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Office of Inspector General



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PATENT AND TRADEMARK OFFICE

Patent Quality Controls Are Inadequate

Audit Report No. PTD-9977-7-0001 / September 1997

Office of Audits, PTO Audits Division





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

September 30, 1997

MEMORANDUM FOR: Bruce A. Lehman
Assistant Secretary and
Commissioner of Patents and Trademarks

FROM: George E. Ross
Assistant Inspector General for Auditing

SUBJECT: Final Report: Patent Quality Controls
Are Inadequate (PTD-9977-7-0001)

This is our final report on the effectiveness of PTO's Office of Patent Quality Review and PTO's efforts to implement a substitute patent quality review process.

PTO agreed with our evaluation of the current patent quality review process, accepted our recommendations, and outlined a course of action to implement them. PTO stated it would carry out our second recommendation to conduct an analysis of OPQR's sampling methodology, and that the study's results would provide the OPQR with the resources to meet the first and third recommendations.

PTO's response adequately addresses our recommendations. After further discussions with PTO officials, we have revised the second recommendation. We would welcome the opportunity to review any recommendations resulting from the study and suggest that PTO include them in its action plan.

A summary of PTO's response to the draft report, along with our comments, begins on page 8. PTO's complete response is attached to the final report. We also have attached additional copies of the report for PTO's convenience.

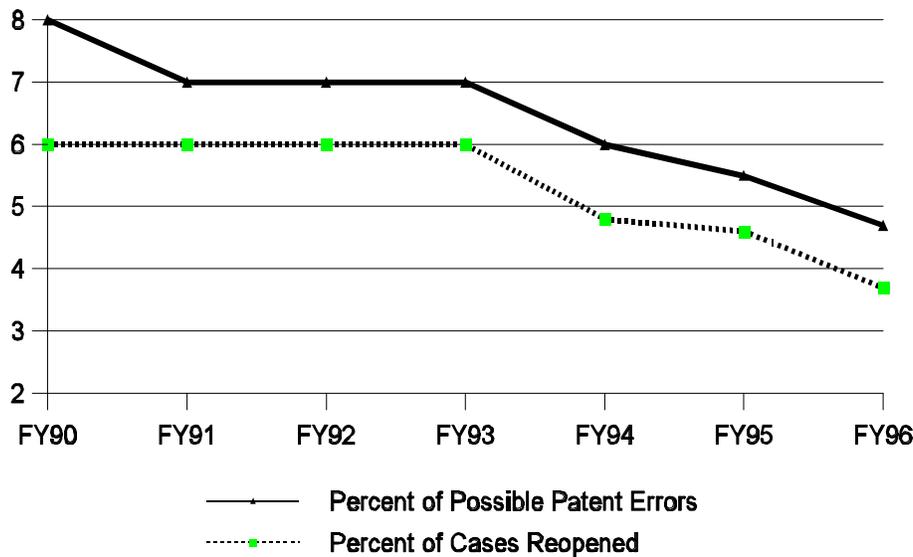
We would appreciate receiving your action plan addressing our recommendations within 60 calendar days, in accordance with Department Administrative Order 213-5. The plan should be in the format specified in Exhibit 7 of the DAO. Should you have any questions regarding the preparation of the action plan, please contact Bruce Carpel, Director, PTO Audits Division, at (703) 306-3315.

INTRODUCTION

PTO established the Quality Review Branch in 1974 in response to growing public criticism of the quality of issued patents. Its purpose was to monitor and evaluate the quality of the patent examination process by reviewing a sample of approved patents and reporting the results each month to PTO management. The Patent Corps uses the information to identify recurring problems with quality, to improve training, and to prevent the issuance of improper patents. The Office of Patent Quality Review, successor to the Quality Review Branch, reports to the Deputy Commissioner for Patents and Trademarks to ensure the independence and the integrity of its reviews.

