USPTO Responses to Questions for the Record - Senator Tillis
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

QUESTIONS ON PATENT PROTECTIONS FOR PHARMACEUTICALS, BIOLOGICS, AND BIOSIMILARS

1. There has been commentary suggesting that drug makers extend their market exclusivity by getting patents for trivial modifications to their drug products. Can you, for example, get a patent on a new color of a pill? Do additional patents on an existing drug extend the original patent for another 20 years?

Response: Additional patents on an existing drug invention do not extend the original patent for another 20 years. Continuation patents, for example, have the same original U.S. filing date, and their terms typically run 20 years from that same date.

Further, in order to receive a utility patent for an improvement to an existing product, the improvement must be new, non-obvious, and meet all of the other statutory requirements for patentability.

These are often complex products, comprising various technologies. If they meet the patentability criteria, separate patents may also exist, with distinct scope and unrelated protection terms, but these would be for other inventions and not an "extension" of the original patented invention.

While an inventor could obtain a design patent to protect ornamental features on a pill, the design patent would not protect the utility of the pill, like its ability to treat diseases or symptoms. The USPTO has not identified any utility patents on a color of a pill.

2. Is the practice of getting patents for product or manufacturing improvements unique to the pharmaceutical industry? Would we expect to find multiple patents on a single product in other fields, such as cell phones or sneakers?

Response: The practice of making improvements to existing products, *i.e.*, incremental innovation, is not unique to the pharmaceutical industry. It is found in all industries. Today's inventors stand on the shoulders of those who have gone before them and building upon previous discoveries. Multiple patents on a single product can be found in all industries. For example, a cell phone may hold patented technology on the communications, design and semiconductors, among many other features.

3. There has been a great deal of commentary on the number of patents on individual drugs. Are there different types of patents that can be relevant to a drug product? For example, could you patent a method of making an old drug more pure and safe? Patent a better way of administering a drug, or extending its shelf life? Patent a new method of using an old drug to treat a different disease other than the one for which the drug was originally approved? Or do all drug patents – including what we call "evergreening patents" – cover only the drug molecule itself? What role does the patent system play in the development of these improvements?

Response: There could be many different types of patents that are relevant to drug products. Generally, patents can cover a product, a method of using a product, and a method of manufacturing of a product. Patents covering a drug product include patents that claim an active ingredient as a chemical composition, patents that claim a formulation including a combination of ingredients, patents that claim methods of manufacturing, as well as patents that claim a delivery system for an active ingredient, such as an injection system or a capsule with specific coatings to control how the medicine is absorbed by the body. The examples provided in the question are all examples of patents that could be granted. All patents, of course, must meet the statutory criteria for patentability.

We must always work to ensure balance in the patent system. Among other things, we must ensure that innovation is incentivized and protected, that all patents meet the criteria for patentability, and that abuses in the system are identified and eliminated. Any abuse of the patent system should be addressed specifically, and only inventions that meet the statutory requirements of the Patent code should be granted a patent.

The patent system, properly balanced, provides a critically important incentive to encourage investments in research and development, in revolutionary technologies as well as evolutionary technologies. The system as a whole must be carefully balanced to incentivize innovation and create jobs in order to grow the economy.

QUESTIONS ON FRAUDULENT TRADEMARKS

1. Since your last visit to the Committee, USPTO has released a rule for comment that requires foreign filers to retain US counsel when filing a US trademark application. This is an important step forward in resolving future applications to register suspicious, possibly fake trademarks in the future. What steps are you taking to address registrations and already pending applications?

Response: In July, and after considering public comments on the proposed rule, the USPTO published its final rule to require foreign-domiciled trademark applicants and registrants to be represented by a U.S. licensed attorney (84 FR 31498; July 2, 2019). It went into effect on August 3. The USPTO believes that this rule requiring foreign-domiciled trademark filers to be represented by a U.S. licensed attorney at the USPTO will increase the accuracy of the submissions to the USPTO and will decrease the incidence of foreign trademark attorneys and agents engaging in the unauthorized practice of law before the USPTO.

Before this rule, the USPTO had already taken a number of steps to address the growing problem of trademark applicants submitting suspicious or fake specimens of use, including: establishing a streamlined version of our informal letter of protest procedure, whereby third parties may bring to the attention of the USPTO evidence that a particular specimen submitted in an application is mocked up or doctored by submitting it to our Specimen Protest email box; investigating software that would allow fake specimens of use to be more easily detected as well as considering options in the pre-examination phase, so that fake specimens can be flagged for further handling; and training our examining attorneys on identifying digitally created or altered specimens and on how to ask applicants for information and proof of actual use. Recently, the USPTO updated its examination guidance to now require that examining attorneys issue a refusal in such circumstances and request additional information and evidence of the mark's use in commerce. The guide is publicly available on the USPTO's website at: https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%2003-19.pdf.

Regarding registrations, since 2012 the USPTO randomly audits post-registration maintenance filings and requests the registrant to provide proof of use for additional goods or services in the registration. If the registrant cannot provide proof that the mark is in use for the queried goods or services, those goods or services are deleted from the registration. The audit has been successful at helping improve the accuracy

of the register and we have increased, and plan to increase even more, the number of maintenance filings that are audited. The TTAB also has implemented a pilot program to expedite resolution of cancellation proceedings involving a claim of non-use or abandonment of the registered mark. The USPTO is considering creating incentives for registrants to ensure that their registrations are and remain accurate regarding the goods or services for which the mark is in use, without waiting until the maintenance filing to do so. For example, the USPTO is considering charging a "zero fee" to file a request to delete unused goods/services outside of the audit or a TTAB proceeding, but charging a fee to amend a registration when goods or services are deleted from a registration as a result of an audit.

The USPTO's audit program has demonstrated that 79% of those audited were represented by counsel and, of those audited who had a lawyer, 52% have been required to delete goods or services for which they previously swore the mark was in use. These statistics are troubling to say the least and suggest a lack of care, knowledge of what the law requires, or both, by mark owners and their counsel. In egregious cases, the USPTO may refer attorneys to the USPTO's Office of Enrollment and Discipline (OED) for investigation of misconduct. But, to ensure that mark owners and their counsel understand U.S. use requirements and their mutual obligations under the USPTO's rules to confirm that the submissions they make to the USPTO are accurate and that claims of use have evidentiary support, we are developing educational materials for our website and will be adding information to our notices. We are hopeful that providing materials that explain what use in commerce is, the importance of use in commerce to having trademark rights and a valid registration, and the steps lawyers and clients should be taking to confirm the facts of use, combined with the U.S. counsel requirement, will help improve the accuracy of submissions to the USPTO.

2. Currently, it is my understanding that for a legitimate actor to file a challenge to a pending application or a registered mark takes anywhere from 6 months to 18 months to resolve. This is in addition to the time it takes for the application or registration to get to a point in the process where it is even open to challenge, which can increase time to three years. For many companies who are looking to register a trademark for a new brand this time is prohibitive to moving forward. Does the USPTO have the authority to expedite this process, especially for blatantly photoshopped or duplicate images?

Response: Currently, a third party can challenge an application after it clears examination and is published for opposition, or the third party can file a petition to cancel a registration after it issues. The overall time it takes for applications to get to the stage where third parties can challenge them cannot be shortened because the applicant has six months to respond to an Office action raising refusals or requirements under the statute. See 15 U.S.C. § 1062. The USPTO cannot waive that 6-month response period. Once challenged by a third party, opposition and cancellation proceedings have typically been difficult to expedite, but the TTAB is looking at ways it could streamline cases raising claims of non-use or abandonment. The USPTO is also looking at other potential measures and changes to help the USPTO and third parties address applications with fake specimens more efficiently and effectively.

3. Director, you indicated that you have provided more training to examiners on suspicious or fraudulent trademark applications coming from foreign filers. Have you considered examiner guidance to further elevate the issue?

Response: Yes. The USPTO is in the process of developing further guidance, including directing examiners to more actively use their authority to require further proof of actual use of the mark when a suspicious specimen raises concerns.

Examining attorneys have limited ability to combat the problem of applicants submitting false or fraudulent applications to the USPTO. If an examining attorney has evidence that a particular specimen

is fake and thus does not meet the statutory requirement to show the mark is in use in commerce, the mark is not eligible for registration. In such a case, the examining attorney can refuse registration on that basis, and the applicant can then submit evidence that may overcome the refusal. The examination process presumes the good faith of the applicant (who swears to the facts of the application subject to criminal penalties). Congress designed the federal trademark process to give interested third parties appropriate tools to challenge trademarks, and the investigation of fraud or bad faith most often arises during inter partes proceedings before the TTAB or the courts. Congress has not provided an express statutory ground for the USPTO to refuse registration based on fraud on the Office in ex parte examination, but fraud is specified as a ground for cancellation by third parties, who may be in a better position to uncover the kinds of evidence to support such a cancellation.

4. It is my understanding that US trademark applications filed by residents of China have increased significantly in the past few years. According to the USPTO's Performance and Accountability Report, there were 6,323 successful applications in 2014.

In 2015, there were 14,144 applications – more than double. In 2016, there were 28,770 successful applications – a 200 percent increase. In 2017, there were over 50,000 successful applications and in 2018 a smaller uptick at 57,879 successful applications.

What direction was given to examiners as these applications increased? Did you identify suspicious specimens or any commonalities in these applications that seemed odd? Do other countries have similar increases?

Response: The USPTO shared information with other global trademark offices on this surge in Chinese applications, and while many offices were experiencing increases, they did not appear to be quite as high as in the USPTO. Further, because most other global trademark offices do not require the applicant to demonstrate use of the mark as a condition for registration, these other offices did not generally share the USPTO's concerns about the veracity of the applications or claims of use.

This surge of Chinese applications at the USPTO had some common features: a significant majority were filed directly into the United States based on use of the mark in U.S. commerce, rather than being based on an intent to use the mark, ownership of a foreign registration, or using the Madrid System for the International Registration of Marks. Moreover, many of these applications were purportedly pro se; however, there were indications in the record that Chinese trademark agents and attorneys who are not authorized to represent applicants at the USPTO were involved in the preparation of the applications.

In response, the USPTO has issued exclusion orders to bar unauthorized foreign practitioners from appearing before the USPTO. We also have hired more examining attorneys to respond to the increased workload. Additionally, the USPTO trained examining attorneys on identifying digitally created or altered specimens, including when the same specimen appears in multiple applications with the only difference being the mark.

