AUDIT REPORT

The United States Patent and Trademark Office Needs to Strengthen Its Patent Examination Quality Review Program

REPORT NO. OIG-25-029-A

AUGUST 28, 2025

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

UNITED STATES DEPARTMENT OF COMMERCE
Office of Inspector General
Office of Audit and Evaluation
Washington, DC 20230

August 28, 2025

MEMORANDUM FOR: Coke Morgan Stewart
Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and
Trademark Office

FROM: Kevin D. Ryan
Acting Assistant Inspector General for Audit and Evaluation

SUBJECT: *The United States Patent and Trademark Office Needs to Strengthen Its Patent Examination Quality Review Program*
Report No. OIG-25-029-A

Attached is the final report on our audit of the effectiveness of United States Patent and Trademark Office's (USPTO's) quality reviews of continuing patent applications. We will post the report on our website per the Inspector General Act of 1978, as amended (5 U.S.C. §§ 404, 420).

Within 60 calendar days, please provide an action plan addressing the report's recommendations, as required by Department Administrative Order 213-5.

We appreciate your staff's cooperation and professionalism during this audit. If you have any questions or concerns about the report, please contact me at 202-750-5190 or Amni Samson, Director for Intellectual Property, at 202-793-3324.

Attachment

The United States Patent and Trademark Office Needs to Strengthen Its Patent Examination Quality Review Program

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What We Audited | Our objective was to determine the effectiveness of the United States Patent and Trademark Office's (USPTO's) quality reviews of continuing patent applications completed in fiscal years 2021–2023.

Why This Matters | USPTO's Office of Patent and Quality Assurance (OPQA) performs quality reviews to ensure decisions to either allow or reject a patent claim comply with all legal requirements. OPQA's reviews are used to generate and report USPTO's statutory compliance measures for quality. Insufficient quality reviews and patent examiner errors can have patent quality and financial implications.

What We Found | We found that USPTO needs to strengthen its quality review program to be more effective at meeting its intended purpose: improving patent quality. Specifically:

- USPTO did not consistently use the results of OPQA reviews to improve the quality of continuing application examination.
- OPQA did not ensure quality assessments were performed on compliant quality review findings.
- USPTO did not report certain patent examination quality errors in its annual performance reports.

These issues resulted from incomplete and insufficient policies and procedures. Addressing them will help USPTO strengthen its quality review program and promote high-quality patent examination and improved patent quality.

What We Recommend | We made six recommendations to help ensure consistent review processes and effective internal controls, as well as accurate reporting of patent examination quality performance measures to Congress and other stakeholders. USPTO concurred with our recommendations and is working to implement them.

Contents

Introduction

The United States Patent and Trademark Office (USPTO) issues patents based on its examination of applications for compliance with all legal requirements. Patents provide exclusivity as a reward for invention and encourage innovation and competition to develop new technologies. Stakeholders have alleged that companies in certain technology sectors (e.g., biotechnology and pharmaceuticals) are being granted multiple patents for the same or similar subject matter. Such a strategy may force others to design around or perhaps litigate numerous patents to develop competing products or services. These steps increase costs to enter markets or can lead potential competitors away from such markets. Higher costs and/or lack of competitors can ultimately drive up prices for consumers.

These allegations primarily refer to continuing applications (i.e., continuations, continuations-in-part, and divisionals), which inventors file to build on prior applications.[1] According to USPTO data, the total number of patent applications filed remained constant from fiscal year (FY) 2017 to FY 2023, at about 650,000 per year. The number of continuing applications, however, increased over that time from about 127,000 to 156,000, accounting for almost 24 percent of all patent applications in FY 2023.

Patent Examination

Patent examination is divided among nine technology centers (TCs) that have jurisdiction over certain assigned fields of technology, such as biotechnology, computer software, and manufacturing. Patent examiners in each TC decide if claimed inventions are patentable in accordance with Patent Act statutes (Title 35 of the United States Code [U.S.C.]) and relevant case law.[2] Specifically, a patent examiner evaluates whether claimed inventions meet four main Patent Act statutes, summarized as follows:

- 35 U.S.C. § 101 – The claimed invention must be new and useful or provide a new and useful improvement.

[1] A continuation is an application for additional claims (i.e., scope of protection) to an invention disclosed in a prior application that has not yet been issued and contains the same subject matter as the prior application. A continuation-in-part is an application repeating some substantial portion or all of the not-yet-issued prior application and adding matter not disclosed in the prior application. A divisional is an application disclosing the same subject matter as a prior application but claiming an independent and distinct invention. USPTO, March 2014, revised February 2023. *Manual of Patent Examination Procedure* (MPEP), 9th edition, section 201, "Types of Applications."

[2] A claim defines the subject matter of the invention for which patent protection is sought. MPEP 1824, "The Claims."

- 35 U.S.C. § 102 – The claimed invention has not already been patented or available to the public before the effective filing date of the application.
- 35 U.S.C. § 103 – The claimed invention is not obvious to one of ordinary skill in the field, given information available to the public before the effective filing date of the application.
- 35 U.S.C. § 112 – The patent application contains a clear and exact description of the claimed invention.[3]

As examiners evaluate claims for compliance with these four statutes, they review them for statutory and non-statutory double patenting.[4] The principle of statutory double patenting rejects a patent claim that is the same as a claim in another of the applicant's patents. The principle of non-statutory double patenting was established by case law and rejects a patent claim that is different from but obviously like claim(s) in a patent the applicant already owns.[5] Its goal is to prevent prolonging the exclusive rights in a patent, as well as lawsuits by multiple parties.

