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# **Recommendations for Statutory Reform of the Patent Term Extension System to Increase Public Accountability and Fight Soaring Drug Prices**

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# Executive Summary

In the past 40 years, patent protections on pharmaceutical drugs have effectively lengthened to nearly double the standard 20-year monopoly intended by patent law. The lengthening of patent monopolies has contributed to skyrocketing pharmaceutical drug prices and healthcare costs. A significant driver of this trend has been the patent term extension (PTE) provision of the Hatch-Waxman Act, 35 U.S.C. § 156, which allows drug companies to delay the expiration dates of already-issued patents on prescription drugs, lengthening their patent monopolies. This paper suggests legislative reforms to the PTE provision to restrict improper patent term extensions and make the patent system more democratic and transparent to the public.

Section I—*Introduction*—provides background. This section opens with a bit of history: When an HIV/AIDS activist group attempted to bring evidence of a drug company’s illicit manipulation of PTE to the United States Patent and Trademark Office (PTO), the PTO rejected the petition without considering its merits, due to a PTO rule barring third-party challenges to PTE. While this PTO rule (which remains in effect) is not required by the PTE statute, it is enabled by a vague PTE statutory provision. Section I also includes a summary of the major statutory reform recommendations set forth later in this white paper. The recommendations aim to increase transparency at the PTO and its accountability to the public in processing PTE applications. The recommendations also aim to curb abuse of the PTE system by drug companies that can harm patients and competition. The proposed solutions include amending the statutory provision to:

- provide a pathway at the PTO for third parties to challenge a breach of the duty of disclosure by the PTE applicant,
- specify a minimum set of information considered “material” under the duty of disclosure and therefore subject to mandatory disclosure, including certain information relevant to the public interest,
- create a range of penalties for failure to disclose material information, and
- place the burden of proof of meeting the duty of disclosure and the due diligence requirement on the PTE applicant.

Section II—*The Patent Term Extension Provision*—explains the patent system generally and the PTE system specifically.

Section III—*Two Important Open Questions on Patent Term Extension Today*—situates this white paper's reform proposals in the PTE system's historical context and describes two important open questions about the PTE system today. First, is PTE worth keeping? Second, if so, what reforms are needed? PTE's very existence was hotly debated at its inception—its opponents did not believe PTE was necessary to incentivize innovation and considered it an unnecessary handout to pharmaceutical companies. These historical arguments against this system continue to be relevant today.

Section IV—*Proposed Amendments to Improve the PTE Provision*—presents 10 specific proposed legislative amendments to the PTE provision, 35 U.S.C. § 156. Most of the proposals center on increasing the public transparency and accountability of PTE applications by strengthening PTE applicants' disclosure requirements. Currently, the PTE statute creates some disclosure requirements to the PTO for the PTE applicant. However, the statute does not provide any guidance on what type of information should be disclosed, and merely delegates authority to the PTO's director to define those requirements. By providing overly broad latitude to the PTO in defining disclosure requirements, the statute affords the requirements little weight. Other proposed statutory amendments would strengthen the ability of third parties to submit relevant evidence to the PTO. Ultimately, the white paper's proposed statutory amendments aim to improve the PTE system by making it less biased in favor of the patent holder, and more responsive and accountable to the public.

# I. Introduction

In December 2019, an HIV-prevention group called PrEP4All filed a petition at the United States Patent and Trademark Office (PTO) to challenge Gilead Sciences' application to extend the patent on one of its HIV drug compounds.<sup>1</sup> PrEP4All had discovered evidence that Gilead was intentionally manipulating the patent term of its compound through a delay tactic in the development of the drug and had unethically withheld evidence of its actions from the PTO. PrEP4All sought to alert the PTO of Gilead's actions while the PTO considered Gilead's request for PTE.<sup>2</sup> Yet, remarkably, the PTO chose to ignore the evidence of Gilead's ethical violation and denied PrEP4All's petition on a technicality.<sup>3</sup> In the words of the PTO, "...the PTE statute, regulations, and procedures do not provide for the PTO, an agency charged with the examination and issuance of patents and trademark registrations and related proceedings, to base a PTE determination on public health and safety interests, let alone on information about an asserted public health and safety interest provided by a third party."<sup>4</sup> Essentially, the PTO rejected PrEP4All's petition without considering its merits based on a rule the office has promulgated to bar third-party petitions on PTE.<sup>5</sup> This highly undemocratic rule was not required by the statutory provision for PTE, but it was enabled by the vague statutory language.

- 1 *See generally* Christopher Rowland, Gilead Delayed Safer HIV Drug to Extend Monopoly Profits, *Advocates Allege*, WASH. POST (Dec. 5, 2019), [https://www.washingtonpost.com/business/economy/gilead-delayed-safer-hiv-drug-to-extend-monopoly-profits-advocates-allege/2019/12/05/71d4d6ae-1538-11ea-8406-df3c54b3253e\\_story.html/](https://www.washingtonpost.com/business/economy/gilead-delayed-safer-hiv-drug-to-extend-monopoly-profits-advocates-allege/2019/12/05/71d4d6ae-1538-11ea-8406-df3c54b3253e_story.html/) The author was part of the legal team that prepared the petition on behalf of PrEP4All.
- 3 *See Statement: USPTO Director Andrei Iancu Rewards Gilead Billions for Intentionally Delaying Safer Drug*, PrEP4ALL, <https://www.prep4all.org/news/statement-uspto-director-andrei-iancu-rewards-gilead-billions-of-dollars-for-intentionally-delaying-a-safer-drug> (last visited May 23, 2020).
- 4 *See* Third Party Petition Relating to the Applications for Patent Term Extension in U.S. Patent Nos. 7,390,791 and 7,803,788, 2020 WL 3468297 (Feb. 14, 2020).
- 5 *See* Scott Graham, PTO Rejects Gilead's Bid to Invalidate US HIV Patents, *LAW.COM* (Feb. 5, 2020), <https://www.law.com/nationallawjournal/2020/02/05/pto-rejects-gileads-bid-to-invalidate-us-hiv-patents/>

PrEP4All's experience challenging Gilead's PTE application illuminated problems with the PTE system as it currently exists. This white paper aims to address the problems of the PTE statutory provision through statutory reform. The paper first briefly traces the history of patent term extension for pharmaceuticals in the United States, then identifies problems with the current statutory provision governing PTE that enables patent manipulation and proposes a short list of solutions to improve the patent term extension system. The proposed solutions include amending the statutory provision to:

- provide a pathway at the US Patent and Trademark Office (PTO) for third parties to challenge a breach of the duty of disclosure by the PTE applicant,
- specify a minimum set of information considered “material” under the duty of disclosure and therefore subject to mandatory disclosure, including certain information relevant to the public interest,
- create a range of penalties for failure to disclose material information, and
- place the burden of proof of meeting the duty of disclosure and the due diligence requirement on the PTE applicant.