QUESTIONS ON SECTION 101: PATENT ELIGIBLE SUBJECT MATTER

1. Director Iancu, earlier this year the USPTO issued revised examination guidance concerning patent subject matter eligibility, which you characterized as an attempt to provide more clarity and increase certainty within the framework the Supreme Court set out in the *Alice* and *Mayo* cases.

> **a. Should section 101 play any role in preventing the issuance of patents that fail to meet other statutory requirements for obtaining patent protection?**

Response: In my view, generally no. The patent laws function best when each of the patent statutes serves the particular purpose for which it was designed. If a patent application does not meet the statutory bases for patentability, one of which is patent eligibility under 35 U.S.C. § 101, it should not be allowed. The subject matter eligibility requirement of 35 U.S.C. § 101 is designed to distinguish between the types of innovation for which patent protection is available and the types for which it is not. The disclosure and definiteness requirements of 35 U.S.C. § 112 are designed to distinguish between patent-eligible innovations that are adequately disclosed and definitely claimed and those that are not. The novelty and non-obviousness requirements of 35 U.S.C. §§ 102 and 103 are designed to distinguish between patent-eligible innovations that are sufficiently different from the prior art to merit patent protection from those that are not.

b. Should it prevent the issuance of overly broad patents or exclude any specific areas of technology?

Response: In my view, generally, no. There are differences between patent eligibility under Section 101, novelty under Section 102, nonobviousness under Section 103, and disclosure-and-definiteness under Section 112. The disclosure and definiteness requirements of 35 U.S.C. § 112 and the novelty and non-obviousness requirements of 35 U.S.C. §§ 102 and 103 are designed to prevent the issuance of patents whose disclosures are too vague or whose claims cover too much. In addition, sometimes claims can be so broad as to cover patent-ineligible matter, such as mental processes for example, in which case Section 101 can also be implicated.

Regarding specific areas of technology, Section 101 should not exclude particular areas of technology; rather, all patent statutes work together to determine whether inventions, in any area of technology, are worthy of patent protection. If a patent application does not meet the statutory bases for patentability, one of which is patent eligibility under 35 U.S.C. § 101, it should not be allowed.

c. Should it play a role in being a gatekeeper to screen poor quality patents?

Response: If a patent application does not meet the statutory bases for patentability, one of which is patent eligibility under 35 U.S.C. § 101, it should not be allowed. The subject matter eligibility requirement of Section 101 is designed to distinguish between the types of innovation for which patent protection is available and the types for which it is not. Other statutes, however, should be used to prevent patents that fail to meet their respective bases for patentability. The disclosure and definiteness requirements of 35 U.S.C. § 112 and the novelty and non-obviousness requirements of 35 U.S.C. §§ 102 and 103 each serve a different purpose, as noted in the answers above.

2. With the improvements made by the implementation of the 101 examination guidance, do any problems or challenges remain with regard to patent subject matter that you lack the statutory authority to resolve?

Response: The January 2019 Patent Eligibility Guidance synthesizes current law and precedent. As I testified at the hearing, the guidance is designed to increase the certainty and predictability of the patent eligibility analyses and provide a more consistent analytical framework to guide inventors, practitioners, examiners, and the public in finding the appropriate lines to draw with respect to patent eligible subject matter. The guidance aims to clarify the appropriate lines as to what is and what is not eligible to help ensure that inventions that should be eligible for patenting are not excluded from patent eligibility, and vice-versa. The guidance also aims to be sufficiently clear and predictable in its application so that USPTO personnel can apply the guidance consistently and correctly, and that patent applicants can draft applications and claims in accordance with the guidance. The USPTO, of course, does not have the

authority to overturn court precedent. In addition, USPTO guidance does not bind the courts, and courts do not have to follow our guidance, as the Federal Circuit recently noted in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*. The January 2019 Patent Eligibility Guidance has been in effect for only a short period of time. The USPTO will continue to monitor the effects of the newly issued guidance.

a. Is there any subject matter that will still be found ineligible which you believe should be subject matter which our patent system should incentivize through patent protection?

Response: The January 2019 Patent Eligibility Guidance has been in effect for only a short period of time. The USPTO will continue to monitor the effects of the newly issued guidance and monitor how the case law is developing. There have been court decisions holding particular inventions not patent eligible for which some stakeholders have expressed the view that the invention is of the type that should be eligible for patenting.

3. You know that the Subcommittee's Ranking Member Mr. Coons and I have convened a series of roundtables to discuss possible legislation to amend section 101 to address the problems that you are unable to resolve at the USPTO.

a. From your perspective, is legislation the proper vehicle to address these concerns?

Response: As noted above, USPTO guidance synthesizes current law and cannot overturn court precedent. In addition, USPTO guidance does not bind the courts, and courts do not have to follow our guidance, as the Federal Circuit recently noted in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*. As a result and as I recently testified in the May 9 oversight hearing before the House Judiciary Committee, if Congress desires to create more certainty in the area of Section 101, legislation may be needed. As I further testified, however, this a complex issue and should be approached carefully. Any legislation should be narrowly tailored without causing unnecessary collateral consequences to the patent system. As Congress considers legislation in this area, the USPTO welcomes the opportunity to provide technical assistance.

b. How would you respond to those who say there is no problem because Alice halted the issuance of vague or overbroad patents such as ideas implemented on a general purpose computer?

Response: Most problems with vague patent claims can be addressed by Section 112. Most problems with overbroad patent claims can be addressed with Sections 102 and 103. Between 2010 and 2014, the Supreme Court issued a series of decisions – *Bilski*, *Mayo*, *Myriad*, and *Alice* – that significantly impacted patent eligibility law and continue to generate substantial public debate.

QUESTIONS ON INTER-PARTES REVIEW

1. The Inter Partes Review process at PTO is clearly a very powerful tool that was designed by Congress under the AIA to provide a low-cost and efficient mechanism to review granted patents and test their validity based on new information. However, after several years and thousands of IPR filings we have begun to see some alarming and abusive tactics such as serial and pile-on IPRs a seemingly concentrated group of large corporations and their proxies are sequentially and in a coordinated way attacking not the weakest patents, but the strongest and most commercially valuable.

PTO seems to have broad statutory authority under the AIA to address this problem.

a. What specifically has the PTO done to tackle this problem and what additional steps are you planning to implement?

Response: The USPTO has taken action in multiple ways to address serial IPRs filed by petitioners in an abusive way. First, we issued a precedential decision, *General Plastic*, to police the situation where a single petitioner files petitions serially for purposes of correcting defects in later-filed petitions noted by PTAB in earlier-filed petitions. In addition, we have recently applied *General Plastic* to other parties who delayed bringing petitions when they knew, or should have known, of a first challenge but chose not to join at that time. We have designated some of these decisions as precedential, and we are evaluating additional decisions to designate as precedential or informative to prevent abusive tactics from succeeding.

Second, we have used 35 U.S.C. § 325(d) to prevent other parties from relying on the same art or arguments that failed in previous IPRs or during examination of the patent.

Third, we have updated our Trial Practice Guide to enable parties to identify other unfair and inefficient practices that are being used to stage attacks. For example, parties can point out co-pending litigation where another tribunal will decide the validity of the patent before PTAB.

We also updated the Trial Practice Guide to focus additional scrutiny on multiple petitions filed at the same time, or at about the same time, against a given patent.

b. Finally, if statutory changes are needed to address this and other abuses of the PTAB process what might those be?

Response: The USPTO is able to handle abuses through the judicious exercise of tools currently at our disposal, such as use of our discretion to institute, as developed through precedential opinions and Trial Practice Guide updates.

Separately, an area of possible ambiguity is the estoppel statute, 35 U.S.C. § 315(e). Because some courts interpret the statutory phrase "reasonably could have raised during that *inter partes* review," to be limited only to issues actually raised to the PTAB by a petitioner, *e.g.*, in a related petition, some parties argue that they may bring a parallel challenge in district court on prior art that arguably could have been raised in the same *inter partes* review that led to a final decision at the Patent Trial and Appeal Board (PTAB). This duplication of patent validity challenges can be wasteful, abusive, and at odds with the intent of the AIA to create a faster, cheaper alternative to district court litigation.

QUESTIONS ON ADMINISTRATIVE CHANGES AT THE PATENT TRIAL AND APPEAL BOARD (PTAB)

1. You have made several changes to PTAB procedure in the past year, including changing the claim construction standard, starting an amendment process pilot program, creating a precedential review panel. How are PTAB proceedings operating after these reforms? Have they increased the predictability and certainty with respect to the patent grant?

Response: The USPTO has instituted a number of changes to America Invents Act (AIA) procedures during the past year with the intent of increasing predictability, certainty, balance, and transparency. These changes are now taking effect and are in the early stages of use by the parties.

The use of the district court claim construction standard in AIA procedures went into effect on November 13, 2018, and applies to petitions filed on or after that date. We have only recently begun to issue institution decisions under the district court claim construction standard, since they typically issue around six months after the petition filing date. In the past, however, when reviewing expired patents, we applied the district court claim construction standard and successfully completed the trials with all statutory deadlines met.

A new pilot program for claim amendments went into effect for all trials instituted after March 15, 2019, and, thus far, sixteen motions to amend have been filed.

We issued a new Standard Operating Procedure (SOP) in September 2018 that set out new processes for making cases precedential and informative. These processes include a new precedential opinion panel (POP) review process. The Board issued the first decision from that precedential opinion panel in March 2019 after receiving briefing from the parties and amici, and after conducting a hearing. The POP panel currently has additional cases under consideration and expects to issue more precedential decisions in the coming months. Since the new SOP, we have also issued other precedential decisions, ratified from prior panel decisions.

We are carefully monitoring the implementation of all of these changes and will make further adjustments, as needed.

2. Can you speak about how the PTAB is performing after the Supreme Court decision in *SAS Institute, Inc. v. Iancu* requiring institution on all issues. What impact has that decision had on increasing the transparency and fairness in PTAB proceedings?

Response: Within two days of *SAS*, we issued guidance to require decisions that institute a review to institute on all claims and challenges (*i.e.*, all claims and all grounds) raised in a petition. The Federal Circuit has since affirmed our approach.

Soon after our *SAS* guidance, we issued a detailed set of Q&As to provide external stakeholders with a further resource to understand how the PTAB would address various issues raised by *SAS*'s requirement for "all or nothing" institution. For example, one issue posed by *SAS* is what to do about petitions with voluminous challenges where only a few challenges meet the institution threshold and most lack merit—meaning the PTAB believes that ultimately most challenges will fail. In those cases, we have exercised discretion to not institute in order to avoid the inefficiency and unfairness of having patent owners defend against a multitude of challenges that the PTAB believes will not succeed based upon the initial record. In another example, although *SAS* allows institution of all claims and all grounds based upon a finding of a reasonable likelihood of success regarding a single claim challenge, we have committed to providing complete and thorough institution decisions, as well as other information that may streamline issues, to increase transparency and promote settlements.

