

September 18, 2024

Emma Walmsley
Chief Executive Officer
GSK
79 New Oxford Street
London
WC1A 1DG
United Kingdom

Dear Ms. Walmsley:

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, GSK received 69 days of excess patent protection for U.S. Patent No. 8,273,360, which claims the active ingredient of GSK's vaccine, Bexsero. The researchers estimate that this additional patent period—based upon an error by the USPTO—could result in approximately \$128.5 million in additional revenue for GSK. Taxpayers already spend a significant amount on Bexsero—including more than \$2.2 billion in Medicare 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 GSK has not reported any errors regarding potential excess PTA for U.S. Patent No. 8,273,360. If this error is not corrected, we fear GSK will receive millions of dollars in gains at taxpayer expense.

To understand GSK's position and intentions with respect to U.S. Patent No. 8,273,360, we ask that you respond to the following questions no later than October 11, 2024:

1. Does GSK dispute that its U.S. Patent No. 8,273,360 received 69 days of excess PTA? If so, please provide GSK's calculation of the proper amount of PTA for the patent.
2. When did GSK become aware of the excess PTA granted to U.S. Patent No. 8,273,360?
3. Does GSK commit to reporting the excess PTA granted to U.S. Patent No. 8,273,360 to the USPTO and asking for a correction? If not, why not?

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

Sincerely,



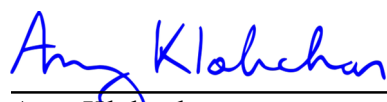
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United States Senator



Amy Klobuchar
United States Senator



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United States Senator