this issue. We look forward to your prompt response.

Sincerely,

Richard J. Durbin
United States Senator

Peter Welch
United States Senator

Richard Blumenthal
United States Senator

Amy Klobuchar
United States Senator

Christopher A. Coons
United States Senator