The integrity of the patent system depends largely on the quality of issued patents. In 1990, the OIG issued an audit report, *Improvements Needed in the Patent Quality Review Program* (EAD-0231-0-0002, February 1990). Citing the fact that error rates had not declined since the program's inception, the report found that PTO was not using the information generated by OPQR to maximum advantage. We made several recommendations to better utilize quality review data and improve OPQR's effectiveness. PTO implemented most of the recommendations. Between 1990 and 1996, PTO experienced a steady decline in both the percentage of possible patentability errors and patent cases reopened, as shown in Graph 1.

Graph 1. Error Rates Reported by OPQR, FY 1990 - FY 1996



However, in 1994 PTO decided to eliminate OPQR in favor of a proposal called the Examination Quality Process (EQP) that would reengineer the patent quality review process. EQP is the product of a multi-year study intended to improve the quality of examinations by increasing the involvement of experienced examiners and PTO customers in the examination process. PTO sought to replace OPQR evaluations with customer satisfaction surveys as the primary measure

of examination quality. Also, PTO stated that quality checks made early in the examination process by experienced examiners would provide more timely feedback than evaluations conducted by OPQR at the end of the process.

When informed of the proposal, we raised serious concerns about the plan and recommended that PTO refrain from eliminating OPQR until it had confirmed that the replacement process worked as advertised. PTO agreed to maintain OPQR's staffing level and continue to sample examiner actions as done in the past (at a four percent sampling rate of allowed patents) until EQP had been proven to be equally effective.

PURPOSE AND SCOPE OF AUDIT

The purpose of our audit was to evaluate the effectiveness of OPQR and the status of PTO's efforts to implement a substitute quality review process. We reviewed corrective actions taken by PTO as a result of recommendations made in our 1990 audit report. We evaluated OPQR's current staffing, patent application review techniques, sampling methodology, and recent conclusions. We reviewed PTO's draft report, *Patent Quality Improvement Reengineering Project, Examination Quality Process*. We also interviewed several key PTO personnel, including senior patent officials, OPQR's Director, and members of the patent office's Continual Quality Improvement team. We did not evaluate internal controls over certain computer-generated data; however, we performed sufficient tests to satisfy ourselves that the data PTO provided was reliable.

We conducted our fieldwork from May through July 1997. Our review was conducted in accordance with generally accepted government auditing standards and was performed under the authority of the Inspector General Act of 1978, as amended, and Department Organization Order 10-13, dated May 22, 1980.

PATENT QUALITY CONTROLS ARE INADEQUATE

PTO has reduced OPQR's staff and responsibilities without confirming an alternative method of measuring and reporting on patent quality. Specifically, we found that PTO has: (1) decreased OPQR's staff and sampling levels, reducing the effectiveness of its quality control program; and (2) delayed implementation of the EQP, which was originally intended to replace OPQR.

The evaluations conducted by OPQR are an important internal control that helps to ensure quality by providing a counterbalance to pressures on the Patent Corps to increase production. These pressures are the result of a steady rise in patent applications and a corresponding backlog of patents waiting to be processed. We believe that without a reliable, independent means of assessing quality, PTO has inadequate management controls to ensure the quality of patent examinations.

Effectiveness of OPQR Has Been Reduced

The quality review process has become more effective as a result of process improvements recommended in our 1990 report. Errors associated with patent examinations have declined from 8 percent in 1990 to less than 4.7 percent in 1996. However, since 1993, the staff of OPQR has been inappropriately reduced from 16 reviewers to as few as 9, necessitating a decrease in the sampling rate from four percent to two percent. PTO cut OPQR's staff because it expected to replace the office with a reengineered quality process. This was a mistake. We question the need to reengineer a process that had been working well. It should be noted that PTO committed to maintaining its existing process and staffing levels until it confirmed that the replacement process was adequate to accurately measure the error rates.

