USPTO Has Opportunities to Improve Its Internal Controls and Oversight Related to PTA and PTE Calculations

FINAL REPORT NO. OIG-21-030-I
JULY 6, 2021

U.S. Department of Commerce
Office of Inspector General
Office of Audit and Evaluation

UNITED STATES DEPARTMENT OF COMMERCE
Office of Inspector General
Washington, D.C. 20230

July 6, 2021

MEMORANDUM FOR: Andrew Hirshfeld
Performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

FROM: Frederick J. Meny, Jr.
Assistant Inspector General for Audit and Evaluation

SUBJECT: *USPTO Has Opportunities to Improve Its Internal Controls and Oversight Related to PTA and PTE Calculations*
Final Report No. OIG-21-030-I

Attached for your review is the final report on the evaluation of the United States Patent and Trademark Office's (USPTO's) Patent Term Adjustment (PTA) and Patent Term Extension (PTE) processes. The objectives were to determine whether USPTO (1) calculates and awards PTA and PTE in compliance with relevant statutes, regulations, and case law; (2) has adequate internal controls to ensure the proper calculation and award of PTA and PTE; and (3) uses valid and reliable data to calculate PTA and PTE.

We contracted with The MITRE Corporation (MITRE)—an independent firm—to perform this evaluation. Our office oversaw the progress of this evaluation to ensure that MITRE performed the evaluation in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation* (December 2020) and contract terms. However, MITRE is solely responsible for the attached report and conclusions expressed in it.

In its evaluation of PTA and PTE, MITRE identified the following:

1. USPTO uses valid and reliable data to calculate PTA, but manual data entry may introduce errors.
2. USPTO calculates PTA and PTE in compliance with statutes, regulations, and case law.
3. USPTO has adequate internal controls to ensure proper calculation of PTA and PTE.

MITRE recommended that the Undersecretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office take the following actions:

1. Direct the Commissioner for Patents to (1) mandate the use of the "safe harbor" form to claim the exception, and (2) ensure the inclusion of clear category and description definitions for applicants while keeping their focus on the task at hand (i.e., the document submission form).

2. Direct Office of Petitions (OPET), Office of Patent Legal Administration (OPLA), and Office of the Chief Information Officer (OCIO) to implement, and keep up-to-date, a comprehensive set of requirements and specifications for the PTA calculator software to ensure continued compliance with current and emerging legislation and case law.
3. Direct OPLA to coordinate with the U.S. Food and Drug Administration and the U.S. Department of Agriculture to determine if electronic filing of PTE applications would be acceptable as a permanent practice after the current public health emergency has passed.
4. Direct the Office of Patent Examination Support Services and the OCIO to: (1) determine the feasibility of implementing a workflow process or tool (similar to the examiner "docket" system) for Legal Instruments Examiner managers; and (2) add clarifying language to the document description codes in the Patent Application Locating and Monitoring system to mitigate the risk of miscoded documents.
5. Direct the Commissioner for Patents to implement a means to identify and remedy the types of events that typically require a manual review (e.g., Information Disclosure Statements) as they occur.
6. Direct OPET to implement a pilot program to perform periodic, OPET-initiated, reconsideration-like audits on a random sampling of PTA calculations.

On June 10, 2021, we received USPTO's response to MITRE's draft report. In response to MITRE's draft report, USPTO concurred with all of the recommendations and described actions it has taken, or will take, to address them. USPTO's formal response is included within the final report as appendix F.

Pursuant to Department Administrative Order 213-5, please submit to us an action plan that addresses the recommendations in this report within 60 calendar days. This final report will be posted on the Office of Inspector General's website pursuant to sections 4 and 8M of the Inspector General Act of 1978, as amended (5 U.S.C. App., §§ 4 & 8M).

We appreciate the cooperation and courtesies extended to MITRE by your staff during this evaluation. If you have any questions or concerns about this report, please contact me at (202) 482-1931 or Amni Samson, Director for Audit and Evaluation, at (571) 272-5561.

Attachment

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Jay Hoffman, Chief Financial Officer, USPTO
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USPTO Patent Term Adjustment/Patent Term Extension Evaluation Report

USPTO Has Opportunities to Improve its Internal Controls and Oversight Related to PTA and PTE Calculations

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Professor Ouellette's contribution to this publication was as a paid consultant and was not part of her Stanford University duties or responsibilities.

Professor John "Jay" Thomas' contribution to this publication as a paid consultant and was not part of his Georgetown University duties or responsibilities.

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Executive Summary

The U.S. Patent and Trademark Office (USPTO) awards patent protection generally lasting for 20 years from the date an inventor, or their agent, files a patent application.[1] This period may be extended to compensate patent owners for delays caused by the government potentially limiting the effective life of a patent. Patent term adjustment (PTA) compensates for delays caused by USPTO while examining the patent.[2] Patent term extension (PTE) compensates for delays caused by a regulatory agency, such as the Food and Drug Administration (FDA), that must approve a patented product before it can be marketed.[3] The Department of Commerce Office of the Inspector General (OIG) engaged The MITRE Corporation to evaluate the calculation and award of PTA and PTE.

Why We Did This Review

Given the economic value of high-quality patent rights, it is important USPTO accurately and reliably calculate patent terms under the PTA and PTE statutes. OIG tasked us with the following three evaluation objectives: to determine if (1) USPTO uses valid and reliable data to calculate PTA and PTE; (2) USPTO calculates and awards PTA and PTE in compliance with relevant statutes, regulations, and case law; and (3) USPTO has adequate internal controls to ensure the proper calculation and award of PTA and PTE.

What We Found

Based on the limited scope of our evaluation, we concluded that USPTO's calculations are generally accurate and reliable. However, we have identified three areas where the USPTO can improve with respect to the three evaluation objectives:

1. **USPTO uses valid and reliable data to calculate PTA, but manual data entry may introduce errors:** Internal controls (e.g., automatic date stamps, limited ability to change dates manually, tracking of changes) support the quality of data used in PTA calculations. However, (1) applicants may obscure or omit required information in an Information Disclosure Statement (IDS), and (2) applicants may submit documents with the wrong document code (see Section 2.1).
2. **USPTO calculates PTA and PTE in compliance with statutes, regulations, and case law:** PTA calculation errors related to compliance are usually temporary, and primarily linked to system software updates and changes in case law (see Section 2.2).
3. **USPTO has adequate internal controls to ensure proper calculation of PTA and PTE:** These include system checks on data entry, day-to-day checks on the process, and post-award reconsideration petitions. However, USPTO could improve some aspects of their internal controls (see Section 2.3).

[1] 35 U.S.C. § 154(a)(2).
[2] 35 U.S.C. § 154(b).
[3] 35 U.S.C. § 156.

What We Recommend

To address the findings in this report, we recommend the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office:

R1: Direct the Commissioner for Patents to (1) mandate the use of the "safe harbor" form to claim the exception, and (2) ensure the inclusion of clear category and description definitions for applicants while keeping their focus on the task at hand (i.e., the document submission form).

R2: Direct Office of Petitions (OPET), Office of Patent Legal Administration (OPLA), and Office of the Chief Information Officer (OCIO) to implement, and keep up-to-date, a comprehensive set of requirements and specifications for the PTA calculator software to ensure continued compliance with current and emerging legislation and case law.

R3: Direct OPLA to coordinate with FDA and the U.S. Department of Agriculture (USDA) to determine if electronic filing of PTE applications would be acceptable as a permanent practice after the current public health emergency has passed.

R4: Direct the Office of Patent Examination Support Services (OPESS) and the OCIO to: (1) determine the feasibility of implementing a workflow process or tool (similar to the examiner "docket" system) for Legal Instrument Examiner (LIE) managers; and (2) add clarifying language to the document description codes in the Patent Application Locating and Monitoring (PALM) system to mitigate the risk of miscoded documents.

R5: Direct the Commissioner for Patents to implement a means to identify and remedy the types of events that typically require a manual review (e.g., IDSs) as they occur.

R6: Direct OPET to implement a pilot program to perform periodic, OPET-initiated reconsideration-like audits on a random sampling of PTA calculations.

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1 Introduction

The Department of Commerce ("the Department") Office of the Inspector General (OIG) seeks to improve the efficiency and effectiveness of the Department's programs and operations, and to prevent and detect fraud, waste, and abuse. The OIG's Office of Audit and Evaluation conducts evaluations of the Department's programs and operations. As required by statute,[4] OIG reports annually on the management and performance challenges facing the Department. In fiscal year (FY) 2020, OIG identified "managing an increasing demand for intellectual property rights" as a top management challenge.[5] Key OIG-identified priorities related to the United States Patent and Trademark Office (USPTO) include: (a) ensuring a thorough, timely, and fair patent examination and review process; and (b) improving the management of information technology (IT) systems and operations.

1.1 Background

USPTO is an agency within the Department, subject to the policy direction of the Secretary of Commerce. USPTO is responsible for administering intellectual property (IP) laws, including those relevant to the examination, processing, and granting of patents; registering trademarks; and promoting intellectual property systems as a means of protecting economic prosperity. USPTO's mission is to "foster innovation, competitiveness and economic growth, domestically and abroad, by providing high quality and timely examination of patent and trademark applications."[6]

Patents have enormous value in the U.S. economy. USPTO estimates that patent-intensive industries contributed $881 billion in value added to the gross domestic product in 2014.[7] Although less than 1 percent of U.S. firms were granted a patent between 2000 and 2011, these firms accounted for 33 percent of U.S. employment.[8] Patents also significantly increase the growth potential of startups.[9]

The length of time before a patent expires ("the patent term") is important to patent holders, particularly in industries where long product lifecycles can prolong commercial availability, such as the pharmaceutical industry. Both patent term adjustment (PTA) and patent term extension (PTE) change the patent term to compensate patent holders for processing delays. Accurate and reliable calculations of increases in patent term under the PTA and PTE statutes are

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[4] 31 U.S.C. § 3516(d).

[5] Commerce OIG, "Top Management and Performance Challenges Facing the Department of Commerce," October 16, 2019, 2, https://www.oig.doc.gov/OIGPublications/OIG-20-001.pdf.

[6] U.S. Department of Commerce, "U.S. Patent and Trademark Office," 2020, https://www.commerce.gov/bureaus-and-offices/uspto.

[7] Justin Antonipillai and Michelle K Lee, "Intellectual Property and the U.S. Economy: 2016 Update," 2016, 22, https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf.

[8] Stuart J.H. Graham et al., "Business Dynamics of Innovating Firms: Linking U.S. Patents with Administrative Data on Workers and Firms," *Journal of Economics & Management Strategy* 27, no. 3 (September 1, 2018): 389, https://doi.org/10.1111/jems.12260.

[9] Joan Farre-Mensa, Deepak Hegde, and Alexander Ljungqvist, "What Is a Patent Worth? Evidence from the U.S. Patent 'Lottery,'" *The Journal of Finance* 75, no. 2 (April 18, 2020): 21, https://doi.org/10.1111/jofi.12867.

economically significant as a matter of fairness to patentees and to give fair notice to competitors of the end of the patent protection period.

1.2 Patent Term Adjustment (PTA) Description

Under the PTA statute,[10] patent holders are compensated for each day of delay caused by USPTO, such as: taking more than 14 months to mail the first action, taking more than four months to respond to an applicant's reply, or taking more than three years to issue a patent. USPTO reduces the PTA award for any "period of time during which the applicant failed to engage in reasonable efforts to conclude…processing…of the application" (i.e., "applicant delay").[11] USPTO uses an automated tool to calculate PTA for every issued patent. When a patent is issued, the Office of Application Engineering and Development (OAED) includes it in a weekly batch to calculate PTA and issue the patents. Of more than 300,000 patents issued each year,[12] nearly half receive at least some PTA. For the approximately 400 reconsideration petitions filed by patent holders each year challenging these calculations, USPTO recalculates PTA through a manual process. See Appendix A for details.

