USPTO Responses to Questions for the Record – Chairman Coons U.S. Senate Committee on the Judiciary Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office"

July 26, 2023 Witness: The Honorable Kathi Vidal, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office Submitted: September 21, 2023

1. In my view, if the Patent Trial and Appeal Board (PTAB) is meant to operate as an alternative to district court litigation, then the invalidity burden should be the same in both forums. The PREVAIL Act (S.2220), which I introduced earlier this year with Senators Tillis, Durbin, and Hirono, would change the burden of proof for invalidity at the PTAB to match the "clear and convincing" burden applied in district court. You appear to agree, as the "compelling evidence" standard for PTAB proceedings proposed in the U.S. Patent and Trademark Office's (USPTO) Advance Notice of Proposed Rulemaking (ANPRM) is essentially the same as the "clear and convincing" burden used in district courts. Should Congress simply make this change by statute?

Response: The ANPRM did not itself seek to raise the standard for institution for all proceedings, nor did it seek to modify what burden of proof would ultimately apply in patentability determinations made by the PTAB, but instead sought input the USPTO will use to determine whether a petition presenting compelling merits should be allowed to proceed even if that petition would otherwise be discretionarily denied (for example, on the basis of pending parallel litigation in district court). As noted by the Office of the Federal Register, the optional ANPRM step is used to solicit "comments aimed at developing and improving the draft proposal or by recommending against issuing a rule."¹

Congress has the sole authority to change the burden of proof for invalidity at the PTAB. The USPTO is ready to provide technical assistance to Congress based on the USPTO's technical expertise in this area including its experiences exercising discretion to deny AIA proceedings in view of parallel district court litigation as well as the feedback it received in response to the ANPRM.

2. In July 2023, you granted Director review of a PTAB decision issued in December 2021 that denied review of a challenged patent and still has a pending request for rehearing. How does your decision in this case—made more than eighteen months later—support the USPTO's strategic goal of promoting the efficient delivery of reliable intellectual property rights?

¹ <u>https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf</u> (*How does the agency involve the public in developing a proposed rule?*)

Response: As discussed in more detail below in response to Question 3, the median processing time for a Director Review request is 55 days. This period begins when a Director Review request email is received by the USPTO, and ends on the day that a decision on Director Review is issued. Occasionally, there are exceptional circumstances that cause a Director Review request to be a statistical outlier. As discussed in response to Question 6, such exceptional circumstances may include the complexity of the legal or technical issues presented in the case, such as issues of first impression. Accordingly, the Director may allow additional party briefing, permit amicus briefing, order discovery, conduct an oral hearing, and/or collaborate with other agencies when necessary. The USPTO makes every effort to ensure that Director Review requests are timely processed. The Director, and her advisory team, further ensure that each Director Review request is given thorough consideration and fair resolution – thereby promoting the reliability of the intellectual property rights involved.

3. What is the average amount of time for the USPTO or the PTAB to decide Director review requests and rehearing requests in inter partes reviews and post grant reviews (collectively, AIA review(s))?

Response: <u>Director Review requests</u>: In the twelve-month period from August 1, 2022 through July 31, 2023, the median amount of time for the USPTO to decide Director Review requests was 55 days and the mean was 67.5 days. This corresponds to the length of time from when a request for Director Review email is received until a decision on Director Review is issued. This does not include any *sua sponte* grants of Director Review, which do not have a corresponding pendency period because they are not requested by a party.

<u>Rehearing Requests</u>: In the twelve-month period from August 1, 2022 through July 31, 2023, USPTO has identified 181 rehearing requests filed. Of those, 130 have been decided as of August 2023, with a median pendency of 73 days and a mean of 87 days.

4. What is the average amount of time for the USPTO to issue a trial certificate in an AIA review once an AIA review is complete because the time for appeal has expired or any appeal has terminated?

Response: After a proceeding fulfills the requirements of 35 U.S.C. § 318(b) for issuance of a trial certificate, the approximate average amount of time to issue a trial certificate in FY2023 (October 1, 2022-August 8, 2023) was 41 days. After a recent significant migration from PTAB's old IT system to its current IT system (Patent Trial and Appeal Case Tracking System or P-TACTs), the USPTO has recently been able to more accurately track AIA review proceedings through the Federal Circuit appeals process and make improvements to management of its data into a more centralized system. The improved trial certificate functionality was fully deployed in June 2022. This has led to a quicker and more efficient process for issuing trial certificates since the IT system migration.

5. What is the average amount of time for the Director or the PTAB to issue a decision on remand in an AIA review?

Response: A proceeding on remand from the Federal Circuit often involves additional briefing from the parties and may involve submission of additional evidence and an oral hearing before the Board. In some rare instances, a remand may require a complete redo of an AIA trial.

For the first 10 months of FY2023 (October 1, 2022—July 31, 2023), the median amount of time for the PTAB to issue a decision on remand from the Federal Circuit in an AIA review was 178 days from the Federal Circuit's mandate and the mean was 202 days.

For FY2022 (October 1, 2021–September 30, 2022), the median amount of time for the PTAB to issue a decision on remand from the Federal Circuit in an AIA review was 181 days from the Federal Circuit's mandate and the mean was 244 days.

During FY2022, a number of additional AIA reviews involved a Federal Circuit remand for the limited purpose of allowing appellant the opportunity to request Director review, pursuant to the Supreme Court's decision in *United States v. Arthrex*, No. 19-1434 (2021). In these cases, the median amount of time for the Director to issue a decision (or for the PTAB to issue a forfeiture order) was 87 days from the Federal Circuit's limited remand order and the mean was 94 days.

- 6. For each of the below sub-parts, please identify the number of AIA reviews and the corresponding AIA review numbers (e.g., IPR20XX-XXXXX).
 - a. How many AIA reviews currently have Director review requests or rehearing requests that have been pending longer than 90 days?

Response: <u>Director Review Requests</u>: As discussed above in Response to Question #3, the pendency of a Director Review request is calculated from the time a Director Review request email is received until a decision on Director Review is issued. There are currently no pending Director Review requests that have been pending longer than 90 days.

While none are currently pending more than 90 days, cases on Director review may occasionally take longer. Director Review requests often present complex legal and/or technical issues, including issues of first impression. Accordingly, the Director may allow additional party briefing, permit amicus briefing, order discovery, conduct an oral hearing, and/or collaborate with other agencies when necessary.

