USPTO Responses to Questions for the Record - Senator Grassley
U.S. Senate Committee on the Judiciary
"Oversight of the U.S. Patent and Trademark Office" - *April 18, 2018*
Witness: Andrei Iancu
Submitted: June 5, 2018

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1. What you are doing to ensure that the competitiveness of American companies is not undermined by IP theft and unreasonable market access restrictions abroad? Is there anything that Congress can do to help the USPTO in these efforts?

Answer: The USPTO engages with government officials in various countries to improve legislation and regulations that promote effective intellectual property systems that will benefit American inventors and companies. This includes engaging with those officials in foreign governments responsible for:

- developing and amending laws to obtain IP protection (for example, patent and trademark office officials); and
- enforcing IP rights in their countries, generally focusing on civil, criminal, and border enforcement (for example, judicial, customs, and law enforcement officials).

We provide policy and technical advice on legislation on civil, criminal, and border enforcement of IP laws to promote a climate that respects intellectual property, and regularly consult with IP stakeholders on the challenges they face. We also provide enforcement training and capacity-building programs for foreign officials. In these efforts, we work with, and provide input to, other Administration agencies (including the Departments of State, Justice, and Homeland Security, and the Intellectual Property Enforcement Coordinator), and we partner with the National Intellectual Property Rights Coordination Center in some of these efforts.

In addition, the USPTO provides technical support to the Office of the United States Trade Representative (USTR) in the negotiation of trade agreements that promote strong and balanced protection and enforcement of intellectual property rights. We also provide input and advice on the Special 301 process to identify countries where improvements are needed.

With respect to congressional action, we continue to consult with others in the Administration and stakeholders on ways to strengthen and enhance existing law to address challenges to the effective protection and enforcement of intellectual property rights. We will continue to work with Congress in these efforts.

2. Do you agree that any modern trade agreement must have strong intellectual property protections and should avoid loopholes that trading partners can abuse to permit free-riding on American innovation and creativity?

Answer: Through its grant of Trade Promotion Authority, Congress defines U.S. negotiating objectives for trade agreements and spells out detailed oversight and consultation processes. The

USPTO provides expert technical advice to the Office of the United States Trade Representative as it further develops and coordinates international trade policy and negotiations. To safeguard American innovation and creativity, I agree that our trade agreements should address any loopholes or abuses that put American inventors and creators at a disadvantage in the global marketplace. Because innovation and creativity are the engines behind economic growth, it is of paramount importance to me that the USPTO fulfils the constitutional authority "to promote the progress of science and the useful arts"-- both domestically and internationally. I believe that American businesses can compete and win against anyone in the global marketplace.

3. The USPTO's IP attaché program has been particularly helpful in protecting and advancing US IP interests abroad. Can this program be improved?

Answer: The IP attachés have proven to effectively advocate for U.S. intellectual property in overseas markets, and we continue to work with our interagency partners to explore possible ways the IP attachés can more effectively engage their foreign counterparts and advance American interests.

4. Some have expressed concerns with the PTAB institution process, urging that members of the PTAB making the institution decision should be distinct and separate from those making the merits determination. What is your position?

Answer: I have met with stakeholders during the past several months and have listened to their concerns in this area. I am continuing to work with USPTO leadership and members of the stakeholder community to evaluate this issue and consider possible options, taking into account the concerns that have been raised as well as the operational impacts of any change.

5. What is your position on the standards for refusal to institute an IPR, do you believe that the current practice is appropriate or do you believe it needs to be modified?

Answer: The current practice provides the Patent Trial and Appeal Board (PTAB) the ability to refuse to institute petitions based on a variety of factors. As an initial matter, the USPTO cannot institute an IPR unless the statutory threshold in Title 35, Section 314 is met--namely, that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the challenged claims.

PTAB recently designated a section of the *General Plastic Industries Co. v. Canon Kabushiki Kaisha* (Case IPR2016-01357 et al., Paper 19 (Sept. 6, 2017)) decision that addresses "serial petitions" as precedential. The opinion sets forth various factors that will be considered in determining whether to institute subsequent petitions filed against the same patent, particularly petitions by the same petitioner. We continue to study this issue, including whether to expand the list of factors to consider on whether to institute.

PTAB can also deny petitions that raise the same or substantially the same art or argument previously presented to the Office pursuant to 35 U.S.C. § 325(d). PTAB is well positioned to

decide, on a case-by-case basis, whether the relative equities favor a denial under § 325(d) and have designated a number of cases informative to provide guidance to the individual panels. We may issue further guidance and/or precedential decisions in this area in the future.

Furthermore, the Office has tools at its disposal to prevent meritless or frivolous challenges brought for harassment purposes. The USPTO has sanctions authority for the "abuse of process, or any other improper use of the proceeding." 35 U.S.C. §§ 316(a)(6) and 326(a)(6). Additionally, attorneys filing or making frivolous challenges for harassment purposes may be subject to discipline by the Office of Enrollment and Discipline.

We will continue to review the standards for refusal to institute and modify as necessary to ensure a predictable, reliable and high quality patent system.

6. In the composition of judging panels, do you believe that there is an appropriate role for the USPTO Director to determine which PTAB judges should be sitting on IPRs?

Answer: The Director should not alter the judging panel for a given case by selecting judges to reach a pre-determined or desired outcome. In accordance with the statute (35 U.S.C. § 6), the Director is directed to designate at least three PTAB members to hear post-grant proceedings, including IPRs. As set forth in the Manual of Patent Examining Procedure and PTAB's Standard Operating Procedure (SOP) 1, that designating authority has been delegated to PTAB's Chief Judge. The Director, or PTAB Chief Judge (acting through delegated authority), also has the authority to designate expanded panels made up of more than three PTAB members. Although rarely used, the Chief Judge has, from time to time, found it necessary to expand a panel.