Examiners document their decision to allow or reject a patent claim in an office action they send to the applicant. There are three main office actions:

- A **notice of allowance** informs the applicant that they are entitled to a patent.
- A **nonfinal rejection** informs the applicant that one or more claims have been rejected, but the application will remain open to further examination.
- A **final rejection** is based on the second or any subsequent examination and informs the applicant that one or more claims have been rejected, and examination will close.

[3] In this report we use the terms "statutes" and "statutory" to refer to these provisions. We refer to specific statutes by section number only. For example, for 35 U.S.C. § 103, we use the term "Section 103."

[4] Throughout this report, we use the term "statutory noncompliance" to denote noncompliance with Sections 101, 102, 103, or 112. We excluded statutory double patenting from our use of this term because USPTO's Office of Patent and Quality Assurance does not report double patenting quality errors to TCs as noncompliance.

[5] "A non-statutory double patenting rejection is appropriate where the conflicting claims are not identical, but . . . not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s)." MPEP 804.II.B, "Definition of Double Patenting" (citing cases). This includes a rejection when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent, or a patent subject to a joint research agreement, when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. *Id.* (citing cases).

Quality Review Program

The purpose of USPTO's quality review program is to improve patent quality.[6] USPTO considers a quality patent to be one that is compliant with all requirements of the Patent Act and case law. USPTO's Office of Patent and Quality Assurance (OPQA) performs independent quality reviews of examiner office actions using a master review form to ensure the examiner's decision to either allow or reject a patent claim complies with the four Patent Act statutes and case law.[7] OPQA's reviews are used to generate and report USPTO's statutory compliance measures for quality. They include random reviews taken from the entirety of office actions submitted during a given period and thus will incorporate some continuing applications. They also include what OPQA calls "robust" reviews, which are specific to notices of allowance with a high number of continuations. When OPQA identifies a quality error during its review, the TC to which the examiner belongs is responsible for taking appropriate action to address the error.

Previously Reported Findings

In a prior report published by our office, the MITRE Corporation identified issues regarding USPTO's patent quality review practices, namely (1) limitations on OPQA review time, (2) challenges setting and calibrating quality performance targets, and (3) barriers to process improvement.[8]

USPTO concurred with MITRE's recommendations related to the findings and implemented corrective actions. These actions included establishing a team to construct quality targets and effectiveness measures for OPQA quality reviews, creating standardized procedures for measuring the effectiveness of OPQA quality reviews, and updating OPQA's quality metrics webpage to include the methodology and results of its reviews. We analyzed USPTO's corrective actions and determined that they met the intent of the recommendations. This audit report provides a more in-depth study of the USPTO patent quality review program, specifically its quality review process for continuing patent applications.

Objective

Our audit objective was to determine the effectiveness of USPTO's quality reviews of continuing patent applications. Appendix 1 provides a detailed description of our scope and methodology.

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[6] MPEP 1308.03, "Quality Review Program for Examined Patent Applications."

[7] The master review form is available at https://www.uspto.gov/sites/default/files/documents/MRF-Current.pdf.

[8] Department of Commerce, Office of Inspector General, December 2, 2021. *USPTO Has Opportunities to Improve its Patent Examination Process and to Advance Patent Decision-Making,* OIG-22-010-I, finding 2.2, p. 2-4.

Findings and Recommendations

Summary: We found that USPTO needs to strengthen its quality review program to be more effective at meeting its intended purpose: improving patent quality. Specifically:

- USPTO did not consistently use the results of OPQA reviews to improve the quality of continuing application examination.
- OPQA did not ensure quality assessments were performed on compliant quality review findings.
- USPTO did not report certain patent examination quality errors in its annual performance reports.

These issues resulted from incomplete and insufficient policies and procedures. Addressing them will help USPTO strengthen its quality review program and promote high-quality patent examination and improved patent quality. Quality examination rewards innovation by awarding patents without unwarranted rejections. It also helps ensure justified rejections, thereby appropriately limiting patent protection and preventing undue burdens on competitors, who will not have to design around or litigate that claim.

USPTO Did Not Consistently Use the Results of OPQA Reviews to Improve the Quality of Continuing Application Examination

As previously noted, the purpose of USPTO's quality review program is to improve patent quality. USPTO policy states that when OPQA returns an application to a TC under the program, the TC should promptly decide what corrective action will be taken. USPTO policy also states that the program should be used as an educational tool to aid in identifying problem areas.[9] TC directors and quality assurance specialists told us that supervisory patent examiners (SPEs) are responsible for correcting OPQA-identified quality errors and coaching examiners on those errors. These actions are critical in ensuring quality reviews are an effective tool for improving patent quality. However, we found that SPEs did not consistently correct quality errors on continuing patent applications and TCs did not ensure that SPEs coached patent examiners on those errors.

[9] MPEP 1308.03, "Quality Review Program for Examined Patent Applications."

TCs Did Not Consistently Correct Quality Errors Identified by OPQA

OPQA demonstrated how it notifies TCs of errors identified during quality reviews in USPTO's integrated quality system (IQS).[10] Once notified, SPEs are responsible for taking appropriate action to correct each error. These actions may include withdrawing an incorrect rejection or rescinding a notice of allowance to avoid a patent being incorrectly issued. IQS also has a control feature that automatically holds notices of allowance with statutory noncompliance, but this feature is not used for double patenting errors. The control is designed to prevent patents from being issued before corrective actions are taken. However, OPQA and TC personnel told us that any TC manager can remove the hold, allowing the patent to be issued regardless of whether the noncompliance was corrected.