<u>Rehearing Requests</u>: Although USPTO does not discuss specific pending matters, generally speaking, requests for rehearing may take longer than 90 days, for example, in view of holds due to parties' concurrent requests for Director Review or review by the USPTO's former Precedential Opinion Panel (POP), holds to ensure consistency with other decisions in related proceedings having different schedules, additional briefing by parties, and the requirement for panels to comply with statutory deadlines in other docketed cases.

Proceeding No.	ReqRhgDate	Status Notes
IPR2021- 00799	16-Nov-22	Pending

IPR2022- 01127	02-Feb-23	Proceeding terminated as to one of two petitioners; pending
IPR2022- 01223	28-Feb-23	Pending
IPR2021- 01466	10-Apr-23	Pending

In addition, the following AIA proceedings have panel rehearing requests that previously were held pending determinations on concurrent requests for POP review:

Proceeding No.	ReqRhgDate	Date Returned to Panel	Status Notes		
IPR2022-	29-Jul-22	5-Oct22	Additional briefing filed;		
00279			pending		
IPR2022-	17-Mar-23	18-Apr-23	Pending		
01356					
IPR2022-	17-Mar-23	18-Apr-23	Pending		
01357					
IPR2022-	17-Mar-23	18-Apr-23	Pending		
01358					
IPR2022-	17-Mar-23	18-Apr-23	Pending		
01359					
IPR2022-	17-Mar-23	8-May-23	Pending		
01523					
IPR2022-	06-Mar-23	25-May-23	Pending		
01257					
IPR2022-	06-Mar-23	25-May-23	Pending		
01258					
IPR2023-	27-Apr-23	7-Jun-23	Pending		
00049					
IPR2023-	27-Apr-23	7-Jun-23	Pending		
00050					
IPR2022-	5-May-23	8-Jun-23	Pending		
01522					
IPR2022-	25-Apr-23	27-Jun-23	Pending		
01497					
IPR2022-	25-Apr-23	27-Jun-23	Pending		
01545					
IPR2022-	31-Aug-22	24-Jul-23	Pending		
00449					
IPR2022-	31-Aug-22	24-Jul-23	Pending		
00450					

IPR2022- 00628	26-Oct-22	24-Jul-23	Pending
IPR2022- 00629	26-Oct-22	24-Jul-23	Pending
IPR2022- 00701	26-Oct-22	24-Jul-23	Pending
IPR2022- 01236	21-Feb-23	24-Jul-23	Pending
IPR2022- 01388	02-Mar-23	24-Jul-23	Pending

b. In the last three years, how many AIA reviews have had trial certificates issued more than 60 days after the AIA review was complete?

Response: In the last three years, there have been approximately 1,235 proceedings that have had trial certificates issued more than 60 days after the proceeding fulfilled the requirements of 35 U.S.C. § 318(b) for issuance of a trial certificate. The vast majority of these proceedings were prior to the deployment of P-TACTs (PTAB's new IT system).

As explained in the response to Question 3, P-TACTS provided significant enhancements over the prior system. Prior to the deployment of P-TACTS, PTAB did not have the ability to track a proceeding through the appeals process at the Federal Circuit. The trial certificate issuance process relied on manual tracking and multiple data repositories outside the IT system. With the deployment of P-TACTs, the USPTO has made significant improvements to the trial certificate issuance process. The USPTO will continue to refine and improve its processes to minimize the amount of time to issue a trial certificate.

c. How many AIA reviews currently have decisions on remand pending for more than 180 days?

Response: There are currently no AIA reviews that have decisions on remand from the Federal Circuit pending for more than 180 days since the Federal Circuit's mandate.

In one set of AIA reviews—IPR2018-00766, -00767—the Federal Circuit issued a limited remand order for the PTAB panel to consider an issue of first impression: the impact of an inventorship correction in an AIA proceeding made after the PTAB's final written decision. However, the Federal Circuit retains jurisdiction of the case since no mandate has been issued. Thus, a decision on remand for this case has been pending for more than 180 days since the Federal Circuit has not issued its mandate.

7. The America Invents Act (AIA) provides that the USPTO is to recover its costs through charging user fees for its services. In cases before the U.S. Court of Appeals for the Federal Circuit, the USPTO has represented that the fees it charges

for an AIA review are lower than the costs of an AIA review to the agency. *See Mobility WorkX, LLC v. Unified Patents, LLC,* No. 20-1441, Brief for Intervenor, ECF No. 54, at 31 (Nov. 9, 2020); *New Vision Gaming & Development, Inc. v. SG Gaming, Inc.*, No. 20-1400, Brief for Intervenor, ECF No. 42, at 9 (Nov. 16, 2022). The USPTO's recent fee-setting proceeding provides its costs and fees for AIA reviews. *See* USPTO, *Table of Patent Fees – Current, Proposed and Unit Cost*, <u>http://www.uspto.gov/sites/default/files/documents/Patent-Fees-Current-Proposed-Unit-Cost-PH2023.xlsx</u> (Apr. 2023) (setting forth USPTO's proposed fees). The table below, which was produced using the data in the USPTO's fee proposal document, illustrates that the USPTO proposes to continue to conduct AIA reviews at a loss to the agency.

Fee Code	Fee Category	Description	Current fee	Proposed fee	FY2020 Unit Cost	FY2021 Unit Cost	FY2022 Unit Cost
1406	PTAB fees	Inter partes review request fee – Up to 20 claims	\$19,000	\$23,750	\$22,556	\$23,052	\$21,980
1414	PTAB fees	Inter partes review post- institution fee – Up to 20 claims	\$22,500	\$28,125	\$39,531	\$34,245	\$37,563
1408	PTAB fees	Post-grant or covered business method review request fee – Up to 20 claims	\$20,000	\$25,000	\$30,018	\$34,287	\$37,683
1416	PTAB fees	Post-grant or covered business method review post institution fee – Up to 20 claims	\$27,500	\$34,375	\$42,414	\$46,998	\$49,198

a. Is the USPTO operating AIA reviews at a loss to the agency; that is, does the USPTO lose money when it conducts an AIA review?

Response: Yes, under the current fee structure, the unit costs for most AIA reviews exceed the fees paid for reviews with up to 20 claims.

b. Given that the fees the USPTO charges for an AIA review are lower than the costs to the agency, how is the USPTO making up those costs?

Response: Section 10 of the AIA requires patent fees to recover patent costs in the aggregate. The patent fee structure maintains cost recovery in the aggregate, instead of an individual fee level.

c. Are patent applicants being charged more fees to subsidize the costs of AIA reviews?

