Overview

The Director of the U.S. Patent and Trademark Office (USPTO), Andrei Iancu, testified on March 13th, before the Senate Judiciary Committee’s Subcommittee on Intellectual Property in an oversight hearing. The hearing was chaired by Senator Tillis (R-NC), also in attendance were Senator (and Ranking Member) Chris Coons (D-DE), John Cornyn (R-TX), Richard Blumenthal (D-CT) and Mazie Hirono (D-HI).

This hearing was the second hearing by the Judiciary Committee’s newly re-established Subcommittee on Intellectual Property. There was broad support for the policies that Director Iancu was implementing in order to increase certainty with respect to patents. The main focus of questions however concerned the role that the patent system, and its perceived abuses, plays in high pharmaceutical drug prices. Other significant topics addressed included: Section 101 (Coons); status of PTAB reforms (Coons, Hirono); patent trolls (Cornyn); and bad faith trademark applications (Tillis and Coons).

Section 101

In his opening statement, Senator Tillis mentioned the stakeholder roundtables that he and Senator Coons were hosting, and stated that he was planning to have a draft bill on section 101 reform ready by early summer. He also noted that he also planned to have a bill that would make statutory changes to PTAB and inter partes review. Senator Coons asked Director Iancu whether the new 101 guidance would resolve uncertainty, and would it obviate the need for legislation. Director Iancu noted that the guidance is working well so far, and the examiners appreciate the guidelines; however, he does not know how Article III courts will continue to analyze the issue, thereby leaving unstated his support for a legislative fix. Senator Coons also expressed his concerns with the fact that medical diagnostics will continue to be denied patents which is disincentivizing research in this area. Director Iancu agreed, noting that it was hard to find medical diagnostics patentable and highlighted the footnote in the recent Athena case where the Court noted that its hands were tied by current Supreme Court precedent. Senator Hirono expressed concerns that the definition of abstract idea in newly issued 101 Guidelines, and specifically the “methods of organizing human activity” would be not be upheld by the Courts given the recent CAFC decision in In re: Golinar which rejected such “methods for organizing human activity”. Director Iancu noted that the Guidelines were based on current Supreme Court jurisprudence, specifically Alice and Bilski, and in this regard was comfortable that they would be upheld.
Patents and Pharmaceutical Pricing

Senator Cornyn was the first to raise concerns that abuses in the patent system could be leading to high pharmaceutical prices, mentioning how one drug had 130 patents associated with it. He noted that he understood the need to reward innovation, but was concerned with gamesmanship in the system. Director Iancu noted that it was important for there to be balance in the system, supporting rewards for innovation but at the same time avoiding gamesmanship. He noted that patents were one facet of the complex drug pricing system and the USPTO’s role is to ensure that they only issue patents on meritorious inventions and only on innovative changes. He noted that examiners are trained to ensure that patents have meaningful innovative changes. Director Iancu noted that while he was unsure about the 130 patents around one drug statistic, he did note that drugs were complex systems and there may be a patent on the molecule, a patent on the method of manufacture, and on the coating/delivery mechanism, and as long as they are all truly innovative, they are deserving of patent protection. Senator Coons followed up these points by asking a hypothetical on how the PTO would determine whether a new element for a drug (he used his “tie” by way of a concrete example) would be patentable. The point he was trying to get across was that a manufacturer would only get additional patents if the changes are innovative. Director Iancu kept repeating his mantra that he does not want to encourage gamesmanship, but it is still important to encourage innovation and research. Senator Coons then asked whether weakening the patent system would help bring about a decrease in drug prices. Director Iancu answered that the US needs a robust patent system because it was important that the US remain at the forefront of research in these areas. Senator Tillis also joined in on this topic, harkening to his days as research manager for the R&D department of IBM and noting that investments in research occurred only after an assessment as to whether the end result was patentable. Director Iancu agreed with the role that patents play in shaping research decisions and noted that it was important to keep a careful eye on the balance in the system to ensure that only truly innovative advances receive patent protection. Senator Tillis, noting Senator Cornyn’s concerns on evergreening of patents, asked Director Iancu whether it was possible for the USPTO to do a study/statistical analysis to detect trends as to where “evergreening” may have occurred. Director Iancu noted that they could do such a study, but it would be important to have a good definition of what is meant by “evergreening”, since “continuation patents” are co-terminus with the parent patents, and terms can be appropriately extended due to FDA clinical trial delays. Lastly, Senator Tillis asked whether the USPTO applied the same statutory standards to pharmaceutical patents as were applied to other patents. Director Iancu stated that yes they did, and then walked the Chairman through the process.

PTAB Reforms

Director Iancu was praised by both Senators Tillis and Coons for recent PTAB reforms, including harmonizing the claim construction standards, creating an amendment process, among others. He was asked by Senator Coons whether Congress should codify the change in the claim construction standard or other measures that have been implemented to increase fairness in the post grant review system. Director Iancu noted that they are currently taking stock in the
changes that they have made and so far the results have been positive. He is still contemplating further changes, including looking at the institution decision. With respect to legislation, he deferred to Congress on whether legislation was necessary, but noted that he would be happy to assist Congress as necessary. Senator Hirono also praised the Director for changing the claim construction standard and asked whether it was important to have legislation so that this change could not be undone. She was unaware that the change had been done via rulemaking and was pleased when Director Iancu noted that fact; Director Iancu again repeated that he would be pleased to support Congress on legislation if they request it. Senator Hirono also asked about serial petitions, and whether anything was being done to stop this. Director Iancu noted that the trial practice guidelines had been revised for the first time since the AIA, and this was one of the areas which was revised.

**Patent Trolls**

Senator Cornyn raised concerns about the fact that Apple has closed down two profitable stores in Plano, Texas, so as to avoid litigation in the Eastern District of Texas, and asked Director Iancu whether he was concerned with abusive patent litigation. Director Iancu replied that he is concerned about any abuse of the patent system, but he prefers to identify specifically what abuse is occurring so that he can develop solutions and fix them. He cautioned against using pejorative terms with respect to the system as a whole. If the concern is about “blunderbuss” demand letters that are not backed by a reasonable rationale, then “let’s figure out that problem and find a solution for it”. But he has concerns about using negative terms since it has a “counterproductive effect and distracts from the real issues.”

**Bad Faith Trademark Applications**

Both Senators Tillis and Coons asked Director Iancu what steps the USPTO was taking to deal with the influx of questionable trademark applications, mainly from China, that were cluttering up the trademark register. Director Iancu pointed to the expedited cancellation pilot project, but noted that while it was fairly new, it was not being used much; he also noted that they are piloting new software to detect photoshopped images that are submitted as specimens of use; the use of post-registration audits which seem to be producing good results; and lastly the USPTO just issued a notice of proposed rulemaking that requires the use of local counsel for foreign trademark applicants.

**Testimony**

Director Iancu’s prepared testimony can be found here:

[https://www.judiciary.senate.gov/imo/media/doc/Iancu%20Testimony.pdf](https://www.judiciary.senate.gov/imo/media/doc/Iancu%20Testimony.pdf)

**Link to the Webcast of the hearing:**