To evaluate whether SPEs corrected OPQA-identified quality errors, we statistically selected 65 office actions for continuing applications to test.[11] We considered that the SPE should have corrected the quality error in either of these situations:

- where OPQA considered that a rejection should have been made, and a patent was issued without that rejection, or
- where OPQA considered a rejection was made in error, potentially causing the applicant to act (e.g., by responding or abandoning) when they would not otherwise have needed to.

We found that SPEs did not correct the quality error in 23 of the office actions tested (35.4 percent). Based on the sample results, we projected that SPEs did not correct 1,040 of 2,938 OPQA-identified quality errors on continuing patent applications in FYs 2021–2023. TCs cited varying reasons why specific quality errors were not corrected. For example, TCs said that SPEs did not correct some of the errors because actions taken by the applicant during prosecution, such as amending or canceling a patent claim, resolved or eliminated the errors. As discussed later in this finding, these actions could have financial and patent protection implications for the applicant.

Of the 23 office actions with quality errors that SPEs did not correct, 11 had at least one statutory noncompliance. If a TC disagrees with a statutory noncompliance, it can rebut it in IQS.[12] OPQA will then review the dispute and either uphold or drop the error. However, we noted that TCs rarely disputed OPQA-identified quality errors. In fact, the TC indicated agreement that a statutory noncompliance existed for 8 of the 11 office actions but the SPE did not correct the error. The other 12 office actions with quality errors that SPEs did not correct had double patenting errors. TCs cannot use the same rebuttal process for these

[10] OPQA uses IQS to document its quality reviews and communicate the results to TCs.

[11] See appendix 2 for our statistical projection methodology.

[12] TCs submit the rebuttal in IQS with an explanation of why the examiner's action was reasonable.

errors, but they can communicate disagreement through IQS and other means, such as email. However, TCs did not provide evidence that they disputed any of the 12 uncorrected double patenting errors.

When SPEs do not correct or withdraw incorrect rejections, it can impact patent quality and present cost implications. The 23 office actions included 15 instances in which OPQA identified an incorrect rejection. To overcome a noncompliant rejection, the applicant would have to spend time and money preparing responsive arguments or claim amendments. The expenses might include attorney fees or USPTO administrative fees or both. Amendments to overcome rejections commonly narrow the scope of or cancel one or more claims, in either case limiting the applicant's patent protection. Thus, uncorrected noncompliant rejections risk extra costs for applicants as well as patent exclusivity the applicants might be entitled to.

Likewise, missed rejections that go uncorrected can impact quality and cost to patent owners, competitors, and consumers. The 23 office actions included 10 instances in which a patent was issued after OPQA identified a missed rejection. A patent being issued with claims that should have been rejected could make it harder for others to bring competing products to market. Competitors may choose to redesign products based on claim protections that should not be allowed or challenge the claim's validity in litigation, with associated costs. This would also delay competing products from entering the market, ultimately driving up prices for consumers.

TCs Did Not Ensure Patent Examiners Were Coached on Quality Errors Identified by OPQA

TCs should use OPQA-identified quality errors as a tool to educate patent examiners. USPTO provided evidence that patent examiners received training at the agency and TC levels based on common quality errors. TCs told us that SPEs also generally coached examiners on individual quality errors. However, we determined that TCs did not ensure SPEs provided this coaching. Of the 65 office actions we tested (described above), TCs did not provide evidence that SPEs coached examiners on 51 quality errors. Based on the sample results, we estimated that TCs did not ensure examiners were coached on 2,303 of 2,938 (78.4 percent) quality errors in FYs 2021–2023.

Patent examiners can review over a hundred patent applications each year. If an SPE does not coach an examiner on an OPQA-identified quality error, it increases the likelihood the examiner will continue to make the same mistake. This is particularly true because USPTO can take a long time to develop and deliver agency-wide training. For example, of the 65 office actions we tested, patent examiners made 13 quality errors with respect to the obviousness statute (Section 103), for which there was no evidence of coaching. Four of

these errors were committed in FY 2021. USPTO did not provide agency-wide training related to these errors until FY 2024, meaning examiners who made these errors could have continued to make the same mistakes for years.

We determined that SPEs did not consistently correct OPQA-identified quality errors and TCs did not ensure SPEs coached examiners on those errors because USPTO (1) did not have agency-wide policies or procedures that explicitly held SPEs responsible and (2) did not require TCs to monitor whether SPEs took these actions. Although two TCs had their own policies and procedures on SPEs' responsibilities for managing quality errors, the other six TCs that we evaluated did not.[13] Additionally, most TC quality assurance specialists told us that SPEs' actions to correct quality errors or coach examiners on those errors are not monitored. Although none of the TCs monitored SPE actions to correct errors, we found that one TC did monitor coaching. However, it only monitored coaching on statutory noncompliance (not double patenting). Developing agency-wide policies and procedures and requirements for monitoring will ensure consistent processes for correcting errors and coaching examiners.

Recommendations

We recommend that the Under Secretary of Commerce for Intellectual Property and Director of USPTO direct the Commissioner for Patents to:

1. Update agency-wide policies and procedures explicitly requiring SPEs to (1) take necessary actions to correct OPQA-identified quality errors and (2) coach patent examiners on the errors.
2. Develop requirements for TCs to monitor (1) actions taken by SPEs to correct OPQA-identified quality errors and (2) coaching that SPEs provide to patent examiners on the errors.