Response: The USPTO sets and collects patent fees in a manner to recover all patent related costs in the aggregate, rather than recover costs on a strict service-by-service basis. Accordingly, the cost of AIA reviews is recovered through aggregate patent fee collections. Patent maintenance fees, paid by patent holders that wish to maintain their intellectual property protection, currently comprise slightly more than half of all patent fees collected. Many USPTO services are partially subsidized by patent maintenance fee collections that do not have a unit recovery cost. Patent filing fees (i.e., applicant fees) only recover a portion of the unit cost for search and examinations performed and are also partially subsidized with maintenance fee collections. Therefore, patent applicants are not necessarily being charged more to subsidize AIA reviews.

d. Why is the USPTO not charging petitioners for the full costs of AIA reviews?

Response: As discussed above, the patent fee structure maintains cost recovery at the aggregate level. Additionally, per 35 U.S.C. § 311(a) and 35 U.S.C. § 321(a) the AIA, review fees should be set at reasonable amounts taking into account the costs of the review. "The Director shall establish, by regulation, fees to be paid by the person requesting the review, in such amounts as the Director determines to be reasonable, considering the aggregate costs of the review." Changes to the review fees are being considered as part of the current rule-making process.

- 8. Hundreds or thousands of patents cover smart phones, but some have criticized pharmaceutical companies for seeking more than one patent related to a drug product. The USPTO's recent *Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights* (RFC) also appears to focus on pharmaceutical products.
 - a. Does the USPTO treat patent applications from the pharmaceutical industry differently than patent applications from other industries?

Response: No. The USPTO applies the same standards for patentability to all utility patent applications, regardless of technology area. All patent applications are examined for compliance with the requirements of eligibility, novelty, non-obviousness, adequacy of the specification under 35 U.S.C. § 112(a), clarity of claims under 35 U.S.C. § 112(b), and double patenting. Based on the complexity of the technology involved, examiners in different technology areas of the office are allotted different amounts of examination time. Additionally, examiners may be given more time for exceptionally complex cases on a case-by-case basis, e.g., to consider obviousness-type double patenting in large patent families.

The Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (RFC) was issued as part of USPTO's response to President Biden's Executive Order 14036 to promote the interests of American workers, businesses, and consumers. The scope of the RFC was not limited to pharmaceutical patents but to improving the robustness and reliability of patents generally. The initiatives did not propose technology-specific changes to examination practice, and any initiatives that are implemented as a result of the RFC will be applied in a technology-neutral manner. The USPTO remains committed to treating all applications equally based on their merits.

b. What objective evidence supports the changes to examination practice (e.g., restricting continuation practice, having the validity of patents "stand and fall" based on other patents) that the RFC contemplates?

Response: The RFC sought input from the public on initiatives and topics directed at bolstering the robustness and reliability of patents while promoting innovation and competition, as well as to gather responses to inquiries from Congressional members.

For continuation practice generally, the USPTO's data show that continuation applications have tripled in the decade from 2011-2021 and, as of 2021, accounted for nearly a quarter of all serialized filings. The RFC seeks feedback on proposals such as whether the USPTO should revise the timing of filing a continuation or divisional application, or whether there should be greater scrutiny of continuation applications. At this time, the USPTO is not considering changing examination practice with respect to when a continuation or divisional application may be filed. That said the USPTO remains committed to issuing robust and reliable patents and will continue to refine internal quality review protocols and other practices to ensure continuation applications are appropriately examined.

With respect to having the validity of patents "stand and fall" together, the RFC asked whether a terminal disclaimer filed after an obviousness-type double patenting rejection should be an admission of obviousness; whether patents tied together by a terminal disclaimer should stand and fall together; and whether any changes need to be made to the patent system generally regarding obviousness-type double patenting. The USPTO continues to evaluate whether it can and should make changes, within its authority, to obviousness-type double patenting and terminal disclaimer practice in order to promote innovation and competition.

As acknowledged in the RFC, "multiple patents directed to obvious variants of an invention can pose a heavy burden on examiners because examiners are required to compare the claims in these multiple patents and pending applications to determine if the claims are patentably indistinct from one another such that a non-statutory double patenting rejection is proper." The USPTO is studying compliance rates for obviousness-type double patenting rejections in examination of patent applications in large patent families. The results of this study and the comments received in response to the RFC will be used to inform changes, if any, including potential rulemaking in this area.

USPTO Responses to Questions for the Record – Ranking Member Tillis U.S. Senate Committee on the Judiciary Subcommittee on Intellectual Property

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1. Following a series of Supreme Court cases, one critical requirement for obtaining a patent – whether a patent is eligible in the first place for patent protection under 35 U.S.C. § 101 – has become the opposite of a model of clarity.

a. You stated during your confirmation hearing that you thought that more clarity around Section 101 was important. Do you still think that this is true?

Response: Yes. Providing greater clarity in the law, including around Section 101, will result in more efficiencies within our intellectual property and innovation ecosystem and will go a long way toward encouraging the investments in innovation the U.S. patent system was designed to incentivize and protect.

b. What has the USPTO done to provide greater clarity in this area?

Response: The USPTO has developed and issued updated guidance on the examination of subject matter eligibility (SME) under § 101. In June 2020, the USPTO issued a revision to the ninth edition of the Manual of Patent Examination Procedure (MPEP), which consolidated and incorporated all prior guidance on subject matter eligibility and responded to public comments. The MPEP (particularly Sections 2103 through 2106.07(c)) is now the single source for the agency's patent eligibility guidance. The USPTO has also issued 46 examples providing eligibility analysis of various fact patterns to assist USPTO personnel and stakeholders in evaluating SME. The examples address a wide range of technologies, including artificial intelligence, biotechnology, business methods, computer-related inventions, diagnostic and treatment methods, pharmaceutical treatments, precision medicine, and software. The USPTO also conducted extensive training over several years to keep its patent examiners informed about SME issues and how to apply the USPTO's guidance when evaluating patent claims.

In June 2022, the USPTO published a report summarizing public views on how the current state of patent eligibility jurisprudence impacts investment and innovation in critical technologies. The following month, the "Director's Blog," entitled "Providing clear guidance on patent subject matter eligibility," summarized the work the USPTO has done on subject matter eligibility and invited the public to comment on the subject matter eligibility guidance. The USPTO extended the period to comment to the blog via a Federal Register Notice (FRN) on September 1, 2022.