1.3 Patent Term Extension (PTE) Description

In contrast, PTE applies only to patents claiming products that cannot be marketed until they are approved by a regulatory agency.[13] The PTE statute[14] allows an extension of patent term to compensate for delays in obtaining marketing approval from these agencies. PTE often carries substantial economic benefit or consequence for the patent holder because it primarily applies to successful pharmaceutical and agricultural products where each additional day of patent protection can equate to increased return on the proprietor's upfront investment for development. A study of best-selling pharmaceutical products in the United States in 2006 documents that nearly 40 percent of sales occurred during patent extensions.[15] Pharmaceutical firms are less likely to invest in candidate drugs with shorter expected patent terms.[16]

USPTO processes approximately 100 PTE applications per year, but calculation of delay periods and requests for reconsideration are handled by the corresponding regulatory agency (e.g., the Food and Drug Administration [FDA]), with little USPTO involvement. For this reason, the bulk of this report focuses on the PTA calculation. See Appendix A for details.

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[10] 35 U.S.C. § 154(b).

[11] 37 C.F.R. § 1.704, 2019, https://ecfr.federalregister.gov/current/title-37/chapter-I/subchapter-A/part-1/subpart-F/subject-group-ECFRe44068b85003df6/section-1.704. Section 1.704 describes all of the rules for calculating applicant delay.

[12] Over 390,000 patents were issued in calendar year 2019. USPTO, "U.S. Patent Statistics Chart Calendar Years 1963 - 2019," 2019, https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm.

[13] Specifically: Food and Drug Administrations (FDA) or United States Department of Agriculture (USDA).

[14] 35 U.S.C. § 156.

[15] Charles Clift, "The Value of Patent Term Extensions to the Pharmaceutical Industry in the USA," *Journal of Generic Medicines* 5, no. 3 (April 4, 2008): 206, https://doi.org/10.1057/jgm.2008.6.

[16] Eric Budish, Benjamin N Roin, and Heidi Williams, "Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials," *American Economic Review* 105, no. 7 (July 2015): 2044–85, https://doi.org/10.1257/aer.20131176.

2 Objectives, Findings, and Recommendations

OIG has not previously studied how USPTO applies PTA and PTE awards for increasing the term of patent rights. Through this evaluation, we intend to provide USPTO with recommendations to correct any deficiencies identified during the evaluation, including potential improvements to USPTO procedures, operations, skills, or systems relating to the calculation and award of PTA and PTE.

The objectives of this evaluation are three-fold:

1. Does USPTO use valid and reliable data to calculate PTA and PTE (see Section 2.1)?
2. Does USPTO calculate and award PTA and PTE in compliance with relevant statutes, regulations, and case law (see Section 2.2 and 2.3)?
3. Does USPTO have adequate internal controls to ensure the proper calculations and award of PTA and PTE (see Sections 2.1 through 2.3)?

See Appendix B for details on this evaluation's scope and methodology. The sub-sections below detail our findings and recommendations.

2.1 USPTO Uses Valid and Reliable Data to Calculate PTA, but Manual Data Entry May Introduce Errors

The data used to calculate PTA consist of the Patent Application Locating and Monitoring (PALM)[17] records of (1) USPTO actions and (2) specific types of information submitted by the patent applicant.[18] This information is recorded both automatically and manually in the system. The relevant PALM data comprise *events* (e.g., information filings, office actions) represented in the system by "event codes" and their dates. The data used to calculate PTA are typically valid and reliable; however, errors may occur during the manual data entry process.

Errors resulting from manual data entry in PALM are concentrated in two parts of the overall process: (1) when the applicant files the patent application for initial processing by the Office of Patent Application Processing (OPAP), and (2) when the applicant submits supplementary materials to USPTO that are processed by Office of Patent Examination Support Services (OPESS).

Dates Used to Calculate PTA are Generally Correct

USPTO stakeholders and patent owners reported that PALM data are generally reliable and valid. The patentees we surveyed largely agreed the dates used to calculate their PTA were

[17] "The PALM (Patent Application Locating and Monitoring) System is the automated data management system used by the United States Patent and Trademark Office (USPTO) for the retrieval and/or online updating of the computer record of each patent application. " USPTO, "Manual of Patent Examining Procedure (MPEP)," *USPTO*, 2018, sec. 1704, https://www.uspto.gov/web/offices/pac/mpep/index.html.

[18] As defined in 37 C.F.R. §§ 1.701 through 1.705. E.g., USPTO failing to "[m]ail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the [filing date]…" [§ 1.702(a)(1)]; or "failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application…[such as]…[Abandonment of the application or late payment of the issue fee…" [§ 1.704(c)(3)].

correct. We confirmed this reliability by first analyzing a sample of PALM data to verify the accuracy of the calculations, then spot-checking PALM data against source documentation contained in USPTO's Public Patent Application Information Retrieval (Public PAIR) portal, "Image File Wrapper" tab. We randomly selected 457 PTA-related events from 457 different patent applications in the PALM data provided to us by USPTO.[19] We found only five events where the event date in the PALM data did not match the date found in the source document in Public PAIR—a 99 percent accuracy rate.[20]

Errors May Occur When USPTO Staff Mis-categorize Documents or Do Not Enter Key Information into PALM

Steps in USPTO's manual data entry process may introduce errors. When USPTO receives documentation (either electronically or in paper form) related to any application, a Legal Instrument Examiner (LIE) in OPESS prepares the file for the examiners. For example, LIEs may manually enter the "mailroom date" of incoming documents, along with other relevant information into PALM to prepare it for examiner review.

OPESS staff report two common error categories:

- **LIEs may enter data incorrectly into PALM or omit it altogether**. When this occurs, examiners may not see the document and miss a required action, unnecessarily delaying the patent prosecution,[21] and/or the PTA calculator may use the wrong date when determining the PTA award (see Appendix A).
- **LIEs may assign an incorrect document code as part of data entry**. Incorrect document codes can (1) delay the patent prosecution and/or (2) result in an incorrect PTA calculation. For example, an LIE may categorize a document as a "letter" (considered miscellaneous correspondence which does not require immediate action) instead of categorizing it as a "response," which is considered high priority and handled first.

OPESS staff reported they would like to see an improvement to the document description codes. A senior official told us there are currently no internal controls intended to ensure documents processed by LIEs are entered into PALM for inclusion in the examiner's docket. To address this deficiency, USPTO could benefit from a more formal workflow process or tool for LIE managers. This workflow process/tool would help to prioritize documentation, assign work, and act as an internal control to confirm that LIE-reviewed documents are entered into PALM.

[19] See Section A.3.7 in Appendix A for details on our sampling methodology.

[20] In those five errant events, the dates were off by one, two, or (in one case) three days.

[21] "Patent prosecution is the process of drafting, filing, and negotiating with the U.S. Patent and Trademark Office (USPTO) in order to obtain patent protection and rights for an invention." JUSTIA, "Patent Prosecution Under U.S. Patent Law," 2018, https://www.justia.com/intellectual-property/patents/patent-prosecution/.

Errors May Occur When Patent Applicants Mis-categorize Submitted Documents or Do Not Highlight Key Statements

Applicants can make manual data entry errors when submitting documents through EFS-Web.[22] Interviewees reported two common applicant errors that could impact PTA: (1) applicants may obscure or omit required information in an Information Disclosure Statement (IDS), and (2) applicants may submit documents with the wrong document code.

In the first scenario, applicants must disclose all information known to be material to patentability to USPTO in an IDS. Under some circumstances, such disclosure may be considered "applicant delay," and PTA may be adjusted downward. If the disclosure is timely, a "safe harbor" rule avoids the PTA reduction, but to assert that rule, the applicant must include a specific statement in or along with the IDS. USPTO provides a form to claim the benefit of the "safe harbor" rule but does not mandate its use. Applicants may instead embed the required statement in the IDS where it may go unnoticed by USPTO.

In the second scenario, when uploading documents to EFS-Web, applicants use drop-down boxes to select one or more of the 11 "categories" available. They then select one of up to 64 different "document descriptions" depending on the category they selected. The EFS-Web user interface provides a link to download a file with USPTO definitions for categories and document descriptions. While this functionality helps applicants, it also navigates them away from the focused task. An incorrectly entered document code can negatively impact the patent prosecution workflow, which, in turn, may affect the PTA calculation.

USPTO could address these data entry issues by providing additional training for LIEs and/or examiners, mandating the use of the "safe harbor" exception form, and providing document category and description definitions to applicants while submitting documents (i.e., without requiring they navigate away from the task at hand).

Recommendation

We recommend the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office:

R1 Direct the Commissioner for Patents to (1) mandate the use of the "safe harbor" form to claim the exception, and (2) ensure the inclusion of clear category and description definitions for applicants while keeping their focus on the task at hand (i.e., the document submission form).

2.2 USPTO Calculates PTA and PTE in Compliance with Statutes, Regulations, and Case Law with Limited, Temporary Exceptions

To assess whether USPTO calculates PTA in compliance with statutes, regulations, and case law, we looked at the PTA calculator itself: how it was built (designed, tested, and maintained); how

[22] "EFS-Web is the United States Patent and Trademark Office's (USPTO's) Web-based patent application and document submission solution. Using EFS-Web, anyone with a Web-enabled computer can file patent applications and documents without downloading special software or changing document preparation tools and processes." USPTO, "About EFS-Web," 2020, https://www.uspto.gov/patents/apply/applying-online/about-efs-web.

it runs during patent prosecution; and the output of the calculation. Where we found errors, we assessed the main reason for those errors. We considered internal guidance, the design of the PTA calculator software, software test results, execution of the PTA calculator, and the output of the PTA calculator. Our analysis confirmed that each step aligns with legal authority. However, we identified some areas for improvement, described below.

PALM Examination and Post-Examination (EXPO) is the sole USPTO system responsible for calculating PTA. USPTO designed and maintains the PTA calculator within PALM EXPO based on a set of business rules developed with internal experts on PTA and vetted with end-users. OPLA, in collaboration with the Office of the Chief Information Officer (OCIO), can amend those requirements when necessary to comply with changes in statutes, regulations, or case law. In our assessment, we found the outputs generated by the automated PTA calculator comply with statutes, regulations, and case law, and that errors related to compliance are usually temporary, and primarily linked to system software updates and changes in case law. The Manual of Patent Examining Procedure (MPEP),[23] USPTO's authoritative reference on the practices and procedures for the prosecution of patent applications, reflects the relevant statutes, case law, and regulations governing patent examination procedures.

System Requirements Issues

In this evaluation we analyzed the June 2014 set of system requirements used to build the PTA calculator. These requirements define every calculation.[24] The sum of the individual calculations results in the total PTA.[25] Each calculation relies on two or more "events" recorded in the PALM database. We found that 92 percent of those requirements were fully compliant with the relevant statutes, regulations, and case law. The non-compliant requirements were mainly missing some details, such as a complete list of event codes. In addition, the requirements specify an internal control on the events to maintain the integrity of the events: only system administrators can edit or delete an event entry, and at least two system administrators must approve of any change to an event entry.

Since the last updates to the system requirements were done in 2015, the backlog of requirements has been growing. USPTO has considered updates to the PTA calculator but has not yet implemented them due to competing IT funding priorities. A PTA calculator that can be readily configured to adapt to new interpretations of PTA-related rules, or identification of errors in calculations, would be more flexible and responsive to needed changes.