7. Your predecessor at the USPTO launched an Enhanced Patent Quality initiative in 2015. What are your thoughts on the results of that work and the current state of patent quality? What more needs to be done to improve the quality of issued patents at the USPTO?

Answer: The Enhanced Patent Quality Initiative (EPQI), launched in 2015, focused on continuous improvement of patent quality and highlighted that patent quality is a joint responsibility shared by patent applicants and USPTO, which led to a more robust collaboration with the intellectual property (IP) community.

For example, as part of the initiative, USPTO implemented a new Quality Metrics approach to evaluating, capturing, and measuring the quality of patent examiners' work products. As another example, the Post-Grant Outcomes program enables the transfer of information from IPR petitions at the Patent Trial and Appeal Board (PTAB) to examiners who are examining related applications to support a more thorough search and examination of pending applications. We are assessing the results of the various EPQI programs.

Looking forward, we will continue to evaluate the effectiveness of current quality efforts and explore other programs as part of bringing increased certainty to patentability decisions and on providing the best prior art as early as possible in prosecution.

8. At the oversight hearing, you referenced studying "a variety of standard operating procedures" in the IPR process, but did not elaborate on what you meant – I would like to get more specifics on your views. Which procedures/issues did you have in mind, why do you believe that they need to be studied, and what is your inclination in the matter of changing them? Please provide a complete list of the topics on which you intend to engage, whether through unilateral action, legislation, rulemaking or litigation, that would affect the IPR process.

Answer: While we continue to take a wholesale examination of the IPR process to determine which areas need improvement and which areas are working well, there are certain areas in which we may take action in the coming months based on our own review and input from stakeholders. As I noted in my testimony, topics we are considering include the institution decision, the amendment process, the composition of judging panels, and the conduct of hearings. Most of these changes can be effected through rulemaking under the USPTO's existing authority, or the issuing of policies and procedures. We are currently undergoing a rulemaking process on claim construction.

We will continue to study and make improvements to the IPR process as necessary to ensure a balanced system.

9. At your confirmation hearing, you indicated that you would work with the PTAB and stakeholders to identify areas most in need of precedential decisions and review procedures for when and how best to designate precedential PTAB cases. Can you tell us what areas have been identified as most in need of precedential decisions and what has been done to facilitate such decisions in those areas?

Answer: I have been working with PTAB and meeting with stakeholders to identify areas that are most in need of PTAB precedential decisions in order to provide increased predictability and guidance. Some areas where PTAB has been taking action include:

- Motion to amend guidance. The USPTO is considering new approaches to considering motions to amend in post grant proceedings. In the meantime, stakeholders have identified the need for guidance under the existing rules in light of the Federal Circuit's *Aqua Prod. v. Matal*, 872 F.3d 1290 (Fed. Cir. 2017) and *Bosch v. Matal*, 878 F.3d 1027 (Fed. Cir. 2017), decisions, which state that USPTO may not place the burden of persuasion regarding the patentability of substitute claims on a patent owner. In response, PTAB issued a public memorandum at the end of last year, as well as subsequent orders more recently that provide guidance regarding burdens and other requirements for motions to amend in light of these recent decisions.

- Denying Institution of "Serial" Petitions. In accordance with 35 U.S.C. § 325(d), PTAB may deny petitions that present the same or substantially the same prior art or arguments that previously were presented to USPTO (including during examination and before PTAB). PTAB recently designated five decisions in this area as informative to provide guidance to individual PTAB panels applying section 325(d) and predictability to stakeholders: *Becton Dickinson & Co. v. B. Braun Melsungen AG* (IPR2017-01587, Paper 8 (Dec. 15, 2017)), *Kayak Software Corp. v. Int'l Bus. Machs. Corp.* (CBM2016-00075, Paper 16 (Dec. 15, 2016)), *Cultec, Inc. v. Stormtech LLC*

(PR2017-00777, Paper 7 (Aug. 22, 2017)), *Hospira, Inc. v. Genentech, Inc.* (IPR2017-00739, Paper 16 (July 27, 2017)), and *Unified Patents Inc. v. Berman* (IPR2016-01571, Paper 10 (Dec. 14, 2016)). The *Becton Dickinson* decision sets forth various factors that will be considered in determining whether to deny institution under § 325(d). PTAB is evaluating whether to designate as precedential a decision applying the *Becton Dickinson* factors, and also what other factors may be considered under § 325(d).

- Denying "Follow-on" Petitions. PTAB has exercised its discretion under 35 U.S.C. § 314(a) to deny institution of *inter partes* review in a number petitions for "follow-on" petitions (petitions filed after another petition challenging the same patent). PTAB recently designated *General Plastic Industries Co. v. Canon Kabushiki Kaisha* as precedential, which set forth various factors that will be considered in determining whether to institute follow-on petitions. To provide further guidance to stakeholders, we are assessing whether to identify additional factors that may be considered in determining whether discretionary denial of institution is appropriate outside the context of follow-on petitions.

- Partial Institution. In light of the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 200 L. Ed. 2d. 695 (April 24, 2018), the USPTO has provided written guidance on the impact of *SAS* on AIA trial proceedings on the USPTO website. Additionally, the Chief Administrative Patent Judge held a "Chat with the Chief" webinar on the impact of *SAS*. The webinar was well received and attracted over 800 attendees. As part of its ongoing efforts, the PTAB will evaluate decisions concerning *SAS* and its impact for precedential designation, as we expect some issues of first impression to arise as a result of *SAS*.

10. At your confirmation hearing, you indicated that you would work with the leadership at USPTO, as well as with Congress and IP stakeholders, to assess the issue of tribal and state sovereign immunity assertions at the PTAB. What is your assessment of this matter now that the PTAB has issued several decisions striking down claims to state and tribal sovereign immunity? Is there more that the USPTO should do to address this conduct? Do you have any opinion on the bills dealing with this issue currently before Congress?

