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United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

September 18, 2024

Christopher A. Viehbacher
President and Chief Executive Officer
Biogen Inc.
225 Binney Street
Cambridge, MA 02142

Dear Mr. Viehbacher:

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, Biogen received 93 days of excess patent protection for U.S. Patent No. 8,017,733, which claims the active ingredient of Biogen's multiple sclerosis medicine, Plegridy. The researchers estimate that this additional patent period—based upon an error by the USPTO—could result in approximately \$37.8 million in additional revenue for Biogen. Taxpayers already spend a significant amount on Plegridy—including \$386.7 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 Biogen has not reported any errors regarding potential excess PTA for U.S. Patent No. 8,017,733. If this error is not corrected, we fear Biogen will receive millions of dollars in gains at taxpayer expense.

To understand Biogen's position and intentions with respect to U.S. Patent No. 8,017,733, we ask that you respond to the following questions no later than October 11, 2024:

1. Does Biogen dispute that its U.S. Patent No. 8,017,733 received 93 days of excess PTA? If so, please provide Biogen's calculation of the proper amount of PTA for the patent.
2. When did Biogen become aware of the excess PTA granted to U.S. Patent No. 8,017,733?
3. Does Biogen commit to reporting the excess PTA granted to U.S. Patent No. 8,017,733 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.

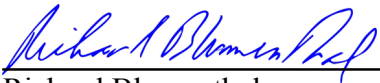
Sincerely,



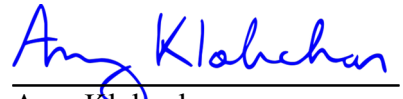
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United States Senator



Peter Welch
United States Senator



Richard Blumenthal
United States Senator



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United States Senator



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