USPTO Lawyer Explains Divergence from CAFC on Eligibility (ipwatchdog.com)

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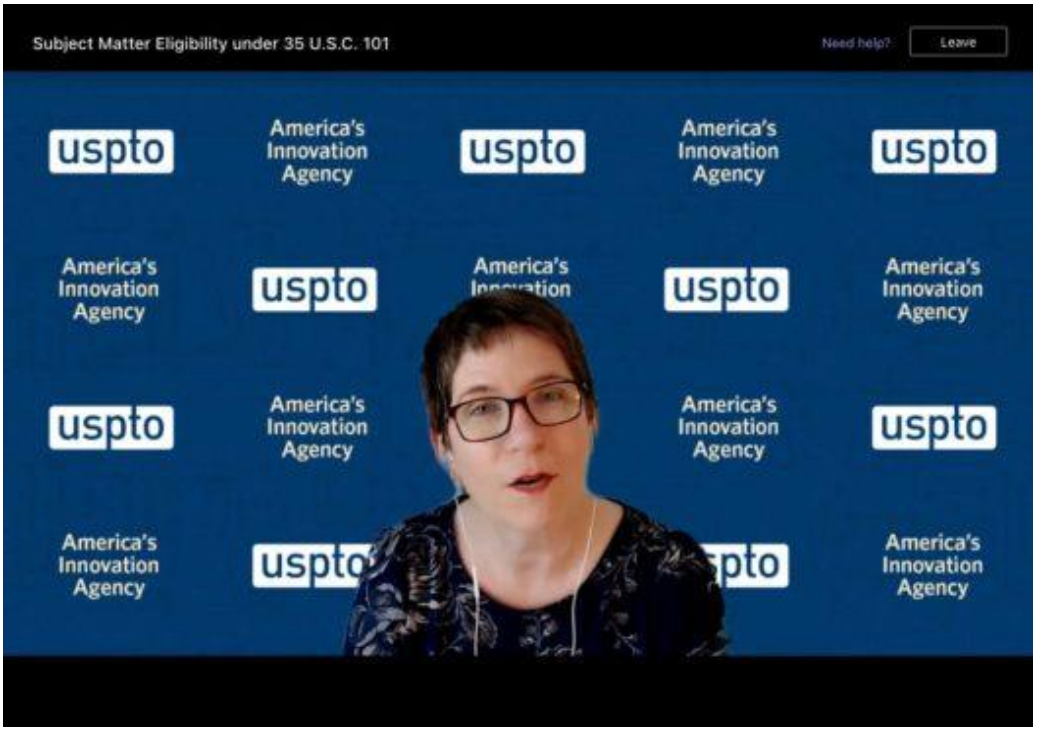
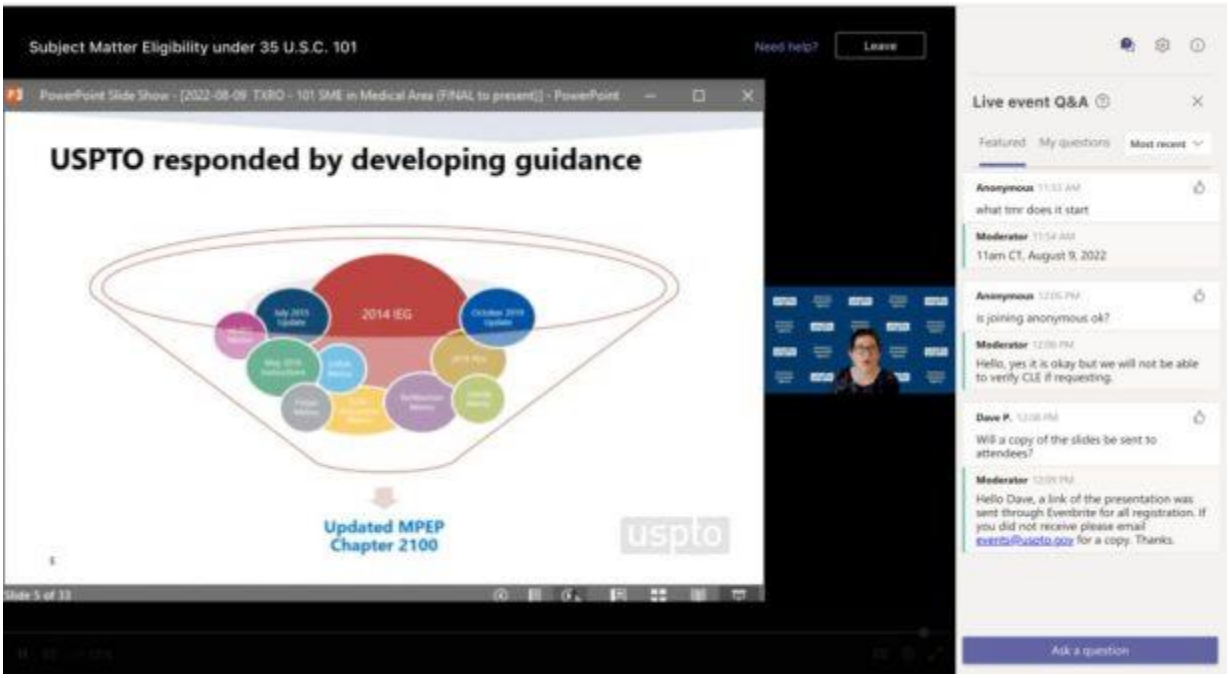