Answer: PTAB has previously held in several proceedings that patent-owning state entities may invoke sovereign immunity as a defense in AIA trial proceedings, citing the Eleventh Amendment of the Constitution. Since my confirmation hearing, two expanded panels of the PTAB, in decisions authored by the Chief Administrative Patent Judge, reaffirmed that a state entity may assert a defense of sovereign immunity, but determined that the immunity is waived if the state entity has previously filed an action in federal court alleging infringement of the patent being challenged. In addition, on the issue of tribal sovereign immunity, a panel of the PTAB found that a tribe may not assert a defense of sovereign immunity in that case for a variety of reasons. The decisions dealing with both state and tribal sovereign immunity have been appealed to the Federal Circuit, and those cases have been stayed at PTAB. After the Federal Circuit issues its decision in these cases, we will carefully study the decisions and reassess the situation to determine what actions, if any, can and should be taken. In addition, along with others in the Administration, we will also work with Congress on these issues.

11. At the oversight hearing, there was a lot of discussion about Section 101 and what technology should be patentable. Do you agree that patent laws should not discriminate between areas of technology?

Answer: At a high level, the approach to Section 101 should be technology neutral. Of course, it may be that some innovations fare differently than others due to the nature of the particular innovation.

12. What are your thoughts on the current state of patent eligibility case law as it relates to medical diagnostics or software related innovations?

Answer: Recent Supreme Court decisions have introduced a degree of uncertainty into the area of subject matter eligibility, particularly as it relates to medical diagnostics and software-related innovations. The recent Supreme Court decisions on subject matter eligibility can, if applied in an overly broad manner, negatively impact innovation in these and other areas. The Supreme Court has cautioned against an expansive read of these decisions, stating for example, "we tread carefully in construing this exclusionary principle lest it swallow all of patent law" (*Alice v. CLS Bank*,134 S. Ct. 2347 (June 19, 2014)). The USPTO is working to improve its subject matter eligibility guidance, in an attempt to clarify what is and what is not patentable.

13. To what extent do other patent offices (e.g. the European Patent Office) offer insights into how to handle subject matter eligibility?

Answers: The USPTO has analyzed the relevant laws and guidelines applicable in the world's five largest patent offices--the United States, China, Japan, Korea, and Europe--as they represent 80% of the world's patent applications, and thus their corresponding laws are applied in examining and granting the overwhelming majority of patents in the world.

For detail on how foreign offices determine patent eligibility, see USPTO's report issued last year following two roundtables on Section 101 issues (*Patent Eligible Subject Matter: Report on Views and Recommendations from the Public* (July 2017) at pages 16-22 ("International Approaches to Defining Patent Eligible Subject Matter")).[1]

14. At the oversight hearing, you expressed a desire to enhance certainty and predictability in Section 101 analysis and stated that you would engage with the Committee, stakeholders and the public to explore viable options. Do you have an opinion on what would be the best approach if changes are necessary – legislative, administrative or judicial action? What would a statutory revision to Section 101 look like, were you to draft it, and what benefits do you see from legislative rather than administrative or judicial pronouncements in this area?

Answer: The USPTO is looking into what it can do to enhance certainty and predictability in the area of subject matter eligibility both administratively, through the issuance of guidance on subject

[1] See https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf

matter eligibility, and judicially, through advocacy at the Federal Circuit and the Supreme Court. There are limits, however, to what the USPTO can do through these routes as the courts are not bound by USPTO guidance on subject matter eligibility.

In addition to guidance, we will closely monitor cases in front of the courts and work with the Committee should it determine that legislative action is needed.

15. In your opinion, to what extent should USPTO re-evaluate its patent examination and maintenance fees to better align with the cost of patent examination?

Answer: The USPTO continually reviews and evaluates fee structure, cost recovery, and fees. The current fee structure, including the alignment of patent examination and maintenance fees with costs, has been thoughtfully set to balance the USPTO's operational requirements and benefits to inventors, patent applicants and holders, the public, and the United States economy.

As the broader IP landscape changes, the USPTO will need to continue to review its fee structure—such as keeping barriers to entry into the IP system low—and the need for sustainable funding for agency operations. At least biennially, the USPTO undertakes a comprehensive review of all fees as required by law, and makes recommendations on revising the fees (as warranted) to reflect expected future costs.

If an adjustment of fees is warranted, the USPTO can currently use its fee setting authority to seek comments through a public notice process in order to begin the rulemaking process that will propose to make such adjustments. This fee-setting authority expires on September 16, 2018, and the President's Budget supports a 10-year legislative extension of that authority.

16. In 2016, GAO reported on a number of challenges examiners face in identifying relevant prior art (GAO-16-479). Is it sufficient for examiners to review only patent literature when determining a patent application's novelty and obviousness? What actions has USPTO taken to improve examiners' access to and knowledge of non-patent literature?

Answer: When other publications are available, it is not sufficient for an examiner to only review patent literature when determining a patent application's novelty and obviousness. The USPTO's guidance on search of patent applications requires that a careful and comprehensive search be conducted in preparing a first action on the merits. This includes a review of non-patent literature (NPL) in addition to patent literature. The USPTO's Manual of Patent Examining Procedure (MPEP) § 904.02 *et seq* provides general search guidelines to be followed during the examination of an application for a patent along with general methodology for selecting search tools. More specific guidance on the choice and use of specific search tools is provided at the application level during examination. An examiner may also consult expert staff in the Office's Scientific and Technical Information Center (STIC) for assistance on selection of databases to search and assistance in developing and conducting the search for a particular application. Training on how to effectively search is also provided to examiners by STIC, the Patent Training Academy and at the operational level. Examiners may also request that STIC conduct an NPL search of an application as needed. In

the last few years, STIC has also conducted an awareness campaign to support effective and efficient searching by examiners. STIC, as a part of its awareness campaign, took action to promote their services to the examining corps and improve examiner access to and knowledge of NPL. These actions included an internal video to provide insight on all of STIC's services to help examiners with their searching needs; an E-Catalog providing a list of training classes, a list of search strategy experts, and a list of commercial database vendors; and numerous training videos on NPL search resources.