These amendments would make the patent system more democratic and transparent by increasing the amount of information that PTE applicants provide the PTO and the public, and by enabling public participation in the patent term extension system. The amendments aim to prevent gamesmanship of the patent term extension system by improving the PTO's detection of manipulation of patent term extension, disincentivizing the PTE applicant from concealing information material to public health, and permitting the PTO to include public interest factors while considering whether to grant PTE. Ultimately, the proposed reforms make prescription drugs and other medical products more affordable by curtailing the manipulation of PTE to artificially lengthen patent monopolies on those products.

## II. The Patent Term Extension Provision

### A. Introduction to the Patent System

The patent system is intended to drive innovation. A grant of monopoly incentivizes the invention of novel products: an inventor who holds a patent can exclude competitors for some period of time, charge high prices and earn large profits, recoup her investment in research, and invest profits in new research. Yet, the patent monopoly is limited by design. When the patent monopoly ends, competitors may make and sell the invention freely, and the public gets access to the invention at a lower cost. In this way, the patent system, by its very nature, balances the need for public access to technology against inventors' incentives to innovate. Limiting the patent monopoly to a relatively short period of years may also promote new invention, as the entrance of competitors can stimulate further innovation.

#### 1. ONE FORM OF MANIPULATION OF THE PATENT SYSTEM: EVERGREENING

Congress has determined that 20 years is an adequate grant of monopoly for the patent system to function as a driver of innovation for the public good.<sup>6</sup> However, over time, sophisticated patentees have developed various tactics to manipulate a monopoly on a particular invention to extend beyond 20 years. The pharmaceutical industry has become perhaps the most sophisticated industry of all at extending its patent monopolies.

One of the most common monopoly-extending tactics is evergreening, which is the piling of new patent protections onto an existing drug by making small changes to the drug, each of which can be patented anew. Evergreening extends the effective duration of patent protection and delays generic competition.<sup>7</sup> Examples of evergreening include patenting new delivery methods, new dosages, slight modifications of the drug compound, or changing the color of the tablets. Most evergreening tactics do not amount to significant medical improvements.<sup>8</sup> A 2018 study on the 12 best-selling drugs in the US shows that through tactics to manipulate patent protection, these drugs have an average of 38 years of patent exclusivity, rather than the 20 years contemplated by the patent statute.<sup>9</sup> Evergreening has sparked justifiable outrage because of its effects on drug prices and the overall cost of healthcare. Due in part to evergreening tactics, drug prices went up by 68% from 2012 to 2018.<sup>10</sup>

<sup>6</sup> See 35 U.S.C. § 154.

<sup>7</sup> See *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, I-MAK at 5. <https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/>; Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J. OF L. & BIOSCI. 3 (Dec. 2018), 590.

<sup>8</sup> See Allie Nawrat, *From Evergreening to Thicketing: Exploring Manipulation of the Pharma Patent System*, I-MAK [https://pharma.nridigital.com/pharma\\_nov19/from\\_evergreening\\_to\\_thicketing\\_exploring\\_manipulation\\_of\\_the\\_pharma\\_patent\\_sys](https://pharma.nridigital.com/pharma_nov19/from_evergreening_to_thicketing_exploring_manipulation_of_the_pharma_patent_sys) (last visited Mar. 19, 2020).

<sup>9</sup> See *supra* note 7 at 2.

<sup>10</sup> *Id.*

## B. Manipulation of Patent Monopolies Through Patent Term Extension

The pharmaceutical industry has ways other than evergreening to extend its patent monopolies. One of these is PTE, which allows drug companies to extend their patent protection without even getting a new patent. Patent term extension attracts less attention than evergreening, yet it too is a significant barrier to competition and patient access to medicines.

To understand patent term extension, a bit of historical context may be helpful. The American public has always had an expectation that it is entitled to enjoy a patented invention after the end of the patent exclusivity period—that is, to make, import, use, and sell the patented invention without any need to pay or obtain the permission of the patent holder. This expectation is a “bedrock principle” of our patent system, so contravening that expectation ought to require extraordinary circumstances.<sup>11</sup> Prior to 1984, consistent with this bedrock principle, Congress granted patent term extensions rarely, on a case-by-case basis, to compensate patent holders for extraordinary circumstances like the disruption of war, or to rectify an inequity affecting a particular patent.<sup>12</sup> Patent term extensions were not granted to patent holders as a matter of right.

Today, things are different. The Patent Term Extension provision,<sup>13</sup> which was first enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, provides a way for certain patent holders to get their patents extended as a matter of course. Patents on prescription drugs, medical devices, animal drugs, food additives, biological products under the Virus-Serum-Toxin Act, and other products regulated by the US Department of Agriculture (USDA) and the Food and Drug Administration (FDA) can and frequently are extended based on the amount of time the product spent in regulatory review. Patents on these products can be extended up to five years,<sup>14</sup> giving the patent holder 25 years of monopoly—five years longer than patent holders in other industries enjoy, and five years longer than the public generally expects.

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11 “[O]n the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property. It is upon this condition that the patent is granted.” *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896); “[I]t is a bedrock principle of our patent system that when a patent expires, the public is free to use not only the same invention claimed in the expired patent but also obvious or patentably indistinct modifications of that invention.” *Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1214 (Fed. Cir. 2014).

12 1 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW *Patent Term Extension* § 6:23 (June 2019 update).

13 See 35 U.S.C. § 156.

14 35 U.S.C. § 156(g)(6)(A).

The patent term extension provision calculates the amount of extension given to a patent based on two distinct periods within the FDA's regulatory review process. The first period is the time the drug spends in clinical development<sup>15</sup> after being given permission under the FDA's Investigational New Drug program (the IND period).<sup>16</sup> The second period is the New Drug Application period,<sup>17</sup> which is the time the FDA reviews the drug sponsor's request for marketing approval (the NDA period).<sup>18</sup> The amount of extension for which the patent is eligible is calculated by adding one-half of the IND period and the full NDA period.<sup>19</sup> The statutory provision states that the extension must be reduced by the amount of time the applicant did not act with due diligence, cannot extend beyond 14 years from the date on which the patented product received regulatory approval, and cannot exceed five years total.<sup>20</sup>

While a patent applicant is presumed to be entitled to a patent by statute,<sup>21</sup> there is no corresponding statutory presumption that a patent owner is entitled to a patent term extension.<sup>22</sup> Yet, while the provision does not create a presumption of patent term extension, the PTO has acted as if it does. Today, the vast majority of patent term extension applications are granted by the PTO. Between 1984 and 2007, 1,113 patent term extension applications were filed for 894 FDA-approved drugs, and only 122 were denied or dismissed<sup>23</sup>—a grant rate of almost 90%. Those applications that were denied or dismissed were denied or dismissed because the applicant did not meet some basic requirement in the statutory provision, such as establishing that the patented drug in question was the first permitted commercial marketing of the active ingredient,<sup>24</sup> that the drug was ever approved by the FDA in the first place, or that the PTE application was timely filed.