June Cohan

June Cohan, Senior Legal Advisor in the Office of Patent Legal Administration at the U.S. Patent and Trademark Office (USPTO) today explained to attendees of an event about the Office's patent eligibility guidance that there are no plans to revise the guidance in light of the denial of certiorari in *American Axle*. She also acknowledged several areas of "divergence," or "outlier cases," between the USPTO and the U.S. Court of Appeals for Federal Circuit (CAFC) approaches to determining patent eligibility which the Office has no plans for revising, despite the fact that the CAFC is the reviewing court for the USPTO.

Bad Odds

Cohan told attendees that, since 2012, following the *Mayo* decision, the CAFC has issued over 190 written decisions on patent eligibility and only about 20% of those have saved at least one claim. Life sciences patents have fared better, with about 30% of decisions in that area finding at least one claim eligible. Lab methods, cryopreservation, methods of making a pharmaceutical and methods of treatment have all been treated well, with seven cases identifying eligible claims. Device claims have odds of about 50-50, while claims involving detecting or diagnosis have terrible odds—the CAFC has struck down all such claims that it's seen since *Mayo*, Cohan said.



While the Supreme Court's decisions in *Bilski*, *Myriad*, *Alice* and *Mayo* fundamentally changed the way the Office examines patent applications, patent owners are still more likely to have luck at the USPTO. Following those decisions, the Office worked on guidance with stakeholders and examiners and ultimately arrived at the present eligibility guidance, now codified in MPEP Chapter 2100. The guidance differs from the CAFC's approach in a few ways, such as the determination of what qualifies as a law of nature, for example, which "has gotten a lot of flak from the courts," Cohan said. She explained:

We created this by going back to Supreme Court cases like *Mayo*, studying very carefully the type of claim language that the Court identified as being a law of nature and then we wrote claims that didn't include that type of language, and then we issued patents in accordance with this guidance, to stakeholders including Cleveland Clinic and Stanford University. But when those patents subsequently got reviewed by the CAFC, the court declined to follow the guidance and held some of them ineligible.

Cohan pointed to *Cleveland Clinic Foundation v. True Health Diagnostics* and *CareDx, Inc. v. Natera, Inc.* as examples of this discrepancy. In the *Cleveland Clinic* case, the Federal Circuit commented on the USPTO's guidance, explaining:

"While we greatly respect the PTO's expertise on all matters relating to patentability, including patent eligibility, we are not bound by its guidance. And, especially regarding the issue of patent eligibility and the efforts of the courts to determine the distinction between claims directed to natural laws and those directed to patent-eligible applications of those laws, we are mindful of the need for consistent application of our case law."

However, as this was only a comment, the USPTO did not consider it necessary to revise its guidance in any way to comport with the Federal Circuit. "We follow the same body of precedent, but certain cases do appear to be outliers," added Cohan. "There are at least some that believe the Federal Circuit is maybe over-interpreting *Mayo* not in line with some of the Supreme Court decisions."

Cohan also noted that the Office's addition of a prong 2 in the Step 2A analysis in 2019 also differs from Federal Circuit precedent. Following public feedback and internal studies, there seemed to be too much emphasis on the role of conventionality in the eligibility analysis, and so the Office went back to the Supreme Court cases and came up with the additional prong, which Cohan calls a "diet Step 2B," as it uses all the same considerations as Step 2B except for "well understood, routine and conventional," which she said makes a big difference. Cohan added that this prong has greatly improved consistency in rejections, taking the Office from a 25% rejection rate on eligibility in 2018 to about 8% today, and has also improved allowance rates in certain areas hard hit by the four big Supreme

Court eligibility decisions. "We're in a stronger place with an improved allowance rate as a result," she said.

No Need for Change Following *American Axle*

When asked about whether the Office planned to update its eligibility guidance somehow in response to the denial of cert in *American Axle*, Cohan said that, while the Office supported granting cert and diverged from the Federal Circuit's approach there as well, the most recent iteration of the guidance came out after the decision issued and "the denial doesn't really add anything to it." Three of the four seminal cases on eligibility were unanimous, and since the court still has a majority from the *Mayo* and *Alice* cases, "they probably haven't changed position," she noted. But Cohan said that the Office's views were outlined fully in the Solicitor General's brief in the *American Axle* case and implied that the writing is on the wall as far as whether the Office thinks the court should change its tune. She concluded:

> We issued those patents, they're presumed to be valid, we did not change our guidance in response to the decision in 2019, so I think that gives you an indication.…We are obligated to follow the body of precedent form the Federal Circuit but there are outlier cases, and *American Axle* might be one of those.

However, USPTO Director Kathi Vidal did announce last month that the Office is soliciting comments on the current eligibility guidance through September 15, 2022, in anticipation of potentially revising the 2019 guidance.

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