PTA Calculation Verification

During the PTA calculation batch process (see Section 1.2), USPTO does not verify the results of the PTA calculations. However, in a sampling of PALM data USPTO provided, we were able to

[23] The MPEP "contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application." (Source: https://www.uspto.gov/patent/laws-and-regulations/manual-patent-examining-procedure)

[24] There was a total of 877 requirements in the June 2014 requirements set.

[25] As defined in 37 C.F.R. § 1.703 and § 1.704, respectively.

verify 93 percent of the PTA calculations.[26] For the patents in the seven percent of cases where our calculation did not match USPTO's, only one of the patent owners petitioned for reconsideration of the PTA awarded.[27] In addition, most of the patent owners responding to our survey did not question their PTA calculation.

Temporary Compliance Issues Related to Case Law

Delays in implementing changes to the PTA calculator based on new federal court decisions can lead to errors until updates are made.[28] For example, the Court of Appeals for the Federal Circuit corrected USPTO's interpretation of the PTA statute in three significant cases: *Wyeth v. Kappos* (2010), *Novartis AG v. Lee* (2014), and *Supernus Pharmaceuticals, Inc. v. Iancu* (2019).

In some cases, such as *Supernus*, an automated fix is not obvious. As discussed in Section 1.2, PTA is reduced for certain periods of applicant delay during prosecution. *Supernus* confirmed that such delay cannot include any time period in which there was nothing the applicant could do to advance prosecution. PALM event codes do not reflect any period of time during which the applicant could *not* reasonably have taken action to move prosecution forward. Developing a reliable software fix to address the *Supernus* decision could take some time.

In other cases, such as *Wyeth*[29] and *Novartis*,[30] the required changes are more straightforward. That being said, there is always a natural delay while USPTO goes through the process of issuing a notice of proposed rulemaking (NPRM)[31] and implementing the new rule in its guidance, training, and software (as applicable). When a new federal court decision requires changes to guidance, training, and the PTA calculator, reconsideration petitions typically surge until USPTO implements the changes.

Patent Term Extension Calculation

USPTO awards PTE in compliance with applicable statutes, regulations, and case law. In drawing this conclusion, we recognized that the governing statute[32] assigns USPTO a much more limited role in calculating PTE than PTA. In particular, the relevant regulatory agency—FDA or USDA[33]—

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[26] We verified the calculation of the duration of the delay period of 14,541 PTA-related events across a sample of 1,055 patents issued in FY2019. In seven percent of the delay periods, the duration we calculated differed from the value calculated by USPTO. Upon deeper examination of the events with a variance in delay durations, we observed that almost two-thirds of them had a variance of less than 10 days. Thus, while seven percent of the events in the sample showed a variance, only 2.4% of them had a variance of 10 days or greater. See Section B.3.6 in Appendix B for details on our sampling methodology.

[27] About half of the 1,055 patents in the sample had at least one PTA calculation we were not able to verify. USPTO granted the petition filed by that one petitioning patent owner, awarding the patentee an additional 75 days of patent term.

[28] See Appendix C for description of some of the key federal court decisions affecting the PTA calculation.

[29] Within a month of the *Wyeth* decision, USPTO issued a notice it was "revising the computer program it uses to calculate patent term adjustment to calculate overlapping delays consistent with the Federal Circuit's interpretation of 35 U.S.C. § 154(b)(2)(A) in Wyeth" and providing a process for correcting related errors in PTA calculations.

[30] In *Novartis,* the Federal Circuit rejected USPTO's view that, during a continued evaluation, "the time after allowance, until issuance, is 'time consumed by continued examination' and so is excluded from adjustments given to the patentee." The Novartis decision is reflected in MPEP § 2732.

[31] Office of the Federal Register, "A Guide to the Rulemaking Process," 2011, https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf.

[32] 35 U.S.C. § 156.

[33] The only agencies with a regulatory review period for which a patent can be extended under the PTE statute are the FDA and USDA.

bears responsibility for determining the length of the regulatory review period for the approved and patented product.[34]

As discussed in Section 1.2, whether an issued patent is eligible for a PTA award or not, USPTO must perform the calculation on every patent issued (i.e., over 390,000 patents in calendar year 2019). In contrast, USPTO receives on the order of 100 PTE applications per year. The much smaller scale of PTE operations makes its management less challenging.

USPTO regulations encourage applicants to file documents with the agency electronically, assessing additional fees for filing documents in paper format.[35] However, USPTO regulations require PTE applications to be submitted in paper form.[36] The continued reliance on paper filings increases costs, processing time, and opportunities for error.

Considering the effects of the public health emergency related to the coronavirus disease (COVID-19) to be an "extraordinary situation,"[37] USPTO released an official notice on May 29, 2020, "permit[ting] the filing of initial patent term extension applications…via the USPTO patent electronic filing systems." While the change is "effective only until the USPTO provides further notice…the USPTO is continuing its efforts to modify…the new electronic filing and retrieval system, so that patent term extension applications can be filed electronically on a permanent basis."[38] Given that USPTO successfully receives over 650,000 patent applications electronically each year, it has demonstrated they possess the ability to convert to electronic filing of PTE applications.

Recommendations

We recommend the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office:

R2 Direct OPET, OPLA, and OCIO to implement, and keep up-to-date, a comprehensive set of requirements and specifications for the PTA calculator software to ensure continued compliance with current and emerging legislation and case law.

R3 Direct OPLA to coordinate with FDA and USDA to determine if electronic filing of PTE applications would be acceptable as a permanent practice after the current public health emergency has passed.

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[34] 71 F.3d 1578 (Fed. Cir. 1995).

[35] 37 C.F.R. § 1.16(t) (2019).

[36] 37 C.F.R. § 740(a) states the "An application for [PTE] must be made in writing…" Further, 37 C.F.R. § 740(b) states "The application…must be accompanied by two additional copies…(for a total of three copies)," implying a paper application is required. 37 C.F.R. § 1.740(a) and (b) (2019).

[37] 37 C.F.R. § 1.183 (2019)

[38] USPTO, "Relief Available to Patentees in View of the COVID-19 Outbreak for Submission of Initial Patent Term Extension Applications Filed Pursuant to 35 U.S.C. 156," 2020, https://www.uspto.gov/sites/default/files/documents/156-efiling-20200529.pdf.

2.3 USPTO has adequate internal controls to ensure proper calculation of PTA and PTE

As introduced in Section 2.2, some events affecting PTA are difficult or impractical to detect through the current software solution, introducing opportunities for error and inconsistency in a small number of cases. In this section we discuss our findings related to USPTO's system-based controls, day-to-day checks on the process, and petitions for reconsideration of PTA awarded.

System-based Controls

Because over 98 percent of patent applications are filed electronically, USPTO built system-based controls into the process to reduce the need for manual data entry, and the potential for data entry errors. For example:

- **PALM automatically generates date stamps when items are entered into EFS-Web or PALM.** When an application or later supporting documentation is filed electronically through the online EFS-Web tool, the event is recorded in PALM, which automatically applies a date stamp.
- **The patent filing date is system-generated.** The system automatically sets the filing date (*the* key date upon which the patent term is established) based on when sufficient documentation is submitted by the applicant and recorded in the system.
- **Dates cannot be changed through routine processes.** Most USPTO staff—including examiners—cannot change dates associated with application-related events (e.g., submission of drawings, responses to office actions). For example, once the filing date is set, only a small number of users ("three or four" according to OPAP) can edit the date. Only on rare occasions can dates be changed manually.
- **Changes are tracked.** PALM tracks and logs all changes made through the system, including changes to dates. This also applies to changes made by system administrators and PALM troubleshooters.[39]

Day-to-day Checks on the Process

As a day-to-day check on the process, USPTO relies on two sources of information to help operations run more smoothly: (1) the PALM Information File Wrapper (IFW) Treasury (PIT) report; and (2) a set of ad hoc reports run by the Patent Operations Research Team (PORT).

The PIT report[40] has been in use for approximately two years to manage workflow and productivity by prioritizing incoming documents for OPESS LIE processing. OPESS leadership considers the PIT report an improvement over the previous process. However, the report currently serves as a workaround in the absence of a workflow tool. While the report provides a

[39] PALM troubleshooters are users with greater expertise and higher system privileges that allow them to change data and fix problems. Their activities are logged, however, to maintain an audit trail.

[40] The Office of Patent Information Management (OPIM) provides the PIT Report to OPESS daily. It contains a list of all incoming responses to office actions from applicants, including the mailroom date, serial number, and the age of the response.

means of prioritizing documentation and assigning work, the process is labor-intensive, relying on supervisors to cut and paste the information and distribute it to the LIEs via email.

Second, PORT's ad hoc reports are more directed at error reduction. The reports present data input by USPTO staff and flag apparent "outliers" that may signal a mistake was made. This could be as simple as data appearing to have been entered incorrectly (e.g., a year of "2091" instead of "2019") or a miscoded document or status resulting in workflow issues.

Immediate supervisors regularly review LIE work. In addition, some of each LIE's work is periodically reviewed by a group of six reviewers within the Office of Patent Quality Assurance (OPQA). Internal controls relevant to PTA calculation also include staff training and feedback received from other processes, such as: (a) an analysis of why cases are referred to examiners; and (b) an occasional OPESS internal issue verification review that may result in refresher training.

Requests for Reconsideration of Awarded PTA

When USPTO grants a patent, which includes the PTA calculation (see Appendix A), and the patentee does not agree with the PTA awarded, the patentee can request USPTO perform a "reconsideration" of the PTA calculation. They do this by filing a reconsideration petition and paying a $210 fee.[41] USPTO receives approximately 400 reconsideration petitions per year.

The PTA reconsideration process acts as a post-issuance check on the system when human intervention is needed.[42] USPTO internal stakeholders describe the reconsideration process as an opportunity for USPTO staff to perform a thorough, manual review of PTA calculations in those cases when there may be a nuance or question the computer system did not or could detect. A commonly cited example is the "safe harbor" statement noted in Section 2.1. According to USPTO staff working in both the patent processing and PTA reconsideration process segments, "there is no easy way for the calculator to pick it up." As described by one USPTO interviewee, the safe harbor statement is "hard to calculate because you [need] a human being [to] look at that specific statement."

Generally, discrepancies between PTA calculations performed by USPTO and applicants occur when there is a misinterpretation of the start and end dates for delay periods, mis-categorization of a document filed by applicants, improper calculation of event dates, or a combination of one or more factors. In response to a reconsideration petition, attorney advisors from OPET perform a complete review of the patent file. This includes not only the petitioner's specific request, but a review of the entire application to perform a full manual re-calculation of the PTA. This is effectively an audit of the complete patent application with respect to PTA. In concept, this "audit" could serve as a model for a USPTO-initiated audit process (e.g., a periodic sampling of issued patents' PTA awards) to improve quality and compliance.

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[41] USPTO, "USPTO Fee Schedule," 2020, https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule.

[42] In these cases, the errors are not identified prior to issuing the patent, but rely on this manual reconsideration review *after* the patent has been issued. Therefore, though the reconsideration process is not, technically, an "internal control," it *does* serve as a means to remedy situations where internal controls may have failed.

The result of a reconsideration may be: (1) granting the petition, (2) changing the PTA amount, or (3) denying the petition. A review may detect an error that occurred during patent prosecution that neither the applicant nor the examiner raised at the time, potentially resulting in an addition to or reduction of the PTA.[43] Attorney advisors will look at the entire record to verify that PTA is correct in all aspects. If they find other issues, they address all issues at the same time. Such additions may sometimes benefit the applicant (i.e., longer PTA amount), but that is not always true (i.e., the review may find additional applicant delay). As of June 20, 2020 (the latest published data), 71 percent of PTA requests for reconsideration decided during the 12 preceding months resulted in a correction to the PTA initially awarded.[44] The number of successful petitions is small compared with the over 390,000 PTA calculations performed each year—less than 0.08 percent.