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15 Before the clinical development stage, animal and toxicology studies are performed to assess risk on human testing. After data from this initial stage is gathered, pharmaceutical companies obtain permission from the FDA's Investigational New Drug (IND) program to start human clinical trials. That period of human clinical testing is the IND period. See *Investigational New Drug (IND) Application*, U.S. FOOD AND DRUG ADMINISTRATION (Jan. 22, 2020), <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application>

16 35 U.S.C. § 156(g)(1)(B).

17 According to the FDA, “[t]he NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. The data gathered during the animal studies and human clinical trials of an Investigational New Drug (IND) become part of the NDA.” *New Drug Application (NDA)*, U.S. Food and Drug Administration (June 10, 2019), <https://www.fda.gov/drugs/types-applications/new-drug-application-nda>.

18 *Id.* § 156(g)(1)(B).

19 35 U.S.C. § 156(c)(2).

20 35 U.S.C. § 156(c)(1), (c)(3), (g)(6)(A).

21 35 U.S.C. § 102(a) (“A person shall be entitled to a patent unless...”).

22 35 U.S.C. § 156(d)(4) (permitting the Director of the PTO to define disclosure requirements), § 156(e) (“If the Director determines that a patent is eligible for extension under subsection (a) and that the requirements of paragraphs (1) through (4) of subsection (d) have been complied with, the Director shall issue to the applicant for the extension of the term of the patent a certificate of extension...”).

23 Erika Lietzan, *Patent Term Restoration - Denied!*, OBJECTIVE INTENT (Jan. 7, 2019), <https://objectiveintent.blog/2019/01/07/patent-term-restoration-denied/>

24 “An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.” *Drugs@FDA Glossary of Terms*, U.S. FOOD AND DRUG ADMINISTRATION (Nov. 14, 2017), <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>

Patent term extension has become common practice for many top-selling pharmaceuticals. Consider the 20 drugs that were the top-selling, by total sales, in the United States as of 2018.<sup>25</sup> Of those 20 drugs, at least 12 have received a patent term extension (as of this writing), keeping competition at bay and prices and revenues high for the patent holders.<sup>26</sup>

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25 Kyle Blankenship, The Top 20 Drugs by 2018 U.S. Sales, FIERCE PHARMA (Jun. 17, 2019 7:00 AM), <https://www.fiercepharma.com/special-report/top-20-drugs-by-2018-u-s-sales>

26 As of spring 2020, patents on at least the following Top 20 drugs have received PTE: adalimumab (Humira), lenalidomide (Revlimid), etanercept (Enbrel), nivolumab (OPDIVO), aflibercept (Eylea), apixaban (Eliquis), elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (GENVOYA), pregabalin (Lyrica), ustekinumab (Stelara), Pneumococcal 13-valent Conjugate Vaccine (Pneumovax 13), recombinant humanized monoclonal IgG1 antibody (Avastin), liraglutide (rDNA origin) injection (Victoza). See *Patent Terms Extended Under 35 USC §156*, USPTO

<https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156> (evidencing grant of PTE for patents covering all products except elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (GENVOYA)); U.S. Patent No. 7,390,791, USPTO, <https://portal.uspto.gov/pair/PublicPair> (search for “7390791” as patent number, then click on the tab “Transaction History” to view grant of PTE for patent covering elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (GENVOYA)).

### III. Two Important Open Questions on Patent Term Extension Today

There are two important open questions regarding the PTE provision today. One is the fundamental question of whether we should have this provision at all. The other is whether, if PTE is worth keeping, the text of the provision unduly favors pharmaceutical companies in various ways and should be amended to rebalance it in favor of the public.

#### A. Is Patent Term Extension Worth Keeping?

Much ink has been spilled over whether we should have a Patent Term Extension provision at all. In the lead-up to the enactment of the PTE provision in the early 1980s, its proponents argued that drug companies and other patent holders whose products require approval by a government body before they can be marketed ought to be compensated for the “effective patent life” that government’s regulatory review takes up.<sup>27</sup>

“Effective patent life” is a concept that PTE proponents promoted, and the concept presumes that the patent law provides a positive grant of the right to commercially exploit an invention for the entire life of the patent.<sup>28</sup> This presumption is incorrect because the patent monopoly is a negative grant; a patentee is granted the right to exclude others from using the patent only during the life of the patent. Whether the patent holder derives commercial benefit from the right of exclusion of others to use the patent is a matter apart from the patent system, and commercial success depends on many factors external to the patent system, such as the “commercial practicality of the invention, the state of development, the existence of market and the existence of other federal and state laws which regulate the conditions under which products or services may be offered for sale.”<sup>29</sup>

Additionally, drug companies have incentives to perform much of the testing required by the FDA even without FDA requirements. For example, the evidence generated on the products’ risks and benefits reduces the risk of product liability suits.<sup>30</sup> Additionally, testing enables companies to identify benefits of their products over competitors’ products, which can be used in marketing. Opponents of PTE argued that the length of government-caused regulatory review is no greater than the period of time it takes a reasonably prudent business to commercially release a product.<sup>31</sup>

27 See Alfred Engelberg, *Patent Term Extension: An Overreaching Solution to a Nonexistent Problem*, 1 HEALTH AFFS. 34, 36 (1982).

28 See *id.*

29 See *id.*

30 See Al Gore, Jr., *Patent Term Extension: An Expensive and Unnecessary Giveaway*, 1 HEALTH AFFS. 25, 31 (1982); Engelberg *supra* note 27 at 35.

31 See Engelberg, *id.*

Much of the 1980s debate focused on the question of how to properly incentivize innovation in pharmaceuticals. At the time Congress was debating the enactment of PTE, proponents of PTE argued that additional capital was required to spur greater innovation because the pharmaceutical industry was in distress, but at that point, the pharmaceutical industry was one of the most profitable of all major manufacturing industries.<sup>32</sup> Opponents of PTE noted then that profit and research and development (R&D) spending was rising in constant dollars year by year, and there was no decline in drug innovation.<sup>33</sup> Some opponents of PTE provision characterized the PTE provision as a “free giveaway”<sup>34</sup> to pharmaceutical companies because the data supporting the idea that longer monopolies spur greater investment in research and development is debatable. Additionally, the pharmaceutical industry simultaneously benefited from changes in tax law at the time, which created new tax credits for R&D.

Today, proponents of longer patent terms continue to rehash the age-old argument that patent terms are encumbered by government regulation and that longer patent terms spur innovation.<sup>35</sup> There is no limit to the general idea that longer patent terms spur innovation, and we have seen patent terms incrementally lengthen since the inception of the patent system. The original patent term under the 1790 Patent Act was 14 years from issuance,<sup>36</sup> which was increased to 17 years from issuance under the Patent Act of 1861,<sup>37</sup> and further modified to 20 years from filing in 1995.<sup>38</sup> Thus, the criticisms and opposition to PTE from the 1980s are just as compelling, if not more so, today. Pharmaceutical companies are more profitable than ever,<sup>39</sup> and they now spend more on marketing than they do on basic research.<sup>40</sup> This state of things conflicts with the argument that longer monopolies are necessary to recoup the cost of innovation.