[13] There are nine TCs, but our sample of 65 office actions did not include any from TC 2900, which examines applications for design patents, protecting the aesthetic design of a product rather than its structure or function.

OPQA Did Not Ensure Quality Assessments Were Performed on Compliant Review Findings

A critical element of OPQA's role is to deliver accurate assessments of patent quality. Quality reviewers assess patent examiner office actions and determine whether they are compliant or noncompliant with all legal requirements. OPQA depends on two processes to ensure the accuracy of quality reviewers' compliant and noncompliant findings: supervisor reviews and consistency audits. OPQA supervisors assess quality reviewers' findings to ensure their accuracy. In addition, an OPQA panel of supervisors and managers conducts consistency audits of specific quality reviewers' findings to ensure the accuracy of the findings. However, we found that neither process provides assurance that quality reviewers' compliant findings are accurate. Ensuring that supervisor reviews and consistency audits are performed on compliant findings could help USPTO's quality reviews be more effective at improving patent quality.

OPQA Did Not Require Supervisory Reviews of Quality Reviewers' Compliant Findings

U.S. Government Accountability Office (GAO) internal control standards state that management should evaluate performance and hold individuals accountable for their internal control responsibilities.[14] The standards further state that management should document internal controls in policies and should document the results of ongoing monitoring to identify internal control issues.[15] To ensure the issuance of quality patents, OPQA should maintain an effective system of internal controls, including evaluating quality reviewers' work, documenting management responsibilities, and documenting ongoing monitoring and evaluations.

We found that OPQA did not have written policies requiring supervisor reviews of quality reviewers' compliant findings even though these findings (1) were not included in other quality assurance reviews and (2) made up about 82 percent of OPQA's findings in FYs 2021–2023. In contrast, the quality reviewer's supervisor, patent examiner's supervisor, and a TC quality assurance specialist all review quality reviewers' noncompliant findings. Noncompliant findings could receive even more OPQA and TC reviews if the TC rebuts OPQA's findings. These additional reviews help ensure the accuracy of the quality reviewer's determination. Table 1 details the review stages for compliant and noncompliant findings of random quality reviews.

[14] Section 5.01 of *Standards for Internal Control in the Federal Government,* GAO-14-704G, September 2014.

[15] Sections 12.02 and 16.09 of *Standards for Internal Control in the Federal Government,* GAO-14-704G, September 2014.

Table 1. Quality Assurance Reviews

● = Review performed ◑ = Review conditional ○ = Review not performed

Quality Assurance Review Stage	Noncompliant Findings	Compliant Findings	When Review Occurs
OPQA Supervisor	●	◑	Performed when quality reviewer identifies a statutory noncompliance; conditional for compliant findings at supervisor's discretion
TC Supervisor of Patent Examiner	●	○	Performed when OPQA notifies TC of noncompliance
TC Quality Assurance Specialist	●	○	Performed when OPQA notifies TC of noncompliance
OPQA Supervisor second review	◑	○	Conditional; performed when TC rebuts noncompliant finding to consider TC's argument
OPQA Rebuttal Panel	◑	○	Conditional; performed by a panel of two or three quality reviewers to consider TC's argument
OPQA Supervisor third review	◑	○	Conditional; performed to consider rebuttal panel's recommendation and make final decision to either uphold or drop the noncompliance
OPQA Director Validation	◑	○	Randomly performed on about 10% of noncompliances the TC rebuts
TC Director	◑	○	Conditional; performed if TC still disagrees with OPQA

Sources: OIG review of OPQA procedures and process maps, TC guidelines and interviews, and OPQA training presentations

OPQA's director said that OPQA supervisors should review compliant findings to evaluate the performance of quality reviewers, but the number of reviews is at the supervisor's discretion. We found that the expectation that supervisors perform reviews of compliant findings is not formalized in policy, and OPQA could not provide evidence that any reviews were completed on compliant findings for FYs 2021–2023. Further, the outcomes of reviews are not evaluated to ensure compliant findings are accurate.

OPQA Did Not Perform Consistency Audits of Quality Reviewers' Compliant Findings

GAO internal control standards state that measurable objectives and data sources should generally be free from bias.[16] OPQA consistency audits aim to ensure quality reviewers are consistently applying the statutes in OPQA random reviews. The procedures for consistency audits specify auditing noncompliant findings of quality reviewers with statistically high rates of noncompliant findings and compliant findings of quality reviewers with low rates of noncompliant findings for a particular statute.[17]

However, OPQA did not audit quality reviewers with low rates of noncompliant findings to ensure the accuracy of compliant findings. For example, we found that 8 of the 62 quality reviewers (13 percent) had significantly lower noncompliance rates in FYs 2021–2023 than the other reviewers in at least 2 of the 3 years. One reviewer only found 3 out of 231 office actions (about 1 percent) they reviewed to be noncompliant with Section 103, when the average noncompliance rate was about 11 percent. OPQA did not perform consistency audits of the work of any of these eight quality reviewers.

OPQA did not perform consistency audits of quality reviewers with low noncompliance rates because OPQA's selection methodology did not account for data bias. OPQA used a threshold of three standard deviations above and below the average noncompliance rate for each of the four statutes to select quality reviewers to audit. However, this methodology resulted in a quality reviewer having to find a negative number of noncompliances to be selected, which is impossible.