QUESTIONS ON PATENT OFFICE'S IT SYSTEM

1. What is the current status of the Commerce Department's Enterprise Services Initiative, which may end up diverting PTO user fees to fund Department of Commerce IT requirements?

Response: The Department of Commerce continues to implement the Enterprise Services (ES) program with the objective of providing for efficient and effective delivery of mission support services in the most high-quality, cost-effective, timely, and flexible manner. For years, the USPTO has enjoyed success in achieving those same goals with its own mission support service delivery. In FY 2018, the USPTO and DOC came to a shared understanding regarding the USPTO's use of the DOC ES program services.

Specifically, through FY 2020, the USPTO will continue to receive and pay for its proportionate share of the cost for ongoing operations of services it used in FY 2018, which are the same services that the USPTO requires to meet its mission support service delivery and has been purchasing from DOC prior to implementation of the ES Program. Those services are:

- Human Resources Management System (HRConnect)
- Learning Management System (CLC)
- Strategic Sourcing for Procurements

The USPTO's more global use of ES services will then be re-evaluated, after DOC further develops the program, and when the USPTO plans to conduct a feasibility assessment to determine whether any of the additional offerings provided by the ES Program are as high-quality, cost-effective, timely, and flexible as the services the USPTO already provides for itself.

Until that feasibility study finishes, the DOC will not ask the USPTO to consider using or paying for any additional ES services. This strategy will ensure the USPTO is only paying for services it actually uses to support its mission and, thus, not diverting user fees.

2. There were a number of challenges associated with the enterprise IT systems in 2018 that repeatedly made it difficult, if not impossible, to electronically file and process patent applications. What has the study conducted by the outside consulting firm told you about what it is going to take to fix the problems? What does the new roadmap and timeline for the fix look like?

Response: The USPTO's legacy patent system outage in August 2018 prompted us to take a deep look at our IT system modernization strategy. In the past, the Office has focused our time and money on building new and modernized IT systems, while touching our legacy systems as little as possible. In hindsight, given the complexity of our modernization plans, the Office should have had a more balanced approach. The USPTO has now engaged a leading consulting firm to look at our IT delivery strategy and provide advice on how to improve this critical area of our operations.

The collaborative study led by an outside firm resulted in a high-level multi-year, multi-pronged approach to address the USPTO's technical challenges. The study confirmed that resolving our challenges will require a comprehensive and precise plan focused on stabilization (including improved redundancy failover, high availability, and disaster recovery) and modernization—in that order. Our initial stabilization efforts will focus on those systems that are both mission critical and have a high risk of failure. The Office anticipates that the complete stabilization effort, once started, will last approximately 18 months. The USPTO is instituting system "health check" dashboards for more effective real-time monitoring while we are also looking at the feasibility of an IT Emergency Response Team to plan and prepare for disaster recovery should we encounter a similar situation as we did in August 2018.

While stabilization is a priority, the USPTO will not pause all of the modernization efforts. Rather, those efforts that do not impair our stabilization goals will continue. Once the most critical systems are stabilized, we will recalibrate our overarching modernization efforts to sequence the development needed to realize state-of-the-art technology at our agency. We continue to work with the outside firm to develop

a detailed modernization roadmap that can be accomplished in parallel with our stabilization plans. We anticipate that this will be a multi-year effort.

With this concentration on stabilization and thoughtfully re-ordered modernization, combined with our concurrent efforts to leapfrog into emerging technologies such as big data and artificial intelligence, the USPTO aims to improve examination and data-driven decision-making leading to quality patents and trademarks.

3. The Patent End-to-End modernization project is well behind schedule. We know modernizing systems is hard work. What do you think is a reasonable timeline and budget for developing and implementing the many changes you have been working on over the past few years? Will you continue to focus primarily on tools for examiners? How are you going to get this done without adversely impacting the quality of the data in your systems and the time it takes for you to review grant applications?

Response: Patents End-to-End (PE2E) was the USPTO's first major modernization effort. We have made tremendous progress and have learned a lot about how best to modernize systems, despite some setbacks and delays. We are in the process of working with an outside firm to update our modernization roadmap. Today the USPTO continues to focus on examination systems because they are core to our mission and enable us to meet patent stakeholder needs, including pendency, quality, and data availability. The USPTO employs the Agile development methodology which requires careful coordination between our IT and Patent organizations to define the core requirements, features, and priorities that will deliver the greatest value to support patent operations.

Through this investment in modern technology we have learned that technology solutions are ever-changing, and that our modernization (or continuous improvement) efforts will continue as the evolving technology landscape, legislative changes, judicial opinions, and internal process improvements demand IT to evolve.

One of the other lessons learned with PE2E is the recognition that the solution components are exceedingly complex, and the requirements necessary to support a production-based operating environment (*e.g.*, high performance, quality, and scalability) require a level of precision that is difficult to achieve. To date, the PE2E investment has delivered two of three most significant examination systems. The PE2E examination workflow tool known as the Docket Application Viewer (DAV), an application docket management tool, has been fully operational since December 2016 and receiving quarterly updates of additional functionality since that time. In November 2018, DAV achieved parity with the legacy MADRAS system, which is scheduled for retirement later this fiscal year. Official Correspondence (OC), an authoring tool, will be rolled out to all examiners this fiscal year, then the legacy system will be retired.

The last critical legacy replacement system, Examiner Search, continues to be refined and is currently in use by a limited user group with a planned roll-out in FY2020. It is still too soon to tell whether the new stabilization and modernization plans we are developing will impact the schedule of the Examiner Search tool.

Beyond the examiner workflow tools, the USPTO has implemented the harmonization of the international Cooperative Patent Classification system and Global Dossier, a secure, one-stop access to the dossier information of all applications that have been filed in participating IP offices, which further improves the quality of search. PE2E has delivered these new systems on a more stable platform that reduces performance issues and improves the quality of examination while being scalable for adapting to future needs.

4. The PTO is frequently criticized for having incomplete and poor quality data in the various patent databases. What is the agency doing currently to enhance public access to patent data?
Response: Given the volume and value of the data the USPTO collects and disseminates, data quality remains an opportunity for continuous improvement. The USPTO is directly involved in the development of a comprehensive Federal Data Strategy under the President's Management Agenda Cross Agency Priority goal, "Leveraging Data as a Strategic Asset." In concert with that effort, the USPTO is evaluating an internal data governance framework and actions to improve access to and usability of our existing data. As we mature the data governance practices, the USPTO will continue to unlock more patent data for public use.

Within the USPTO system databases, data quality and documentation continues to improve. With each full implementation of the next generation platforms, we can achieve higher quality. This allows the USPTO to steadily enhance public access through dissemination via award-winning websites. Examples of deployed and delivered public products follow:

- Developer Hub site - https://developer.uspto.gov/
    - USPTO Interactive Analytic Visualizations https://developer.uspto.gov/visualizations
    - API access - https://developer.uspto.gov/api-catalog
- Patent Trial Appeal Board: RSS decision notification service for the public - https://developer.uspto.gov/ptab-feed/notifications.rss
- Easier Access to Bulk Data - https://bulkdata.uspto.gov/
    - Easier Access to Patent Bulk Data - https://ped.uspto.gov/peds/
    - PatentsView site - http://www.patentsview.org/web/#viz/locations

ARTIFICIAL INTELLIGENCE AND PATENT ELIGIBILITY

1. Director Iancu, on February 11, President Trump issued an executive order on "Maintaining American Leadership in Artificial Intelligence." I support keeping the United States in the lead on AI research and development. But I understand that China is investing heavily in the development of artificial intelligence, and that Chinese companies have secured far more patents for AI technologies than have U.S. companies. I am concerned that the current state of the law for Section 101 of the Patent Act is making AI patents harder to get in the United States, putting us at a disadvantage relative to the Chinese in the development of this critical new area. Do you think the current law on Section 101 is undermining U.S. competitiveness in artificial intelligence and thereby harming national security?

Response: America's national security and economic prosperity depend on the United States' ability to maintain a leadership role in AI and other emerging technologies. A January 2019 report by the World Intellectual Property Organization has identified American companies IBM and Microsoft as the number one and number two filers, respectively, of patents on AI globally. To ensure that our nation remains at the forefront of AI and other technologies, we must, among other things, provide a reliable and predictable legal framework to incentivize and protect innovation here at home. Towards that effort, the USPTO issued guidance to USPTO personnel in January in an effort to synthesize and clarify the law around Section 101. The USPTO will continue to engage stakeholders and the public about ways to provide a reliable and predictable framework.

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

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

---

1. **My STRONGER Patents Act proposed curbing the filing of abusive "serial" inter partes review petitions by limiting how many can be instituted and imposing broader estoppel provisions. Can you describe the steps the U.S. Patent and Trademark Office (USPTO) is taking to address this issue and any additional steps you think are necessary?**

   Response: The USPTO has taken action in multiple ways to address serial IPRs filed by petitioners in an abusive way. First, we issued a precedential decision, *General Plastic*, to police the situation where a single petitioner files petitions serially for purposes of correcting defects that were specifically noted by PTAB in previous petitions. In addition, we have recently applied *General Plastic* to other parties who delayed bringing petitions when they knew, or should have known, of a first challenge but chose not to join at that time. We have designated some of these decisions as precedential, and we are evaluating additional decisions to be designated as precedential or informative to prevent abusive tactics from succeeding.

   Second, we have used 35 U.S.C. § 325(d) to prevent other parties from relying on the same art or arguments that failed in previous IPRs or during examination of the patent.

   Third, we have updated our Trial Practice Guide to enable parties to identify other unfair and inefficient practices that are being used to stage attacks. For example, parties can point out co-pending litigation where another tribunal will decide the validity of the patent before PTAB.

   We also updated the Trial Practice Guide to focus additional scrutiny on multiple petitions filed at the same time, or at almost the same time, against a given patent.