Meanwhile, the cost of pharmaceutical drugs has skyrocketed. The cost of per capita drug spending in the United States dwarfs that of any other high-income country, doubling the amount spent by other industrialized nations like Germany and France, and the gap in spending between the United States and the rest of the world continues to grow.<sup>41</sup> To keep the cost of drugs accessible, we should not be relying on government-granted monopolies to serve as an incentive for research and development in infectious diseases. Instead, we ought to rely on other

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32 See Gore, *supra* note 30, at 26.

33 *Id.* at 28.

34 *Id.* at 28.

35 See Adam Mossoff, *Patent Term Extensions Will Help Speed Up Development of the Coronavirus Drugs*, THE WASHINGTON TIMES (Mar. 12, 2020), <https://www.washingtontimes.com/news/2020/mar/12/patent-term-extensions-will-help-speed-up-development/>

36 See Office of Technology Assessment, *Patent-Term Extension and the Pharmaceutical Industry* 50 (1981).

37 See *id.*

38 Kenneth J. Burchfiel, *U.S. Gatt Legislation Changes Patent Term*, 77 J Pat & Trademark Off Soc’y 222, 222 (1995).

39 See Alex Kacik, *Drug Prices Rise As Pharma Profit Soars*, MODERN HEALTHCARE (Dec. 28, 2017), <https://www.modernhealthcare.com/article/20171228/NEWS/171229930/drug-prices-rise-as-pharma-profit-soars>

40 See Alexander Eichler, *Pharmaceutical Companies Spent 19 Times More On Self-Promotion Than Basic Research: Report*, HUFF POST (May 08, 2013) [https://www.huffpost.com/entry/pharmaceutical-companies-marketing\\_n\\_1760380](https://www.huffpost.com/entry/pharmaceutical-companies-marketing_n_1760380); Katherine Ellen Foley, *Big Pharma Spent An Additional \$9.8 Billion on Marketing in the Past 20 Years. It Worked.*, QUARTZ (Jan. 9, 2019), <https://qz.com/1517909/big-pharma-spent-an-additional-9-8-billion-on-marketing-in-the-past-20-years-it-worked/>

41 See Dana O. Sarnak, David Squires, and Shawn Bishop, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, THE COMMONWEALTH FUND (Oct. 5, 2017), <https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier>

forms of incentives for research and development that do not contribute to the lengthening of monopolies, such as increasing government capacity to engage in infectious diseases research and development, and non-patent incentive mechanisms—for example, prize funds.<sup>42</sup>

While a more detailed examination of whether to retain Patent Term Extension is beyond the scope of this paper, the fact that the very existence of the Patent Term Extension provision has been controversial from the start suggests that the time is ripe to consider whether the provision should be reformed in some way.

## B. If Patent Term Extension is Worth Keeping, Does it Need Reform?

Given how long PTE has existed in the United States, given that some benefits do arguably flow from PTE, and given the enormous political influence of the pharmaceutical industry, it may be impossible to amend the Patent Act to eliminate PTE altogether. Here, then, is the central question of this paper: If the patent term extension provision is here to stay, how could it be amended to make it work better? Which reforms are most critical?

The way the statutory provision is currently written has structural problems that limit public oversight and encourage sophisticated patent owners to manipulate the PTE system. Most of the requirements for PTE set forth by the provision are trivially easy for drug companies to meet. The provision affords very limited room for the PTO to exercise meaningful discretion to reject patent term extension requests. Although the provision was carefully written to avoid creating a presumption of PTE, the PTO's implementation of the provision has created, in practice, almost an effective presumption of Patent Term Extension, if the patent term holder checks off a few simple, mechanical requirements for PTE.

The deficiencies with the provision as it is currently written can be readily fixed, as the following sections illustrate.

One note on the scope of this white paper's recommended statutory reforms is in order. The proposed statutory amendments are written with their impact on the pharmaceutical industry in mind because the economic impacts on other industries that benefit from PTE are comparatively small. The vast majority of PTEs go to drugs: approximately 12% of the patent terms awarded PTE were to medical devices regulated by the FDA, 10% to agricultural products regulated by the USDA, and the rest of the PTE granted are mostly pharmaceutical products.<sup>43</sup>

Thus, the economic impact of this paper's proposed amendments to non-pharmaceutical industries would be comparatively small. If the proposed reforms would have a harmful impact on the medical device or agricultural industry, the amendments could be tailored to drug products specifically, such as by limiting the amendments to small-molecule drugs approved by the FDA under 21 U.S.C. § 355 and biologic drugs licensed by the FDA under 42 U.S.C. § 262.

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42 See *What is Delinkage?*, DELINKAGE.ORG <https://delinkage.org/overview/> (last visited Apr. 2, 2020).

43 See *Patent Terms Extended Under 35 USC §156*, USPTO <https://www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156> (last visited Apr. 17, 2020).



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## IV. Proposed Amendments to Improve the PTE Provision

Short of eliminating PTE altogether, certain incremental changes could dramatically improve the PTE system, making it less biased in favor of the patent holder and more democratic. This white paper proposes 10 of such potential incremental reforms to the PTE provision, 35 U.S.C. § 156. The proposals mostly center on amending the disclosure<sup>44</sup> and due diligence<sup>45</sup> requirements.

### A. Proposed Statutory Amendments to the Disclosure Requirement

35 U.S.C. § 156 codifies the parts of the Hatch-Waxman Act that formally create PTE.<sup>46</sup> One specific provision, 35 U.S.C. § 156(d)(4), creates disclosure requirements for PTE applicants. It states, “An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director.” This provision both imposes a requirement on the PTE applicant to disclose information to the PTO, and delegates authority to the PTO to define what information, exactly, must be disclosed. The director of the PTO is vested by this provision with the responsibility to review every PTE application and make a determination based on disclosed information as to whether and how much PTE should be granted. However, the PTO has neutralized its own oversight power through its regulations (discussed below) and thus defeated the intention of the provision.

Based on a study in 2017, it appears that there has never been a denial of a PTE application due to a breach of the disclosure requirements<sup>47</sup>; 1,113 PTE applications were filed from 1984 to 2017 for 894 drugs, and of those applications, 122 were denied or withdrawn for reasons unrelated to the breach of disclosure.<sup>48</sup> This raises the troubling question of how much effort, if any, the PTO invests in uncovering whether there have been any such breaches.

<sup>44</sup> 35 U.S.C. § 156(d)(4).

<sup>45</sup> 35 U.S.C. § 156(d)(2)(B).

<sup>46</sup> 35 U.S.C. § 156.

<sup>47</sup> See Lietzan, *supra* note 23.

<sup>48</sup> *Id.* Twelve of those applications were denied or withdrawn for unstated or unclear reasons.

## 1. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD EXPLICITLY PROVIDE A THIRD-PARTY PATHWAY TO CHALLENGE PTE APPLICANTS' SATISFACTION OF DISCLOSURE REQUIREMENTS.