As a result of lapses in both processes (i.e., supervisor reviews and consistency audits), OPQA did not have assurance that compliant findings were correct. Further, USPTO may have missed the opportunity to identify incorrect reviews of compliant findings. As discussed in the previous finding, not identifying patent examiner errors can have patent quality and financial implications. In addition, decreased scrutiny of reviewers with fewer noncompliant findings could lead to reviewers intentionally or subconsciously becoming more lenient in their reviews, leading to compliant findings that might have been noncompliant. Correcting these issues would help ensure USPTO does not overstate patent examination quality to Congress and other external stakeholders.

[16] Sections 6.04 and 13.04 of *Standards for Internal Control in the Federal Government,* GAO-14-704G, September 2014.

[17] *OPQA Consistency Audit Standard Operating Procedure,* June 7, 2023.

Recommendations

We recommend that the Under Secretary of Commerce for Intellectual Property and Director of USPTO direct the Commissioner for Patents to:

3. Develop policy that requires supervisory reviews of compliant OPQA quality findings and that the results of these reviews be documented and evaluated to ensure compliant findings are accurate.
4. Develop and document a methodology for OPQA consistency audits that ensures quality reviewers with low levels of noncompliant findings are identified and evaluated.

➤ Certain Patent Examination Quality Errors Were Not Reported in USPTO's Annual Performance Reports

USPTO is required to report the quality of its work to Congress.[18] To meet this requirement, USPTO publishes various performance and quality metrics in its annual performance reports, including those from OPQA on patent examination quality.[19] OPQA performs random and robust quality reviews (further defined below) to evaluate examiners' determinations to approve or reject a patent claim. OPQA uses the results of these reviews to calculate error rates that it presents to USPTO leadership. While leadership is aware of error rates related to double patenting under both statute and case law, USPTO has never included them in its annual performance reports because it focused on patent issues it considered to have higher significance. Reporting double patenting errors will raise the awareness of stakeholders and can help identify needs for revisions to law or practice toward improving patent quality.

USPTO Did Not Report Double Patenting Errors OPQA Identified in Random Quality Reviews

OPQA performs about 12,000 random quality reviews annually to support USPTO's quality metrics program.[20] OPQA calculates error rates (i.e., quality metrics) related to the statutes and non-statutory double patenting. USPTO began reporting the results of OPQA's random reviews in its annual performance reports in FY 2017, in part to improve transparency of

[18] 35 U.S.C. § 13, "Annual report to Congress."

[19] USPTO publishes these reports to provide information on its performance results and progress toward achieving the strategic goals and objectives in its strategic plan. Prior to FY 2022, USPTO reported patent examination quality in its annual performance and accountability reports.

[20] USPTO's quality metrics program measures and evaluates the quality of patent examiner work products.

examination quality. In FYs 2021–2023, examiners' overall error rate on continuing applications was about 17 percent. As previously noted, that rate did not include double patenting quality errors. For that period, OPQA identified such errors in 871 of 10,375 examiner office actions on continuing applications (approximately 8 percent). Including these errors would increase the overall error rate to about 25 percent.

USPTO did not report these double patenting quality errors because the office emphasized other issues. Its chief patent statistician told us that as it established its quality metrics program around 2016, USPTO decided to only report statutory noncompliance. This was because non-statutory double patenting rejections only accounted for about 10 percent of all examiner rejections at that time. He added that USPTO is now considering reporting double patenting errors because non-statutory double patenting rejections currently account for about 14 percent of rejections. That decision would be made by the Patent Internal Control Board, which is responsible for setting quality goals and deciding what quality metrics are reported.[21] A member of the board told us that, as of September 2024, the board has not addressed quality metrics or whether to report double patenting errors. Rather, it has been focused more on the time and cost of examining patent applications.

USPTO Did Not Report Any Patent Examination Errors OPQA Identified in Robust Quality Reviews

In addition to its random quality reviews, OPQA started performing robust quality reviews in FY 2022. These are performed on certain notices of allowance for patent applications with a high number of continuations, with an emphasis on identifying double patenting errors. In FYs 2022–2023, OPQA found quality errors in almost 39 percent of these reviews. Notably, OPQA found double patenting errors in approximately 21 percent of robust quality reviews. However, USPTO did not report the results of OPQA's robust quality reviews.

OPQA's director told us the reason these errors are not included in the quality metrics that are reported is because they are not statistically selected and cannot be extrapolated to the population of examined patent applications. Nevertheless, concerns expressed to us about double patenting indicate that such errors should be included in annual performance reports. For example, OPQA's director told us that double patenting is the main concern with continuing patent applications, particularly examiners missing rejections. One TC director said that applications with many continuations become difficult to examine, so an examiner can easily miss a double patenting problem. Another

[21] USPTO created the Patent Internal Control Board in response to our evaluation report *USPTO Has Opportunities to Improve its Patent Examination Process and to Advance Patent Decision-Making* (December 2, 2021, OIG-22-010-1), which recommended that USPTO establish a quality control oversight body.

TC director told us that their quality assurance specialists have recommended training for examiners on double patenting.

These concerns, in light of the rate of double patenting errors OPQA found in robust reviews, confirm the need for USPTO to report and raise awareness of double patenting quality issues. Reporting double patenting results from these random and robust reviews in annual performance reports will raise the awareness of Congress and other external stakeholders and can help identify needs for revisions to law or practice toward improving patent examination and quality.