2. **In January, the USPTO provided revised guidance for patent examiners regarding patent eligibility under Section 101 of the Patent Act. I commend your efforts to "extract and synthesize the key concepts" identified by the courts in order to "improve the clarity, consistency, and predictability of actions across the USPTO," and I hope and expect that this guidance will improve the patent examination process. A number of stakeholders across the patent community have expressed difficulty in trying to predict how courts will adjudicate patent eligibility. Indeed, one Federal Circuit judge recently characterized the state of the law as "incoherent" and noted that, in some situations, it is "nearly impossible to know with any certainty whether the invention is or is not patent eligible." Do you agree that legislation could help clarify what inventions are and are not eligible for patent protection?**

   Response: The USPTO guidance synthesizes current law, but it cannot overturn court precedent. In addition, USPTO guidance does not bind the courts, and courts do not have to follow our guidance, as the Federal Circuit recently noted in *Cleveland Clinic Foundation v. True Health Diagnostics LLC*. As a result and as I recently testified in the May 9 oversight hearing before the House Judiciary Committee, if Congress desires to create more certainty in the area of Section 101, legislation may be

needed. As I further testified, however, this a complex issue and should be approached carefully. Any legislation should be narrowly tailored without adding unnecessary collateral consequences to the patent system. As Congress considers legislation in this area, the USPTO welcomes the opportunity to provide technical assistance.

3. **Strong intellectual property protections not only ensure economic competitiveness for United States companies but also promote national security. These protections historically have enabled our leadership role in developing next-generation technologies like artificial intelligence. I understand that China is investing heavily in the development of artificial intelligence, and that Chinese companies have secured far more patents for artificial intelligence technologies than have U.S. companies. I am concerned that the current state of patent eligibility law is making artificial intelligence patents harder to get in the United States, putting us at a critical disadvantage.**

   a. Do you think the current law on Section 101 is undermining U.S. competitiveness in artificial intelligence and thereby harming national security?

   Response: America's national security and economic prosperity depend on the United States' ability to maintain a leadership role in AI and other emerging technologies. A January 2019 report by the World Intellectual Property Organization has identified American companies IBM and Microsoft as the number one and number two filers, respectively, of patents on AI globally. To ensure that our nation remains at the forefront of AI and other technologies, we must, among other things, provide a reliable and predictable legal framework to incentivize and protect innovation here at home. Towards that effort, the USPTO issued guidance to USPTO personnel in January in an effort to synthesize and clarify the law around Section 101. The USPTO will continue to engage stakeholders and the public about ways to provide a reliable and predictable legal framework

   b. Do you think the current law on Section 101 is harming our national competitiveness in other critical areas of research and development, such as medical diagnostics and personalized medicine?

   Response: America's national security and economic prosperity depend on the United States' ability to maintain a leadership role in research and development, including in research intensive areas such as medical diagnostics and the emerging field of personalized medicine. To ensure that our nation remains at the forefront, we must, among other things, provide a reliable and predictable legal framework to incentivize and protect innovation here at home.

4. **A May 5, 2018, Wall Street Journal article entitled "Flood of Trademark Applications from China Alarms U.S. Officials" describes the massive influx of trademark applications filed by Chinese entities and individuals. You testified about some of the measures the USPTO has taken to identify frivolous applications and registrations and noted that some of the USPTO's efforts have been less successful than expected. What additional steps does the USPTO plan to take to flag problematic applications and declutter the trademark register?**

   Response: In July, and after considering public comments on the proposed rule, the USPTO published its final rule to require foreign-domiciled trademark applicants and registrants to be represented by a U.S. licensed attorney (84 FR 31498; July 2, 2019). It went into effect on August 3. The USPTO believes that this rule requiring foreign-domiciled trademark filers to be represented by a U.S. licensed attorney at the USPTO will increase the accuracy of the submissions to the USPTO and

will decrease the incidence of foreign trademark attorneys and agents engaging in the unauthorized practice of law before the USPTO.

Before this rule, the USPTO had already taken a number of steps to address the growing problem of trademark applicants submitting suspicious or fake specimens of use, including: establishing a streamlined version of our informal letter of protest procedure, whereby third parties may bring to the attention of the USPTO evidence that a particular specimen submitted in an application is mocked up or doctored by submitting it to our Specimen Protest email box; investigating software that would allow fake specimens of use to be more easily detected as well as considering options in the pre-examination phase, so that fake specimens can be flagged for further handling; and training our examining attorneys on identifying digitally created or altered specimens and on how to ask applicants for information and proof of actual use. Recently, the USPTO updated its examination guidance to now require that examining attorneys issue a refusal in such circumstances and request additional information and evidence of the mark's use in commerce. The guide is publicly available on the USPTO's website at: https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%2003-19.pdf.

Regarding registrations, since 2012 the USPTO randomly audits post-registration maintenance filings and requests the registrant to provide proof of use for additional goods or services in the registration. If the registrant cannot provide proof that the mark is in use for the queried goods or services, those goods or services are deleted from the registration. The audit has been successful at helping improve the accuracy of the register and we have increased, and plan to increase even more, the number of maintenance filings that are audited. The TTAB also has implemented a pilot program to expedite resolution of cancellation proceedings involving a claim of non-use or abandonment of the registered mark. The USPTO is considering creating incentives for registrants to ensure that their registrations are and remain accurate regarding the goods or services for which the mark is in use, without waiting until the maintenance filing to do so. For example, the USPTO is considering charging a "zero fee" to file a request to delete unused goods/services outside of the audit or a TTAB proceeding, but charging a fee to amend a registration when goods or services are deleted from a registration as a result of an audit.

The USPTO's audit program has demonstrated that 79% of those audited were represented by counsel and, of those audited who had a lawyer, 52% have been required to delete goods or services for which they previously swore the mark was in use. These statistics are troubling to say the least and suggest a lack of care, knowledge of what the law requires, or both, by mark owners and their counsel. In egregious cases, the USPTO may refer attorneys to the USPTO's Office of Enrollment and Discipline (OED) for investigation of misconduct. But, to ensure that mark owners and their counsel understand U.S. use requirements and their mutual obligations under the USPTO's rules to confirm that the submissions they make to the USPTO are accurate and that claims of use have evidentiary support, we are developing educational materials for our website and will be adding information to our notices. We are hopeful that providing materials that explain what use in commerce is, the importance of use in commerce to having trademark rights and a valid registration, and the steps lawyers and clients should be taking to confirm the facts of use, combined with the U.S. counsel requirement, will help improve the accuracy of submissions to the USPTO.

5. **The USPTO recently released a report finding that only 20 percent of U.S. patents list a woman inventor and that in 2016, only 12 percent of all unique inventors awarded U.S. patents were women. These findings comport with similar studies, which also have found disparities in the number of patents awarded to African Americans and low-income inventors. I appreciate your support for what you have called the "critically important" task of closing the gap for "communities that have been underrepresented in the innovation ecosystem." I look forward to**

the forthcoming report from USPTO, which is being prepared in consultation with the Small Business Administration pursuant to the SUCCESS Act, on the gaps in patenting among women, inventors of color, low-income inventors, and veteran inventors. How can Congress, the USPTO, other agencies in the administration, and the private sector work together to increase patenting among women, low-income inventors, inventors of color, and veteran inventors to help them patent and commercialize their innovations?

Response: Broadening the innovation ecosphere to increase the participation of women and other underrepresented groups is critical to increasing innovation, driving economic growth, and maintaining America's global competitiveness. The USPTO has recently started an initiative to spur innovation opportunities in underserved communities, specifically among women and underrepresented communities. The USPTO hopes to use the findings in its recent report, *Progress and Potential: A profile of women inventors on U.S. patents*, to stimulate further discussion on the importance of diversity in the innovation space.

The USPTO has undertaken a proactive approach to encourage women, as well as other underrepresented groups, to innovate and secure patents to protect their innovations. These efforts include, among other things, the USPTO's inventor assistance resources, hosting an annual Women's Entrepreneurship Symposium, supporting pro-bono networks around the country, and building *pro se* resources in patents to make navigating the patent process more accessible, especially for first time applicants. Resources such as the USPTO's Patent and Trademark Resource Center Program are located in more than eighty public, state, and academic libraries – many in minority and underserved communities – providing a direct link to the community through regular programming, virtual office hours with USPTO subject matter experts, and librarians trained to assist with IP searching and information. The USPTO also recently updated its website to make it easier for inventors to find resources in their area.

The USPTO also supports dozens of other STEM-related programs and events to provide basic education to young women about intellectual property such as the Girl Scout IP patch, which is administered to Girl Scout troops across the nation, and Camp Invention in school districts in every state.

A few months ago, I held a roundtable with Rep. Zoe Lofgren in the USPTO's Silicon Valley Regional Office to facilitate discussions across the IP community on this important topic, and I have also held roundtables in New York and Austin. Leaders from the USPTO will continue to meet with stakeholders in private industry, academia, and government agencies to identify ways to increase inventor diversity in all facets of the economy. There is untapped potential in the community and the USPTO wants to do everything possible to encourage diversity in innovation, create equal opportunities for every inventor, and ensure that all voices are heard.

The USPTO will continue to advance the national dialogue around this issue and engage with industry, academia, and other government agencies to drive real change.

6. You testified that you would support the re-designation of IP attachés as "Counselors" in order to better reflect the responsibilities they shoulder overseas and the importance of intellectual property to U.S. global competitiveness. Can you describe the benefits that this change in title would achieve?

Response: The IP attachés have proven to be effective advocates for U.S. intellectual property in foreign markets, and we continue to work with our interagency partners and other bureaus within the Department of Commerce to explore possible ways the IP attachés can more effectively engage their

foreign counterparts and advance American interests, including, as I testified at the hearing, through a diplomatic rank of "Counselor" for the IP attachés.

7. **You have previously testified about the USPTO's efforts to investigate and incorporate new technologies such as machine learning and "big data" analytics into the patent and trademark examination processes. Please provide an update regarding the status of these initiatives and any new efforts to harness the power of new technologies at the USPTO.**

   Response: The USPTO's efforts continue to unlock more data and insights to fuel machine learning and "big data" analytics into the patent and trademark examination processes. The USPTO continues exploring the use of big data as a foundation to the machine learning & artificial intelligence techniques for search and search query expansion in patent examination to enhance consistency in prior art searches across multiple databases. The USPTO also issued a Request for Information (RFI) and asked industry for recommend techniques that leverage AI for purposes of improving our patent examination processes. For trademarks, the USPTO is exploring these technologies for the potential areas of image search for trademark examination and image classification.

   The USPTO is directly involved in the development of a comprehensive Federal Data Strategy under the President's Management Agenda Cross Agency Priority goal, "Leveraging Data as a Strategic Asset." This ties to the USPTO's internal Data Reform initiative, which aims to constitute a data governance framework to ensure the highest level of data-driven decision making and performance management while harnessing the power of new technologies.