PTO determined in 1978 that a sampling rate of four percent was necessary to provide a valid statistical basis for evaluating the quality of work produced by each art unit, the smallest organizational unit of the Patent Corps. OPQR needed to maintain a staff of at least 16 reviewers during the 1990s to achieve this level of sampling. However, since 1993 the Director of OPQR has not been permitted to fill positions that have become vacant through attrition. As a result, OPQR no longer reviews enough patent applications to effectively identify systemic weaknesses in the examination process and produce meaningful statistics about patent quality.

As illustrated in Table 1, the size of OPQR's samples and its sampling rate have declined, along with its staffing levels. Data for FY 1997 is incomplete. However, OPQR projects it will review about 2,472 allowed patents. Should PTO issue at least as many patents in FY 1997 as it did in FY 1996, the result will be an even lower sampling rate in FY 1997.

Table 1. OPQR Sampling Levels, FY 1992 - FY 1996

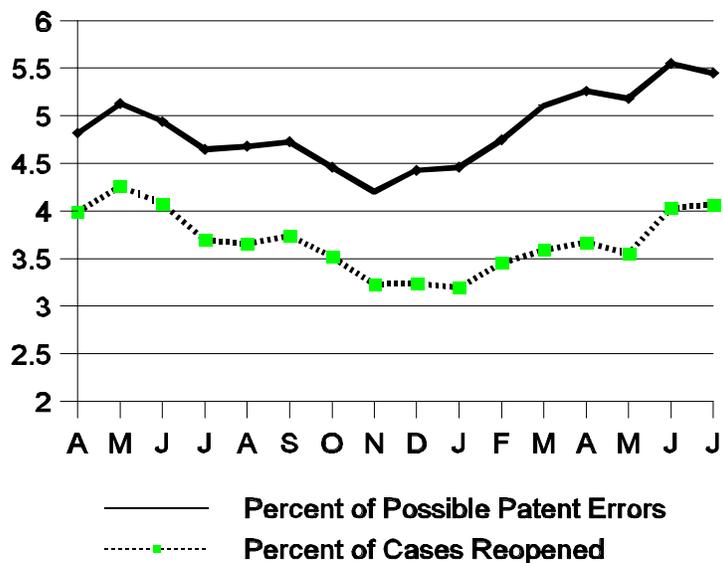
	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996
Patents Allowed	114,106	116,151	119,609	119,521	135,321
4% Sample	4,564	4,646	4,784	4,785	5,412
Patents Reviewed	4,320	4,067	4,233	3,644	2,832
Difference	244	579	551	1,141	2,589
Sample Rate	3.8%	3.5%	3.5%	3.0%	2.1%
Patent Reviewers	16	15	14	13	9

In April 1996, PTO officially reduced OPQR's sampling rate to two percent. Actually, OPQR's sampling rate had already fallen below two percent in the Chemical discipline. Although PTO acknowledges that two percent samples are not adequate to validate the quality of work performed by each art unit, it asserts that the samples are large enough to provide statistically

valid information at the group level. However, PTO is unable to substantiate this assertion. No statistical analysis was performed to justify the reduction in OPQR's sample size, or to determine whether other changes in the sample design are necessary as a result of the reduction.

Since the sampling rate was reduced, error rates reported by OPQR have gradually increased, as shown in Graph 2.

Graph 2. Error Rates Reported by OPQR, April 1996 - July 1997



Also, the decrease in sample size makes it more likely that problems confined to an individual art unit will remain unidentified. As a result, OPQR will identify fewer common problems, or systemic trends, in the examination process. Formerly, problems identified at the art unit level could be addressed through targeted corrective actions, such as additional training. The decrease in sample size will not allow PTO to pinpoint problem areas. Consequently, PTO will need to spend more money to administer solutions, i.e., training more examiners than would have been necessary using the original sample size.

Problems Plague EQP

The new Examination Quality Process, originally scheduled to be completed by October 1995, could face further delays as a result of problems encountered during a pilot test. Those problems undermine claims that the new process will improve quality and be cost effective.