17. In 2016, the GAO surveyed patent examiners at the USPTO and found that 70% said they did not have enough time to do a thorough examination. What steps, if any, are you considering to address this issue?

Answer: USPTO recently conducted an analysis of examination time, including the historical and current factors influencing examination time, stakeholders' perceptions of what impedes and enhances examination, and methodologies of routing applications and assigning time for patent examination. This effort was called the Examination Time Analysis (ETA). The ETA team was comprised of representatives from all Technology Centers (TCs) and many business units across the Office.

The analysis began with a review of examination time goals. Examination time goals vary by technology and represent the average amount of time that a patent examiner is expected to spend examining a patent application in a particular technology. Next, the ETA team collected input from external and internal stakeholders and analyzed that feedback to understand stakeholders' perceptions about factors that impede or enhance examination.

In addition to analyzing stakeholders' input, the ETA team studied the impact of the substantial changes in patent prosecution since the time goals were established. For example, there are new and converging technologies and increased technological complexity; a growing volume of available prior art; increased use of electronic tools; changes in legal landscape or examination practices; and USPTO's transition from the United States Patent Classification (USPC) system to the Cooperative Patent Classification (CPC) system for examination activities (*e.g.,* search).

The ETA team gathered and analyzed data on application attributes (*e.g.*, number of claims, size of specification), relationships between performance and examination time, and historical methodologies of assigning time and associated outcomes and impacts to performance.

Further, as the time examiners are given to examine applications is the critical link between pendency and quality, the ETA team analyzed potential impacts on pendency and cost to enable optimal pendency, cost, and quality levels.

The many inputs and variables considered over the course of the ETA initiative are deeply connected as they relate to the time examiners need to perform a thorough examination. The research and analysis from the effort can be used by the USPTO to inform future decisions regarding examination time goals, define the critical activities during prosecution to focus examiners' time and subsequent evaluation, and operational processes and tools to support quality examination in a manner that responses to stakeholders' needs and interests.

Based on the findings from the ETA, the USPTO will be considering a number of possible changes in the coming year to reflect stakeholder comments and operational needs to best incentivize examiner productivity and quality.

18. What concrete steps, if any, has the USPTO taken to correct time and attendance abuses and to prevent them from happening again?

Answer: The USPTO takes any allegation of time and attendance abuse in our workplace seriously. In recent years, we have made workforce management a critical focus and have invested significant time and effort to improve our overall management of time and attendance compliance – for teleworking employees and those stationed at one of our physical facilities.

Specifically, some of the Agency's past efforts included:

- Providing guidance to patents and trademark supervisors to specifically monitor indicators of potential time and attendance issues, such as responsiveness to supervisory communications; inconsistent workload activity (*e.g.*, claiming 80 hours of examining time in a bi-week, but not claiming any work credits); and customer inquiries or complaints;
- Issuance of an Agency-wide refresher on time and attendance obligations and training for all USPTO employees and supervisors on USPTO time and attendance policies;
- Launching a patents operations program to improve supervisory mentoring of patent examiners with low or inconsistent production;
- Providing guidance to all patent supervisors to regularly utilize their IT dashboard tool to monitor examiners' production and timeliness, which can provide an early warning sign of potential time and attendance issues;
- Revisions to its overtime policy for patent examiners to require an examiner to be performing at least at the fully successful level in all critical elements before being authorized to work overtime hours; and
- Continued assessment of the time and goal requirements across the patent examining corps through its Examination Time Analysis (ETA) initiative, including seeking input on examination time goals from Agency stakeholders, employees, and management through public forums, a Web-based collaboration tool, and a Federal Register request for comments.

Significantly, beginning in April 2017, the USPTO rolled out a new Policy on Time and Attendance, Communication, and Collaboration. This policy requires all employees to:

- Badge-in and badge-out at all locations with individual badge-in/badge-out capacity;
- Log-in and log-out of the USPTO network at the beginning and end of any period of time for which the employee claims hours of work while teleworking;
- Use all Agency-provided collaboration tools (*e.g.*, the presence indicator), regardless of physical location, when the collaboration tools are available; and
- Post their schedule information and update the information to reflect any prospective schedule changes.

As part of this policy, the USPTO has also reactivated its badge-out requirement for employees to leave secure areas, adding another building access data point for employees and supervisors. At the same time, the agency has deployed its on-line Record Sharing Platform (RSP) so that

employees can see their badge-in/out and log-in/out records in near real time to assist with preparing their timesheets. In conjunction with this policy, USPTO supervisors have received extensive training on all Agency time and attendance policies and procedures. Now, supervisors have several tools in place to help monitor employees' attendance and productivity, regardless of whether they are reporting to work on campus or working remotely.

USPTO has implemented all of the recommendations in the 2016 DOC Office of Inspector General's report on time and attendance issues and has taken additional actions it identified as needed or helpful. Together, these changes seek to enhance collaboration and strengthen time and attendance controls. We will continue to assess the effectiveness of these efforts and consider additional tools and training for supervisors as necessary.