The USPTO received 33 comments in response to the FRN. The USPTO is evaluating the comments to determine next steps.

The AI-inventorship Federal Register Notice sought stakeholder input on the current state of AI technologies and inventorship issues under 35 U.S.C. §§ 101 and 115 that may arise in view of the advancement of such technologies, especially as AI plays a greater role in the innovation process. The USPTO received 69 written comments from a diverse group of stakeholders. The Office is in the process of considering the feedback and determining next steps.

The USPTO staff continues to engage with stakeholders to provide greater clarity in this area through participation in various public events.

In recent years, the USPTO has worked closely with the Department of Justice (DOJ) on multiple Calls for View of the Solicitor General (CVSG) briefs, in which the government asked the Supreme Court to either clarify how patent eligibility should be properly analyzed or to correct the Federal Circuit's misapplication of the Alice two-step framework. (*See e.g., HP, Inc. v. Berkheimer*, No. 18-415; *Hikma Pharms. USA Inc. v. Vanda Pharms. Inc.*, No. 18-817; *Interactive Wearables, LLC v. Polar Electro Oy*, No. 21-1281; *Tropp v. Travel Sentry, Inc.*, No. 22-22.) The USPTO, in coordination with DOJ, continues to look for opportunities to participate as an intervenor or amicus in appropriate cases to assist in clarifying patent eligibility law.

c. As innovation continues to rapidly develop in emerging technology areas such artificial intelligence, medical diagnostics and biotechnology, would greater certainty in what can be protected by patents further help fuel innovation?

Response: Yes. The U.S. patent system can only play its role of incentivizing and protecting innovation, including in certain key technological areas, if it is clear that what technologies are protectable and if there is sufficient certainty in our laws to enable inventors and investors to rely on the patent grant.

d. Would more clarity around what categories can be patented and those that cannot, such as natural laws and unmodified genes, help fuel innovation and help maintain American competitiveness?

Response: Yes. The U.S. patent system can only play its role of incentivizing and protecting innovation, including in certain key technological areas, if it is clear that what technologies are protectable and if there is sufficient certainty in our laws to enable inventors and investors to rely on the patent grant.

e. Do you agree that the Patent Eligibility Restoration Act prohibits the literal patenting of the DNA in one's body?

Response: The Patent Eligibility Restoration Act of 2023, introduced in the Senate on June 22, 2023, states that "[a]n unmodified human gene, as that gene exists in the human body" is not eligible for patent protection. Thus, under this proposed language, an unmodified human gene as it exists in the human body would not be eligible for patent protection.

f. Criticism has been raised regarding patents being obtained on frivolous or obvious ideas simply because they are tied to technology, such as a computer – something like the patenting of a method to propose marriage over the internet.

Do you agree that the Patent Eligibility Restoration Act prohibits the patenting of something like a marriage proposal simply because a claim makes a passing reference to "doing it over the internet?"

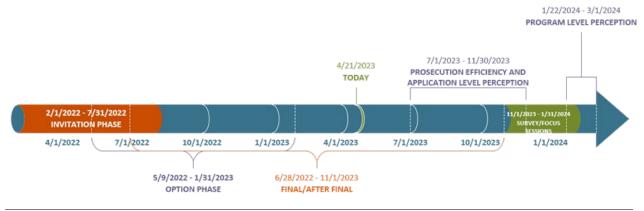
Response: The Patent Eligibility Restoration Act of 2023, introduced in the Senate on June 22, 2023, states that "a process that is substantially economic, financial, business, social, cultural, or artistic, even though not less than 1 step in the process refers to a machine or manufacture" would not be eligible for patent protection, unless "[t]he process described [...] cannot practically be performed without the use of a machine or manufacture." Whether the scenario set forth in the question would be eligible for patenting under the proposed language set forth in the Patent Eligibility Restoration Act would depend on the specific claims of the patent application.

g. Would you agree that the Patent Eligibility Restoration Act would go further than the current USPTO guidance can, under the current law, to provide better guidance to examiners, and by extension, to anyone seeking a patent?

Response: The USPTO is required to follow current law, and the guidance set forth in the MPEP and the examples on SME follow the current law. The Patent Eligibility Restoration Act of 2023 seeks to change the current law by eliminating all existing judicial exceptions to patent eligibility and sets forth criteria for determining whether an invention is eligible for patenting.

2. What is the status of the USPTO "Deferred Subject Matter Eligibility Response Pilot Program?"

Response: A timeline for the pilot is set forth below. The USPTO is on course to complete the pilot by mid-year FY2024. Currently, around 85% of pilot applications have reached disposal. The USPTO is continuing to gather prosecution data and surveying examiners to assess impacts at the application level. The USPTO also plans to hold examiner focus sessions and develop an applicant survey to collect examiner and applicant feedback about the program. The USPTO currently expects to complete the focus sessions and the applicant survey by the end of the first quarter of FY2024 and to issue a final report by the second quarter of FY2024.



- 3. There are a wide range of proposals presented in the USPTO's April 2023 Advance Notice of Proposed Rulemaking. Several of which are in conflict with what is being considering in the PREVAIL Act.
 - a. While Congress continues to explore legislative change, can you provide assurances that the USPTO is taking into consideration this proposed bipartisan bicameral legislation with regard to the steps that you are and will be taking?

Response: The USPTO welcomes and will take into consideration the feedback it receives from all stakeholders, including Congress.

b. While it's vital that changes to PTAB be made, concerns have been raised about whether the USPTO has authority to make some of them without further Congressional authorization.

Can you comment on the USPTO's position on the scope of the Director's regulatory authority versus when legislative action is required?

Response: The Director's authority to prescribe regulations in general for USPTO is found in 35 U.S.C. § 2(b)(2), which provides that the Director may establish regulations, not inconsistent with law, which shall govern the conduct of proceedings before the USPTO. Other sections of the Patent Act authorize the Director to prescribe regulations concerning specific procedures, e.g., 35 U.S.C. § 135(b) provides that the Director shall prescribe regulations setting forth standards for the conduct of derivation proceedings. In the Leahy-Smith America Invents Act (AIA), Congress provided the Director with specific authority to prescribe regulations governing the conduct of AIA proceedings before PTAB, including regulations concerning inter partes review (35 U.S.C. § 316) and regulations concerning post grant review (35 U.S.C. § 326). When USPTO undertakes rulemaking in connection with PTAB proceedings, it relies upon the Director's authority provided for in Title 35 to prescribe such regulations.