35 USC § 156(d)(4) authorizes the director of the PTO to define disclosure requirements for PTE, but this section is the only sentence in the provision that mentions disclosure requirements. Although the provision provides a pathway for third parties to challenge the PTE applicant's lack of due diligence at the FDA,<sup>49</sup> the provision does not explicitly provide a pathway for third parties to challenge the PTE applicant's compliance with the separate disclosure requirements set forth by the PTO. Consequently, the PTO has had wide latitude to interpret the disclosure requirements and to bar third-party submissions of evidence relevant to a PTE applicant's compliance with the duty of disclosure.

Unfortunately, the PTO has used its discretion under the statute to promulgate a rule<sup>50</sup> that prohibits submissions by third parties that seek to challenge an applicant's PTE request or simply submit evidence that may be relevant to disclosure requirements.<sup>51</sup> This rule that bars third-party challenges is not required by statute. According to the PTO's decision on a third-party petition, "35 U.S.C. § 156 contains no provision for the PTO to permit third-party participation at the PTO in a PTE proceeding, but to the contrary expressly provides for the relevant regulatory review agency (the FDA for an approved pharmaceutical) to invite and consider third-party input during a PTE proceeding. This strongly reflects a clear legislative design that the regulatory review agency be the only venue to permit third-party participation during a PTE proceeding."<sup>52</sup> (In its commentary, the PTO cited no legislative history to support this proposition.)

Here is the problem with the PTO's interpretation of the statutory provision: the PTE applicant has incentives to avoid disclosing material information that could negatively impact the success of the PTE application. It will always be difficult for the PTO to know what it does not know and thus to uncover hidden information. The PTO might not have the time, resources, or expertise to investigate the disclosure requirements deeply, whereas an interested third party might have the time, resources, and expertise to investigate and might possess relevant, material information that the PTE applicant withheld from the PTO. Without a pathway for third parties to bring potentially relevant information to the PTO's attention, the director is effectively forced to rely on the good faith of the PTE applicant in fulfilling the disclosure requirement, limiting the utility of the requirement. For this reason, the provision should be amended to explicitly provide a pathway for third parties to challenge the breach of disclosure requirements.

This proposed amendment is consistent with the spirit of the patent system and an existing, similar statutory provision that already encourages public participation at the PTO at an earlier stage in a patent's life. Currently, the Patent Act explicitly encourages third-party submissions of relevant information during the patent examination process—that is, when patent owners apply for a patent and the PTO examines the patent to decide whether to grant it.<sup>53</sup> Because the original patent examination process allows for interested third parties to introduce evidence and raise concerns, the procedure for PTE could and should mirror this rule.

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49 35 U.S.C. § 156(d)(2)(B).

50 37 C.F.R. § 1.765(d).

51 See generally *supra* note 4.

52 *Id.* at 6.

53 35 U.S.C. §122(e).

## 2. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD SPECIFY WHAT INFORMATION IS MATERIAL IN DISCLOSURE REQUIREMENTS.

Another problem with the statutory provision on disclosure requirements is its vagueness. This is the only sentence in the provision mentioning disclosure requirements: “An application for the extension of the term of a patent is subject to the disclosure requirements prescribed by the Director [of the PTO].”<sup>54</sup> The vague provision affords the PTO very broad latitude to decide what information must be disclosed by the PTE applicant. The PTO has defined that set of information so narrowly that it recently said explicitly that matters related to public interest are not a relevant consideration for the PTO in determining PTE.<sup>55</sup> As the PTO stated in response to a petition, “...the PTE statute, regulations, and procedures do not provide for the PTO, an agency charged with the examination and issuance of patents and trademark registrations and related proceedings, to base a PTE determination on public health and safety interests, let alone on information about an asserted public health and safety interest provided by a third party.”<sup>56</sup> The PTO went on to suggest that only the FDA, not the PTO, is authorized to receive and consider evidence of harm to public health and safety. The PTO took this confined view of the disclosure requirements even though the FDA’s participation in the PTE application process is limited to the calculation of the applicable regulatory review period, and Section 156 vests authority only in the PTO, not the FDA, to reject, deny, or delay a PTE request.

The PTO has promulgated a rule, 37 C.F.R. §1.765(c), titled “Duty of disclosure in PTE proceedings.” This regulation purports to define the duty of disclosure, but it is vaguely written. The regulation defines material information under the duty of disclosure as “information adverse to a determination of entitlement to the extension,” but does not provide any explanation of what types of information are material. The PTO’s Manual of Patent Examining Procedure, which provides commentary on this regulation, is just as unhelpful: “Information is material where there is a substantial likelihood that the Office or the Secretary would consider it important in determinations to be made in the PTE proceeding.”<sup>57</sup> This appears to be a tautological statement that information is material when it is material. The lack of clarity in the provision and the regulation, in effect, gives the PTE applicant the power to withhold almost all information. A PTE applicant can plausibly claim that most any information is immaterial. The PTO won’t know what information is withheld because it does not know what it does not know and will therefore impose no penalties for the withholding. In other words, the PTE applicant is able to evade disclosure of certain information, and, absent a pathway for third-party challenge, the PTO will never discover this information on its own, given its limited resources.

The following is an illustration of how the PTO’s current PTE rules permit a PTE applicant to withhold material information from the PTO and yet still receive PTE, thereby manipulating the PTE system. This illustration draws from PrEP4All’s petition to the PTO (with which the author was involved) that brought to the PTO’s attention to the fact that Gilead, a major pharmaceutical company, failed to disclose material information to the PTO. This

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54 35 U.S.C. § 156.

55 See *supra* note 4 at 9.

56 *Id.*

57 See MPEP 2762 *Duty of Disclosure in Patent Term Extension Proceedings* (USPTO commentary on 37 C.F.R. §1.765), UNITED STATES PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/web/offices/pac/mpep/s2762.html>

failure of disclosing material information ultimately led to a grant of PTE that Gilead should not have received.<sup>58</sup> Gilead developed two closely related chemical compounds used as drugs for HIV prevention and treatment, tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF). TDF was invented in 1996.<sup>59</sup> TAF was invented in 2000,<sup>60</sup> only four years after TDF's invention. Yet there was a 14-year lapse between the dates in which Gilead received FDA approval and began selling drugs containing the two chemical compounds—2001 for TDF,<sup>61</sup> and around 2015 for TAF.<sup>62</sup> This lapse happened not because of long delays at the FDA or because of scientific difficulties but rather because Gilead intentionally halted clinical development of TAF for many years, solely for business reasons.