USPTO Responses to Questions for the Record - Senator Sasse
U.S. Senate Committee on the Judiciary
"Oversight of the U.S. Patent and Trademark Office" - *April 18, 2018*
Witness: Andrei Iancu
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1. **In light of the Supreme Court's recent decision in *SAS Institute v. Iancu*, do you anticipate either an increased backlog in the *inter partes* review process or a change in the quality or thoroughness of the Patent Trial and Appeal Board's decision-making process?**

   Answer: It is unclear at this point what sort of short and long term operational impacts *SAS* will have on PTAB's operations. PTAB issued guidance on this decision on April 25. Additionally, the Chief Administrative Patent Judge held a "Chat with the Chief" webinar on the impact of *SAS*. The webinar was well received and attracted more than 800 attendees. We will continue to monitor what sort of impact *SAS* will have, including how it will affect workload. The Office will work to ensure that PTAB has sufficient resources to absorb any increases without creating a backlog in *inter partes* reviews or negatively affecting the quality and thoroughness of the PTAB's decision making.

2. **To what degree of specificity can you estimate any such impacts?**

   Answer: The Office is still evaluating the decision in *SAS* and formulating procedures for handling existing cases, as well as ones that have yet to be instituted. For that reason, the full impact of the decision is difficult to estimate with high specificity. We expect to continue to issue decisions to institute *inter partes* reviews that address the merits of the parties' arguments and to provide as much information as possible to the parties on the PTAB's evaluation of the merits.

3. **What specific authorities and management strategies do you plan to utilize to reduce any such negative consequences?**

   Answer: The Office is still evaluating what short- and long-term operational impacts *SAS* will have on PTAB operations. We will continue to monitor and evaluate the workload of the PTAB to ensure that *SAS* does not cause negative consequences. Among the tools available to PTAB are reassigning judges that typically handle *ex parte* patent application appeals to handle AIA trials.

   In addition, 35 U.S.C. § 316(a)(11) provides specific authority for the Director to, for good cause shown, extend the one-year deadline for reaching a final written decision by not more than six months. Extensions can be considered, on a case-by-case basis, to address any timing implications of the *SAS* decision.

4. **In your view, should the Director of the Office have the statutory authority to institute *inter partes* review of some but not all of the challenged claims of a patent? Why or why not?**

   Answer: The Supreme Court has decided that the Director has a binary choice: either to institute on all of the claims in the petition or to deny institution. The USPTO will take whatever steps necessary to implement the Supreme Court decision. We will continue to monitor the impact that *SAS* has on *inter partes* review. Should the Committee determine that the USPTO should have the statutory authority to review some, but not all of the challenged claims of a patent, the USPTO will work with the Committee in its consideration of this issue.

5. **In your April 11, 2018 speech to the U.S. Chamber of Commerce, you expressed a desire to increase examiners' ability to find the best prior art during examination in order to ensure that the Office issues appropriate scoped patents. What specific plans do you have to accomplish this goal?**

   Answer: Identifying and considering the most relevant prior art during the original examination is important to the ultimate reliability of granted patents. We are taking a critical look at our current search procedures and resources and exploring avenues that will enhance the effectiveness and efficiency of the examining search process in both the short and long term. Areas we are exploring include: how to better leverage our internal search expertise; attuning the time allotment examiners receive to examine an application which includes searching for prior art and drafting an application; enhancing automation tools that provide better access to databases, search queries, and prior art; and providing external stakeholders with mechanisms to submit relevant prior art during prosecution. In addition, we are evaluating incoming applications to identify attributes in an application that enhance the ability of examiners to efficiently and effectively prosecute the application and perform a quality search. Lastly, we are also exploring how other technologies, such as the use of big data and artificial intelligence, can assist with identifying prior art. These are examples of our current activities to increase the examiners' ability to find the best prior art.

6. **How else do you plan to marshal the resources available to the Office to improve the examination process?**

   Answer: Some of the options being considered to improve the examination process include: seeking "big data" and information analytics solutions to determine where focused training could be provided to our patent examination staff; working with the innovation community to study and develop new, modern administrative processes, which are less costly and more efficient; providing search and examination data to our examiners from foreign IP offices in corresponding cases and providing greater access to non-patent literature data which is increasing in scope and availability; and deploying artificial intelligence tools where possible to improve searching and systemic workflows during the examination process. This is in addition to ongoing improvements specific to our IT tools, quality and management.

USPTO Responses to Questions for the Record - Senator Coons
U.S. Senate Committee on the Judiciary
"Oversight of the U.S. Patent and Trademark Office" - *April 18, 2018*
Witness: Andrei Iancu
Submitted: June 5, 2018

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1. The day after this oversight hearing, the U.S. Patent and Trademark Office ("USPTO") issued updated guidance to patent examiners on patent eligible subject matter determinations following the Federal Circuit's decision in *Berkheimer v. HP Inc.* (Feb. 8, 2018).

a. Does the USPTO plan to have tutorials or learning modules accompany the written Berkheimer guidance?

Answer: The USPTO conducted a series of webinars to inform the examiners and their supervisors of the Federal Circuit's decision in *Berkheimer v. HP Inc.*, and the USPTO's memorandum on this decision. The USPTO is preparing more comprehensive examiner training on the change in examination practice under *Berkheimer*, and expects to begin that training in May.

b. In the past, for patent eligibility decisions decided by the Federal Circuit or Supreme Court that the USPTO has deemed significant enough to issue examiner guidance, such guidance has issued relatively quickly. For example, after the Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the USPTO issued guidance the following day to examiners, which was later supplemented with more detailed guidance. Was there an earlier, interim memo issued for *Berkheimer*, and if not, what was the cause for the delay between that decision's issuance and the USPTO guidance to examiners?