   For example, the USPTO recently released the Patent Enriched Citation Data that leverages machine learning/artificial intelligence techniques to extract the associated citations and related rejection type. This is foundational to improving search quality and patent examination analysis by linking citations that are most relevant to individual applications. This is made possible with a "Big Data Reservoir" that contains more than 8 million patent office actions. This empowers us to harness data to measure work product consistency across our entire patent corps and systematically focus our quality improvement efforts. It further enables the USPTO to answer fundamental questions such as: "How many—and what types of —§101 rejections are our examiners making and consistently applying throughout the examination corps?"; "How can examiners more effectively use non-patent literature in prior art rejections?"; "And, what impact has our guidance and training had on examination outcomes?" Efforts like these, as well as other patent quality studies, have resulted in re-allocating millions of dollars in training expenses to more localized areas for optimal rate of return.

USPTO Responses to Questions for the Record - Senator Cornyn
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

---

1. Drug Patent Issues

a. Many modern products, including biologic drugs, are incredibly complex, and so many patents are granted for a single drug. But the pace and number of patents granted on a drug long after that drug was originally patented is troubling. Do you have concerns about the number of secondary patents granted to drug makers? What is your office doing to ensure each of those patents is valid?

Response: Innovation in the life science sector, which includes the development of a molecule having therapeutic benefits, often continues well beyond that initial identification of a candidate drug or biologic product. Identification of the therapeutic activity of a molecule is but one step on a multi-step pathway to obtaining drug or biologic approval and the subsequent marketing a drug or biologic product in the United States. The molecule itself may be patentable, as well as other related inventions of distinct scope. A patented drug or biologic product must not only provide the therapeutic benefit initially identified, but it must also be capable of mass production, shelf stable, shippable, bioavailable to the patient, safe and effective, among other things. Innovation can and often does occur at various points along this path. The patent system should incentivize and protect all such innovation, including improvements down the line if appropriate, as long as the system is balanced and all the statutory requirements for a patent are met.

The USPTO does not use the terms "primary" and "secondary" patents. The first patent that might be granted could be a method of use, and only years later, a patent on the chemical substance might issue – a distinct patentable invention. The USPTO works to ensure that all patents it issues meet the statutory bases for patentability.

We continue our efforts to increase the reliability of patents, including preventing improper issuance of patents over pre-existing technology. To that end, during the past several years, the USPTO has implemented quality initiatives that strive to ensure that the patent examination process properly identifies the most relevant prior art that our examiners can apply to the patent applications that are under examination. In addition, we have conducted specialty training on proper claim construction, clarity of the written description of inventions, rationales for determinations of obviousness and updated training on identifying issues with non-statutory double patenting. In addition, pursuant to the AIA, the post-issuance proceedings at the PTAB are available for interested third parties to challenge patents they believe to have been improperly granted.

The USPTO continues its efforts to improve the examination process and ensure that issued patents are appropriately scoped and meet all statutory requirements.

b. At the hearing, you discussed your attempts to address potential gamesmanship by patent owners. What specific steps are you taking to solve that problem? Do patent examiners have the training needed to see these issues when they arise?

Response: In order to adequately address potential gamesmanship in this area, the USPTO is looking at a variety of issues surrounding our operations to ensure that all patents we issue meet the statutory criteria for patenting. For example, we are assessing new ways of addressing non-statutory double patenting and obviousness considerations with respect to related applications. As another example, we are assessing (and will be discussing with FDA) various policy considerations surrounding the listing of patents in FDA's Orange Book.

The USPTO has an Office of Patent Training that trains new examiners and provides updated training for current examiners when laws are changed. In addition, the USPTO provides "refresher" training for examiners on topics that seem to be challenging, as identified by examiners, feedback from the public and from results of the Office of Patent Quality Assurance reviews. Several times a year, examiners receive training on topics that address patentability determinations in order to ensure that the examiners have the most up-to-date tools to properly apply the patent statutes to the examination of patent applications.

c. Do you think the definition of 'non-obvious' used by the Patent Office has negative consequences when applied to these secondary patent applications? Why or why not?

Response: No, we do not think the definition of non-obvious as used by the USPTO has negative consequences. The USPTO follows the statutory basis for determinations of obviousness, 35 USC § 103. Additionally, we follow any relevant judicial determinations from precedential courts which interpret the application of 35 USC § 103. The definition of non-obviousness, when properly applied, results in patents that meet the statutory requirements and rejections of patent applications for those that cannot surpass the obviousness hurdle.

2. Chinese IP interference

How is your office handling the threat of Chinese interference with American intellectual property? What is the PTO's role in protecting those rights?

Response: The USPTO has a dedicated group of attorneys in its Office of Policy and International Affairs (OPIA) with specific expertise and experience on China's intellectual property system to help U.S. companies address the threat of Chinese interference with American intellectual property. The attorneys are located in USPTO headquarters in Alexandria, Virginia and an additional group of both U.S. and China licensed attorneys located in U.S. Mission Embassy offices in China (Beijing, Guangzhou and Shanghai).

There are many ways in which our China team can help U.S. companies with IP issues in China. First, the China team can assist any U.S. entity requesting specific assistance in protecting or enforcing its intellectual property in China. While China team members cannot provide legal advice, they can provide important information, updates, and insights into the IP system in China. U.S. entities may request assistance from the China team at USPTO headquarters in Alexandria, Virginia, or one of the three IP Attaché offices in Beijing, Guangzhou and Shanghai. If the U.S. entity raises concerns of a systemic IP issue that harms U.S. companies, our China team and its IP Attachés may send a letter on behalf of the US government to the Chinese government to signal U.S. interest and concern about the case. In other cases, the IP Attaché may attend a court hearing on behalf of the U.S.

entity to observe whether that the appropriate rules and regulations are followed and whether proceedings are fair and transparent without bias against the U.S. entity.

Second, the China team assists U.S. departments and agencies in assessing whether China's IP laws provide adequate and effective protection and enforcement of intellectual property rights in China, including those held by U.S. entities. Many Chinese agencies provide for a public comment period for draft laws, agency regulations and rules, and other legislation. The China team confers with U.S. industry representatives and works closely with U.S. departments and agencies in the preparation of comments of the United States Government on draft legislation to ensure the interests and concerns of the United States are reflected. In some circumstances, Chinese agencies have revised laws or rules based on U.S. Government comments. In addition, the China team has also, in the past, provided training to Chinese government officials responsible for the administration of the protection and enforcement of intellectual property to help address technical substantive concerns as well as to improve key procedures and practices, which can be helpful to U.S. companies seeking to protect and enforce their IP in China.

Third, the China team organizes China Intellectual Property (IP) Road Shows, which are free, one-day programs conducted throughout the United States to help U.S. entities navigate the IP landscape in China. Speakers include members of our China team, other U.S. government officials with China-related expertise, academics, attorneys, and business leaders.

Since 2017, the USPTO has conducted more than 20 of these programs, both in large metropolitan areas such as Boston, Chicago and New York, and in smaller cities, such as Boise, Idaho; Iowa City, Iowa; Louisville, Kentucky; and Portland, Oregon. The topics covered in China IP Road Shows include how to file patent and trademark applications in China; China's systems for protecting copyrights and trade secrets; how to enforce IP rights in China through administrative, civil, and criminal measures; and how to work with U.S. customs to keep counterfeit goods from China out of the U.S. market.

Finally, the China team actively works with its colleagues at the Department of Commerce and the Office of the United States Trade Representative (USTR) in negotiations and other engagements to improve China's IP environment and to ensure there is a level playing field for American IP owners. The China team provides input for the annual Notorious Markets List, which USTR issues each year. Our IP Attachés' reporting on China's IP environment also informs the annual Special 301 Report on intellectual property protection and enforcement in various countries, including China. For example, the China team provided helpful contributions to the development of the recent Section 301 investigation of China's acts, policies and practices, and the WTO case against China on forced technology transfer.

3. Patent enforcement

It has come to my attention that United States patent law is limited in the water column of the Exclusive Economic Zone. This can have potential consequences for companies who operate technology only in the water column that does not touch the ocean floor. I am concerned that foreign companies, including from China, could infringe on American patents, and that these companies have no recourse. Has the Patent and Trademark Office experienced this issue? Does your office have a position on patent protection in the water column?

Response: With respect to the ability of American patent holders to obtain recourse for infringement of their U.S. patents by foreign companies under 35 USC § 271 (infringement of a patent), when such infringement occurs in the Exclusive Economic Zone (EEZ) of the United States, it should be noted

that the Supreme Court held last summer in *WesternGeco LLC v. ION Geophysical Corp.*, 136 S. Ct. 2486 (2018), that WesternGeco, a U.S. company, could recover lost foreign profits resulting from infringement under 35 USC § 271(f)(2) in which the infringer manufactured components of the "patented" technology in the United States and sold those components to foreign customers for assembly and use. Under the Supreme Court's decision, *WesternGeco* could recover the lost profits for the marine-seismic surveys that were conducted on the high seas. The lower courts are considering the implications of the Court's decision in *WesternGeco* for the recovery of damages for direct infringement under Section 271(a).

The USPTO is aware of one U.S. company that is concerned about whether it can obtain recourse against foreign companies that directly infringe their patents in the EEZ. The USPTO continues to monitor developments and welcomes the views of other U.S. stakeholders on this matter.

USPTO Responses to Questions for the Record - Senator Leahy
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

---

1. As you know, the creation of the Inter Partes Review (IPR) process was a cornerstone of the Leahy-Smith America Invents Act (AIA). The Leahy-Smith AIA was the culmination of nearly a decade of work by Congress and it passed with overwhelming majorities in both the Senate and House of Representatives in 2011. Multiple pieces of legislation were introduced over several Congresses, hundreds of meetings were held with patent community stakeholders representing all points of view, and this Committee held numerous hearings and several markups. I think the outcome of the Leahy-Smith AIA has proven balanced and lasting and it has, indisputably, helped to modernize our patent system. Given this background, I have some questions regarding any additional changes to the IPR process that you may be contemplating.

a. As the steward of the IPR process at the PTO, how do you plan to ensure the system remains as strong as provided in the Leahy-Smith AIA?

Response: The USPTO is continually monitoring the AIA trial proceedings to ensure that they are fair, balanced, and transparent, achieve the objectives of the AIA, and provide predictability and certainty of the patent grant.

Second, we regularly meet with stakeholders to receive feedback about the AIA trials.