Gilead halted clinical development of TAF despite knowing that TAF is safer than TDF for at least some patients: a clinical study Gilead conducted between 2002 and 2003 demonstrated that TAF has a higher antiviral potency at a lower dosage, which is likely to reduce the risk of side effects to kidney and bone when compared to TDF.<sup>63</sup> Aware of the compound's benefits, Gilead touted TAF's promise to investors through at least mid-2004,<sup>64</sup> yet halted the development of TAF in October 2004 and did not resume clinical development work for TAF for almost six years.<sup>65</sup> Gilead delayed TAF's development because, as Gilead's then-president John Milligan explained in 2011, Gilead didn't want evidence of TAF's purported kidney and bone safety benefits to hinder the sales of TDF,<sup>66</sup> which would remain patent protected through 2017. Through 2010 and 2011, Milligan informed investors of Gilead's plan to continue profiting from its existing TDF franchise until around 2015, and then to shift patients to the TAF franchise.<sup>67</sup>

In other words, after learning about the promising results for TAF, Gilead strategically delayed TAF's development and approval process in order to enjoy its full patent monopoly on TDF before bringing TAF to market.<sup>68</sup> When

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58 See generally, *supra* note 4.

59 Gilead filed its first patent application on TDF in 1996. See U.S. Provisional Appl. No. 60/022,708, filed July 26, 1996.

60 See U.S. Provisional Appl. No. 60/220,021, filed on Jul. 21, 2000.

61 See U.S. FDA Approves Gilead Sciences' Anti-HIV Drug Viread™, Gilead (Oct. 26, 2001), <https://www.gilead.com/news-and-press/press-room/press-releases/2001/10/us-fda-approves-gilead-sciences-antihiv-drug-viread#:~:text=Foster%20City%2C%20CA%20%2D%2D%20October%2026%2C%202001&text=The%20approval%20comes%20six%20months,people%20living%20with%20HIV%20today>

62 See U.S. Food and Drug Administration Approves Gilead's Single Tablet Regimen GENVOYA® (Elvitegravir, Cobicistat, Emtricitabine and Tenofovir Alafenamide) for Treatment of HIV-1 Infection, NATAP (Nov. 5, 2015), [https://www.natap.org/2015/HIV/110615\\_01.htm](https://www.natap.org/2015/HIV/110615_01.htm)

63 Martin Markowitz et al., *Phase I/II study of the pharmacokinetics, safety and antiretroviral activity of tenofovir alafenamide, a new prodrug of the HIV reverse transcriptase inhibitor tenofovir, in HIV-infected adults*, Oxford Academic (Feb. 6, 2014), <https://academic.oup.com/jac/article/69/5/1362/683435> (This study was not published until 2014, but the results were collected in 2003.)

64 Q2 2004 Gilead Sci. Earnings Conference Call, 3, July 29, 2004.

65 U.S. Patent No. 7,390,791, Appl. for PTE, 7, filed Dec. 14, 2015.

66 Gilead Sci. at RBC Capital Markets Healthcare Conference, 5, Mar. 2, 2011.

67 See Gilead Sci. at 22nd Annual Piper Jaffray Healthcare Conference - Final, 5, Nov. 30, 2010; Gilead Sci. at Deutsche Bank Sec. Healthcare Conference, 2, March 3, 2011; Gilead Sci. at Goldman Sachs Global Healthcare Conference, 3, June 7, 2011 (Exhibit 14).

68 *Id.*

the company later resumed the development of TAF, it requested a PTE, and did not disclose its own intentional delay in the PTE application.<sup>69</sup> The intentional delay is material because the PTE statute allows for PTE only for the period of time spent in regulatory review that occurs after patent issuance.<sup>70</sup> The PTO granted Gilead's first patent for TAF in 2008.<sup>71</sup> If Gilead had not intentionally delayed development of TAF between 2004 and 2010, most or all of the regulatory review would have taken place before the patent was issued. This means that if it had not intentionally delayed development of TAF, Gilead would not have been eligible for three years' worth of term extension, but instead would be eligible for much less, and possibly no patent term extension at all.

In short, the delay in clinical development of TAF was Gilead's and not the FDA's, and Gilead's delay was apparently motivated by the company's financial incentives to maximize its eligibility for PTE, rather than by science. A reasonable person would conclude that these facts were material to the question of whether the PTO should grant Gilead's request for PTE—they reveal Gilead's intent to manipulate the letter of the law of PTE and to violate its spirit. Yet Gilead withheld them from the PTO.

The PTO ultimately granted Gilead's PTE application, which extends Gilead's patent monopoly on TAF an extension of about three years.<sup>72</sup> At the end of the day, the duration of the PTE was increased because of Gilead's own manufactured delay. This use of the PTE system is at odds with the legislative intent of the PTE provision, which was to compensate patent holders for delays caused by the FDA and other regulators, not to reward them for intentionally delaying development and commercialization of their own patented inventions.

It appears that Gilead can get away with not disclosing to the PTO their intentional delay in TAF's development in part due to the PTO's vague regulation, 37 C.F.R. §1.765(c), titled "Duty of disclosure in PTE proceedings." The regulation purports to define the duty of disclosure, but as previously mentioned, the regulation is vaguely written, giving Gilead and other PTE applicants wide latitude to withhold material information and claim that they reasonably believed it was immaterial. The regulation is based on the similarly vague PTE statutory provision requiring duty of disclosure. The vagueness of both the PTE statutory provision and the PTO regulation renders the duty of disclosure nearly effectively useless. While Congress delegated authority to the PTO to interpret the statutory provision on disclosure requirements,<sup>73</sup> it intended the provision to have some effect; the provision must require some disclosure of information beyond the basic PTE requirements listed by the statute, or else that provision would be redundant. The PTO's regulation, in effect, directly contravenes congressional intent by ignoring the statutory duty of disclosure.

Given the importance of maintaining the integrity of the PTE provision, the provision should spell out specific types of information that must be disclosed. The following section shows how the provision could do exactly that.

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69 See U.S. Patent No. 7,390,791, Appl. for PTE, filed Dec. 14, 2015.

70 35 U.S.C. § 156 only allows PTE for regulatory review that occurs *after* patent issuance. 35 U.S.C. § 156(c).

71 See U.S. Patent No. 7,390,791, USPTO, <https://portal.uspto.gov/pair/PublicPair> (search for "7390791" as patent number, click on the tab "Transaction History" and see "Patent Issue Date Used in PTA Calculation" on June 24, 2008).

72 See *id.* (search for "7390791" as patent number, and click on "Image File Wrapper" for "Patent Term Extension Certificate" on Aug. 19, 2020).

73 35 U.S.C. 156(d)(4).

### **3. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD MANDATE DISCLOSURE OF INFORMATION RELEVANT TO THE PUBLIC INTEREST AS A TYPE OF MATERIAL INFORMATION, AND THE PTE SHOULD BE DENIED WHEN IT APPEARS THAT PTE WOULD BE AGAINST THE PUBLIC INTEREST.**

One type of disclosure that ought to be mandatory for every PTE applicant is any information suggesting that the extension of the patent term could potentially conflict with the public interest. In a sense, any PTE is likely to contradict the public interest in some way, at least insofar as the public has an interest in the availability of low-cost generic medication. However, what this proposed amendment aims to do is not to prohibit PTE across the board, but to expose to the PTO and to the public any unethical or patently harmful acts by the PTE applicant. Therefore, this provision ought to name a minimum set of specific, but non-exhaustive, types of information that pertain to the “public interest” and must be disclosed.