As provided for in 35 U.S.C. § 2(b), the Director's authority to prescribe regulations extends to regulations that are not inconsistent with existing law. When USPTO undertakes rulemaking it does so within the bounds of this authority. The USPTO also welcomes the opportunity to provide technical assistance to Congress on any statutory language concerning proposed changes to PTAB procedures, or other Office proceedings.

4. Some court judges use the technique of putting both experts on the stand together and allow each to clarify where and why he disagrees with the counter-expert.

Have the Administrative Patent Judges used this technique, and if so, why not?

Response: The PTAB receives relatively few requests from parties to present live testimony. The PTAB will hear live testimony at the oral hearing when it is helpful to the decision-making in that proceeding. For example, the PTAB has authorized live testimony on several occasions involving fact witnesses. A request for live testimony is more likely to be granted where the PTAB determines that the demeanor of a witness is critical to evaluating that witness's credibility, e.g., where an inventor is attempting to antedate a reference by establishing a prior reduction to practice. *See K-40 Electronics, LLC v. Escort, Inc.*, Case IPR2013-00203 (PTAB May 21, 2014) (Paper 34) (precedential).

Generally, the PTAB does not hear live expert testimony because the credibility of experts usually turns less on demeanor and more on the plausibility of their theories. The PTAB, which consists of technically trained and legally experienced judges, evaluates the expert's theories by considering the expert's declaration(s) and supporting evidence, any cited testimony of the expert elicited at deposition, and the underlying prior art references. Expert testimony that is conclusory and unsupported by evidence is typically entitled to little weight. *See Xerox Corp. v. Bytemark, Inc.*, IPR2022-00624, Paper 9 (PTAB Aug. 24, 2022) (precedential). This practice leverages the technical expertise of the judges and lowers costs to the parties.

While the PTAB has not yet employed the specific technique proposed, the PTAB would be open to using the proposed technique, if helpful in a particular case.

5. Director review of PTAB decisions is required by the Supreme Court, though the review likely requires the assistance of subordinates who may not be Administrative Patent Judges.

What policies and procedures do you follow to conduct Director review? How often are such decisions delegated to subordinates, and by what authority are you able to delegate such authority?

Response: The USPTO has set forth its interim policies and procedures to conduct Director Review on the USPTO website at <u>https://www.uspto.gov/patents/ptab/decisions/revised-interim-</u> <u>director-review-process.</u> In July 2023, the USPTO updated the interim processes for Director Review stating that Director Review is available for decisions on institution and final written decisions of AIA post-grant proceedings. In general, a party may request Director Review of a decision on institution or a final written decision of an inter partes review or post-grant review by timely filing a request for rehearing of that decision and emailing the USPTO at Director_PTABDecision_Review@uspto.gov to request Director Review.

Although the USPTO has established an Advisory Committee, which includes representatives from different business units at the USPTO (and thus includes non-judge members), the determination of whether to grant or deny Director Review is exercised only by the USPTO Director. The Advisory Committee only serves to advise the Director, whereas all decision-making authority on Director Review resides with the USPTO Director.

The USPTO's July 2023 update provides that the Director may choose to delegate Director Review to a Delegated Review Panel (DRP). The DRP comprises of executive judges from the PTAB and operates as a panel independent of the Director. However, the Director retains the ability to review decisions *sua sponte* from the DRP. This update also established an Appeals Rehearing Panel (ARP). The ARP consists of the USPTO Director, Commissioner for Patents, and the PTAB Chief Judge. The Director, in her sole discretion, may convene the ARP to *sua sponte* review a decision in an *ex parte* appeal, reexamination appeal, or reissue appeal. 6. Cross-examination of experts is often crucial to determining credibility, sound basis of opinions, and therefore truth. Yet in IPR and PGR proceedings live testimony is rarely ordered.

As many cases turn on the "battle of the experts," would it be reasonable to require live testimony by witnesses, at least for focused cross-examination? Would you support such a policy?

Response: As discussed in the Response to Question 4, the PTAB generally does not have live expert testimony in IPR and PGR proceedings. The PTAB's rules permit seven hours of cross-examination of opposing experts as part of "routine discovery." Thus, the transcripts of the cross-examination provide substantial information to the PTAB panel in its decision-making.

As also discussed above in Response to Question 4, live testimony is permitted on a case-bycases basis when helpful to the PTAB in decision-making. While the PTAB has not yet employed the specific technique described in your question, the PTAB would be open to using the proposed technique, if helpful in a particular case.

7. Last year, I sent two letters to the USPTO regarding findings published by the "Initiative for Medicines, Access & Knowledge" (I-MAK) on drug-related patents that appear to overstate the periods of exclusivity for many medicines based on their analysis of the relevant patent protection. The USPTO, in conjunction with the FDA, was asked to provide its own data on this topic.

What is the current status of your investigation into this matter?

Response: Over the past year, the USPTO, in consultation with the FDA, has completed this study and has drafted a report summarizing the results. The study provides an assessment and analysis of patent, exclusivity, and drug approval data to help inform USPTO and FDA's shared goals of fostering affordable access to medicine while incentivizing innovation. Specifically, the USPTO conducted a transparent analysis of a representative sample of drugs listed in the FDA's Orange Book between 2005-2018 using available public data points (e.g., patent numbers and exclusivities listed in the Orange Book, patent filing and issue dates, and drug application approval dates). Mapping the scope and duration of exclusivity and patent protections associated with a particular FDA-approved drug product can be complex and may inform but not fully reflect the time it took (or can be expected to take) for a generic or biosimilar version of that product to come to market.

8. Concern has been raised regarding the European Union's recent proposal to create a new "competency center" that would attempt to set prices for standard-essential patents.

Can you expand upon what you and the Administration have done, in particular, to push your European colleagues to reconsider this misguided proposal, and what you are planning to do going forward? **Response:** The USPTO, along with other in the Department of Commerce, are closely tracking the European Commission's SEP proposal. On April 26, Secretary Raimondo testified before the Senate Appropriations Committee, indicating she shared Congress' concerns about the EU SEP proposal and that her team in Brussels had met with the EU to discuss the proposal. She also informed Congress that when she attended the U.S.-EU Trade and Technology Council in May, she would broach the SEP proposal with her EU colleagues.

