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USA – Delaware: Trends & Developments

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USA – DELAWARE

Trends and Developments

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Young Conaway Stargatt & Taylor, LLP has enjoyed more than 60 years as one of Delaware's largest, most prestigious and multi-faceted law firms. Over the years, the firm has expanded to more than 125 attorneys with offices in Wilmington, Delaware, Charlotte, North Carolina, and at Rockefeller Center in New York. Young Conaway offers clients sophisticated national bankruptcy, corporate, commercial and intellectual property practices along with local and regional tax, trusts, employment, business law, commercial real estate, tort, and environmental practices. Thirty-two attorneys were ranked in the 2025 edition of Chambers USA: America's Leading Lawyers for Business.

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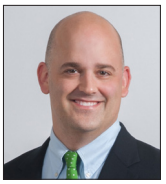
Anne Shea Gaza is a member of Young Conaway's management committee and co-chair of the firm's intellectual property group. With over 25 years of experience, she focuses her practice on litigation in the United States District Court for the District of Delaware, the US Court of Appeals for the Third Circuit, the US Court of Appeals for the Federal Circuit, the Delaware state courts, and other courts. Anne represents national and international clients in intellectual property and complex commercial cases. She has handled, as lead or Delaware counsel, over 400 cases spanning a diverse range of industries and technologies.



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2025 Changes to USPTO Policies Will Impact Patent Litigation in Federal District Courts

In 2025, some of the most significant developments likely to have far-reaching impacts on patent infringement litigation in United States federal district courts were changes made to the policies and procedures of the United States Patent and Trademark Office (USPTO). Specifically, the USPTO implemented new policies regarding institution of an inter partes review (IPR) of patent validity, thereby continuing and accelerating trends at the USPTO that are likely to affect patent litigation for years to come.

The IPR regime

For over a decade, IPRs have provided accused patent infringers an alternative to attempting to prove patent invalidity in a district court. An IPR petition requests the USPTO, rather than a court, decide the validity of an issued US patent. IPRs are decided by panels of the Patent Trial and Appeal Board (PTAB), a board of administrative judges. Over time, the percentage of IPRs that were "instituted" ranged annually from 56% to 87%, with the portion of instituted IPRs that resulted in invalidation of some claims of a patent ranging from 73% to 90%. Historically, the Director of the USPTO has delegated the authority to determine whether IPRs should be instituted to the PTAB, which also makes ultimate decisions on patent validity. That changed in 2025 with the appointment of a new USPTO Director, John Squires, and the initial days of Director Squires' tenure have begun to reduce these rates of institution and invalidation.

Changes to Director institution and review of IPRs

Throughout 2025, first under Acting Director Coke Morgan Stewart, then under Director Squires, the USPTO has overhauled IPRs and other post-grant review mechanisms. The reforms enacted by Director Squires reflect the USPTO's attempt to reduce duplicative challenges to patent validity and enhance the agency's efficiency, including by limiting institution of IPRs in certain situations.

Director Squires revoked the prior delegation to the PTAB to make institution decisions, and the new process of "Director Institution" – under which the Director bears ultimate responsibility for institution decisions – has resulted in fewer IPRs ever beginning. Correspondingly, fewer patent claims are now invalidated by the PTAB as well. In the Director Institution process, panels of PTAB judges provide recommendations to the Director but do not vote, and only the Director ultimately decides whether to institute an IPR. The Director's institution decision is published in a concise "summary notice" rather than a detailed legal opinion addressing the merits of invalidity challenges to patent claims, as the PTAB typically issued prior to 2025.

In addition, the Director expanded and prioritised consideration of certain discretionary factors beyond the standard merits-based considerations of whether a patent claim may be anticipated or obvious. These discretionary considerations allow the Director to determine that an IPR should not be instituted for

reasons unrelated to the legal merits of invalidity, and the determination to decline institution of an IPR can be made without even reaching those legal merits. Considerations that may lead to discretionary denial were originally set forth by the PTAB in two 2020 decisions in *Apple v Fintiv* and *Sotera Wireless v Masimo Corp*. The "*Fintiv factors*" are:

- whether a stay is likely in the co-pending district court proceeding;
- the proximity of the trial date in the co-pending proceeding to the PTAB's projected statutory deadline for a final written decision;
- investment in the co-pending litigation;
- overlap in issues raised in the co-pending litigation and the IPR petition;
- whether the parties are the same as those in the co-pending litigation; and
- other considerations.