USPTO tracks which petitions were granted, dismissed, or denied (i.e., the number of each), but not why requests were made in the first place nor the specific outcome of the decision (e.g., why a petition was denied). An exception was in 2019, when OPET analyzed 80 PTA cases. This effort was aimed at gauging the potential impact of the *Supernus* decision as USPTO considered revisions to the rules that would be needed in light of the court ruling.

We reviewed a random sample of 202 reconsideration petition decisions in response to patentee requests for reconsideration of PTA, comparing the petition decisions to dates and information available via Public PAIR.[45] We found that 78 percent of the decisions we analyzed resulted in granting the petition (i.e., correcting the PTA).

While looking at the data was generally informative, we were not able to reach clear conclusions regarding patent processing errors reflected in the reconsideration or the frequency of those errors. The unstructured data contained in the petition decision files limited our ability to determine primary events triggering incorrect calculation, frequency of events, event combination, etc., thus making it difficult to determine retrospectively the reason(s) for the reconsideration request and the rationale for the petition decision. Tracking this information in real-time may provide insights to improve USPTO's understanding of what PTA errors are made during patent processing and refine internal controls to address those errors.

USPTO would benefit from continuing to enhance its knowledge management capabilities and continuing to expand the range of knowledge beyond one or two key individuals in one office. A running log of petitions[46] would be an important component of the accumulated institutional knowledge.

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[43] USPTO, "MPEP 2734-Application for Patent Term Adjustment; Due Care Showing," 2019, https://www.uspto.gov/web/offices/pac/mpep/s2734.html.

[44] USPTO, "Patent Term Adjustment Petitions," March 30, 2019, https://www.uspto.gov/patents-application-process/petitions/timeline/patent-term-adjustment-petitions.

[45] See Section B.3.7 in Appendix B for details on our sampling methodology

[46] Including reasons for the request for reconsideration, issues discovered during the audit, and the final resolution of the petition.

Recommendations

We recommend the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office:

R4 Direct OPESS and OCIO to: (1) determine the feasibility of implementing a workflow process or tool (similar to the examiner "docket" system) for LIE managers; and (2) add clarifying language to the document description codes in PALM to mitigate the risk of miscoded documents.

R5 Direct the Commissioner for Patents to implement a means to identify and remedy the types of events that typically require a manual review (e.g., IDSs) as they occur.

R6 Direct OPET to implement a pilot program to perform periodic, OPET-initiated reconsideration-like audits on a random sampling of PTA calculations.

3 Conclusion

Overall, our evaluation of USPTO's calculation of PTA and PTE found the calculations and the data upon which they are based mostly accurate and reliable. However, we did identify some areas to improve data reliability, maintain compliance with the laws and regulations, and to augment internal controls related to the calculation.

Existing internal controls enable data reliability, and the system allows users to track all of the PTA-related event dates. Some key dates are entered manually, introducing opportunities for error that the current controls may miss. Nevertheless, our analysis of PTA calculation results from the source data confirmed that the calculations are correct over 93 percent of the time.

We found that, with limited, temporary exceptions (e.g., appellate court or Supreme Court decisions), the PTA calculation is performed in compliance with current statutes, regulations, and case law. When a patentee discovers discrepancies, they have recourse to the PTA reconsideration process which effectively audits the entire application. USPTO could leverage this process to periodically audit a random sampling of applications to look for recurring problems and discover issues before they impact a patentee.

Finally, we found that USPTO awards PTE in compliance with applicable statutes, regulations, and case law. However, until the recent public health emergency, USPTO regulations required PTE applications to be submitted "in writing"—in other words, in paper form. USPTO has an opportunity to reduce the overhead associated with the paper-based process by making this shift to the allowance of electronic filing of PTE applications permanent.

4 Summary of Recommendations

To address the findings in this report, we recommend the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office:

R1: Direct the Commissioner for Patents to (1) mandate the use of the "safe harbor" form to claim the exception, and (2) ensure the inclusion of clear category and description definitions for applicants while keeping their focus on the task at hand (i.e., the document submission form).

R2: Direct OPET, OPLA, and OCIO to implement, and keep up-to-date, a comprehensive set of requirements and specifications for the PTA calculator software to ensure continued compliance with current and emerging legislation and case law.

R3: Direct OPLA to coordinate with FDA and USDA to determine if electronic filing of PTE applications would be acceptable as a permanent practice after the current public health emergency has passed.

R4: Direct OPESS and OCIO to: (1) determine the feasibility of implementing a workflow process or tool (similar to the examiner "docket" system) for LIE managers; and (2) add clarifying language to the document description codes in PALM to mitigate the risk of miscoded documents.

R5: Direct the Commissioner for Patents to implement a means to identify and remedy the types of events that typically require a manual review (e.g., IDSs) as they occur.

R6: Direct OPET to implement a pilot program to perform periodic, OPET-initiated reconsideration-like audits on a random sampling of PTA calculations.

5 Summary of Agency Response

In response to our draft report, USPTO concurred with all of our recommendations and provided some technical comments. We accepted the technical comments, as appropriate, and included them in the final version of this report. We have included USPTO's formal comments in Appendix F.

In their response, USPTO disagreed with some of our PTA calculations. We performed our calculations based on the data provided by USPTO and the PTA calculation rules. In addition, in section 2.2 we acknowledge that variances were mostly small (i.e., less than 10 days). Finally, the data USPTO provided did not clearly identify whether an application was a Patent Cooperation Treaty (PCT) national stage application, so our calculations could not incorporate that special case.

In concurring with recommendation R1, USPTO indicated they will propose a rule to encourage the use of the "safe harbor" form and consider ways to allow easier access to document category definitions. In agreeing with recommendations R2, R3, R5, and R6, USPTO shared they are currently taking action to make these changes. In concurring with recommendation R4, USPTO acknowledged they will assess the feasibility of implementing a workflow tool for LIEs and improve document description codes.

We appreciate the courtesies extended by USPTO personnel at all levels during the course of this evaluation.

Appendix A Calculating PTA and PTE

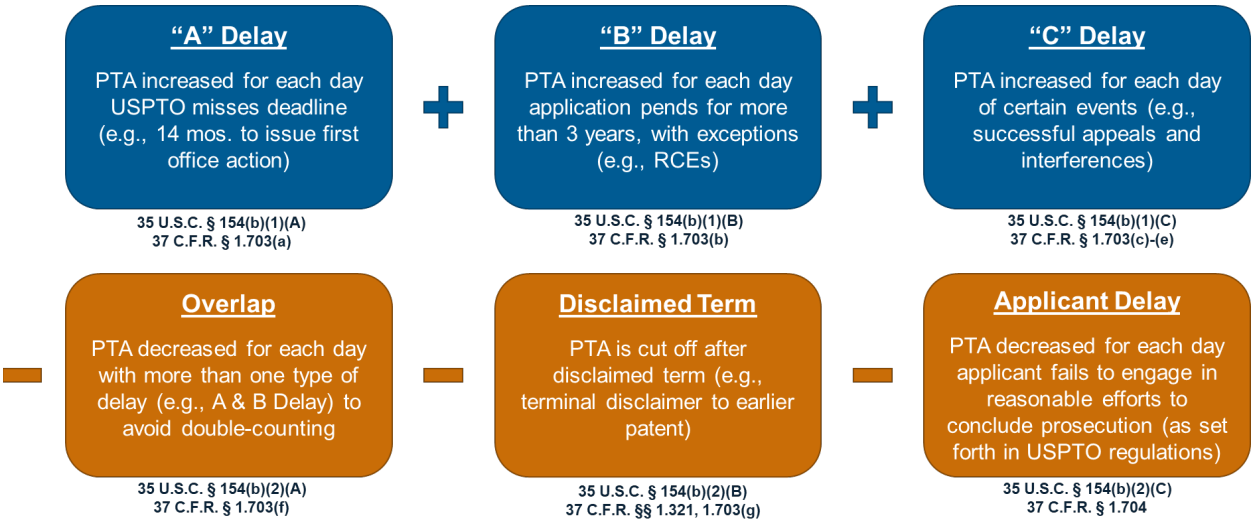
This appendix describes the PTA and PTE calculations.

A.1 Patent Term Adjustment Calculation

PTA alters the duration of a patent, potentially giving the patentee additional time to enforce its proprietary rights. Patents ordinarily last 20 years from the effective filing date of an application,[47] contingent upon the payment of maintenance fees. Congress recognized that lengthy USPTO delays between the application's filing date and agency approval erode a patent's period of enforceability. Under PTA legislation, certain USPTO delays result in a day-per-day increase in a patent's term. Any USPTO delay that occurs while the patent application is being examined—a period known as *patent prosecution*—is offset by delays caused by the patentee.

Enacted in November 1999 as part of the American Inventors Protection Act, the PTA statutory provisions were codified at 35 U.S.C. § 154(b). USPTO regulations implementing this statute are codified at 37 C.F.R. §§ 1.701-785.

Figure A-1. Calculating the Patent Term Adjustment.



Source: MITRE, derived from USPTO PTA and PTE overview slides

As shown in Figure A-1, PTA amount increases under three circumstances, referred to as "delay":

- "**A" delay:** Time added to PTA amount for each day USPTO misses a deadline. For example, USPTO has 14 months in which to issue its first office action, or initial decision

[47] A patent application has an effective filing date that is earlier than its actual filing date if it claims priority to (or benefit of) an earlier application's filing date. 35 U.S. Code, §§ 119(e) and 120.

on whether the patent application should be granted or rejected. For each day beyond those 14 months, the calculation adds a day of PTA.

- **"B" delay:** Time added to PTA amount for each day that a patent application pends longer than the three-year deadline to issue the patent. This three-year period does not include time consumed by certain events like Requests for Continued Examination (RCEs).
- **"C" delay:** Time added to PTA amount for each day of other specified events. For example, a successful appeal or interference can increase the PTA amount.

PTA amount decreases if there is overlap of delay type (to avoid double-counting), or for "applicant delay," if an applicant fails to engage in "reasonable efforts to conclude prosecution." PTA is also cut off after the term of the patent is disclaimed (i.e., a "terminal disclaimer").[48] If the decreases bring the award below zero, then no PTA is awarded (i.e., the patentee will not get a patent term *reduction*, PTA is set to zero).[49]

Each portion of the calculation corresponds to specific sections of law and regulation, as shown in Figure A-1.

A.2 USPTO PTA Calculation Process

Over 98 percent of patent applications are currently filed electronically.[50] As USPTO processes each patent application, data are collected, stored, and tracked in the agency's PALM database. "The PALM…System is the automated data management system used by the [USPTO] for the retrieval and/or online updating of the computer record of each patent application. The PALM System also maintains examiner time, activity, docket records, and technical support staff backlog records."[51] PALM records "event codes" related to each action and the date the action occurred. Some of these events are relevant to the calculation of PTA (e.g., first office action, RCE, successful appeal).