The USPTO and others in the Department of Commerce are closely working with colleagues across the U.S. Government to engage with the EU on its proposed initiative We are carefully considering the proposal and its ramifications in detail. Moreover, the proposed regulation still needs to be passed by the European Parliament and the Council of the European Union to enter into force. Additionally, as I indicated in my Senate Oversight hearing, I've met with our colleagues at the European Union Intellectual Property Office and other stakeholders in Europe to discuss this issue. The USPTO held a public listening session on September 20, alongside the International Trade Administration and the National Institute of Standards and Technology, that gathered stakeholder views on the proposal.

- 9. In recent years, there has been growing concern about the involvement of foreign interests and particularly of foreign sovereign wealth funds in funding U.S. patent litigation. Currently, such parties are allowed to fund patent litigation with few restrictions, and there is no nationwide requirement that such funding be disclosed to the judge or opposing party.
 - a. Do you agree that the involvement of foreign interests in funding domestic patent litigation raises significant concerns with respect to U.S. national and economic security?

Response: Where patent litigation funding is provided by foreign third parties, especially sovereign funds owned or under the control of governments hostile to U.S. interests, the USPTO agrees that concerns could arise about U.S. national and economic security.

b. If so, do you think that U.S. law should require disclosure when foreign interests – and particularly foreign governments – are involved in funding patent infringement suits against U.S. companies?

Response: The USPTO supports a robust, reliable and transparent patent system.

10. Currently, there appears to be little negotiation occurring between the USPTO of the United States Trade Representative and its Chinese counterpart on IP. This makes the USPTO's role, including its China-based attachés, even more important.

Can you please tell us what related activities the USPTO both has, and is, engaged in?

Response: The USPTO is pursuing five main lines of effort to protect America's innovators, creators, and brand owners.

First, through its team of experts based at USPTO headquarters and in three cities in the People's Republic of China (PRC), USPTO engages and educates U.S. rights holders on the importance of IP protection, including outreach to American IP right holders on challenges in protecting and enforcing intellectual property rights in the PRC. These efforts include providing free online written materials designed to be especially helpful to small- and medium-sized enterprises, free in-person seminars and webinars featuring government, business, and academic experts on U.S. and the PRC intellectual property systems, such as the USPTO's "China IP Roadshows," and engaging with American rights holders in two-way information exchanges to accurately assess rights holders' needs and in private one-on-one meetings as requested, including consultations with the USPTO's PRC-based personnel.

Second, the USPTO engages with its counterparts at both the national and local levels in the PRC Government to advance U.S. interests, press for legal reform, provide training, and share illustrative rights holder experiences. The USPTO will continue to press the PRC to level the playing field for American companies and rights holders and to encourage the PRC to comply with its international and bilateral treaty obligations involving IP, including full implementation of all intellectual property commitments of the Economic and Trade Agreement between the Government of the United States of America and the Government of the People's Republic of China (also known as the Phase One Trade Agreement).

Third, the USPTO focuses on capacity building for protection and enforcement of IP in key countries along international trade routes, improving IP systems in key transit points around the world to reduce the flow of counterfeit and piratical goods.

Fourth, the USPTO serves as a resource for the executive and legislative branches to advise on PRC-related IP issues including the preparation of reports on critical IP issues, such as the PRC's use of subsidies for patent and trademark applications, which have cluttered IP registries and harmed legitimate rights holders. The USPTO will continue to serve as a resource for technical evaluation of draft legislation upon request.

Fifth and finally, the USPTO supplements bilateral engagement by coordinating with likeminded foreign governments bilaterally and in multilateral forums to pursue initiatives that address PRC IP concerns.

11. What is your reaction to China's recently released new IP "abuse" rules and a proposed new guideline on SEP litigation and antitrust?

Response: On June 29, 2023, the PRC State Administration for Market Regulation issued final revised "Provisions on Prohibiting Intellectual Property Abuse to Preclude or Restrict Competition" and on the same day a draft measure entitled "Anti-Monopoly Guidelines for Standard Essential Patents." The USPTO's views are consistent with the 2023 Special 301 report issued by the Office of the United States Trade Representative, which indicates that "[r]ight holders have raised concerns about the application of [the PRC's] Anti-Monopoly Law (AML) to the licensing of patents in certain instances[,]" including that AML enforcement could be "misused for the purpose of depressing the value of foreign-owned IP in key technologies." The USPTO agrees with the report's conclusion that it is critical that AML enforcement be "fair,

transparent, and non-discriminatory" and "afford due process to parties", and that the competition law "should not be used when there is no harm to competition or the competitive process to advance industrial policy or other non-competition goals." Furthermore, the USPTO has recently issued a request for comments seeking feedback from U.S. stakeholders on standard essential patents.

12. Concern has been raised regarding proposals by the USPTO to restrict or apply greater scrutiny to well established U.S. continuation practice (e.g., terminal disclaimers, continuation applications, continuation-in-part applications, and divisional applications).

What is the objective evidence that the USPTO is relying upon to make the determination that such changes are needed?

Response: The Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights (RFC) sought input from the public on initiatives and topics directed at bolstering the robustness and reliability of patents while promoting innovation and competition, as well as to gather responses to inquiries from Congressional members.

For continuation practice generally, the USPTO's data show that continuation applications have tripled in the decade from 2011-2021 and, as of 2021, accounted for nearly a quarter of all serialized filings. The RFC seeks feedback on proposals such as whether the USPTO should revise the timing of filing a continuation or divisional application, or whether there should be greater scrutiny of continuation applications. The USPTO is not, at this time, considering changing examination practice with respect to when a continuation or divisional application may be filed. That said, the USPTO remains committed to issuing robust and reliable patents and will continue to refine internal quality review protocols and other practices to ensure continuation applications are appropriately examined.

13. Prior art searching by a Patent Examiner is a vital component to patent examination and strong patents.

Do you agree that an emphasis should be placed on performing complete and thorough searches at all stages of prosecution?

Response: MPEP sections 904 through 904.02(b) set out the appropriate process for conducting the patentability search for a patent application. The USPTO instructs examiners to, after having obtained a thorough understanding of the invention disclosed and claimed in the application, conduct a search of the prior art as disclosed in foreign and domestic patents and published applications, as well as other published documents (non-patent literature). The USPTO also indicates that an inventor name search should be made to identify other applications and/or patents which may be applicable for double patenting.

The initial search should cover the invention as described and claimed, including the inventive concepts toward which the claims appear to be directed. Following the first Office action, however,

the examiner need not ordinarily make a second search of the prior art. An additional search may be necessitated by the applicant's amendments to the claims in response to the first Office action to determine whether any more pertinent reference has become available subsequent to the initial prior art search.