Answer: When the Supreme Court issues a decision concerning patent subject matter eligibility (or any condition of patentability), the USPTO generally issues a brief memorandum promptly bringing the decision to the attention of examiners, such as in the *Mayo* case. Once the USPTO has had the time to thoroughly review the decision and consider its implications, it issues more detailed guidance. As for patent subject matter eligibility decisions issued by the Federal Circuit, the USPTO carefully reviews each decision to determine whether it requires the issuance of additional guidance to the examiners. When the USPTO determines that a decision warrants further guidance, such as in *Berkheimer* given the technical nature of the changes to examination practice, we issue that guidance to examiners.

The USPTO memorandum that issued on April 19, 2018, was the first USPTO memorandum issued that related to *Berkheimer*. Given the subject matter of this memorandum, it was important to take the time necessary to carefully consider its implications and issue a memorandum that provides detailed and specific guidance.

c. Does the USPTO plan to update its guidance in response to another recent Federal Circuit patent eligibility case, *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited* (Apr. 13, 2018)? Why or why not?

Answer: The USPTO is engaged in a comprehensive reevaluation of its subject matter eligibility guidance. The USPTO is currently evaluating whether it is preferable to issue a separate guidance memorandum on *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited* (Apr. 13, 2018), or to simply include this decision in more comprehensive subject matter eligibility guidance. The Federal Circuit's decision in *Vanda* does not by itself require a change to USPTO examination practice, as the USPTO has already indicated in its training materials that claims similar to those at issue in *Vanda* were to be considered patent eligible (Subject Matter Eligibility Examples: Life Sciences, Example 29 (Diagnosing and Treating Julitis)). If the USPTO issues a memorandum to examiners on the Federal Circuit's decision in *Vanda*, the USPTO will promptly post that memorandum on the USPTO website.

2. I understand that there has been a significant uptick in trademark registrations from China, possibly due to government subsidies for such applications.

a. Is this an accurate description of what is happening and its cause?

b. If yes, what is the magnitude of the increase in applications?

c. If yes, how is this application increase affecting USPTO operations, and is there anything Congress should be contemplating in response?

Answer: During the last three years, the USPTO has experienced increased trademark filings from Chinese applicants. Over ten percent of our 400,000 applications are now of Chinese origin. This represents an increase of 1,127% since 2013.

To date we have addressed the increase in filings through hiring without negatively impacting application pendency, but the continuing projected increase in filings may present challenges. Our fee structure and resource allocation rely on assumptions, many of which are undermined by the fact that many of these Chinese applicants are submitting questionable statements of use along with relying on the services of unauthorized Chinese practitioners who evade USPTO sanctions for the unauthorized practice of law. If many or most of these registrations are not ultimately maintained, the trademark revenue model will likely be negatively impacted, resulting in a potential shortfall of fee revenues to total costs.

Additionally, these filings could affect the integrity and reliability of the U.S. Trademark Register. The Trademark Register must accurately reflect use of registered marks in U.S. commerce to be most useful for businesses. The USPTO has been working to improve the accuracy of the Trademark Register to enhance business certainty.

To address these problematic filings, the USPTO is considering adoption of new rules requiring certain filers to have U.S. counsel, which should help improve the integrity of filings and

allegations of use. A Notice of Proposed Rulemaking was published on this issue on May 30, 2018. This practice is a requirement that many other countries impose on foreign trademark applicants and is an effective solution to combat the growing problem of foreign applicant failure to comply with U.S. law. At this stage, we believe that amending the U.S. Rules of Practice through rulemaking may be sufficient.

3. A bill I recently introduced with Senator Hatch, the BIG Data for IP Act (S. 2601) calls upon the USPTO to consider whether and how to incorporate new technologies such as machine learning and "big data" analytics into the examination process through a reporting requirement.

a. Is the USPTO currently investigating how to incorporate such tools into patent and trademark examination?

Answer: Yes.

b. If yes, please provide a brief description of the USPTO's efforts-to-date.

Answer: Some of our efforts include:

Patent Advanced Analytics Platform: Management and quality review tool that provides data driven insights on consistency and quality and includes machine learning/algorithms and modeling to assess risk scores/factors on multiple dimensions/traits of prosecution. The tool includes advanced search capabilities (segmented document searching) and is capable of leveraging user feedback from cogitative augmentation (big data) of examiner tools that, in turn, may also be used to enhance reporting.

Patent AI Search capability (ASC): Search capacity that uses Natural Language Processing to provide cognitive searching capability that can be integrated with any portion of examination to augment our Next Generation tools. This is currently a proof of concept and requires additional input from examiners.

Trademarks Quality Review: Automates the manual process of the quality review for trademarks first actions, final actions, publications, and statements of use (SOUs).

Trademark recommended mark classification (AI image-search): Uses machine learning to identify candidate classifications of trademark images. Currently in alpha testing.

Developed in-house AI & Big Data capability: Deployed Big Data Reservoir capable of big-data analytics and visualization as well as artificial intelligence based machine learning and natural language processing that is scalable, fault tolerant, and cost-efficient. This platform was used to deploy the solutions in the Open Data Portal/Developer Hub, PTAB RSS Feed, and the Bulk search & download.

c. If yes, how much has the USPTO budgeted for such activities in fiscal year 2018? What is the anticipated expenditure in fiscal year 2019? Approximately what percent of the overall IT budget does this expenditure equate in each fiscal year?

Answer: For fiscal years 2018 and 2019, the USPTO has budgeted approximately $10 million for each year, which accounts for approximately 1-2 % of the overall IT budget each fiscal year.

4. A decade ago, 24% of patent applications filed at the USPTO were by solo inventors; today, solo inventors make up only 4% of applications. Additionally, the United States recently experienced the lowest startup birth rate in 40 years.

a. Do you think the U.S. patent system is doing enough to support individual inventors and start-ups?