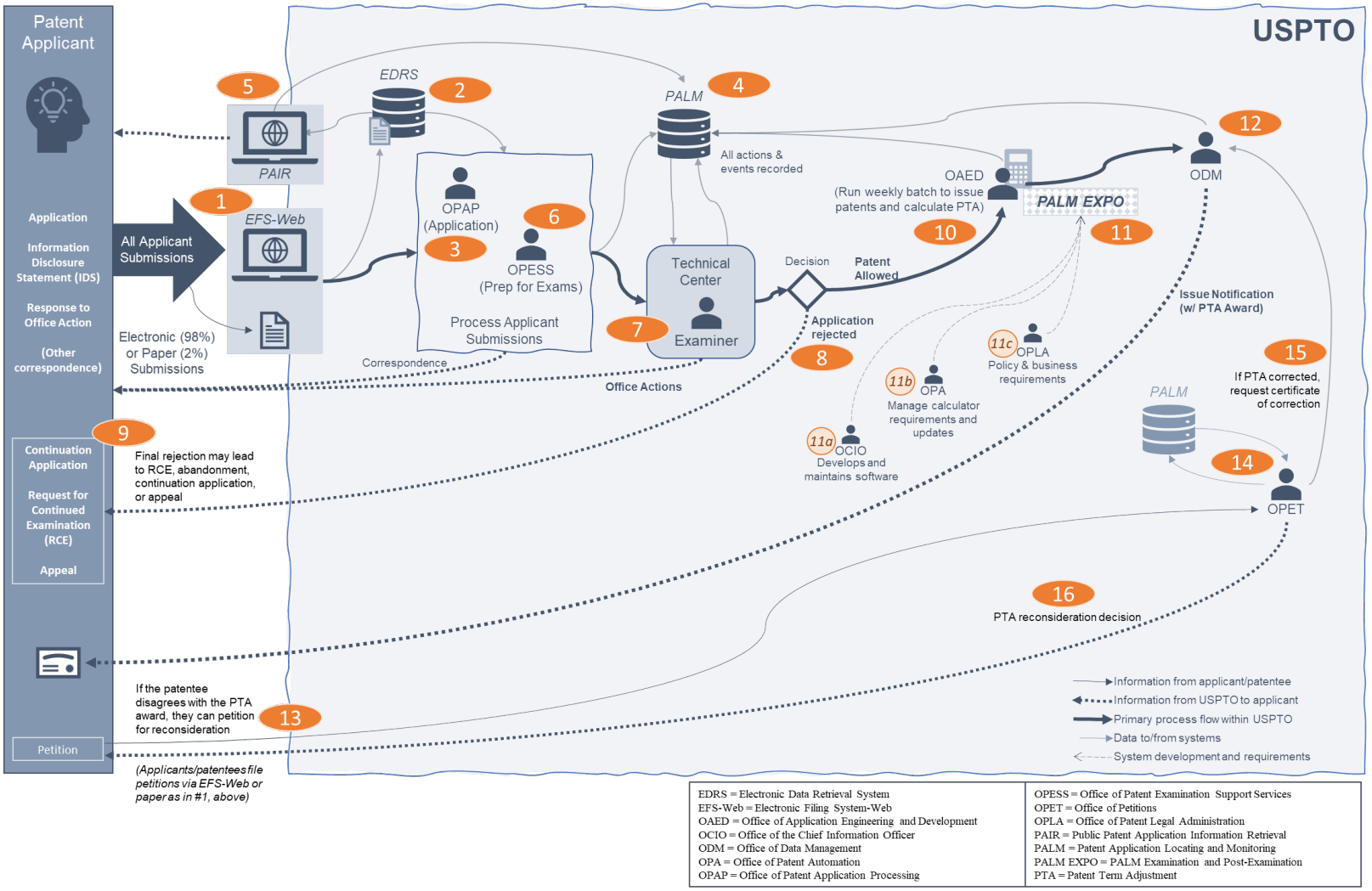
[48] "A terminal disclaimer is a statement in which a patentee or applicant disclaims or dedicates to the public the entire term or any terminal part of the term of a patent or patent to be granted (filed in an application)." (https://www.uspto.gov/web/offices/pac/mpep/s1490.html)

[49] Stuart J.H. Graham, Alan C. Marco, and Richard Miller, "The USPTO Patent Examination Research Dataset: A Window on Patent Processing--Appendix E: Description of the Patent Term Adjustment Data Release," 2015, https://www.uspto.gov/sites/default/files/documents/Appendix E.pdf.

[50] USPTO, "Using EFS-Web: 5 Electronic Filing Pitfalls and How to Avoid Them," InventorsEye, November 2014, https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/using-efs-web-5-electronic-filing-pitfalls-and-how.

[51] USPTO, "MPEP 1704-Application Records and Reports [R-07.2015]," 2015, https://www.uspto.gov/web/offices/pac/mpep/s1704.html.

Figure A-2. Step-by-Step High-Level Process for PTA Calculation and Reconsideration.



Source: MITRE, derived from multiple USPTO sources

Figure A-2 illustrates the high-level process for the PTA calculation, including the office(s) involved.[52] The following steps correspond to the numbers on the process map:

1. A patent applicant or their assignee may submit applications and any other correspondence electronically through the EFS-Web portal or by paper.
2. The Electronic Data Retrieval System stores images of all applicant submissions.
3. OPAP processes all applications.
4. OPAP adds a record of the application into Patent Application Locating and Monitoring (PALM). Note that *all* actions and events (and their corresponding dates) related to the patent application are recorded in PALM.
5. The applicant can view the status of their application at any time through the Private Patent Application Information Retrieval (PAIR) portal.
6. OPESS processes most other submissions, adding data to PALM.
7. An examiner in one of the Technical Centers (depending on the subject of the patent application) examines the patent application.
8. If the examiner rejects the application, the applicant can submit an RCE, submit a continuation application, or file an appeal. Each of those actions follow the same path as the original application and other submissions (i.e., they start at Step 1).
9. The applicant can also abandon the application, choosing none of the options in Step 8.
10. If the patent is allowed, the Office of Application Engineering and Development (OAED) will include it in a weekly batch to calculate PTA and issue the patents.
11. PTA is calculated in PALM EXPO.
    a. OCIO develops and maintains the PALM EXPO software.
    b. The Office of Patent Automation (OPA) manages the PTA calculator requirements and updates.
    c. OPLA owns PTA-related policy and business requirements.
12. When the patent is issued, ODM performs all the final processing on the patent before it is printed. The preliminary PTA awarded is noted on the "Issue Notification."[53]
13. Once the patent is granted, the applicant, if they believe the calculation of PTA on the granted patent was less than they were entitled to, can petition for reconsideration of the PTA award, either electronically (through EFS-Web) or by paper (Step 1). The patentee must file the petition "no later than two months from the date the patent was granted."[54]

[52] Note that the figure and accompanying description are intended for illustration purposes only to provide context for this report and are not intended to be an exhaustive representation of the patent application and examination process.
[53] "Manual of Patent Examining Procedure (MPEP)," sec. 2733.
[54] 37 C.F.R. § 1.705 (2019). The two-month period may be extended under the provisions of 37 C.F.R. § 1.136(a).

14. OPET performs a full audit of the patent application record in PALM and the corresponding image files in EDRS to determine if the calculation was correct.
15. If OPET decides some correction to the PTA awarded is necessary, they will request a certificate of correction to the patent (PTA is printed on the patent).
16. Regardless of the outcome, OPET sends a PTA reconsideration decision to the patentee.

Of note, if a patentee is awarded PTA that is *greater* than expected, they may "disclose the error to the Office in a letter in compliance with the practitioner's duty of candor and good faith in practice."[55] USPTO will place these letters in the file of the patent without comment. They will not review these letters nor issue certificates of correction solely based on these letters.

A.2.1 PTA calculator is an automated tool

To calculate PTA for a specific patent application, USPTO uses its PTA calculator—an automated tool in the PALM EXPO system. The PTA calculator applies the calculation illustrated in Figure A-1 using inputs—event codes and associated dates—that have been automatically (i.e., through electronic filing) or manually (i.e., by USPTO staff) entered into PALM. USPTO organizations responsible for processing applications include OPAP and OPESS. The latter is responsible for preparing documentation for examiners in one of the Technical Centers (depending on the subject of the patent application) who examines the patent application.

The OAED within the OCIO executes the PTA calculation once at the time of patent issue. The calculation is performed for *every patent issued*, although in roughly half of the patents issued, the PTA award is zero days. Figure A-2 provides a high-level look at the USPTO process and the systems involved in calculating PTA.

A.2.2 Reconsideration process addresses PTA disputes between USPTO and patentee

Once PTA is calculated and a patent issued, a patentee who disagrees with the amount of PTA granted may petition for a reconsideration. The patentee can request that USPTO review the PTA calculation under 37 C.F.R. § 1.705(b). OPET will then undertake the reconsideration through a manual calculation process. When addressing a PTA reconsideration petition, OPET not only evaluates the specific petition request, but also revisits the entire calculation, making additional adjustments as appropriate. In this way, the reconsideration process serves as an applicant-requested "audit" of the file (see Section 2.3 for additional information regarding the reconsideration process).

A.2.3 USPTO Organizations Involved in the PTA Calculation

USPTO's Office of the Commissioner for Patents is responsible for examining applications and granting patents when required conditions are met. Within this office, multiple organizations share responsibility for the key aspects of PTA calculation, as outlined in Table A-1.

[55] USPTO, "Manual of Patent Examining Procedure (MPEP)," sec. 2733.

Table A-1. USPTO Offices with PTA Calculation Responsibility.

Process Segment	Office		Responsibility for PTA Process
Patent Processing			
	Office of Patent Application Processing	OPAP	Conducts initial processing when application first filed
	Office of Patent Examination Support Services	OPESS	Prepares documents for examiners when filed
	Patent Examining Group Centers		Determines whether the application meets patentability requirements
	Office of Data Management	ODM	Issues the patent (with PTA amount included) when granted and certificate of correction as needed
PTA Calculator			
	Office of Patent Legal Administration	OPLA	Business owner for requirements and updates
	Office of Patent Automation	OPA	Manages calculator requirements and system updates
	Office of the Chief Information Officer	OCIO	Develops PALM, PALM EXPO, eDRS, the PTA calculator tool, etc.
	Office of Application Engineering and Development	OAED	Executes weekly batch job to print issued patents and calculates PTA
Reconsiderations			
	Office of Petitions	OPET	Performs manual reconsideration of PTA amount/audit of entire file
	Office of Patent Legal Administration	OPLA	Provides policy expertise and review
	Manual of Patent Examination Procedure, editor office	MPEP	Provides policy expertise and review

Source: MITRE, derived from multiple USPTO sources

For illustrative purposes we have divided the process into three segments: patent processing, development and maintenance of the PTA calculator, and reconsiderations.

A.3 Patent Term Extension Calculation

PTE applies to patents claiming products that must be approved by a regulatory agency (FDA or USDA) prior to being marketed. Enacted in 1984 as part of the Drug Price Competition and Patent Restoration Act (Hatch-Waxman Act), the PTE statute provides additional patent term to compensate patentees for delays in obtaining marketing approval from the regulatory agency.[56]

[56] 35 U.S.C. § 156.

Unlike the PTA process, applying for and calculating PTE is a mostly manual process (e.g., paper-filing with multiple copies) requiring coordination between USPTO and the appropriate regulatory agency. USPTO attorneys from the OPLA within the OPEP process the PTE application. The regulatory agency ultimately bears responsibility for determining the duration of the regulatory delay that extends the patent term.

While USPTO addresses PTA disputes itself through its reconsideration process, any disputes regarding the amount of PTE are handled through the corresponding regulatory agency, not USPTO. The regulatory agency publishes the regulatory delay calculated on the Federal Register and USPTO uses this value as the data input for calculating PTE in compliance with statute, regulation, and case law. USPTO has minimal visibility into how regulatory agencies calculate regulatory delay.