Recommendations

We recommend that the Under Secretary of Commerce for Intellectual Property and Director of USPTO direct the Commissioner for Patents to:

5. Ensure results of OPQA's random and robust quality reviews, including double patenting errors, are included in USPTO's annual performance reports.
6. Regularly evaluate OPQA quality review results to ensure pertinent patent examination quality information is included in USPTO's annual performance reports.

Summary of USPTO's Response and OIG Comments

USPTO reviewed a draft version of this report and responded to our findings and recommendations. In its response to our draft report (received June 2, 2025), USPTO concurred with all six of our recommendations and described actions it has taken or plans to take to address them. USPTO's full response is included in this report as appendix 3.

USPTO also provided technical comments on the draft report. We considered these comments and revised the report where appropriate.

We are pleased that USPTO concurs with our recommendations and look forward to reviewing its corrective action plan.

Appendix 1. Scope and Methodology

The objective of our audit was to determine the effectiveness of USPTO's quality reviews of continuing patent applications. Our audit work focused on USPTO quality reviews of patent examiner office actions on continuing patent applications completed in FYs 2021–2023. To accomplish our objective, we performed the following actions:

- Interviewed officials and staff from USPTO's Office of the Commissioner for Patents, TCs, OPQA, Patent Internal Control Board, and Patent Training Council.
- Reviewed applicable laws, regulations, and standards as well as USPTO policies and procedures relevant to quality reviews of continuing patent applications, including:
    - 35 U.S.C., *Patents*
    - GAO *Standards for Internal Control in the Federal Government* (GAO-14-704G), issued September 2014[22]
    - USPTO *Manual of Patent Examination Procedure,* 9th edition, issued March 2014, revised June 2020 and February 2023
    - OPQA *Consistency Audit Standard Operating Procedure,* issued June 7, 2023
- Reviewed USPTO annual performance reports for FYs 2016 through 2023 to gain an understanding of the patent examination quality information that USPTO included.
- Analyzed OPQA quality review results on continuing patent applications for FYs 2021–2023.
- Analyzed OPQA consistency audit information to evaluate the office's methodology for selecting quality reviewers to audit.
- Selected a statistical sample of 65 patent examiner office actions on continuing patent applications in which OPQA identified a quality error (see appendix 2 for more detail).
- For the 65 sampled office actions, gathered evidence from USPTO's Patent Center system and other internal records, such as OPQA master review forms and emails, to evaluate the sufficiency of:
    - Actions taken by SPEs to correct errors identified in OPQA quality reviews
    - Coaching SPEs provided to patent examiners on errors identified in OPQA quality reviews

[22] We used this version of the standards because it was effective in FYs 2021–2023.

- Evaluated training material developed by USPTO for patent examiners based on common OPQA-identified quality errors.

In addition, we gained an understanding of internal control processes significant within the context of the audit objective by interviewing USPTO officials and reviewing documentation for evidence of internal control procedures. We assessed USPTO internal controls that were significant to the audit objective in the components of control environment, risk assessment, information and communication, and monitoring. We identified weaknesses in the controls related to USPTO's holding personnel accountable for performing internal control responsibilities, documentation of internal control responsibilities in policies, documentation of the results of ongoing monitoring, and ensuring that measurable objectives and data sources were free from bias.[23] Although we identified and reported on internal control deficiencies, our audit found no instances of fraud, waste, or abuse.

In addition, to assess the reliability of data from the IQS and Patent Center systems, we (1) performed electronic testing for obvious errors in accuracy and completeness, (2) worked with agency officials knowledgeable about the systems to identify any data problems, and (3) traced a sample of key fields in the data to source documents. We determined that the data was sufficiently reliable to support the findings and conclusions in this report.

We conducted our audit from March 2024 through April 2025 under the authority of the Inspector General Act of 1978, as amended (5 U.S.C. §§ 401-424), and Department Organization Order 10-13, as amended October 21, 2020.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence that provides a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

[23] GAO, September 2014. *Standards for Internal Control in the Federal Government,* GAO-14-704G.

Appendix 2. Statistical Sampling

To determine whether SPEs (1) corrected patent examiner quality errors identified in OPQA quality reviews and (2) coached examiners on those errors, we evaluated a sample of office actions on continuing patent applications in which OPQA identified an error. We selected from a universe of 2,938 quality reviews in OPQA's IQS for FYs 2021–2023.

From the universe, we statistically selected 65 quality reviews, stratified by the type of quality review error. This stratification ensured the selected sample contained a representative number of both statutory noncompliance and double patenting quality errors. The sample size was based on a 90 percent confidence level and a margin of error no greater than 10 percentage points. Table A details the team's sampling selection methodology.

Table A. Sampling Selection by Strata of Quality Review Error

Quality Error by Strata	Total Number of Quality Reviews	Percentage of Universe	Number Selected
Only statutory noncompliance	1,574	53.6%	35
Only double patenting error	1,044	35.5%	23
Both statutory noncompliance and double patenting error	320	10.9%	7
Total	**2,938**	**100.0%**	**65**

Source: OIG sampling methodology using data from OPQA's IQS

We found that SPEs did not correct 23 of the 65 (35.4 percent) statistically sampled office actions in which OPQA identified a quality error. We projected these results onto the population of 2,938 quality reviews. Based on the results of testing, the team weighted the results and estimated that at a 90 percent confidence level, SPEs did not correct 1,040 quality errors identified by OPQA in FYs 2021–2023, with a margin of error of about 9.8 percentage points. Table B details the team's statistical projections along with the upper and lower bound estimates.