PTO recently completed a pilot to assess the viability of the two major components of EQP: Coach/Counseling and Customer Involvement. Although the report on the pilot stated that the quality of the examination process was improved in six of eight categories measured, it noted that too many coach-counselors (experienced examiners) were employed during the pilot. The

ratio of coach-counselors to examiners was in some cases as low as 1:1. PTO acknowledged that this arrangement would not be cost-effective on a regular basis, and that the increased oversight during the pilot may have caused the improvement in quality observed to be overstated. In addition, the report cited “severe weaknesses” in the use of customer surveys as primary measures of quality. Most importantly, pilot participants found that the response rate of customer feedback surveys was too low to be conclusive.

Final implementation of the reengineered patent quality process may be further delayed because of uncertainty surrounding the amount of PTO’s FY1998 funding and negotiations with employee unions. PTO is expecting the Congress to permanently withhold \$92 million in surcharge fees, thereby constraining the agency’s resources. Any actions initiated by management that affect patent examiners’ working conditions must be negotiated with the unions. An agreement with the union can take as long as 18 months to negotiate, resulting in further delays of management’s initiatives. As a result, reengineering projects, including EQP, are on hold.

OPQR Role Should Be Expanded

Our 1990 report on patent quality found that reviewing only allowed patents was too limited and recommended that OPQR expand its sampling to include certain types of first actions (the initial decision by an examiner to either allow or reject an application), namely rejections. At that time, PTO responded that budgetary constraints prevented it from adopting the recommendation. Subsequently, the pilot report on EQP recommended that PTO maintain OPQR but change its emphasis from reviewing allowed patents to reviewing first actions.

Many patent managers now believe that the review of allowed patents frequently occurs too long after the initial patent examination to provide timely feedback to the Patent Corps. We disagree. The review of allowed patents is valuable. It not only provides feedback to management, but also gives the public assurance that patent examinations are being performed effectively. Despite the time lag, the reviews are a good source of feedback for management because patentability issues change little over time. In the 1970s, PTO appointed a committee to study the issue of patent examination quality. After reviewing a number of potential measures, the committee concluded: “No single indicator or group of indicators have been found which could be used to reliably measure examination quality over time. Each offers help and the data from the Quality Review Program offers the most.”

We strongly reaffirm our 1990 position that a review of first actions is worthwhile. We believe that the types of reviews conducted by OPQR should be expanded to offer additional information about patent quality to PTO and the public.

CONCLUSION

We believe that a strong, independent Office of Patent Quality Review is needed to ensure that production is not increased at the expense of quality. In addition, OPQR enhances PTO’s

credibility with regard to quality at a time when the Congress is considering giving PTO increased independence from government oversight by allowing PTO to become a performance based organization. PTO prematurely reduced OPQR's staff before EQP was complete, or proven to be an effective quality control measure, thereby preventing OPQR from conducting four percent samples as it has since 1978. We estimate that reinstating the necessary OPQR staff would require no more than 10 additional FTEs. Because of the importance of maintaining public confidence in the quality of allowed patents, PTO should restore OPQR to full strength.

RECOMMENDATIONS

We recommend that the Assistant Secretary and Commissioner of Patents and Trademarks:

1. Provide the additional staff to OPQR to sample approved applications at the previously validated rate of four percent. Increase OPQR's staff as necessary to maintain statistically valid samples at the art unit level.
2. Conduct a statistical analysis of OPQR's sampling methodology to determine what level of sampling is necessary to produce statistically valid results at all organizational levels, including the proposed realignment to industry sectors.
3. Instruct OPQR to expand the patent quality review process to include the review of first actions and other work products that may be meaningful to patent managers.

PTO RESPONSE AND OIG COMMENTS

PTO agreed with our evaluation of the current patent quality review process, accepted our recommendations, and outlined a course of action to implement them. PTO stated it would carry out our second recommendation to conduct an analysis of OPQR's sampling methodology, and that the study's results would be the basis for providing the OPQR with the resources to meet the first and third recommendations.