Appendix B **Objective, Scope, and Methodology**

We conducted this evaluation in accordance with *Quality Standards for Inspection and Evaluation* (January 2012) issued by the Council of the Inspectors General on Integrity and Efficiency.[57] Those standards require that the evidence supporting the evaluation's findings, conclusions, and recommendations should be sufficient, competent, and relevant and should lead a reasonable person to sustain the findings, conclusions, and recommendations. We believe that the evidence obtained provides a reasonable basis for our findings, conclusions, and recommendations based on our review objective.

B.1 Objectives

The objectives of this evaluation were three-fold, to determine if:

1. USPTO uses valid and reliable data to calculate PTA and PTE.
2. USPTO calculates and awards PTA and PTE in compliance with relevant statutes, regulations, and case law.
3. USPTO has adequate internal controls to ensure the proper calculation and award of PTA and PTE.

To address these objectives, we used the following approaches:

1. **Data Reliability**: Determine if the data that the PTA calculator uses were valid and reliable. This includes determining stakeholders' (internal and external) subjective views on the reliability of the data and considering points in the process where USPTO and applicants input data.
2. **Compliance with Statute, Regulation, and Case Law**: Determine if the processes and the PTA calculator were compliant with the relevant statutes, regulations, and case law. That is, did the USPTO guidance, system requirements, and software test results align with the governing law and regulations? Were each of these kept up-to-date as new case law is introduced? Was the result of the USPTO-generated calculation valid and reliable?
3. **Additional Internal Controls**: Determine if the USPTO processes (e.g., patent prosecution) for capturing information related to PTA and PTE, and the process for calculating PTA and PTE had controls built-in to ensure data reliability. At each step, identify potential errors that could occur (e.g., system errors, manual data entry error, calculation error, etc.), the actions USPTO was currently taking to address these potential errors, and where USPTO could make further improvements.

The three objectives worked together to ensure USPTO was providing high-quality PTA calculations. If the data USPTO collected and stored were valid and reliable (i.e., USPTO used the correct data), and the data were fed into a calculator reflecting the full set of legal requirements (i.e., USPTO used the correct calculation), then, the final calculation and award of

[57] Council of the Inspectors General on Integrity and Efficiency (CIGIE), *Quality Standards for Inspection and Evaluation*.

PTA would also be correct, and internal controls would be in place to assure the quality of the calculation and award of PTA and PTE.

In assessing each objective, we recognized that internal controls were necessarily a part of the discussion for both data reliability (Objective 1) and compliance with statute, regulation, and case law (Objective 2). As such, we provided a broad look at the internal control environment in the introduction to our findings (Section 2), summarizing control activities identified across the full PTA process. Within the sections corresponding to Objective 1 and 2 (Sections 2.1 and 2.2, respectively), we provided detail regarding what controls currently existed to maintain data reliability and compliance, and where improvements could be made. For Objective 3, we focused on the role of the reconsideration process—both as a mechanism in place when internal controls failed to detect error and as a missed opportunity to provide a supplementary internal control.

In addition, because a key piece of the PTE calculation—determining the duration of the regulatory delay that extends the patent term—is performed by FDA or USDA with little USPTO involvement, we discussed PTE only in Section 2.2. As a result, the bulk of this assessment focused on PTA data, processes, and calculation.

B.2 Scope

The scope of our work was limited to the assessment of PTA for USPTO delays during patent examination as defined by statute[58] and PTE for delays caused by FDA or USDA regulatory actions as defined by statute.[59] The assessment included a comprehensive review and analysis of data, calculations, processes, procedures, internal controls, statutes, regulations, case law, and literature relevant to PTA and PTE. Another form of patent term extension was enacted as part of the 1994 Uruguay Round Agreements Act,[60] but this provision applies only to patents filed before June 8, 1995, and is considered out-of-scope for this evaluation.

Our review of PTA and PTE calculations considered patents awarded between October 2018 and September 2019. We examined statutes, regulations, and case law.[61] This evaluation focused on the validity of the calculations themselves and did not assess USPTO's ability to decrease the amount of "A" delay or "B" delay through more prompt examination services.

Because over 98 percent of patent applications are filed electronically and the initial PTA award is calculated entirely by software, this evaluation included the guiding system requirements and current state of the relevant IT systems involved in the calculation of PTA. However, a full software code analysis of the PTA calculator was out-of-scope for our effort.

As described above, because eligible patentees file only a relatively small number of PTE applications every year (about 100 per year for the past four years) with low and manageable error rates, the bulk of this evaluation focused on PTA. Further, because the fieldwork phase of

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[58] 35 U.S.C. § 154(b).

[59] 35 U.S.C. § 156.

[60] World Trade Organization, "Understanding the WTO - The Uruguay Round," 2020, https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm.

[61] Including but not limited to 35 U.S.C. § 154(b) (PTA), 35 U.S.C. § 156 (PTE), 37 C.F.R. §§ 1.701 – 1.705 (PTA), 37 C.F.R. §§ 1.710 – 1-791 (PTE), and the case law discussed in Appendix C.

this evaluation concluded as the public health emergency related to COVID-19 started in January 2020—and prior to notice of the temporary process change described Section 2.2, Patent Term Extension Calculation subsection—this report did not include analysis of these current events.

B.3 Methodology

This evaluation applied technical research and analysis, program evaluation, risk management, federal agency modernization expertise, business transformation expertise, and relevant legal expertise as applicable to USPTO's calculation of PTA and PTE.

In conducting this evaluation, we applied U.S. Government Accountability Office's *Green Book*[62] and relevant aspects of its *Assessing Data Reliability* guide.[63] We also conducted this evaluation in accordance with the *Blue Book*.[64]

We conducted an extensive literature review to discover previously identified issues related to PTA or PTE. We reviewed, in-depth, the governing statutes, regulations, and case law. Additionally, we performed a comprehensive analysis of USPTO's guidance related to PTA and PTE (MPEP Chapter 2700).

To gather stakeholder input, we conducted interviews with 38 staff at USPTO, selected for their knowledge and expertise with respect to the PTA or PTE processes. As appropriate, we held information gathering sessions with USPTO organizations related to PTA and PTE and sent a survey invitation to nearly 600 patent holders to collect their views on the PTA calculation process.

We analyzed a sampling of source documentation and system data to validate PTA calculations, inspected the software requirements documentation to verify the system was designed correctly to make compliant PTA determinations, and reviewed test documentation for successful PTA calculation validation. Finally, we evaluated a large sample of PTA reconsideration decisions to determine if there were any trends or key issues with the calculation. In performing this evaluation, we assumed that all documentation and data provided by USPTO was shared in good faith and without alteration.

B.3.1 Research and Analysis

We conducted research from October 2019 through August 2020. We consulted the types and quantities of information summarized in Table B-1. This material included the relevant statutes, regulations, and case law.

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[62] U.S. Government Accountability Office, "Standards for Internal Control in the Federal Government - GAO 14-704G (The Green Book)," 2014, https://www.gao.gov/products/GAO-14-704G.

[63] U.S. Government Accountability Office, "Assessing Data Reliability (GAO-20-283G)," 2019, https://www.gao.gov/assets/710/703275.pdf.

[64] Council of the Inspectors General on Integrity and Efficiency, "Quality Standards for Inspection and Evaluation (*Blue Book)*." See Appendix D for a description of the alignment of MITRE practices with the *Blue Book* standards.

Table B-1. Types and Number of Sources Consulted.

Type of Source	Number of Sources
Direct Observations	2
External Document: Journal Article	23
External Document: Misc.	11
External Document: Misc.	3
Internal Documents	39
Internet Resource: Article	12
Internet Resource: Document	34
Internet Resource: Video	1
Interview	38
Study	7
Subject Matter Expert	4

B.3.2 Interviews

We conducted 38 interviews during the evaluation, from representatives of all the organizations and roles primarily responsible for the PTA and PTE calculations, including the leading experts on PTA and PTE in USPTO and senior leadership. We interviewed individuals from the following offices:

- Office of Data Management (ODM)
- Office of Patent Application Processing (OPAP)
- Office of Patent Examination Policy (OPEP)
- Office of Patent Examination Support Services (OPESS)
- Office of Patent Legal Administration (OPLA)
- Office of Patents Legal Administration (OPLA)
- Office of Petitions (OPET)
- Office of Stakeholder Outreach and Patents Ombudsman
- Office of the Commissioner of Patents
- Patent Operations Research Team (PORT)
- Office of Patent Automation (OPA)
- Office of the Chief Information Officer (OCIO)
- Office of Patent Quality and Assurance (OPQA)
- Office of Patent Planning and Data Analysis

B.3.3 Survey

We developed a short survey of a representative random sample of external stakeholders to gauge their views on PTA, data reliability, the compliance of the PTA calculation, and PTA reconsiderations.

Out of 369,783 records in the original data file of patentees for all patents awarded between October 2, 2018, and March 10, 2020, we found that 9,179 records (2.5%) contained no email address. Of the remaining 360,604 records, there were 8,111 (2.2%) unique email addresses. The target sample size for a population of 8,111 allowing a margin of error of 0.05, and assuming a response rate of 50 percent, is 734. We balanced the distributions to get a representative sampling by U.S.-v.-foreign applicants, micro/small/undiscounted applicants, Technical Center, filing year, and issue year. The sample contained roughly the same percentage of each category as were in the total population.

We received 79 responses. Since the surveys were anonymous, we could not directly determine if the responses were representative of the population. However, our sampling strategy (i.e., representative random sample) coupled with our judgment that any selection bias would not necessarily be biased toward or away from any one category (except perhaps foreign applicants due to the potential for a language barrier), gave us some assurance that the responses were representative. Due to the low response rate, we could not perform any multi-factor analysis, therefore our observations and conclusions from the survey are limited to generalized findings (e.g., "most respondents agreed…"), and could only be used in corroboration of our other, more supportable findings.

B.3.4 Compliance Review

To assess whether USPTO's PTA calculation and award is compliant with relevant statutes, regulations, and case law (Objective #2), we performed the following analyses:

- **Guidance Compliance**

  To verify USPTO guidance is compliant with relevant statutes, regulations, and case law (Objective #2), we constructed a matrix to map the relevant sections of 35 U.S.C. and 37 C.F.R. to the MPEP. This resulted in a "heat map" showing any potential gaps in the MPEP.

- **Software Requirements Analysis**

  To verify PTA calculator was designed to be compliant with relevant statutes, regulations, and case law (Objective #2), we analyzed the latest available set of software requirements USPTO provided. We mapped each requirement to the relevant statute, regulation, or case law, to identify any gaps or errors in the requirements.

- **PALM EXPO Test Results**

  To verify the system design was implemented correctly, we reviewed the test results from the reports and data USPTO provided.

B.3.5 Organization and Process Review

To understand the process, identify any gaps, bottlenecks, etc., and to look for opportunities for error and/or internal controls, we reviewed the processes related to PTA and PTE, as well as the organizational structure.

B.3.6 Data Analysis

PALM Data Analysis

To verify the outputs of the PTA calculator are compliant with relevant statutes, regulations, and case law (Objective #2), we analyzed a sampling of PALM data provided by USPTO for patents issued in 2019. USPTO provided PALM data on 54,644 patents. We took a representative random sample based on U.S.-v.-foreign applicants, micro/small/undiscounted applicants, Technical Center, filing year, and issue year, and by bins of PTA actually awarded (e.g., "0 days", "1-249 days"). If the true proportion of correct calculations is 90 percent, to get a margin of error of 0.05, a statistically significant sample size would be 138. However, our methods allowed for a much larger sample size to better verify the PTA calculations. We randomly selected a representative sample of 1,055 patents to verify the calculations for all the PTA-related events for that patent application in PALM. This provided a total of over 18,000 event records to verify. We recorded the number/percentage of correct calculations by type (e.g., "A" delay, "B" delay), down to the individual rule level (e.g., "A.14.A1," "Applicant.B", "Applicant.C4").