Table B. Statistical Projections of Quality Errors Identified by OPQA That SPEs Did Not Correct

Category	Point Estimate (Projection)	Margin of Error	90% Confidence Interval	
			Lower Limit	Upper Limit
Estimated number of uncorrected quality errors	1,040 (35.4%)	+/- 9.8 percentage points	752 (25.6%)	1,328 (45.2%)

Source: OIG data analytics results projected over the universe

We found that TCs did not provide evidence SPEs coached patent examiners on 51 of the 65 (78.5 percent) statistically sampled office actions in which OPQA identified a quality error. We projected these results onto the population of 2,938 quality reviews. Based on the results of testing, the team weighted the results and estimated that at a 90 percent confidence level, TCs did not ensure SPEs coached patent examiners on 2,303 quality errors identified by OPQA in FYs 2021–2023, with a margin of error of about 8.1 percentage points. Table C details the team's statistical projections along with the upper and lower bound estimates.

Table C. Statistical Projections of Quality Errors Identified by OPQA That SPEs Did Not Coach Patent Examiners On

Category	Point Estimate (Projection)	Margin of Error	90% Confidence Interval	
			Lower Limit	Upper Limit
Estimated number of quality errors examiners were not coached on	2,303 (78.4%)	+/- 8.1 percentage points	2,064 (70.3%)	2,543 (86.6%)

Source: OIG data analytics results projected over the universe

Appendix 3. USPTO Response

USPTO's response to our draft report begins on the next page.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

DATE: June 2, 2025

MEMORANDUM FOR: Kevin D. Ryan
Acting Assistant Inspector General for Audit and Evaluation

FROM: Coke Morgan Stewart
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office

SUBJECT: Response to Draft Report, "The United States and Trademark Office Needs to Strengthen Its Patent Examination Quality Review Program"

We appreciate the detailed work that you and your staff undertook in reviewing the United States Patent and Trademark Office's (USPTO) patent examination quality review program. The efforts made by your team to understand all our USPTO processes, both specifically in the Office of Patent Quality Assurance (OPQA) and across the Technology Centers (TCs), are to be commended. Moreover, the thoughtful, detailed recommendations in your report evidence your staff's appreciation of the importance of the work being performed by the USPTO.

The USPTO views performing high-quality patent examination and issuing durable patents to be critically important to our mission, and the USPTO's patent examination quality review program supports this important objective. While the USPTO has taken constructive steps to strengthen our patent examination quality review program, we acknowledge that additional measures, such as those detailed in your office's recommendations, can further strengthen our program. The USPTO concurs with OIG's recommendations as explained in our detailed responses below.

Recommendation #1:

Update agency-wide policies and procedures explicitly requiring SPEs to (1) take necessary actions to correct OPQA-identified quality errors and (2) coach patent examiner on the errors.

USPTO response:

SPEs are expected to take appropriate actions to address OPQA-identified quality errors, and SPEs regularly coach patent examiners on quality issues, including quality issues identified by OPQA. Specifically, SPEs use Quality Tracker, which is a feature of USPTO's integrated quality

system (IQS), to enter information regarding any review that rises to the level of an error in the examiner performance appraisal plan (PAP). The examiner PAP specifically provides the parameters for charging a PAP error, with quality expectations increasing with the authority level and grade of the examiner. Ultimately, the SPE has the authority to charge a PAP error. Not all issues raised by OPQA are appropriate to be held as a PAP error and, as such, there may not be documentation of a corrective action and/or coaching in the Quality Tracker. Nonetheless, SPEs regularly coach patent examiners on quality issues. In FY23, over 68,000 reviews were completed by SPEs and entered into Quality Tracker these include OPQA-identified errors held as PAP errors, coaching related to OPQA-identified issues that do not rise to the level of a PAP error, and positive feedback on work well done.

In addition, some TCs currently have policies and procedures requiring SPEs to take appropriate actions to correct OPQA-identified quality errors and coach examiners on the errors. The USPTO agrees that having an explicit agency-wide policy and procedure will help strengthen our patent examination quality review program and concurs with this recommendation.

Recommendation #2:

Develop requirements for TCs to monitor (1) actions taken by SPEs to correct OPQA-identified quality errors and (2) coaching that SPEs provide to patent examiners on the errors.

USPTO response:

As noted above, Supervisory Patent Examiners (SPEs) are required to enter into the Quality Tracker any review, including those performed by OPQA, that rises to the level of an error in the examiner performance appraisal plan (PAP). In FY23, over 68,000 reviews were completed by SPEs and entered into Quality Tracker – these include OPQA-identified errors held as PAP errors, coaching related to OPQA-identified issues that do not rise to the level of a PAP error, and positive feedback on work well done. The TCs can utilize the information in Quality Tracker to monitor actions taken by the SPEs to address quality issues, including OPQA-identified quality errors. The USPTO agrees that establishing consistent requirements across the TCs to monitor actions taken by SPEs to address OPQA-identified quality errors, including coaching examiners on the errors, will help strengthen our patent examination quality review program, and concurs with this recommendation.

Recommendation #3:

Develop policy that required supervisory reviews of compliant, OPQA quality findings and that the results of these reviews be documented and evaluated to ensure compliant findings are accurate.