Planning and conducting searches are also major activities in the Patent Examiner Performance Appraisal Plan (PAP) Quality element. Examiners are expected to both plan (i.e., identify the most appropriate strategies, reference sources, and classification relevant to the technology) and conduct (i.e., find and cite the closest or best prior art to make rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103) a complete and thorough search in every application as early in prosecution as possible. To this end, the PAP Quality element further identifies exemplary activities related to search, such as searching the applicant's inventive concept as defined at the time of the first action on the merits and citing prior art on the record pertinent to significant though unclaimed features of the defined invention.

14. A significant aspect to searching prior art, when performed by a Patent Examiners, is looking for non-patent literature (NPL).

a. What is the USPTO's long-term plan for improving the non-patent literature (NPL) sources that are available to Patent Examiners for use during examination?

Response: The USPTO maintains an extensive collection of NPL resources. The vast majority of these are available electronically and are primarily categorized as books, journals, and databases. The USPTO electronic library includes over 600,000 books, over 72,000 journals and access to over 40 commercial databases. The link below lists our available resources as of October 2021. https://www.uspto.gov/learning-and-resources/support-centers/scientific-and-technical-information-center-stic/prior-art

In addition to maintaining curation of the electronic library, our future plans include continuing our examiner education and information dissemination programs, focusing our Scientific and Technical Information Center research staff on assisting patent examiners with non-patent literature searching, and integrating access to electronic NPL sources into the primary search tool used by patent examiners and working overtime to federate that search mechanic to allow a single query language to work in all databases and collections.

b. Does the USPTO need anything from Congress to help with making NPL more accessible?

Response: The USPTO always stands ready to work with Congress on ways to ensure that it issues robust and reliable patents, including ensuring a robust prior art search.

15. For decades there has not been a major change to the time afforded to Patent Examiners for the examination of patent application, yet the nature of the technology from which these patent applications are derived and the complexity of this technology

have only increased. In addition, the proliferation of prior art which Patent Examiners must search for and review, in order to make patentability determinations, has only increased and it has done so at a rapid pace.

Do you believe that additional time should be afforded to patent examiners to examine patents?

Response: Timely issuance of high-quality patents by our examiners is critical to providing the certainty that businesses and entrepreneurs need to invest in, develop, and roll out innovative new products and services. The USPTO's strategic plan to issue and maintain robust and reliable patents and improve patent application pendency recognizes this, and the USPTO is diligently working to equip our examiners with the guidance, training, tools, advanced technology, and procedural resources they need to address increasingly complex patent applications. Application pendency and examination quality do not separately exist in vacuums. For example, too expeditious of an examination could result in uncertainty of rights in the marketplace due to insufficient patent quality, while drawn out, improperly focused, and overly detailed examination could impede a business or innovator's ability to make timely and cost-effective decisions. Thus, a careful balance is necessary.

Therefore, the time patent examiners are allotted to examine applications is a critical link between patent application pendency and quality. In fiscal year (FY) 2021, the USPTO implemented a process that revised the time allotted for examining patent applications. This implementation was possible due to an initial phase that started in FY 2020 and offered an increase in the base or minimum time patent examiners are allotted to examine each application. Through this revision, additional time is allotted for applications that contain particular attributes above a specified threshold, including the overall number of claims, the length of the specification, and the number of pages in any filed Information Disclosure Statement. Examination time is now also based on an application's classification "picture," which represents the full scope of technology covered in an application and accounts for multidisciplinary inventions. The new method for allotting examination time is more transparent and flexible as adjustments can be made as the patent examination or prosecution conditions change. This flexibility allows for maintaining the necessary time to ensure stakeholder confidence in the certainty of resultant patent rights and enables optimal pendency, cost, and quality levels. The USPTO continues to study the impacts of these changes on patent examiners and stakeholders, collecting information and feedback to develop targeted solutions to continue improving the processes by which time is allotted for examining patent applications. We are also evaluating whether further adjustments to examination time—or new, creative measures to make examination more efficient—may benefit patent quality, recognizing at the same time that such adjustments may affect patent pendency. The USPTO implemented AI solutions into examiner-facing search tools last fiscal year to ensure examiners have the best search tools possible and to aid in efficiently considering ever-increasing volumes of prior art. The USPTO also uses AI to route patents to patent examiners with the appropriate technical background. In regard to pendency, though the use of AI may have some impact, there are numerous non-technology factors which may have a more significant impact on pendency.

These include pre-examination processes, the number of examiners on staff, examination time, and filing trends from applicants.

- 16. Over the years internal goal posts for defining "quality" for patent examination can shift annually within the USPTO. There is concern that this can potentially lead to confusion on the part of the Patent Examiner, because rather than having all aspects of quality examination equally reinforced, a single particular area becomes the primary focus for a given year.
 - a. Do you have similar concerns about the shifting focus of "quality?"
 - b. How can a more holistic approach to quality be achieved to ensure thorough, consistent, and high quality of examination of patent applications?

Response to 16a and 16b: The USPTO seeks to ensure robust and reliable patents by monitoring patent quality using a variety of indicators including patent quality metrics, process measures, and perception surveys.

The patent quality metrics are determined from a random sample of Office actions reviewed by the Office of Patent Quality Assurance (OPQA) for statutory compliance. For fiscal year (FY) 2023, through the end of quarter 2, the percentage of Office actions reviewed that meet statutory compliance for each statute is:

- 35 USC 101: 98.3%
- 35 USC 102: 96.4%
- 35 USC 103: 92.1%
- 35 USC 112: 94.5%

The granularity of data obtained by reviewing all claims in an Office action for statutory compliance provides meaningful feedback to Technology Center (TC) management and quality assurance specialists and facilitates the identification of quality trends, training opportunities, as well as an evaluation of recent training at the examining corps level and below. In addition to the random reviews that underpin the statutory compliance metric, OPQA conducts numerous other reviews throughout each fiscal year, often in partnership with the TCs.

The USPTO also leverages process measures that assist the agency in tracking the efficiency and consistency of the examination processes. This includes evaluating certain types of transactions in the Patent Data Portal (PDP) as well as use of a standard review form to identify trends and examiner behaviors indicative of best practices, potential quality concerns and consistency of practice.