Some examples of information that relates to public interest include intentional delay of clinical development in product development to increase eligibility for PTE (as Gilead did); encouragement or expansion of patent-based antitrust violations like reverse payment agreements (also known as *pay-for-delay*) and any other anti-competitive agreement with generic companies; unconscionable effects that PTE would have on pricing and access (which could require the PTE applicant to disclose information about what disease the product treats, how many Americans have this disease, and how many can afford treatment); and disclosure of any lawsuits related to the drugs for which PTE is requested, including suits filed after the PTE application is filed.

This evidence would provide the PTO with a fuller picture of the context and possible consequences of granting each PTE request. The PTO would be at less of an information disadvantage and could better exercise its discretion to deny PTE when the applicant has committed unethical acts, or when granting the PTE would not be in the public interest. Indeed, a patent holder who committed unethical acts may be dissuaded from applying for an extension in the first place (a PTE applicant would undoubtedly prefer to avoid submitting evidence of unethical acts into the PTO’s public file). If the statute listed these factors specifically, the patent applicant would be foreclosed from claiming that their withholding of information is based on a reasonable belief that the information in question is immaterial.

#### **4. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD MANDATE DISCLOSURE OF ANY STRATEGIC DELAY OF CLINICAL DEVELOPMENT AS A TYPE OF MATERIAL INFORMATION, AND THE STRATEGIC DELAY SHOULD BE CONSIDERED AS GROUNDS FOR THE PTO TO REJECT THE PTE.**

The PTE applicant should be required to disclose whether any days of delay were caused by the applicant itself, and if so, whether the delay was strategic. In other words, the provision should be amended to require the applicant to disclose delays that are part of a business strategy, such as “patent life cycle management.”<sup>74</sup> Disclosing information that a delay is attributed to the PTE applicant’s strategy rather than delays in the FDA’s or USDA’s regulatory review processes would put the PTO on alert to the possibility of manipulation of the patent term.

As noted in the above illustration of PTE manipulation, Gilead withheld information about the nature of its delay of a drug’s clinical development during its request for extending its patent term. The delay was manufactured by Gilead in order to, in effect, stop the clock on a drug patent so that it could time the release of the drug in a way that minimizes overlap with the marketable patent term of an older drug. Gilead asked for the PTE with this strategy in mind. It was easy for the company to get away with this form of gamesmanship, in part because it technically met the requirements of the statutory provision even as it gamed the system.

The information Gilead disclosed, such as the date the company deactivated its clinical trials, did not reveal the reasons for the delay, because disclosure of those reasons wasn’t required. Mandating the disclosure of strategic delay would be helpful because it is indicative of manipulation of patent term. This amendment would deter applicants who engaged in patent manipulation, and would send a message that this type of behavior is discouraged. Disclosure of strategic delays would also provide additional information for the PTO to weigh while making a decision on whether to grant the PTE.

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<sup>74</sup> “Product lifecycle management (PLM) refers to the handling of a good as it moves through the typical stages of its product life: development and introduction, growth, maturity/stability, and decline. This handling involves both the manufacturing of the good and the marketing of it. The concept of product life cycle helps inform business decision-making, from pricing and promotion to expansion or cost-cutting.” Troy Segal, *Product Life Cycle Management*, INVESTOPEDIA (Jul. 5, 2019), <https://www.investopedia.com/terms/p/product-life-cycle-management.asp>

## **5. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD INCLUDE PENALTIES FOR FAILURE TO DISCLOSE MATERIAL INFORMATION.**

The provision should include penalties, other than outright denial of the PTE, for failing to meet disclosure requirements. Currently, under 37 C.F.R. § 1.765(c), a violation of the duty of disclosure through bad faith or gross negligence leads to the patent's ineligibility for an extension. This regulation, and the underlying statutory provision, gives the PTO the binary option of either approving or rejecting the PTE application, and the regulation as written favors approval, because it suggests that any infraction less serious than outright bad faith or gross negligence is likely to result in PTE approval.

To encourage full disclosure, and to discourage the PTE applicant from testing how much potentially material information they can get away with hiding, there should be fines and other intermediate penalties associated with the breach of disclosure, with a lower evidentiary standard for finding such breach. The PTO should have the option of reducing the number of days the PTE awarded, in the event material information is not disclosed but the PTO otherwise deems the PTE application allowable. The reduction of number of days would serve as a way for the PTO to grant an extension it deems proper on the whole while penalizing (and disincentivizing) insufficiently disclosing material information. This would allow the PTO to balance the various interests at play when the PTO does not wish to outright deny the request for extension.

## **6. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD PLACE THE BURDEN OF PROOF OF MEETING THE DISCLOSURE REQUIREMENTS ON THE PTE APPLICANT.**

Currently, the provision does not explicitly specify who bears the burden of proof to establish that a PTE applicant's disclosure requirements have been met. The statutory provision should clearly place the burden of proof on the PTE applicant, not third-party petitioners or the PTO. For one, while there is a statutory presumption of getting a patent, there is no statutory presumption of getting a PTE. That suggests the PTE applicant should have to do more to prove its entitlement to the PTE than a normal patent applicant does. Additionally, the system of third-party checks will be ineffective if the burden of proof is placed on third-party petitioners, who face practical barriers, such as having less access to information than the PTE applicant on the applicant's own behavior. An informational asymmetry exists, not just between the applicant and the petitioner, but also between the applicant and the PTO, which might lack resources or incentives to carefully check the applicant's compliance with disclosure requirements. Not only does the PTO have less access to information, it also has less at stake than the applicant and might be more interested in expediency. For this reason, the provision should be amended to place the burden squarely on the PTE applicant to prove the adequacy of the disclosure (and all other requirements for PTE).

## **7. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD PROVIDE AN ADEQUATE PERIOD FOR THIRD-PARTY PETITIONS CONCERNING THE BREACH OF DISCLOSURE REQUIREMENTS.**

The provision currently provides 180 days for third parties to file a petition to the FDA challenging the PTE applicant's failure to act with due diligence during the applicable regulatory review period.<sup>75</sup> Similarly, a third-party petition process at the PTO should mirror this period of time and provide for 180 days that begin after the end of the FDA's 180-day window.

## **B. Other Proposed Amendments to the Statute**

### **1. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD PLACE THE BURDEN OF PROOF FOR THE DUE DILIGENCE REQUIREMENTS ON THE PTE APPLICANT AND NOT ON THE PETITIONERS.**

35 U.S.C. § 156(d)(2)(B) is the statutory provision that creates due diligence requirements, and it delegates authority to the FDA (or USDA) to make the determination of whether the PTE applicant acted with due diligence during the regulatory review period. The FDA determines—for drug product, device, or additives subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act—whether the due diligence requirements have been met. The USDA does the same for products subject to the Virus-Serum-Toxin Act. Due diligence is defined by the provision as “degree of attention, continuous direct effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.”<sup>76</sup>

The statutory provision does not explicitly place the burden of proof for the due diligence requirements on the PTE applicant. Because the statute is silent on who bears the burden of proof, the FDA promulgated a rule, 21 C.F.R. §60.44, that states that “the party requesting the due diligence hearing shall have the burden of proof at the hearing.” This is a problem because there is an informational asymmetry between the applicant and petitioner, and the FDA has limited resources and incentives to review each application closely. Similar to the recommended amendment above that would squarely place the burden of proof on the applicant to establish that the duty of disclosure has been met, there should be a similar amendment of the due diligence requirement to place the burden of proving diligence squarely on the PTE applicant.