Source Documentation Verification

Using the same data analyzed above, we performed a spot-check of the dates in PALM against the dates on the source documents found in Public PAIR for each application. We assigned a random number to each of the 14,379 events in the PALM data used in the analysis described above. Using limited time allotted to us, we then sorted the list in descending order; this was a very slow, manual process involving looking up one record at a time through the Public PAIR portal. From this work, we were able to validate 457 individual events (representing 457 different patents). This is not a representative, nor statistically significant sample size, however, we were able to see enough to corroborate our other related findings.

B.3.7 PTA Reconsideration Analysis

Finally, we reviewed a sampling of reconsideration decisions for fiscal year (FY) 2018 and FY2019 along with some preceding reconsideration decision data provided by USPTO as part of an earlier data set. We reviewed 202 decisions.

B.4 Synthesis and Reporting

We used a MITRE-developed application ("RIGOR") to record all our sources, observations, conclusions, and recommendations, and to maintain traceability ensuring all of our recommendations were evidence-based. After presenting our initial findings to the Office of the Inspector General, we developed this report to record the results of our assessment.

Appendix C Summary of Case Law Related to Patent Term Adjustment (PTA)

C.1 Summary

USPTO's PTA calculator must be updated regularly to account for new legislation and case law. For example, in 2013, Congress made technical amendments to the PTA statute[65] to fix some small drafting flaws. Additionally, the U.S. Court of Appeals for the Federal Circuit has clarified how the statute should be applied in a number of cases brought by patent applicants challenging USPTO's interpretation of the statute.

When a court issues a ruling that reverses—in whole or part—USPTO's interpretation of PTA statute, the reversal results in an operational change as to how USPTO calculates and awards PTA. Changes to case law equate to changes to USPTO PTA processes, system changes, or both. USPTO must then update its guidance and training to reflect the new interpretation. As part of this assessment, we reviewed the cases listed in Table C-1 to ensure USPTO updated its PTA calculator and associated guidance in accordance with the referenced holdings.

Table C-1 includes the most significant PTA case law from 2010 to the present.

Table C-1. Summary of Case Law Pertaining to PTA Calculation.

Case	USPTO Affirmed or Reversed	Summary of Holding	Title 35 U.S.C. Title 37 C.F.R.
***Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010)**	Reversed	A patentee may obtain both "A" delay term extension accrued during the first three years from the filing date of the application and "B" delay that accrues after that three-year date, provided that they do not occur on the same calendar day.	154(b)(2)(A) 1.703(f) *See also* 75 Fed. Reg. 5043 (Feb. 1, 2010)
***Novartis AG v. Lee*, 740 F.3d 593 (Fed. Cir. 2014)**	Affirmed in part, Reversed in part	(1) The 180-day time limit for appeals applies to all PTA redeterminations. (2) The time between allowance and issuance may qualify as "B" delay, even if the applicant files a request for continued examination.	(1) 154(b)(4)(A) (2) 154(b)(1)(B) 1.703(b)(1), 1.704 *See also* 80 Fed. Reg. 1346 (Jan. 9, 2015)
***Gilead Sciences, Inc. v. Lee,* 778 F.3d 1341 (Fed. Cir. 2015)**	Affirmed	Applicant delay may include the period between the examiner's imposition of a restriction requirement and the applicant's filing of a supplemental Information Disclosure Statement.	154(b)(2)(C) 1.704(c)(8)
***Mohsenzadeh v. Lee*, 790 F.3d 1377 (Fed. Cir. 2015)**[66]	Affirmed	A divisional patent is not entitled to a term adjustment based on delays during prosecution of its parent application.	154(b)(1)(A)

[65] 35 U.S.C. § 154(b).
[66] 790 F.3d 1377 (Fed. Cir. 2015)

Case	USPTO Affirmed or Reversed	Summary of Holding	Title 35 U.S.C. Title 37 C.F.R.
***Daiichi Sankyo Co. v. Lee*, 791 F.3d 1373 (Fed. Cir. 2015)**	Affirmed	USPTO was entitled to limit its interim procedure for PTA reconsideration in light of *Wyeth v. Kappos* to petitions filed within 180 days of patent grant.	154(b)(4) 1.705(d), 1.183
***Pfizer, Inc. v. Lee*, 811 F.3d 466 (Fed. Cir. 2016)**	Affirmed	The "A" delay period is calculated based on the time that passes between the 14-month deadline and the mailing of the First Office Action, even if the First Office Action is later shown to be erroneous.	154(b)(1)(A)
***Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019)**	Reversed	Applicant delay does not include a period time during which the applicant could not have taken any action to conclude prosecution.	154(b)(2)(C)(i) 1.704(c) *See also* 84 Fed. Reg. 53090 (Oct. 4, 2019)
***Mayo Foundation v. Iancu*, 938 F.3d 1343 (Fed. Cir. 2019)**	Affirmed	The time between the end of an interference and the mailing of a notice of allowance is not a "B" delay.	154(b)(1)(B)(i) 1.703(b)(1)
***Intra-Cellular Therapies, Inc. v. Iancu*, 938 F.3d 1371 (Fed. Cir. 2019)**	Affirmed	Applicant delay includes the period of time between the applicant's filing of a non-compliant and compliant submission, after the examiner had issued a Final Rejection.	154(b)(2)(C)(i) 1.704(b)

Source: MITRE, derived from multiple sources

C.2 Impacts on the PTA Calculation

The Court of Appeals for the Federal Circuit corrected USPTO's interpretation of the PTA statute in three significant cases: *Wyeth v. Kappos* (2010), *Novartis AG v. Lee* (2014), and *Supernus Pharmaceuticals, Inc. v. Iancu* (2019).

C.2.1 Wyeth v. Kappos

The 2010 *Wyeth v. Kappos*[67] case focused on the subtraction from the PTA calculation of any "overlap" of "periods of delay" under § 154(b)(2)(A) to avoid double-counting. The agency concluded that applicants could receive either "A" delay or "B" delay (whichever was greater), but not a combination of the two. The Federal Circuit held that this position "cannot be reconciled with the language of the statute" and a patentee can obtain both "A" and "B" delay, provided they do not occur on the same calendar day.[68]

Within a month of the Wyeth decision, USPTO issued a notice it was "revising the computer program it uses to calculate patent term adjustment to calculate overlapping delays consistent with the Federal Circuit's interpretation of 35 U.S.C. § 154(b)(2)(A) in Wyeth" and providing a

[67] 591 F.3d 1364 (Fed. Cir. 2010)
[68] 591 F.3d 1364 (Fed. Cir. 2010)

process for correcting related errors in PTA calculations.[69] The Wyeth interpretation is now reflected in 37 C.F.R. § 1.703(f) MPEP § 2731, and in the PTA calculator software.

C.2.2 Novartis AG v. Lee

In the 2014 *Novartis AG v. Lee* case, the Federal Circuit concluded the agency was "partly incorrect in its interpretation of § 154(b)(1)(B)," the "B" delay provision.[70] This provision increases PTA for each day after three years from filing that the patent application remains pending, with exceptions including "time consumed by continued examination."[71] The Federal Circuit rejected USPTO's view that, during a continued evaluation, "the time after allowance, until issuance, is 'time consumed by continued examination' and so is excluded from adjustments given to the patentee."[72]

Almost a year after Novartis, USPTO revised its regulations to account for this change.[73] The Novartis decision is reflected in MPEP § 2732.[74] The requirements provided by USPTO pre-date the Novartis decision, so we could not verify this decision was built into the PTA calculator software. In the year after Novartis, the number of reconsideration petitions nearly doubled (to about 900). Due to a lack of reliable data about reconsiderations, however, (discussed in Section 2.3, Requests for Reconsideration of Awarded PTA subsection), this increase is only anecdotal: "when Novartis happened the flood gates opened and then they went away;" and "After [the Novartis decision] a lot of petitions were filed and when the office changed the calculator they started to tail off." Attorney advisors who process those reconsiderations receive training to prepare them for possible scenarios that might arise in light of the decision.

C.2.3 Supernus Pharmaceuticals, Inc. v. Iancu

Most recently, the Federal Circuit corrected USPTO's interpretation of the requirement under § 154(b)(2)(C)(i) that PTA be reduced for applicant delay—that is, each day "during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." In *Gilead Sciences, Inc. v. Lee*, the Federal Circuit upheld the agency's interpretation of this statute where "Congress has not addressed the precise question at issue."[75] In *Supernus Pharmaceuticals, Inc. v. Iancu*, however, the Federal Circuit held that USPTO "exceed[ed] its statutory authority" in issuing regulations in 37 C.F.R. § 1.704 under which the agency would "count as applicant delay a period of time during which there was no action that the applicant could take to conclude prosecution of the patent."[76]

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[69] 75 Fed. Reg. 5043 (2010). This change led to additional litigation from applicants whose PTA was calculated with pre-*Wyeth* rules, as in *Daiichi Sankyo Co. v. Lee*, 791 F.3d 1373 (Fed. Cir. 2015).
[70] 740 F.3d 593 (Fed. Cir. 2014)
[71] 35 U.S.C. § 154(b)(1)(B)(i).
[72] 740 F.3d 593 (Fed. Cir. 2014) 740 F.3d 593 (Fed. Cir. 2014)
[73] 80 Fed. Reg. 1346 (2015)
[74] https://www.uspto.gov/web/offices/pac/mpep/s2732.html
[75] 778 F.3d 1341, 1349 (Fed. Cir. 2015)
[76] 913 F.3d 1351 (Fed. Cir. 2019)

Seven months later, in October 2019, USPTO issued a notice of proposed rulemaking amendments to 37 C.F.R. § 1.704 in light of Supernus.[77] On June 16, 2020—during the writing of this report—USPTO published the final rule in the Federal Register.[78]

[77] 84 Fed. Reg. 53,090 (2019)
[78] 84 Fed. Reg. 116, 36335 (2020)

Appendix D **Alignment of MITRE and Blue Book Standards**

MITRE conducted this evaluation work according to MITRE standards for the conduct of evaluations and in alignment with the Council of the Inspectors General on Integrity and Efficiency, Quality Standards for Inspection and Evaluation (January 2012, Blue Book). Table D-1 describes the alignment between Blue Book standards and MITRE standards.

Table D-1. Alignment of MITRE and Blue Book Standards

Blue Book Competencies	MITRE Independent Assessment (Evaluation) Standard
Competency The staff assigned to perform inspection work should collectively possess adequate professional competency for the tasks required.	MITRE carefully selects staff who have the knowledge, skills, abilities, and expertise necessary for the task, including assessment (evaluation) methodologies; technical domain; and the ability to quickly develop a working familiarity with the organizations, programs, activities, and/or functions identified for assessment.
Independence In all matters relating to inspection work, the inspection organization and each individual inspector should be free both in fact and appearance from personal, external, and organizational impairments to independence.	Working in the public interest requires MITRE to render impartial services that are free of conflict. MITRE maintains strict adherence to the principles of independence—personal, external, and organizational—so that observations, findings, conclusions, and recommendations will be viewed as valid and impartial by knowledgeable third parties.
Professional Judgment Due professional judgment should be used in planning and performing inspections and in reporting the results.	MITRE is committed to exercise reasonable care and diligence and to adhere in all matters to the principles of serving in the public interest. MITRE highly esteems its reputation for maintaining the highest degree of integrity, objectivity, and independence in applying professional judgment to all aspects of its work.
Quality Control Each Office of the Inspector General organization that conducts inspections should have appropriate internal quality controls for that work.	MITRE maintains disciplined internal processes and procedures for ensuring the work performed and the products delivered meet an exceptional quality standard.
Planning Inspections are to be adequately planned.	MITRE follows a disciplined and structured methodology for conducting assessments, beginning with comprehensive planning and preparation that meets well-understood expectations and lays the groundwork for a timely, impactful, and relevant assessment result.
Data Collection and Analysis The collection of information and data will be focused on the organization, program, activity, or function being inspected, consistent with the inspection objectives, and will be sufficient to provide a reasonable basis for reaching conclusions.	MITRE defines key focus areas and points of contention; focuses on answering assessment questions. MITRE considers resources, time, and data available; the need for different expertise; and time to integrate findings and recommendations.