Third, we have established a new Standard Operating Procedure (SOP) that creates new avenues to issue precedential decisions. The SOP provides for designation of a Precedential Opinion Panel (POP) to decide issues of exceptional importance (*e.g.*, involving agency policy or procedure). The SOP also provides for a review procedure for designating Board decisions, other than Precedential Opinion Panel decisions, as precedential or informative authority. We are using both of these avenues to identify areas where additional guidance is needed. For example, in March, the POP issued a precedential decision on the topic of joinder, interpreting the statutory language of 35 U.S.C. § 315(c). We also designated other decisions as precedential that address the use of live testimony at hearings and procedures to file motions to amend; privy and real party-in-interest; and factors to consider in determining whether to institute an *inter parties* review. We have also designated five decisions addressing subject matter eligibility as informative. Additional decisions are under consideration for designation as precedential and informative, as well.

Fourth, we updated the Trial Practice Guide, and may continue to do so, in order to address issues and questions that arise over time about the AIA trial proceedings.

Finally, we are monitoring a new pilot program related to motions to amend and may make additional changes to the amendment process as needed based upon the information gathered during the pilot program.

b. Is the PTO working on, or considering, any additional changes to the IPR process outside of changes to claim construction and the motion to amend practice pursued last year?

Response: The USPTO is continually engaging with stakeholders to identify additional ways to improve the IPR process to provide increased certainty, predictability, fairness, and transparency in AIA proceedings. In September 2018, we established a new Standard Operating Procedure to issue guidance on a regular basis through the issuance of precedential and informative decisions based upon stakeholder and internal USPTO feedback. We are now issuing precedential decisions under this process. For example, we have issued precedential decisions (including one from the Precedential Opinion Panel) and informative decisions in the areas of joinder, use of live testimony at hearings, procedures to file motions to amend, institution factors under 35 U.S.C. §314(a), and subject matter eligibility. Additional decisions are under consideration. Further, we may update the Trial Practice Guide to provide clarification about additional aspects of AIA trials, including topics identified by stakeholders.

2. Shortly after you were confirmed to the role of Under Secretary of Commerce for Intellectual Property and Director of the PTO, I asked you about the PTO's Patents for Humanity program, which I strongly support. I have long encouraged patent owners and pharmaceutical and biologic industries to do more to provide access to life-saving medicines abroad. In previous years, Senator Grassley and I have introduced legislation to authorize the Patents for Humanity program and to make the acceleration certificates to patent owners transferable. At the time, you stated that you believed the program was successful and to the extent we could make the certificate transferable, it would provide further incentives for this important work.

a. You have now been serving as the Director of the PTO for over a year, what are your current thoughts on the Patents for Humanity program and do you still support making the certificate transferable?

Response: Yes. The Patents for Humanity program has been extremely successful in promoting innovation by inventors who have developed ways to provide affordable, scalable, and sustainable solutions for the less fortunate. By recognizing those who use technology to meet global humanitarian challenges, we can promote and incentivize these inventors for the good of the U.S. and the entire world and making the certificate transferable can only provide further incentives for these inventions.

USPTO Responses to Questions for the Record - Senator Blumenthal
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

---

1. During your nomination hearing, I submitted a question for the record regarding the USPTO's Patent Pro Bono Program. In response to that question, you indicated that you would "advocate for a robust pro bono program" and agreed that "more can be done with respect to pro bono at the USPTO."

a. Since you have been confirmed, how have you advocated for the pro bono program?

Response: Since my confirmation, the USPTO has continued its efforts to grow patent practitioner and inventor participation in the pro bono program. For example, in 2018, the USPTO incentivized practitioner participation by expanding its volunteer recognition program to include law firms and corporations who allow their employees to volunteer their time to the program during business hours. In 2018, the USPTO recognized 22 law firms and 84 registered patent practitioners for their participation in the pro bono program.

The USPTO has also promoted the availability of the pro bono program through its public outreach. Recently, the USPTO made the online basic patent training for pro bono applicants available in Spanish.

The USPTO also seeks to establish additional local pro bono programs in states with sufficient inventor and practitioner populations to meet the needs of the inventors and small businesses in those states. The USPTO also seeks to dedicate resources to further the sustainability of these local not-for-profit programs.

The USPTO also recently updated its website to make it easier for inventors to find pro bono assistance, and other resources, in their area.

b. How do you define success for the pro bono program?

Response: Success for the pro bono program is currently defined by year-over-year growth in several critical metrics, including the number of inventors and small businesses matched with volunteer registered patent practitioners. On this metric, the number of inventors and small businesses matched with practitioners has risen more than 70% since 2015 when the USPTO first collected this information. Other measures of success for the pro bono program include: 1) the number of registered patent practitioners available to volunteer to assist inventors and small businesses; 2) the number patent applications filed for inventors and small businesses; and 3) the number of inquiries by potential pro bono applicants. While there has been some fluctuation in these metrics quarter to quarter, overall when comparing the metrics from 2015 with equivalent metrics from 2018, there has been a 157% increase in the number of registered patent practitioners available to volunteer, a 73% increase in the number of patent applications filed, and a 12% increase in the number of inquiries by potential pro bono applicants. For each of these metrics, the USPTO currently strives to achieve yearly growth. A final measure of success for

the pro bono program is continued nationwide availability of the program to inventors and small businesses.

c. Does the USPTO have enough resources for the program to be successful?

Response: The USPTO believes that it currently has the resources it needs to maintain the program. As I have stated, a robust pro bono program is important to the USPTO. The USPTO continues to educate and assist inventors and small businesses across the country who wish to participate in the pro bono program.

d. What do you think can be done to improve the Patent Pro Bono Program?
e. Is congressional action needed to improve the Patent Pro Bono Program?

Response to (d) and (e): The USPTO has found that its support is critical to the sustainability of the regional not-for-profit programs across the country. These regional not-for-profit programs are the local interface between the underserved inventors and small businesses and volunteer registered patent practitioners. Without support from the USPTO, some of these not-for-profit programs may never become self-sustaining, inhibiting their ability to provide services to the underserved inventor and entrepreneurial community.

2. **As you know, there are two main procedures for challenging the validity of patents: post grant review and inter partes review. These procedures allow individuals to challenge the validity of an issued patent. Some of my constituents favor these procedures. Other constituents hate them.**

a. What would you say to my constituents who are skeptical of the post-grant review processes?

Response: The AIA created IPRs and PGRs to be "a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rept. 112-98. IPRs and PGRs provide for a short-time frame and limited discovery system to challenge patents without resort to district courts' higher litigation costs. Because we harness the information provided to the USPTO in the AIA proceedings and utilize it during the examination of applications related to the AIA-challenged patent, we are also enhancing patent quality.

b. Are the current procedures for challenging the validity of patents successful in improving patent quality?

Response: The USPTO continues to assess the procedures put in place by the AIA and has made substantial improvements after listening to stakeholders and the public.

c. Do you believe these procedures produce significant harmful or unintended consequences?

Response: The patent system, including AIA proceedings, needs to be balanced. With the benefit of having more than six years of experience conducting AIA trials, we have identified ways to improve, and bring more balance to, the proceedings. Recently, we harmonized the claim construction standard to match that used by the district courts, updated the Trial Practice Guide to provide additional guidance and transparency about certain aspects of proceedings, and released a new pilot program for motions to amend. With these changes, we believe that the AIA

procedures are working even better, and we are continually considering other ways to improve them.

USPTO Responses to Questions for the Record - Senator Durbin
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

---

1. Director Iancu, thank you for your leadership at the U.S. Patent and Trademark Office. I appreciate your efforts to promote and encourage innovation and to help restore balance to a debate over our patent laws that had become skewed.

I never bought into the argument that patent trolls had run amok and that we needed to fundamentally weaken patent protections in response. That's why I opposed patent litigation reform legislation that would have made it far more difficult for legitimate patent holders to protect their patents from infringement.

I have also been supportive of Senator Coons' bill, the Stronger Patents Act, that would correct problems with the last major patent reform law, the 2011 America Invents Act. I appreciate that you have taken steps administratively to carry out some of the reforms proposed in the Stronger Patents Act, including harmonizing the claim construction standard at the Patent Trial and Appeal Board with the standard applied in federal court.

I have a record of working to make sure that legitimate inventors can appropriately protect their intellectual property. But even I have hit my limit when it comes to abuses we are seeing with the pricing of pharmaceuticals. I think we need to explore how gaming of the patent system may be enabling drug companies to excessively inflate drug prices for American consumers.

Specifically, under the Hatch-Waxman Act, when a generic drug company files an application with the FDA, it can challenge the validity of patents covering a brand-name drug (Paragraph IV certification). This then allows the brand manufacturer to file a patent infringement suit against the generic company. If that occurs, it triggers an automatic, 30-month stay of FDA approval for the generic.

This 30-month stay extends the monopoly period for a brand-name drug, and incentivizes the filing of secondary patents that may be superfluous. These secondary patents may not add to the efficacy or safety of the drug, and may be for superficial changes like the pill coating.

According to Harvard professor Dr. Aaron Kesselheim, this automatic, 30-month stay encourages pharmaceutical companies to seek to amass large numbers of secondary patents, no matter how peripheral the patent may be to the active drug ingredient.

a. Does the USPTO see any reason not to consider narrowing the 30-month stay of FDA approvals for generic competition so that the stay only applies to "primary" patents on the chemical substance of a drug, rather than on "secondary" patents for formulation and method of use?

Response: The provisions of the Hatch-Waxman Act have been carefully balanced in light of years of experience and extended public debate. Each provision plays a role in this balanced system, and disturbing one might disturb others. As an example, the 30-month stay helps promote the early resolution of any patent disputes prior to the marketing of follow-on pharmaceuticals. If only some patents were to benefit from the thirty-month stay, then a generic drug could potentially be approved earlier, even though it would still be at risk for patent litigation. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 generally precludes multiple 30-month stays for those generic drug applications to which it applies, even if additional patents are listed in the Orange Book. The Hatch-Waxman Act also incentivizes generic applicants to challenge patents that may be invalid.

Furthermore, the USPTO does not use the terms "primary" and "secondary" patents. The first patent that might be granted could be a method of use, and only years later, a patent on the chemical substance might issue – a distinct patentable invention. The USPTO works to ensure that all patents it issues meet the statutory bases for patentability.

b. What other changes should be considered to address potential gaming of secondary patents for the purpose of hampering generic competition for high-cost drugs?

Response: To adequately address potential gamesmanship in this area, the USPTO is looking at a variety of issues surrounding our operations to ensure that all patents we issue meet the statutory criteria for patenting. For example, we are assessing new ways of addressing non-statutory double patenting and obviousness considerations with respect to related applications. As another example, we are assessing (and will be discussing with FDA) various policy considerations surrounding the listing of patents in FDA's Orange Book. In addition, we continue to train our examiners on non-statutory double patenting and obviousness rejections.