PTO's response adequately addresses our recommendations. After further discussions with PTO officials, we have revised the second recommendation. We would welcome the opportunity to review any recommendations resulting from the study and suggest that PTO include them in its action plan.

A summary of PTO's response along with our comments follows. A complete copy of PTO's response is attached to the final report.

Recommendation #1

Provide the additional staff to OPQR to sample approved applications at the previously validated rate of four percent. Increase OPQR's staff as necessary to maintain statistically valid samples at the art unit level.

PTO Response

PTO will immediately post vacancy announcements for chemical, electrical, and mechanical review examiner positions. PTO expects to add the necessary staff to OPQR so that the sample of reviewed applications could be adjusted to a level consistent with the objective behind previous sampling techniques; that is, to report statistically valid results on the quality of the art units' examination process. The exact number of reviewer positions to be filled will be determined when the study is completed and the sample verified. Specifically, PTO stated it would analyze the results and expand OPQR so that it can conduct a statistically valid sample not only of allowed applications but of first actions as well.

PTO feels that a new statistical validity study must be conducted to determine the precise sample for review and, correspondingly, the resources OPQR would need. PTO will contract with a professional statistician to assist in this determination. PTO acknowledged that it has been some time since a statistical validity study has been made and that OPQR's selection of a constant sample from each art unit rather than a percentage from each art unit, as had been done since 1978, was controversial. PTO also stated that budgetary and other constraints have contributed to the constant sample rate being adjusted decreased.

OIG Comments

We concur with PTO's response to our recommendation. We agree that PTO should conduct a statistical validity study *before* staffing OPQR to sample approved applications at the previously validated rate of four percent.

In its response, PTO noted that Table 1 of our draft report calculates the sample from the number of patents issued, although OPQR has been sampling allowed applications. We corrected the data accordingly.

Recommendation #2 (original wording in draft report)

Conduct a statistical analysis of OPQR's sampling methodology to determine what level of sampling is necessary to produce statistically valid results at the Group level.

PTO Response

PTO agreed with our recommendation. PTO is in the process of hiring an outside, independent, professional statistician to determine the level of sampling necessary to produce statistically valid results both at the group and art unit levels. The study will operate on the premise that PTO desires to not limit sampling to allowed applications but to a meaningful sample including at least first actions.

OIG Comments

We concur with PTO's response to our recommendation. We have reworded our recommendation to state that the analysis should review all levels, not just the group level, as well as the proposed industry sectors. We agree that the study should form an objective foundation on which OPQR can conduct its reviews, and this was the intent of our recommendation.

We were encouraged by PTO's comments that the statistician may have to address the pertinence of results generated from the recommended sample rates in making conclusions about the quality of specific aspects of the examination process. We believe PTO can only benefit from such analysis.

PTO invited our office to review the statistical validity study as well as any resulting recommendations, and we would welcome the opportunity to assist PTO once the study is completed.

Recommendation #3

Instruct OPQR to expand the patent quality review process to include the review of first actions and other work products that may be meaningful to patent managers.

PTO Response

PTO agreed with our recommendation. PTO stated that OPQR will be instructed to take the steps necessary to include a review of first actions and other work products that may be meaningful to patent managers. PTO stated that a large amount of the work produced by the Patent Corps does not result in allowed applications. While a review of allowed cases has merit and will continue to be conducted, an emphasis solely on allowed applications to the exclusion of other work products gives a delayed and slanted view of the quality of the examination process. However, it does provide an important baseline against which more current data (e.g., first actions) can be compared.

PTO stated the required resources to meet this recommendation will depend on the statistical validity study. Presently, PTO does not know how many first actions would constitute a valid sample. Nonetheless, in its response, PTO discussed how OPQR and patent managers can work together to facilitate a review of first actions that meets the needs of patent managers and their goal of issuing quality patents.