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<sup>75</sup> 35 U.S.C. § 156(d)(2)(B)(i).

<sup>76</sup> 35 U.S.C. § 156(d)(3)

## **2. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD REQUIRE THE FDA TO SUPPLY RECORDS TO THE PTO INFORMING THE PTO OF LIKELY EFFECTS OF PTE ON COMPETITION.**

As noted above, one factor that the PTO ought to consider while weighing its discretion whether to grant an extension for a patent is what effect such grant would have on competition. There might be a strong public interest in denying the PTE to promote competition. The statute should be amended to expand the FDA's role in the PTE application process and require the agency to supply records on whether the product or products covered by the patent being considered for PTE have any prospective generic competition. In particular, the FDA and USDA could be required to disclose to the PTO whether any generic applications relying on the application that is the basis of the PTE request have been filed. The PTO may then consider this information in deciding whether to grant the PTE. Given that these agencies hold this information, they should have a duty to supply the records, perhaps at the same time they send their letters to the PTO certifying the regulatory review period.

## **3. PROPOSED AMENDMENT: THE PTE PROVISION SHOULD INCREASE THE COST OF PTE APPLICATION TO FUND MORE THOROUGH REVIEW.**

The PTO and FDA might currently be under-resourced to review PTE requests carefully. A way to expand agency resources could be to make PTE a more expensive procedure, such as requiring \$100,000 per application, and dividing the fee between the PTO and FDA. This would allow the agencies to hire more staff to carefully review PTE. Currently, the application fee costs, at most, \$400 per application.<sup>77</sup> The pharmaceutical drugs covered by patents that are subject to PTE applications are generally blockbusters reaping millions, even billions, in revenues and profits, so this application fee is not intended to be a deterrent but is instead a funding mechanism with minimal financial impact on the PTE applicant.

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<sup>77</sup> C.F.R. § 1.17(f).

## V. Conclusion

Pharmaceutical companies' tactics to extend their patent monopolies have led to skyrocketing drug prices and significantly contributed to the cost of healthcare. Today, PTE is the norm for top-selling pharmaceuticals. Patent manipulation tactics, which have effectively doubled the period of monopoly for many top-selling drugs, ultimately stifle competition, keep revenues high for patent holders, and make drugs less accessible for those who are unable to afford them. We need a PTE system that is more democratic, transparent, and fair to the public. The proposed reforms of the patent term extension system presented in this paper will make the application process more democratic by allowing third parties to challenge extension requests, more transparent by strengthening disclosure requirements, and fairer to the public by strengthening the PTO's authority to deny improper requests for PTE.

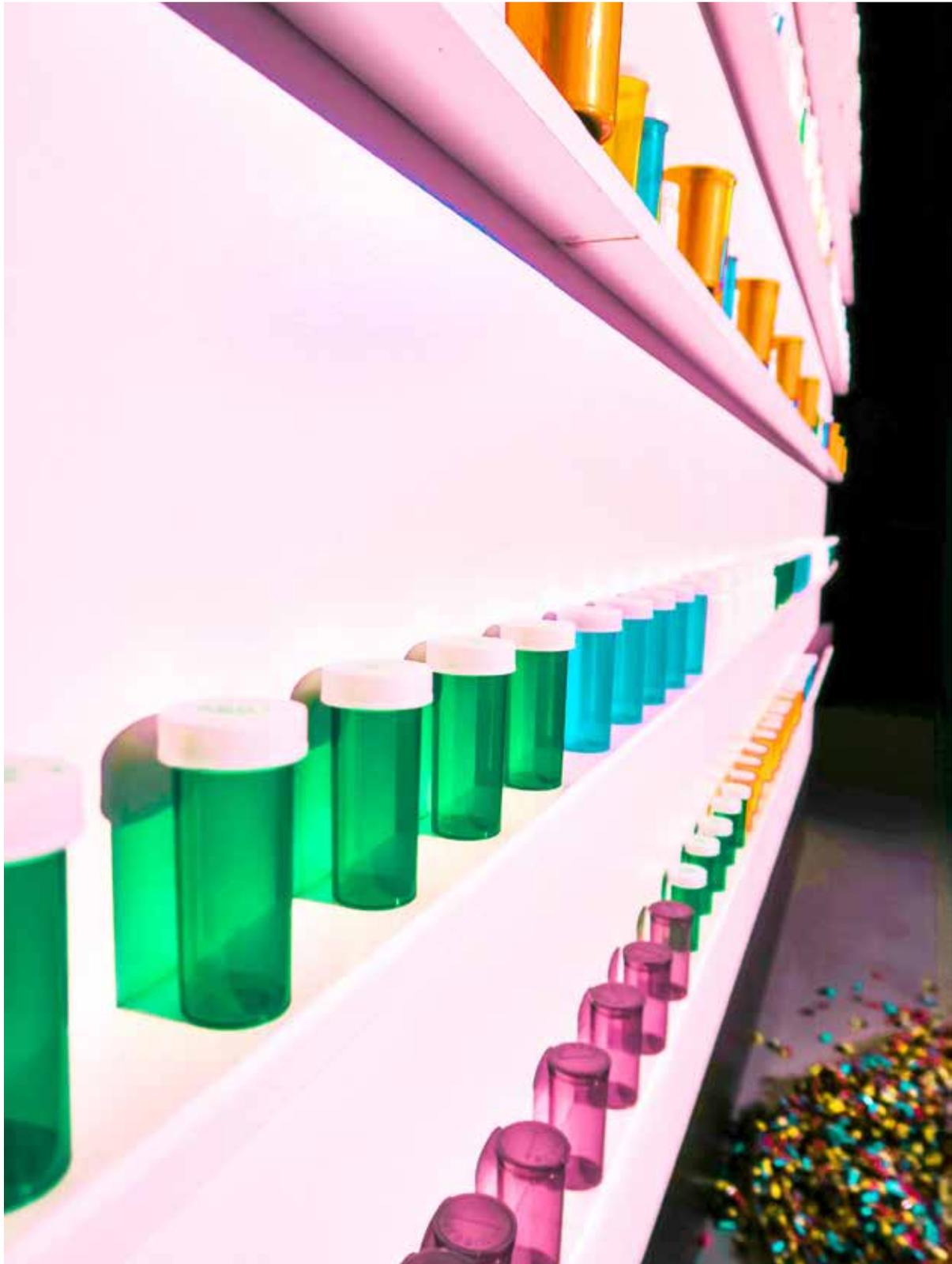


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