2. I am concerned about the price of insulin, which approximately 7.5 million Americans rely on for their survival. The prices of insulin brands like Humalog, Lantus, and Novolog have increased 600 percent over the past two decades.

Insulin was first discovered in 1921. It troubles me that a 20th century cure can be so unaffordable in the 21st century.

I am eager to understand the role that patent policy and incentives may play in excessively high insulin pricing. For example, it is my understanding that the insulin drug Lantus, which has been on the market since 2000, has received 49 follow-on patents after the drug's approval, providing for a 37-year monopoly. Of the patent applications on Lantus insulin, 95 percent were filed after the drug was approved for the market.

Will you commit to examine the possible role that patent incentives and possible gaming of the patent system may be playing in the high price of insulin?

Response: Yes.

3. How can the USPTO improve coordination with the FDA to limit potential drug patent abuses and anti-competitive practices?

Response: The USPTO has been meeting with the FDA to learn more about each agency's respective roles and to determine what can be done to limit potential drug patent abuses and anti-competitive practices.

4. **Is the USPTO ensuring that FDA has the most relevant, up-to-date list of patents in the FDA's Orange Book when a generic company submits an application, including patent information that may be updated following a PTAB ruling? If not, does the USPTO see any reason not to ensure the most up-to-date patent information is included in FDA's Orange Book?**

   Response: The USPTO does not currently ensure that the FDA's Orange Book is up to date. Rather, applicants are required to identify and notify the FDA of relevant patents when a new drug application is filed and to provide timely updates to the patent information with the FDA, including requesting the patent information be removed when a patent is invalidated. These patents are then listed in the FDA's Orange Book. The FDA also has a process for third parties to dispute the accuracy or relevance of patent information that has been published in the Orange Book.

   Furthermore, the USPTO is an entirely fee-funded agency -- those fees are paid by applicants seeking to secure or maintain patents and trademarks, and the USPTO must use those fees to provide the patent and trademark services for which the users have paid them. The USPTO review of accuracy and relevance of patents listed in the Orange Book would require allocation of additional staffing and financial resources from the fees we collect.

5. **If a drug company has been found to have engaged in some criminal violation or anticompetitive act, such as a pay-for-delay deal or illegal marketing, with respect to a patented drug, should that company face some penalty in terms of the company's ability to seek secondary or follow-on patents for the company's drugs?**

   Response: The patent system benefits the public because, among other things, it encourages innovation and the prompt disclosure of inventions so that others can learn from those disclosures. All patent applications are evaluated according to the same statutory standards of patentable subject matter, novelty, non-obviousness, and disclosure. In reviewing criminal violations and anticompetitive acts, a judge could fashion a remedy that is specific to those circumstances, such as limiting the ability to enforce other patents. Rather than introducing a new patentability requirement to the patent system, which could discourage innovation and disclosure of inventions, there may be other, more precise alternatives.

6. **What percentage of patent applications is filed by individual inventors in the most recent year for which such data is available?**

   Response: In fiscal year 2018, approximately three percent of all patent applications were filed by inventors without the assistance of legal representation; also known as "*pro se* inventors."

7. **In your view, are individual inventors currently able to adequately protect their patents from infringement by larger companies?**

   Response: Civil remedies for patent infringement are available to all patent holders, irrespective of their company size.

8. What can the USPTO or Congress do to help individual inventors and small startups be more successful in navigating the patent system?

Response: The USPTO provides numerous outreach and educational programs designed to inform small businesses and independent inventors about the services available at the USPTO to aid in the development and protection of enforceable IP rights. These programs not only help stakeholders in solving real-life IP problems, but they re-enforce and foster a national environment that respects and protects intellectual property rights.

These efforts can be grouped into at least three categories: (1) Public Outreach and Education through the Office of Innovation Development, the Office of Education and Outreach, and Trademark Outreach; (2) Stakeholder Services for Small Businesses and Individuals through the USPTO's *Pro Se* and Pro Bono Programs as well as the USPTO's Law School clinics, the USPTO's Inventors Assistance Centers, and the Patent and Trademark Resource Centers in local libraries throughout the nation; and (3) Federal Interagency Cooperation, including the SBA-administered SBIR/STTR program that provides patent system users with value added educational strategies about intellectual property, including how to navigate the patent system and how to leverage available resources during the filing process. Each of these categories include public services that are either free to users or quite affordable.

The USPTO's regional offices also provide educational public programing on the intellectual property system and how to navigate successfully through the patent and trademark systems. The USPTO also updated its website to make it easier for inventors to find help in their area

9. You mentioned in your testimony the concern with a surge in Chinese applications for U.S. trademarks. A significant percentage of these applications appear to be questionable or even fraudulent. I understand that USPTO has taken steps to address this increase in fake trademark applications, including by using a pilot software program to see if an application has been digitally altered. Will this pilot program be renewed?

Response: The USPTO is currently investigating software that would allow fake specimens of use to be more easily detected. We also are considering options to detect fake specimens in the pre-examination phase so they can be flagged for further handling.

10. I appreciate the proposed rule that the USPTO issued a few weeks ago that would require foreign trademark filers to retain U.S. counsel when filing a U.S. trademark application. This should help ensure accountability for fraudulent trademark filings. What other actions is the USPTO considering to help address the wave of fraudulent Chinese trademark applications?

Response: In July, and after considering public comments on the proposed rule, the USPTO published its final rule to require foreign-domiciled trademark applicants and registrants to be represented by a U.S. licensed attorney (84 FR 31498; July 2, 2019). It went into effect on August 3. The USPTO believes that this rule requiring foreign-domiciled trademark filers to be represented by a U.S. licensed attorney at the USPTO will increase the accuracy of the submissions to the USPTO and will decrease the incidence of foreign trademark attorneys and agents engaging in the unauthorized practice of law before the USPTO.

Before this rule, the USPTO had already taken a number of steps to address the growing problem of trademark applicants submitting suspicious or fake specimens of use, including: establishing a streamlined version of our informal letter of protest procedure, whereby third parties may bring to the attention of the USPTO evidence that a particular specimen submitted in an application is mocked up

or doctored by submitting it to our Specimen Protest email box; investigating software that would allow fake specimens of use to be more easily detected as well as considering options in the pre-examination phase, so that fake specimens can be flagged for further handling; and training our examining attorneys on identifying digitally created or altered specimens and on how to ask applicants for information and proof of actual use. Recently, the USPTO updated its examination guidance to now require that examining attorneys issue a refusal in such circumstances and request additional information and evidence of the mark's use in commerce. The guide is publicly available on the USPTO's website at: https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%2003-19.pdf.

Regarding registrations, since 2012 the USPTO randomly audits post-registration maintenance filings and requests the registrant to provide proof of use for additional goods or services in the registration. If the registrant cannot provide proof that the mark is in use for the queried goods or services, those goods or services are deleted from the registration. The audit has been successful at helping improve the accuracy of the register and we have increased, and plan to increase even more, the number of maintenance filings that are audited. The TTAB also has implemented a pilot program to expedite resolution of cancellation proceedings involving a claim of non-use or abandonment of the registered mark. The USPTO is considering creating incentives for registrants to ensure that their registrations are and remain accurate regarding the goods or services for which the mark is in use, without waiting until the maintenance filing to do so. For example, the USPTO is considering charging a "zero fee" to file a request to delete unused goods/services outside of the audit or a TTAB proceeding, but charging a fee to amend a registration when goods or services are deleted from a registration as a result of an audit.

The USPTO's audit program has demonstrated that 79% of those audited were represented by counsel and, of those audited who had a lawyer, 52% have been required to delete goods or services for which they previously swore the mark was in use. These statistics are troubling to say the least and suggest a lack of care, knowledge of what the law requires, or both, by mark owners and their counsel. In egregious cases, the USPTO may refer attorneys to the USPTO's Office of Enrollment and Discipline (OED) for investigation of misconduct. But, to ensure that mark owners and their counsel understand U.S. use requirements and their mutual obligations under the USPTO's rules to confirm that the submissions they make to the USPTO are accurate and that claims of use have evidentiary support, we are developing educational materials for our website and will be adding information to our notices. We are hopeful that providing materials that explain what use in commerce is, the importance of use in commerce to having trademark rights and a valid registration, and the steps lawyers and clients should be taking to confirm the facts of use, combined with the U.S. counsel requirement, will help improve the accuracy of submissions to the USPTO.

USPTO Responses to Questions for the Record - Senator Hirono
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

---

1. **The PTO's recent report *Progress and Potential: A profile of women inventors on U.S. patents* highlights the dearth of information collected by the PTO regarding the demographics of named inventors. Notably, the PTO collects only the full name and city and state or country of residence of each inventor; it does not collect information on, for example, the gender, race, ethnicity, national origin, age, income level, or veteran status of inventors. The failure to collect this information makes investigation into the demographic make-up of inventors difficult, if not impossible.**

   a. Is the PTO opposed to collecting demographic information from inventors on a mandatory or voluntary basis? If yes, please explain your response.

   Response: The USPTO is not necessarily opposed to the collection of demographic information from inventors, but any such collection would have to be carefully considered before adoption and implementation. The USPTO notes that there are significant privacy implications with respect to a demographic collection. Currently, published patent applications are available *in their entirety* to the public. The USPTO would have to make sure an appropriate system of records notice under the Privacy Act was in place before collecting any such demographic data. If the information collection would be made part of the patent application, *e.g.*, in the Application Data Sheet, then that information would presumably have to be protected from public release because it would contain sensitive personal information about inventors. Potentially significant changes to the IT systems housing these applications would also be necessary. There are additional issues that such a collection could raise, including concern by applicants as to the use of such data.

   b. Does the PTO require new statutory authority to collect demographic information from inventors?

   Response: The USPTO's current authority under 35 USC § 2 and 35 USC § 115 jointly operate to permit the USPTO to establish regulations concerning the granting and issuing of patents and the registration of trademarks and allow the Director to "specify additional information relating to the inventor and the invention that is required to be included in an oath or declaration." We would need to evaluate whether USPTO has authority under these provisions to collect demographic information from applicants. A collection would also need to be reconciled with the Privacy Act's requirement at 5 USC § 552a(e)(1) that agencies collect and maintain this type of information only when it is relevant and necessary to a purpose the agency is required to accomplish by statute or by the executive order of the President.