Answer: The USPTO works to ensure the U.S. patent system is accessible and transparent to independent inventors, entrepreneurs, and small business. There are many initiatives to address the demands of novice patent filers and programs that educate the independent inventor and small business communities on the benefits of intellectual property and how to navigate the patent process to secure a quality patent. We are always exploring and identifying new avenues to reach out and educate independent inventors.

b. What programs or initiatives does the USPTO have to help solo inventors and startups, and is the USPTO considering any changes to further increase the effectiveness of such programs or initiatives?

Answer: The USPTO has a wide range of ongoing programs and initiatives that serve to educate, assist and guide small businesses and independent inventors in obtaining and maintaining appropriate protection for their inventions. Many programs focus on ensuring that under-resourced independent inventors and small businesses are educated on the importance and benefits of intellectual property, the process to follow in an effort to obtain patent protection, and the resources that are available to assist them with securing a quality patent. Some examples of these programs include the Pro Se Assistance Program, Patent Pro Bono Program, Law School Clinic Certification Program and Inventors Assistance Center, among others.

The USPTO also partners with other agencies (for example, the Small Business Administration (SBA)) to provide outreach programs to inventors and small businesses. One such program is Invention-Con (formerly the Independent Inventors Conference), where agencies like the SBA and the Minority Business Development Agency work with the USPTO and other agencies to discuss intellectual property and commercialization best practices that can help attendees be better positioned for success.

5. Concerns have been raised about a practice at the PTAB in which the normal three-judge panel is expanded, *sua sponte*. This panel expansion has led to changed outcomes in some cases. I understand that more recent panel expansions have not changed the outcome, but rather have been intended to signal that the PTAB leadership wishes to emphasize that there

was a significant doctrinal development in that case. The possibility of an expanded panel being used to change the outcome of a given case nonetheless remains.

a. What is your response to those who argue that the current panel expansion process presents due process concerns?

Answer: PTAB panels have been expanded primarily to provide forward-looking guidance on reoccurring issues or at the request of a party during rehearing. Expanded panels have been employed in order to provide forward-looking guidance or uniformity with respect to statutory interpretation, the requirements for a petition in an AIA trial, motions procedures, sanctions, and constitutional issues (*e.g.*, sovereign immunity). In cases when panels were expanded on rehearing, such expansion did not occur *sua sponte*, but was done pursuant to the suggestion of a party to the proceeding who requested the expansion. When expansion occurred on rehearing, the expanded panel reached the same underlying result as the original panel in almost all cases. The only exceptions were the PTAB's *Target* (IPR2014-00508 and IPR2014-00509 and *Nidec* (IPR2014-01121) cases, which both involved the issue of same party joinder. Both cases were decided more than three years ago and were expanded to ensure consistency on this issue of statutory interpretation and treat similarly situated parties the same. Recent panel expansions have not changed the outcome the original three-judge panel reached but, rather, have been utilized to emphasize PTAB practice or signal developments in PTAB practice. Such decisions add the Chief Judge, Deputy Chief Judge, and/or Vice Chief Judges as members of the panel and explain the reason(s) for panel expansion.

b. Do you intend to formalize or otherwise address the panel expansion practice?

Answer: Yes, we are currently assessing the panel expansion process.

USPTO Responses to Questions for the Record - Senator Klobuchar
U.S. Senate Committee on the Judiciary
"Oversight of the U.S. Patent and Trademark Office" - *April 18, 2018*
Witness: Andrei Iancu
Submitted: June 5, 2018

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1. **Recent Supreme Court cases have created uncertainty among innovators as to whether their inventions are eligible for patents. In your testimony, you note that the PTO is working to improve the predictability of patent eligibility.**

   - **Do you believe that the PTO will be able to resolve the current confusion over what is and what is not patent eligible without corrective legislation?**

     Answer: The USPTO is looking into what it can do to enhance certainty and predictability in the area of subject matter eligibility through administrative means, *e.g.,* the issuance of USPTO guidance on subject matter eligibility, and through judicial advocacy at the Federal Circuit and the Supreme Court. The USPTO, however, is bound by Supreme Court precedent. We will continue to assess whether our guidance can provide the predictability needed in this area of the law.

   - **Are you concerned that the current state of patent eligibility laws puts the United States at a competitive disadvantage with respect to other countries?**

     Answer: We believe that U.S. businesses can compete and win against anyone in the global marketplace. To that end, it is important to have a reliable and predictable IP system. The USPTO, for its part, is working to improve its subject matter eligibility guidance to clarify the appropriate lines as to what is and what is not patentable.

2. **I have long been concerned about high prescription drug costs, and I have led legislation with Chairman Grassley to prevent anticompetitive pay-for-delay settlements for years. Many have claimed that drug companies use the patent laws to extend their monopolies on blockbuster drugs—including making minor, therapeutically insignificant changes to drugs and then filing for patents on those changes to delay the introduction of cheaper generic alternatives.**

   - **Do PTO examiners account for tactics like these as part of the patent examination process, and if so, how?**

     Answer: All patent applications are reviewed according to the standards defined by the patent laws. In the pharmaceutical field, this will exclude from patenting changes to existing drugs that are not novel and non-obvious. Our examiners are provided regular technical and legal training to ensure the quality of our patents. We also monitor all of our examiners' dockets for timeliness of examination in order to help avoid, to the extent possible, the necessity of awarding Patent Term Adjustments for delays in office responses.

The patent laws must be carefully balanced. The innovation incentive provided by our patent laws helps to spur the development of new, lifesaving and life-changing drugs, which fill the pipeline for tomorrow's generic drugs. At the same time, patents should not be awarded for applications that are not novel, that represent no more than an obvious variation of the prior art, or that otherwise do not meet the statutory standards for patentability.