Since 2006, the USPTO has conducted both internal and external stakeholder perception surveys semi-annually. The internal quality survey administered to patent examiners focuses on internal and external factors impacting examiners' ability to provide high-quality patent examination. The external survey gathers perceptions about examiners' adherence to rules and procedures and satisfaction with search and prior art. The results of these surveys are a vital quality indicator and used to validate other USPTO quality related metrics assuring alignment with our stakeholders' perceptions. While the survey questions remain static to facilitate longitudinal analyses, a single open-ended question is incorporated during each enumeration to explore current topics of interest to the USPTO, such as specific effects of recent quality efforts or considerations for pending

quality initiatives The key performance measure obtained from the external perception survey is a quality Net Promoter Score (NPS) that measures the net difference of customers rating overall examination quality as "good or excellent" and those reporting quality of work product as "poor or very poor". An NPS target of greater than 50 is sought by USPTO, which is a widely-adopted threshold to signify the healthy performance of an organization. The quality-related NPS for USPTO has remained strong over the past two years and is currently well above target at 57. Recent improvements in the score can be attributed to a focus on response to applicant's arguments, a statistically-derived key driver of customer perceptions. The monitoring of these indicators supports the investigation of specific quality issues relevant to our stakeholder community as well as to the specific needs of each TC providing insight into whether patent quality is improving as well as whether a particular patent quality initiative is successful.

In addition to measuring the success of our ongoing quality initiatives, the USPTO continues to implement new initiatives including the Post Grant Outcomes, a collaborative effort between the Patent Trial and Appeal Board (PTAB) and the Patents (examination) division to establish a learning loop, which leverages and readily introduces PTAB decisions into patent examination to improve patent prosecution. In April 2023, the USPTO launched a new Research and Development (R&D) Unit to drive transformative innovation and improvements in patent examination practices. Focused on sound problem solving principles and data-driven decision making, the R&D Unit comprises a group of examiners drawn from all utility patent technology areas. The unit explores potential solutions to challenges faced in a complex examination system and then tests initiatives for efficacy and impacts on a multitude of factors, including quality, pendency, and employee and customer experiences. Using standardized procedures to create, develop, and analyze clear measures of success for the initiative allows the unit to determine whether the initiative is successful in meeting its stated objectives before the agency decides to pursue it on a larger scale.

17. A recent Bloomberg report cited a scam where a Chinese company filed 2,000 applications under the name of a dead American lawyer. Scammers are impersonating trademark examiners, misusing the USPTO seal, and demanding payment on the threat of canceling a trademark registration. The Trademark Modernization Act of 2020 granted resources to the USPTO Register Protection Office and that the office has been sanctioning bad actors.

a. What is the USPTO doing under your leadership to make the Registry work better and support American IP?

Response: Protecting the Trademark Register from these scams and ensuring the accuracy and integrity of the registrations the USPTO issues and maintains remains a top priority of mine and the USPTO. The USPTO's Register Protection program includes tools that we can use internally as well as tools that our external stakeholders can use to fight scams. We continue to grow our capacity and are in the process of formally establishing the Register Protection Office (RPO).

Since mid-2021, we have issued over 300 orders for sanctions that have terminated over 19,000 invalid applications and sanctioned 3,500 invalid registrations. This year, we added a staff attorney to lead the investigation and monitoring of USPTO.gov accounts. This attorney

recommends the suspension and take down of offending accounts whenever warranted. During this period, we suspended more than 40 USPTO.GOV accounts. We have also referred more than 50 individuals to the Office of Enrollment and Discipline for investigation and possible discipline.

Another internal Register Protection tool is Director-initiated expungement and reexamination nonuse cancellation proceedings that was established under the Trademark Modernization Act for those registrations that are not in use and to eliminate registrations emanating from scammers. Since mid-2021, we have instituted more than 150 Director-initiated proceedings against registrations that are not in use, with 1,466 goods and services cancelled and removed from involved registrations. The USPTO is also collecting evidence for use in several hundred more of these cases, most of which are linked to so called "specimen farms," which are e-commerce websites designed solely to incubate fake specimens of use to satisfy USPTO requirements.

The Post-registration audit is yet another internal tool through which the USPTO requests proof of use to establish that the mark is actually in use on the goods and service identified in the registration at the time of the maintenance filing and, if proof is not provided, the USPTO imposes a \$250 penalty. The USPTO currently audits 5,000 registrations a year.

The USPTO also spends significant resources trying to get the word out to our customers to avoid scams that include impersonations of the USPTO, misleading solicitations, or unauthorized practitioners, and to contact us if they get scammed so the USPTO can gather information about evolving scams. The USPTO recently started sending out official "Welcome Letters" to trademark applicants to help them more quickly and easily navigate the trademark application process and connect them with relevant resources, including directing them to the USPTO's website that helps them protect against trademark scams. Unfortunately, like some many other industries, the USPTO has seen exponential growth in the number of trademark scams being reported to the USPTO. In FY2021, we counted 190 emails from customers about scams, which increased to 357 in FY2022, and exploded to 965 through the third quarter of FY2023. Our staff reviews each email that we receive, and we provide tips to help customers avoid being scammed and what they should do if they have fallen victim to a scam. Since the USPTO does not have criminal or civil enforcement authority, we are limited as to what we can do to help customers scammed by private actors. However, we will continue to partner with federal agencies who do have this authority.

In addition to our internal Register Protection tools, the USPTO also has external register protection tools that stakeholders can use to join us in our efforts to protect the register and to fight scams. One such tool is the Trademark Trial and Appeal Board (TTAB), where parties may file petitions to cancel a mark at the TTAB for fraud, abandonment, nonuse, or that an application or registration is void *ab initio*, which may be based on findings made in orders issued through our Administrative Sanctions program. Another tool created by the Trademark Modernization Act is the ability for third parties to file petitions to request institution of *ex parte* nonuse proceedings before the Director. We have received 357 third party petitions since 2021 and have instituted nonuse proceedings on the registrations identified in 182 of those petitions.

As a result, we have cancelled a total of 2,302 goods and services. Third parties can also file letters of protest wherein they can submit evidence that the specimens of use submitted in a pending application are fake or fraudulent to the USPTO for consideration.

Through the end of June 2023, we received 122 Letters of Protest providing evidence of nonuse. The evidence was relevant in 58 of those cases and forwarded to the examining attorney for consideration. In about 18 of those cases, the evidence was used in a refusal to register, 15 cases are awaiting examining attorney action, and 3 cases expressly abandoned before examining attorney action.

b. Does the USPTO require any additional tools?

Response: The USPTO is evaluating whether additional tools are needed and stands ready to work with Congress to address this issue.