USPTO response:

OPQA-identified compliant findings are a confirmation of the work considered by a primary examiner (i.e., an examiner that has full signatory authority) in the TC. That is, OPQA's compliant findings reflect agreement between the OPQA reviewer and a primary examiner in the TC–either the primary examiner's own work or work originating from a junior examiner that was reviewed by the primary examiner. This contrasts to noncompliant findings where there is a disagreement between the OPQA reviewer and a primary examiner in the TC. It is precisely because of this contrast that supervisors in OPQA directly oversee all noncompliant findings while maintaining supervisory oversight over the compliant findings.

The report recognized that Supervisory Quality Assurance Specialist (SRQAS) are responsible for the supervisory oversight of the reviews with compliant findings. It is acknowledged that while this supervisory oversight is being performed by the SRQASs, there is no explicit documentation of the procedures to be followed. The USPTO agrees that explicit documentation of the SRQAS requirements with regard to random checks of compliant review findings would improve confidence in the accuracy of OPQA findings and, as such, concurs with this recommendation.

Recommendation #4:

Develop and document a methodology for OPQA consistency audits that ensures quality reviewers with low levels of noncompliant findings are identified and evaluated.

USPTO response:

OPQA monitors outlier behavior (high and low levels of compliant reviewer findings) utilizing the 3-sigma statistical approach to quality control. This approach is a well-respected, methodology which applies data to a normal distribution. Deviations that are more than three standard deviations (sigma) from the average are considered outside of process control and are investigated as outliers. Given that 80% of office actions do not have issues of noncompliance raised, the 3-sigma range is more likely to identify individuals with high averages of noncompliance as outside the control limits and thus subject to audit. While the 3-sigma approach is less sensitive to low compliance outliers, this methodology will identify reviewers of low compliance when meeting outside the 3-sigma range. This skewing to high outliers over low outliers was already recognized by OPQA.

A pilot is currently being tested with regard to compliant findings audit methodology to ensure compliant reviews are regularly assessed in an objective manner in parity to noncompliant reviews. The goal of the pilot is to ensure RQASes consistently receive feedback regardless of their noncompliance rates and that those with low levels of noncompliance findings are adequately monitored for accuracy. As such, the USPTO concurs with this recommendation.

Recommendation #5:

Ensure results of OPQA's random and robust quality reviews, including double patenting errors, are included in USPTO's annual performance reports.

USPTO response:

The USPTO is dedicated to sharing data publicly that represents the quality of its work products. The USPTO's Annual Performance Plan and Annual Performance Report (APPR) provides a link to data, which includes double patenting error rates, from the random reviews of office actions, which are representative of USPTO's overall performance with respect to patent examination quality.[1]

Robust quality reviews were performed as a part of an initiative prompted by a letter to the USPTO from members of Congress expressing concerns regarding "patent thickets" or large numbers of patents that cover a similar invention. The objective of this effort was to investigate resources and tools required to more effectively examine applications with large patent families, identify prosecution characteristics and potential root causes that corelate to patentably indistinct inventions, and provide data-informed recommendations to address claims to patentably indistinct inventions.

In view of the small sample size of the robust quality reviews performed each year, the USPTO has not published the results of the robust quality reviews in its annual performance reports. However, over the past three years, the USPTO has conducted a total of approximately 2,500 robust quality reviews. Having collected a sufficient level of robust quality review data, the USPTO has suspended these reviews and is evaluating the findings, and communicating with stakeholders for input with regard to next steps.[2]

As the findings of the robust quality reviews are evaluated, the USPTO will share the results publicly including in the USPTO's annual performance reports or other publicly available reporting mechanisms. As such, the USPTO concurs with this recommendation.

Recommendation #6:

Regularly evaluate OPQA quality review results to ensure pertinent patent examination quality information is included in USPTO's annual performance reports.

USPTO response:

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[1] https://www.uspto.gov/sites/default/files/documents/USPTO_FY23_FY25_APPR.pdf
See page 40, Source – click link "Quality metrics| USPTO"> Review results> MRF Data Summary Table – Fiscal Year (FY) 2024 – see tabs Statutory DP and Non-Statutory DP.

[2] https://www.gao.gov/products/gao-25-107218 See discussion related to "GAO Leading Practices for Effective Pilot Design"

The USPTO's APPR highlights our achievements and results of the Agency's programmatic performance. This report shows our stakeholders, including the general public, our efforts to promote transparency and accountability as we strive to maintain America's intellectual property system as the gold standard around the world. The report is designed to meet the requirements of the annual performance reporting requirements of the Government Performance and Results Act Modernization Act of 2010 and Office of Management and Budget (OMB) Circular No. A-11 (Preparation, Submission, and Execution of the Budget). Each year the data included in the report is reviewed and adjusted. Nevertheless, the USPTO is committed to ensuring that pertinent quality performance measures are reported publicly. As such, the USPTO concurs with this recommendation.

USPTO Technical Comments to OIG Draft Report:
"USPTO Needs to Strengthen Its Patent Examination Quality Review Program"

Recommended Changes for Factual/Technical Information
Provide changes to factual or technical information in this section. Cite page number and other specific references (see examples below). Do not include editorial comments, which will be covered in the next section.

Page 1, Footnote 1, "A divisional is an application disclosing ~~claiming~~ the same subject matter as a prior application but ~~carving out~~ claiming an independent and distinct invention".

Page 5, in 4th paragraph, "TCs cannot utilize the rebuttal process to dispute these errors ~~in IQS~~, but they can in the period for TC feedback provide disagreement through IQS and by other means, such as by email".

Editorial Comments
Provide editorial comments (such as grammatical changes) in this section. Cite page number and other specific references.

None.

REPORT

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