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

September 18, 2024

The Honorable Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the U.S. Patent and Trademark Office
U.S. Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Dear Director Vidal:

We write regarding recent research that found pharmaceutical companies are benefitting from U.S. Patent and Trademark Office (USPTO) errors in the calculation of patent term adjustment (PTA). Those errors have extended the lives of drug patents held by the companies beyond the expiration dates dictated by statute. As a result, pharmaceutical companies are able to delay generic competition and continue charging monopoly prices, potentially costing consumers and taxpayers hundreds of millions of dollars in excess costs.

PTA allows a patent holder to extend the term of their patent to account for delays caused by the USPTO during the prosecution of the patent. In the ordinary course of business, the USPTO calculates PTA using a computer program that accesses information recorded in the Patent Application Locating and Monitoring (PALM) system. As the USPTO has recognized, "[t]he PALM system was not originally designed for the purpose of calculating patent term adjustment."[1]

Whether due to shortcomings of the PALM system or the complex nature of the PTA calculation, errors in PTA are not uncommon.[2] In recognition of these errors, USPTO regulations allow patent holders to request reconsideration of PTA. The USPTO conducts a manual determination of PTA in response to such a request.

The profits earned on the sale of brand-name drugs ensure that pharmaceutical companies confirm the USPTO's PTA calculations for all patents covering their drugs and seek reconsideration of any PTA calculation that shortchanges the company. After all, blockbuster drugs can earn pharmaceutical manufacturers millions of dollars per day, so there is an incentive to maximize each additional day of market exclusivity. When successful, a request for reconsideration can correct significant USPTO errors and extend the life of a patent by one year

[1] Revisions To Implement the Patent Term Adjustment Provisions of the Leahy-Smith America Invents Act Technical Corrections Act, 79 Fed. Reg. 27,757 (May 15, 2014).
[2] *See* Dinis Cheian, *I See Dead Patents: How Bugs in the Patent System Keep Expired Patents Alive*, 33 Fordham Intell. Prop. Media & Ent. L.J. 1, 21-27 (2022) (describing at least two types of PALM errors leading to excess PTA).

or more.[3] However, pharmaceutical companies have challenged PTA calculations when the error is as small as a single day.[4]

These same financial incentives may lead pharmaceutical companies to refrain from reporting USPTO errors that result in PTA that is longer than deserved. An article recently published in the journal *Nature Biotechnology* found that eight of 200 key drug patents reviewed received excess PTA.[5] The excess PTA granted extended the lives of these patents by between 32 and 190 days. If the extended patent terms successfully delay generic competition, the pharmaceutical companies can make additional revenue of between $37.8 million and $519.6 million.

Surprisingly, the USPTO does not require pharmaceutical companies to disclose these errors when discovered. In fact, the USPTO's *Manual of Patent Examining Procedure* (MPEP) makes disclosure of such an error entirely voluntary, stating that "[i]f a registered practitioner receives a patent term adjustment indicated on the front of the patent that is longer than expected, the practitioner ***may disclose*** the error to the Office."[6] This contrasts with the duty of candor and good faith the USPTO imposes on patent applicants. That duty ***requires*** applicants to disclose information material to patentability during the examination process.[7] Failure to meet that duty can result in the patent being found unenforceable.

We urge the USPTO to update its approach to PTA, particularly in the case of patents listed in the U.S. Food & Drug Administration's (FDA's) *Approved Drug Products with Therapeutic Equivalence Evaluations*, or "Orange Book," and *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, or "Purple Book." These are patents that include claims that cover, among other things, drug products and approved methods of use. Because entry of lower-cost generic drugs and biosimilars often is keyed to the expiration dates of Orange Book- and Purple Book-listed patents, any excess PTA granted to those patents ultimately costs consumers and U.S. taxpayers.

To better understand the USPTO's current approach to PTA and potential alternatives, please respond to the following questions no later than October 11, 2024:

1. Other than when a patentee petitions for reconsideration of PTA for its patent, does the USPTO take any steps to ensure PTA calculations are correct? If not, why not?
2. Has the USPTO undertaken any investigation, study, or other effort to understand how often errors in PTA occur? If not, will the USPTO commit to undertaking such an effort now?
3. What caused the errors in PTA identified in the article recently published in *Nature Biotechnology*? Were these errors one-time issues or emblematic of more systemic issues in the calculation of PTA? What corrective action has the USPTO taken or will the USPTO take to ensure similar errors do not occur in the future?

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[3] *See, e.g.*, U.S. Patent No. 7,445,775 (including manual adjustment of 659 days)
[4] *See ArQule, Inc. v. Kappos*, 793 F. Supp. 2d 214 (D.D.C. 2011).
[5] *See* S. Sean Tu et al., *The Cost of Drug Patent Expiration Date Errors*, 42 NATURE BIOTECHNOLOGY 1024 (July 2024).
[6] MPEP § 2733 (emphasis added).
[7] 37 C.F.R. § 1.56.

4. The USPTO has recognized that its PALM system "was not originally designed for the purpose of calculating patent term adjustment." What shortcomings does the PALM system have in calculating PTA? What additional funds or resources are necessary to address those shortcomings or create a new system better designed for calculating PTA?
5. Will the USPTO commit to reviewing PTA calculations for patents listed in the FDA's Orange Book and Purple Book, and to correcting those PTA calculations where necessary? If not, why not?
6. Why is reporting excess PTA left to the discretion of patentees? Will the USPTO commit to updating the MPEP to require patentees to report excess PTA?
7. Should reporting excess PTA be part of a patentee's duty of candor and result in patent unenforceability, or other penalty, when violated?

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