USPTO Responses to Questions for the Record - Senator Blumenthal
U.S. Senate Committee on the Judiciary
"Oversight of the U.S. Patent and Trademark Office" - *April 18, 2018*
Witness: Andrei Iancu
Submitted: June 5, 2018

As you know, technical standards are important to establish norms and increase the adoption of new technologies. Recently, Assistant Attorney General Makan Delrahim has given an increasing number of speeches in which he has expressed concerns about the government's prior approach to "patent hold-up" in the context of standard setting organizations ("SSO"). Specifically, the Assistant A.G. has suggested that patent hold-up is not a significant problem (and is less important than "patent hold-out") and in any event should be addressed through contract law rather than antitrust law. As you are aware, the Department of Justice and Patent and Trademark Office released a joint statement on January 8, 2013 discussing a number of competitive issues that occur when the owner of a standard-essential patent ("SEP") attempts to engage in patent hold-up.

In your written responses to the questions for the record submitted after your nomination hearing in November 2017, you explained that "antitrust laws can play an important role" in balancing the various interests associated with SSOs.

1. Can you be more specific in defining that role?

Answer: Antitrust law and patent law are complementary and reinforce each other to create an environment that fosters innovation. There is no dispute around the importance of SSOs, including, for example, in developing the next generation of telecommunications or in fostering the growth of the Internet of Things. It is important to allow the SSOs to develop voluntary, private sector solutions to the issues confronting them.

2. Is patent hold-up a problem?

Answer: Any anti-competitive behavior is problematic when it stifles innovation and violates the antitrust laws.

3. Is there a role for antitrust law when a holder of a SEP breaches its commitment to license on fair, reasonable, and non-discriminatory terms ("FRAND") terms?

Answer: The Antitrust Division of the U.S. Department of Justice is the executive branch component vested with responsibilities for enforcing the antitrust statutes. I look forward to working with Assistant Attorney General Delrahim, as needed, as he continues to address this important issue.

4. Should SSOs be encouraged to give definition to the meaning of FRAND to foster private resolution of licensing disputes, where the definition is consistent with judicial decisions on patent remedies?

Answer: It would be most beneficial to allow SSOs to develop and periodically amend their policies independently and without government intervention, based on what is necessary and best for their participants in their respective industry and technological areas.

5. How do we balance the need for collaborative technical standards with individual patent rights?

Answer: Patent rights promote advanced technical standards by incentivizing investment in and commercialization of new technologies that may be incorporated into technical standards. In terms of defining FRAND, there is no "one size fits all" solution, but rather different SSOs may require different solutions and it is the industries and organizations themselves that are in the best position to determine what the balance should be.

USPTO Responses to Questions for the Record - Senator Booker
U.S. Senate Committee on the Judiciary
"Oversight of the U.S. Patent and Trademark Office" - *April 18, 2018*
Witness: Andrei Iancu
Submitted: June 5, 2018

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1. I'd like to better understand what the U.S. Patent and Trademark Office (PTO) plans to do to keep the path clear for the development and marketing of generic prescription drugs. Millions of Americans struggle to afford prescription drugs for themselves or their loved ones. Indeed, more than 25 percent of Americans who take prescription drugs report having difficulty affording their medicine. Generic medicines tend to be much cheaper than brand-name drugs that remain protected by patents. Pharmaceutical companies, however, have been engaging in a variety of legal tactics to try to extend the life of their patents and prevent generic drugs from entering the market.

a. Is the PTO currently taking, or planning to take, any systematic actions to ensure that pharmaceutical companies are not unfairly extending the life of their drug patents to prevent the development and marketing of generic competitors?

Answer: All patent applications are reviewed according to the standards defined in the patent laws drafted by Congress. In the pharmaceutical field, this will exclude from patenting changes to existing drugs that are not novel and non-obvious. Our examiners are provided regular technical and legal training to ensure the quality of our patents. We also monitor all of our examiners' dockets for timeliness of examination in order to help avoid the necessity of awarding Patent Term Adjustments for delays in office responses.

The patent laws must be carefully balanced. The innovation incentive provided by our patent laws helps to spur the development of new, lifesaving and life-changing drugs, which fill the pipeline for tomorrow's generic drugs. At the same time, patents should not be awarded for applications that are not novel, that represent no more than an obvious variation of the prior art, or that otherwise do not meet the statutory standards for patentability.

b. What specific steps is the PTO considering taking to put an end to these legal maneuvers to keep generic drugs off the market? If the PTO is not currently considering any concrete actions, please outline what kinds of actions the PTO could take.

Answer: The USPTO reviews patent applications for compliance with the statutory requirements for patenting, including novelty and non-obviousness. In order to ensure the quality of USPTO work products, we review examination quality and train examiners on the latest court decisions relating to the written description, novelty, and non-obviousness requirements, and the non-statutory double patenting prohibition. We also monitor all of our examiners' dockets for

timeliness of examination in order to help avoid the necessity of awarding Patent Term Adjustments for delays in office responses.

2. Food and Drug Commissioner Scott Gottlieb has said that pharmaceutical companies should "end the shenanigans" that delay or restrict competition from generic drugs. Commissioner Gottlieb specifically noted that the system "must work at both ends of the marketplace: the end where the highly innovative drugs are developed and rewarded, and also at the other end, where those medicines face brisk competition once their patents and exclusivities have lapsed." This model, he added, "depends on the generic approval process working as intended."

a. From your vantage point as PTO Director, will you make the same call on pharmaceutical companies to stop this kind of gamesmanship with respect to patents?

Answer: I will continue to strive for high-quality examination in accordance with the patent laws and timely examination, which avoids the necessity for adjusting patent term due to office delays.

b. From your vantage point as PTO Director, do you believe that the approval process for generic drugs is currently working as intended?

Answer: USPTO is not involved in the approval process for generic drugs. The Department of Health and Human Services, which conducts these reviews, is in a better position to opine on this issue.