Blue Book Competencies	MITRE Independent Assessment (Evaluation) Standard
Evidence Evidence supporting inspection findings, conclusions, and recommendations should be sufficient, competent, and relevant and should lead a reasonable person to sustain the findings, conclusions, and recommendations.	MITRE considers data-supported, evidence-based analysis as one of the hallmarks of its work. MITRE's disciplined quality standards are designed to ensure sufficient evidence is provided such that any reasonably informed person will concur in the findings, conclusions, and recommendations provided.
Records Maintenance All relevant documentation generated, obtained, and used in supporting inspection findings, conclusions, and recommendations should be retained for an appropriate period.	MITRE carefully catalogs and maintains all relevant documentation generated during the conduct of the assessment that is used to support inspection findings, conclusions, and recommendations. All data is carefully controlled and stored in accordance with the sponsor's and MITRE's security policies and sponsoring agreements. There shall be no sharing or release of sponsor sensitive information without express permission by the government, need to know, and appropriate clearance.
Timeliness Inspections should strive to deliver significant information to appropriate management officials and other customers in a timely manner.	MITRE scopes the assessment with consideration of the resources, data availability, time to integrate findings, and recommendations, and conducts comprehensive internal and sponsor reviews and delivers an impactful and relevant assessment result.
Fraud, Other Illegal Acts, and Abuse In conducting inspection work, inspectors should be alert to possible fraud, other illegal acts, and abuse and should appropriately follow up on any indicators of such activity and promptly present associated information to their supervisors for review and possible referral to the appropriate investigative office.	MITRE is committed to performing all work activities to the highest achievable standards and will promptly report any findings that may indicate the possibility of fraud or other illegal acts and abuse.
Reporting Inspection reporting shall present factual data accurately, fairly, and objectively and present findings, conclusions, and recommendations in a persuasive manner.	MITRE will assure all reported findings are represented factually and fairly and are verifiable by multiple unbiased sources.
Follow Up Appropriate follow up will be performed to ensure that any inspection recommendations made to Department/Agency officials are adequately considered and appropriately addressed.	MITRE considers follow-up an important phase in the lifecycle of an assessment and recommends the sponsoring agent solicit the services of MITRE or any reputable independent organization to conduct follow-on activities that increase the likelihood of successful implementation of assessment recommendations.
Performance Measurement Mechanisms should be in place to measure the effectiveness of inspection work.	MITRE considers this competency the responsibility of the sponsoring organization and encourages the same.

Blue Book Competencies	MITRE Independent Assessment (Evaluation) Standard
Working Relationship and Communication Each inspection organization should seek to facilitate positive working relationships and effective communication with those entities being inspected and other interested parties.	MITRE considers the establishment of trust and transparency a critically important first step in the conduct of an assessment. Once these are established, positive working relationships and effective communications with the entity being assessed can thrive.

Source: CIGIE Blue Book

Appendix E **Acronyms**

Term	*Definition*
eDRS	Electronic Data Retrieval System
EFS-Web	Electronic Filing System-Web
FDA	Food and Drug Administration
EXPO	Examination and Post-Examination
FY	Fiscal Year
GAO	U.S. Government Accountability Office
IDS	Information Disclosure Statement
IFW	Image File Wrapper
IP	Intellectual Property
IT	Information Technology
LIE	Legal Instrument Examiner
MOE	Margin of Error
MPEP	Manual of Patent Examining Procedure
NPRM	Notice of Proposed Rulemaking
OAED	Office of Application Engineering and Development
OCIO	Office of the Chief Information Officer
ODM	Office of Data Management
OIG	Office of the Inspector General
OPA	Office of Patent Automation
OPAP	Office of Patent Application Processing
OPEP	Office of Patent Examination Policy
OPESS	Office of Patent Examination Support Services
OPET	Office of Petitions
OPIM	Office of Patent Information Management
OPLA	Office of Patent Legal Administration
OPQA	Office of Patent Quality Assurance
PAIR	Patent Application Information Retrieval
PALM	Patent Application Locating and Monitoring

Term	*Definition*
PALM EXPO	(Patent Application Locating and Monitoring) Examination and Post-Examination
PIT	PALM-IFW Treasury
PORT	Patent Operations Research Team
PTA	Patent Term Adjustment
PTE	Patent Term Extension
QA	Quality Assurance
RCE	Request for Continued Examination
USDA	U.S. Department of Agriculture
USPTO	U.S. Patent and Trademark Office
WTO	World Trade Organization

Appendix F **Agency Response**

UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

June 9, 2021

MEMORANDUM FOR: Frederick J. Meny, Jr.
Assistant Inspector General for Audit and Evaluation

FROM: Andrew Hirshfeld Users, Hirshfeld, Andrew Digitally signed by Users, Hirshfeld, Andrew Date: 2021.06.09 17:40:36 -04'00'
Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

SUBJECT: Response to Draft Report, *USPTO Has Opportunities to Improve Its Internal Controls and Oversight Related to PTA and PTE Calculations*

Executive Summary

We appreciate the effort you and your staff made in reviewing the United States Patent and Trademark Office's (USPTO) internal controls and oversight related to the calculation of Patent Term Adjustment (PTA) and Patent Term Extension (PTE).

The USPTO is pleased with the OIG's findings that PTA and PTE are calculated in compliance with statutes, regulations, and case law, and that the USPTO has adequate internal controls to ensure proper calculation. As the OIG found, the USPTO uses valid and reliable data to calculate PTA, but manual data entry may introduce errors. The USPTO is working to identify internal and external process improvements that will reduce or eliminate the potential for error.

The OIG was able to verify 93% of PTA calculations in its sample. The USPTO reviewed the remaining 7% of the OIG sample, and found that the vast majority were also calculated properly, resulting in greater than 99% accuracy in this sample. For example, 46% of the calculations the OIG stated they could not verify reflected an end-date that fell on a weekend or holiday, resulting in an extension to the next business day, and 25% involved Patent Cooperation Treaty (PCT) national stage applications, which use a different date for PTA calculation than other types of applications.

After careful consideration, we concur with the recommendations made in the report. Our response to each recommendation is discussed in detail below, and the USPTO provided technical comments under a separate cover.

Response to Recommendations

IG Recommendation that the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office take the following action (1): *Direct the Commissioner for Patents to (1) mandate the use of the "safe harbor" form to claim the exception, and (2) ensure the inclusion of clear category and description definitions for applicants while keeping their focus on the task at hand (i.e., the document submission form).*

USPTO Response:
The USPTO concurs with this recommendation to decrease the likelihood that applicant submissions will result in inaccurate PTA calculations. The USPTO will initiate the notice-and-comment rulemaking process to propose that use of the "safe harbor" form be required in order to claim the exception and will also consider alternative options to encourage applicants to use the form, which allows the PTA calculator to automatically apply the exception. The USPTO will also consider ways to improve the document submission form to allow easier access to the definitions of document categories and descriptions to facilitate applicants' ability to correctly categorize their submissions, further allowing for accurate automatic calculation of PTA.

IG Recommendation that the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office take the following action (2): *Direct Office of Petitions (OPET), Office of Patent Legal Administration (OPLA), and Office of the Chief Information Officer (OCIO) to implement, and keep up-to-date, a comprehensive set of requirements and specifications for the PTA calculator software to ensure continued compliance with current and emerging legislation and case law.*

USPTO Response:
The USPTO concurs with the recommendation to ensure that the PTA calculator is appropriately updated to reflect changes in the law and to automate calculations that previously required manual correction when possible. The USPTO is reviewing its current protocols for updating the PTA calculator and will clearly document the process, along with any future process improvements, to ensure that PTA calculator software updates are made promptly and efficiently by the relevant business units and subcomponents.

IG Recommendation that the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office take the following action (3): *Direct OPLA to coordinate with the U.S. Food and Drug Administration and the U.S. Department of Agriculture to determine if electronic filing of PTE applications would be acceptable as a permanent practice after the current public health emergency has passed.*

USPTO Response:
The USPTO concurs with this recommendation. The USPTO is conferring with the FDA and USDA to determine if PTE applications can continue to be filed electronically.

IG Recommendation that the Undersecretary of Commerce and Director of the U.S. Patent and

Trademark Office take the following action (4): *Direct the Office of Patent Examination Support Services and the OCIO to: (1) determine the feasibility of implementing a workflow process or tool (similar to the examiner "docket" system) for Legal Instruments Examiner managers; and (2) add clarifying language to the document description codes in the Patent Application Locating and Monitoring (PALM) system to mitigate the risk of miscoded documents.*

USPTO Response:
The USPTO concurs with this recommendation to decrease the likelihood of inaccurate PTA calculations when manual data entry by Legal Instrument Examiners (LIEs) is required. The USPTO will assess the feasibility and potential effectiveness of implementing a workflow tool for LIE managers. The USPTO will also consider ways to improve the document description codes within PALM to reduce the likelihood of documents being miscoded and causing inaccurate PTA calculation.

IG Recommendation that the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office take the following action (5): *Direct the Commissioner for Patents to implement a means to identify and remedy the types of events that typically require a manual review (e.g., Information Disclosure Statements) as they occur.*

USPTO Response:
The USPTO concurs with this recommendation. The USPTO will continue its efforts to identify instances in which manual review has been necessary to ensure accurate PTA calculation, and we will use this information to identify opportunities to make appropriate adjustments to the PTA calculator algorithm or to find other process improvements to decrease the likelihood of inaccurate calculations.

IG Recommendation that the Undersecretary of Commerce and Director of the U.S. Patent and Trademark Office take the following action (6): *Direct OPET to implement a pilot program to perform periodic, OPET-initiated, reconsideration-like audits on a random sampling of PTA calculations.*

USPTO Response:
The USPTO concurs with this recommendation and is already taking steps to put in place a process to audit a random sample of PTA calculations. The USPTO appreciates the OIG's recognition that the comprehensive review performed by OPET when an applicant petitions for reconsideration serves as a valuable control to ensure proper PTA calculation. Performing similar reviews of PTA calculations outside of the petition process through a random audit process will further enable the USPTO to identify recurring issues where the calculator algorithm can be updated or where other process improvements can be implemented, as discussed in response to Recommendation (5).

Conclusion

In closing, we appreciate the OIG's review of the United States Patent and Trademark Office's (USPTO) internal controls and oversight related to the calculation of PTA and PTE and thank the Assistant Inspector General for Audit and Evaluation for providing us with this report. The USPTO always looks to make process improvements in order to provide the best service for our stakeholders. The USPTO has already begun to make improvements to implement the report's recommendations, and we are confident in our abilities to satisfy these recommendations in a timely manner. We look forward to working with your office in the future as we continue our efforts to improve our oversight of PTA and PTE calculation.

If additional information is needed please contact:

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