OIG Comments

We concur with PTO's response to our recommendation. We believe that increased cooperation between OPQR and patent managers can only serve to strengthen the quality review program. We agree with PTO's decision to include OPQR in discussions with patent managers as it seeks to expand the quality review process to include first actions.

Attachment



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SEP 25 1997

MEMORANDUM FOR Frank DeGeorge
Inspector General

FROM: *B. Lehman*
Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks

SUBJECT: Draft Response to Draft Audit Report No. PTD-9977-7-XXXX:
"Patent Quality Controls Are Inadequate"

We appreciate the effort your auditing staff has made in evaluating our patent quality review process. We have carefully considered the three recommendations made in the subject draft report for improving the Office of Patent Quality Review ("OPQR") and find them appropriate. For the following reasons, we substantially accept these recommendations and will, given the resources, implement the necessary changes. We have concluded that, to meet all three recommendations, the second recommendation should be addressed immediately. Therefore, with the assistance of a professional statistician, we would undertake a statistical validity study of sampling rates for the art unit and group levels for approved (i.e., allowed) applications and first office actions. The results of this study would be essential if we are to accurately provide OPQR with the resources to meet the first and third recommendations.

IG Recommendation #1: Provide the additional staff to OPQR to sample approved applications at the previously validated rate of four percent. Increase OPQR's staff as necessary to maintain statistically valid samples at the art unit level.

PTO Response:

To meet this recommendation, we will immediately, upon the Commissioner's approval of the necessary FTE levels, post vacancy announcements for chemical, electrical and mechanical review examiner positions. We would expect to add the necessary staff to OPQR such that the sample of reviewed applications could be adjusted to a level consistent with the objective behind previous sampling techniques; that is, to report statistically valid results on the quality of the art units' examination process.

However, as explained more fully below, we feel a new statistical validity study must be conducted to determine the precise sample for review and, correspondingly, the resources OPQR would need. To that end, we will contract with a professional statistician to assist us in this determination. While this study is being conducted and if additional FTE's are

proffered as a possibility, the process will proceed toward obtaining a pool of candidates. The exact number of reviewer positions to be filled will be determined when the study is completed and the sample verified. Once FTE levels are approved, individuals will be selected from the pool of candidates.

It has been some time since a statistical validity study has been made. The last known study occurred in 1981 culminating with a "Quality Review Report" by Professor Kenneth Case of Oklahoma State University [May 2, 1981; addressed to S. William Yost, Assistant Commissioner for Finance and Planning]. He indicated that the sampling rate was not dependent on a percentage but remained at a constant 37 cases per art unit. In his Report, Professor Case stated:

"The optimum sample size to be taken over the entire PTO depends upon the exact objectives to be accomplished by sampling. If sampling is to be used for gathering information for subsequent prevention activity, testing hypotheses about Art Unit performance, observing trends, etc., a sample size of 37 per Art Unit is believed to be quite satisfactory. This provides considerable data for analysis, although it is only about a 4% sample overall."

While the Inspector General is correct that "PTO determined in 1978 that a sampling rate of four percent was necessary to provide a valid statistical basis for evaluating the quality of work produced by each art unit," that sampling rate, which was determined to be 4% of each art unit's allowed applications, lasted only three years. Beginning in 1981, as a direct result of Professor Case's study, OPQR set the sample rate at a relatively constant 37 cases per art unit per year. Our records show, however, that OPQR's selection of a constant sample from each art unit rather than a percentage from each art unit - as had been done since 1978 - was controversial. Some have believed that a percentage is more appropriate because art units have varying rates of allowed applications. Furthermore, in recent years, due to budgetary and other constraints, the constant sample has been adjusted downward to as low as 31 cases per art unit per year. (Please note that Table 1. of the Draft Audit Report calculates the sample from the number of "Patents Issued", although OPQR has been sampling "Allowed Applications".)