   Other concerns could also arise, including those discussed in response to question 1a above.

2. **I understand that the PTO is in the process of converting from using the United States Patent Classification (USPC) system to the Cooperative Patent Classification (CPC) system when assigning patent applications to examiners and setting the time permitted for examination.**

Patent examiners have expressed concerns that—because there is not a one-to-one relationship between USPC subclasses and CPC symbols—examiners may be assigned applications in technology areas in which they have not developed an expertise. I fear that the result of this mismatch could be a loss of efficiency for patent examiners and a decrease in overall patent quality.

a. What steps is the PTO taking to ensure that applications continue to be assigned to patent examiners with the requisite expertise and experience after conversion to the CPC system?

Response: The new CPC-based application routing system will better enable the USPTO to match an application with a specific examiner's work experience.

The CPC system has improved granularity over the USPC system because more distinct technology classifications are identifiable. This improved granularity allows the USPTO to generate a unique profile for each application based on the inventive technologies disclosed therein, as well as a unique portfolio for each examiner based on the distinct technologies they have previously examined.

The new routing process will match the unique technological profile of each application with the work experience of a particular examiner, thereby ensuring that applications are assigned to examiners with the requisite expertise and experience. There will also be options for manual modifications to a portfolio to ensure an examiner's expertise is appropriately represented.

This level of technological granularity has never previously been incorporated into the routing of applications, and the USPTO is committed to a smooth transition and maximizing the retention of expertise and institutional knowledge of examiners. After implementation of the changes, there will be a transition period throughout which feedback will be collected and analyzed to ensure a balance of retaining examiners' expertise and optimizing pendency, cost, and quality levels.

b. When does the PTO expect to complete its conversion to the CPC system for patent examination?

Response: We expect to complete conversion to the CPC system in early fiscal year 2020.

3. **I further understand that the PTO is in the process of limiting the number of applications assigned to a patent examiner at any given time—an approach known as "short-docketing."**

a. What is the PTO's rationale for moving to short-docketing?

Response: Smaller docket sizes will provide many benefits, including greater certainty and reliability to stakeholders regarding application pendency for initial examination.

Currently, larger dockets may result in examiners selecting applications for examination out of turn (*e.g.*, newer applications examined before older applications). Smaller dockets, on the other hand, will further assist in meeting pendency goals by providing another mechanism to ensure that the oldest cases are assigned and prioritized for examination.

Smaller docket sizes will also improve the balance of work distribution throughout the examination corps and increase the ability to assign applications that best match an examiner's work history and experience to the technologies in an application.

b. What effect does the PTO expect the change to short-docketing to have on examiner efficiency and morale?

Response: The USPTO expects that the smaller docket sizes will provide many benefits to its examiners and its stakeholders, including improved balance of work distribution throughout the examination corps and increased ability to assign applications that best match an examiner's work history and experience to the technologies in the application. The USPTO expects improved efficiency, is committed to a smooth transition, and will collect and analyze examiner feedback and production levels in order to identify and appropriately mitigate any impacts to efficiency and morale.

4. **In response to a question from Sen. Coons regarding the flood of fraudulent trademark applications from China, you mentioned that the PTO is piloting software that you hope will be able to identify digitally-altered photographs that claim to support a trademark's use in commerce.**

   Please provide a status on the pilot program, including whether the software has been successful in identifying digitally-altered photographs and whether the pilot program will be extended.

   Response: The USPTO is currently investigating software that would allow fake specimens of use to be more easily detected. We also are considering options to detect fake specimens in the pre-examination phase so they can be flagged for further handling.

5. **In March 2018, the PTO announced the Trademark Specimen Protests Email Pilot Program to streamline the process for interested individuals to report "improper specimens," including those that have been digitally created, altered, or fabricated.**

   Please provide a status on the pilot program, including the number of protests received, the number of employees dedicated to the program, and the number of registrations/applications that have been cancelled through the program.

   Response: To address the growing problem of trademark applicants submitting suspicious or fake specimens of use, the USPTO trained our examining attorneys on identifying digitally created or altered specimens, the requirements for a specimen to show use in commerce in the ordinary course of trade under the statute, and how to ask applicants for information and proof of actual use when the specimen appears suspicious. The USPTO also established a streamlined version of our informal letter of protest procedure, whereby third parties may bring to the attention of the USPTO evidence that a particular specimen submitted in an application is mocked up or doctored by submitting it to our Specimen Protest email box. This process has helped examining attorneys get evidence to support refusals of fake specimens that the examining attorney may otherwise have not detected.

   The Specimen Protest email box pilot program is designed as a mechanism for the examining attorney to receive evidence of fake, mocked up, or duplicate specimens in pending applications on which the examining attorney could base a refusal to register. If the evidence submitted on its face would not substantiate a refusal or if the evidence is submitted on a registered mark rather than a pending application, it will not be sent to the examining attorney.

USPTO Responses to Questions for the Record - Senator Harris
U.S. Senate Committee on the Judiciary
Subcommittee on Intellectual Property

"Oversight of the U.S. Patent and Trademark Office" – *March 13, 2019*
Witness: The Honorable Andrei Iancu, Undersecretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office
Submitted: August 15, 2019

Patentability of Algorithms

When you testified before the Committee last year, you and I discussed the patentability of algorithms. You said that "as a general proposition, human-made algorithms that are cooked up—invented as a result of human ingenuity—are different from discoveries and mathematical representations of those discoveries," but you also said that algorithms should be evaluated on a case by case basis. The patentability of algorithms is a complicated issue, but inventors and tech entrepreneurs require a reliable patent system in order to achieve the next innovation. The guidance that the USPTO issued in January 2019 seeks to resolve ambiguities created by the courts and provide tech innovators with some degree of certainty.

1. **Aside from the formal notice and comment process, to what extent did the USPTO interact with or survey outside stakeholders during the initial development of the guidance?**

Response: The USPTO had extensive interactions with outside stakeholders. Since being confirmed, I have met with well over 100 stakeholders from companies, trade organizations, advocacy groups, inventors, and universities representing a variety of technology areas—large and small entities with varying levels of access to the resources needed to best navigate the patent process.

Additionally, the USPTO has invited input on its subject matter eligibility guidance from all members of the public on an on-going basis since May 2016. The USPTO also invited input from all members of the public on its subject matter eligibility guidance when it published updated guidance on determining whether a claim element is well-understood, routine, or conventional for purposes of subject matter eligibility in April 2018. In addition, the USPTO receives input when it interacts with outside stakeholders during frequent presentations on its subject matter eligibility guidance.

The USPTO considered the input from stakeholders in developing the January 2019 Patent Eligibility Guidance.

2. **Did the USPTO interact with or survey stakeholders with experience in developing algorithms or artificial intelligence during the initial development of the guidance?**

Response: Yes. Many of the above interactions included stakeholders with experience in developing algorithms or artificial intelligence. Also, the USPTO's requests for comments on subject matter eligibility specifically requested input on any aspect of the USPTO's subject matter eligibility guidance, which would include its application to computer-implemented innovations, including those pertaining to the use of algorithms and artificial intelligence.

Diversity in the IP System

The technology sector is not a monolith—tech innovators are businesses both large and small, often with extraordinarily different business models. The next technological breakthrough is just as likely to be born in an inventor's garage as it is in a Silicon Valley boardroom. But there is often a disparity of resources between large tech companies and smaller businesses or independent inventors.

3. **In developing the guidance issued in January 2019, to what extent did the USPTO take into account the different level of resources that large companies and small businesses are able to leverage when navigating the IP system?**

Response: The input that we received and took into consideration in developing the January 2019 guidance reflected a broad and diverse group of stakeholders – entities both large and small and from various technology areas.

In your testimony, you committed to "continue to engage stakeholders and the public about ways to reduce the uncertainty around these critical areas of patent law." You also underscored the importance of ensuring that the innovation ecosphere include women and other underrepresented groups.

4. **In developing the guidance issued in January 2019, to what extent did the USPTO take into account the diversity of stakeholders who rely on a predictable IP system?**

Response: As noted above, the many stakeholder interactions and input received took into account a very diverse group of stakeholders. Additionally, our study providing data on the gender diversity of issued patents, *Progress and Potential: A profile of women inventors on U.S. patents*, has allowed us to engage interested stakeholders in conversations about challenges that may exist for female inventors. The USPTO will continue to advocate for increased diversity in the patent system and likewise the impact of the current guidance on stakeholder resources.

5. **Moving forward, will you commit to including diverse stakeholders and underrepresented communities among the stakeholders that you engage?**

Response: Yes. Broadening the innovation ecosphere to increase the participation of women and other underrepresented groups is critical to increasing innovation, driving economic growth, and maintaining America's global competitiveness. We will continue to include diverse stakeholders and underrepresented communities in our various engagements. The USPTO has recently started an initiative to spur innovation opportunities in underserved communities, specifically among women and underrepresented communities. The USPTO hopes to use the findings in its report, *Progress and Potential: A profile of women inventors on U.S. patents*, to stimulate further discussion on the importance of diversity in the innovation space.

The USPTO has undertaken a proactive approach to encourage women, as well as other underrepresented groups, to innovate and secure patents to protect their innovations. These efforts include, among other things, the USPTO's inventor assistance resources, hosting an annual Women's Entrepreneurship Symposium, supporting pro-bono networks around the country and building *pro se* resources in patents to make navigating the patent process more accessible, especially to first time applicants. Resources such as the USPTO's Patent and Trademark Resource Center Program are located in more than eighty public, state and academic libraries – many in minority and underserved communities – providing a direct link to the community through regular programming, virtual offices

hours with USPTO subject matter experts, and librarians trained to assist with IP searching and information. The USPTO also recently updated its website to make it easier for inventors to find resources in their area

The USPTO also supports many other STEM-related programs and events to provide basic education to young women about intellectual property such as the Girl Scout IP patch, which is administered to Girl Scout troops across the nation, and Camp Invention in school districts in every state and many other programs.

A few months ago, I held a roundtable with Rep. Zoe Lofgren in the USPTO's Silicon Valley Regional Office to facilitate discussions across the IP community on this important topic, and I have also held roundtables in New York and Austin. Leaders from the USPTO will continue to meet with stakeholders in private industry, academia, and government agencies to identify ways to increase inventor diversity in all facets of the economy. There is untapped potential in the community and the USPTO wants to do everything possible to encourage diversity in innovation, create equal opportunities for every inventor, and ensure that all voices are heard.

The USPTO will continue to advance the national dialogue around this issue and engage with industry, academia, and other government agencies to drive real change.