We feel it is important to first reestablish the sampling rate which will produce a statistically valid sample for measuring art unit performance. Such a study can take into account advances in the field of statistics over the past 16 years and officially settle the controversy raised by the Case report. Moreover, we will be able to include concerns that have not been previously addressed. One such concern is that current reviews are limited to the allowed end result. Instead, the PTO is interested in information which will improve the quality of the entire examination process. We are, therefore, in agreement with the Inspector General's 1990 position which recommended that we add a review of first office actions. By revisiting the sampling rate, we hope to address this and thereby make more timely, accurate, and comprehensive conclusions about an art unit's examination process. At the completion of such a study, we will analyze the results and expand OPQR so that it

can conduct not only a statistically valid sample of allowed applications but first actions as well.

IG Recommendation #2: Conduct a statistical analysis of OPQR's sampling methodology to determine what level of sampling is necessary to produce statistically valid results at the Group level.

PTO Response:

We agree with this recommendation. As mentioned above, we are in the process of hiring an outside, independent, and professional statistician. At the direction of both the Office of the Comptroller and OPQR, the statistician will be assigned the task of determining the level of sampling necessary to produce statistically valid results both at the Group and Art Unit levels.

The statistician will have to be educated about the patent examination process, especially in view of PTO's desire to improve the quality of the entire examination process. This means that we would rather not limit sampling to allowed applications but to a meaningful sample including at least first office actions. Even as to allowed applications and first office actions, there are numerous factors to consider. The statistician may have to address the pertinence of results generated from the recommended sample rates in making conclusions about the quality of specific aspects of the examination process, such as the handling of certain statutory requirements for patentability, and the level (art unit, group, etc.) to which these conclusions should apply. Issues to be reviewed will also depend on the information that patent management considers to be helpful in assessing the quality of the patent examination process. Issues important to the customer should also be included.

We invite the Inspector General to review the statistical validity study when completed, and we welcome a review of any resulting recommendations. Once approved by PTO management, the study will form an objective foundation on which OPQR can conduct its reviews. An official statistical validity study will increase confidence, reliability, and trust in the quality review process.

IG Recommendation #3: Instruct OPQR to expand the patent quality review process to include the review of first actions and other work products that may be meaningful to patent managers.

PTO Response:

We wholly agree with this recommendation, and OPQR will take the steps necessary to include a review of first actions and other work products that may be meaningful to patent managers. With the increasing need to use our resources efficiently, it is important that patent managers receive timely information about the quality of the examination process so that relevant corrective actions can be taken at the time they occur. Allowed applications are reviewed long after the substance of the examination is complete.

Furthermore, a large amount of the work produced by the patent corps does not result in allowed applications. While a review of allowed cases has merit and will continue to be conducted, an emphasis solely on allowed applications to the exclusion of other work products gives a delayed and slanted view of the quality of the examination process. Nonetheless, it does provide an important baseline against which more current data (e.g., first actions) can be compared.

The required resources to meet this recommendation will depend on the statistical validity study. At present, we do not know how many first actions would constitute a valid sample.

To meet this recommendation, we believe patent managers and OPQR must work closely together. By partnering, OPQR will be able to focus on issues pertinent to patent managers while patent managers receive the benefit of more relevant and timely information. Some issues change over time due to changes in legislation, for example. It is therefore critical that OPQR remain current and that patent managers receive quality information on exigencies in the examination process. To achieve this cooperative arrangement, we are taking steps to include OPQR in discussions with patent managers on various quality issues. The discussions will produce a survey of useful questions upon which OPQR can base a review of first office actions and which meets the needs of patent managers and their goal of issuing quality patents.

Again, we thank the Inspector General for the forthright and comprehensive audit report of our quality review process. We intend to meet the recommendations, as set forth above, in a diligent manner, and we will gratefully accept suggestions as we move forward to ensure that an effective quality review process is established.