In *Sotera Wireless*, the PTAB found that when a petitioner files a stipulation agreeing to "not pursue in the District Court Litigation any ground raised or that could have been reasonably raised in an IPR" if the IPR was instituted, the *Fintiv* factor regarding overlap between issues raised in the IPR and the litigation weighs strongly in favour of not exercising discretionary denial. This became known as a "*Sotera stipulation*".

Additional changes through USPTO proposed rules

In 2025, the Director moved to codify the discretionary denial factors through proposed agency rule-making and made clear that additional factors could be considered as well. The proposed rule states that the PTAB shall not institute an IPR if it is "more likely than not" that a parallel proceeding, whether in a district court, the International Trade Commission, or another PTAB proceeding, will adjudicate the validity of the claims before the PTAB issues its decision. Because the IPR timeline is statutorily fixed, requiring a decision 12 months after institution (or approximately 18 months after filing), a petitioner must file an IPR petition almost immediately upon being sued to ensure the PTAB decision is issued before a district court trial. If a district court sets a somewhat fast trial schedule, the Director may deny the IPR solely based on that timing.

The USPTO's changes have been met with some legal challenges, but the Federal Circuit has supported the agency's approach. In a recent decision, *In re Motorola Solutions, Inc.*, the Federal Circuit addressed a constitutional challenge to the Director's discretionary denial practices. The IPR petitioner in *Motorola* argued that the Director's refusal to institute an IPR based on discretionary factors violated the Due Process Clause. But the Federal Circuit rejected this argument, holding that: (i) there is no property interest in the institution of an IPR, and the statute grants the Director broad discretion to decide whether to institute an IPR; and (ii) the statutory language that institution decisions are "final and nonappealable" bars judicial review of the Director's discretionary criteria.

The USPTO's proposed rule-making also includes a bar on institution of an IPR if the challenged claim has previously been found "not invalid" in any prior proceeding, including judgments from district courts, the International Trade Commission, and prior PTAB proceedings. Traditionally, a finding that a patent is "not invalid" binds only the parties to that specific case. The proposed rule, however, would extend this preclusion to non-parties, effectively making it a judgment that the patent is "valid" at least for the purposes of IPR institution.

Finally, the USPTO's proposed rule-making introduces a required "Stipulation for Efficiency" as a precondition for institution of an IPR. Under this rule, a petitioner must file a stipulation in both the PTAB and the parallel litigation – whether in district court or the International Trade Commission – agreeing not to pursue any invalidity challenge that a patent is anticipated or obvious if the IPR is instituted. This is a significant expansion of the "*Sotera stipulations" that became common between 2020 and 2024 and typically required a petitioner to waive only grounds that were raised or reasonably could have been raised in the IPR. The new rule, on the other hand, requires a waiver of all anticipation and obviousness arguments. In effect, this forces IPR petitioners to forfeit the right to use any*"system art" or "on-sale bar" arguments, ie, claims that a patent is invalidated by a prior physical

product, in district court. Such system art arguments are based on anticipation or obviousness but cannot be adjudicated in IPRs, which are limited to anticipation and obviousness based on printed publications. (IPRs also do not include other types of validity challenges such as indefiniteness or lack of written description.) This reform requires an IPR petitioner to elect a preferred venue for all purposes for anticipation and obviousness arguments, preventing petitioners from first trying to invalidate patent claims at the PTAB based on printed publications and later making system art arguments to a jury in a district court.

Policy reasons for the changes

Under Director Squires, the USPTO has taken the approach that the primary solution to patent quality issues is rigorous initial examination, rather than post hoc invalidation. This reflects a sense by some that the pendulum had swung too far towards the PTAB's reputation as a "death squad" for patents. By contrast, the USPTO's recent changes reflect the philosophical approach that "[r]eliable patent rights encourage the inventor or others to invest in the patented technology" but "[e]ven extremely strong patents become unreliable when subject to serial or parallel validity challenges". If a patent owner must defend the same claims in district court, the International Trade Commission and the PTAB, the cost of defence acts as a tax on innovation, regardless of the ultimate finding of validity of the claims. Thus, the USPTO now prioritises the stability of property rights over the availability of repeated administrative challenges.

The 2025 policy changes and proposed rules are thus designed to restore "quiet title" to a patent once it has survived a validity challenge. Similarly, the idea of quiet title to a property right is reflected in the USPTO's explanation of the "settled expectations" discretionary factor. That factor allows the Director to deny institution if a patent has been in force for a significant period such as seven or more years without challenge to its validity. The rationale is that, after such a long period, the patent owner and the market have relied on the validity of the patent, and disturbing those expectations would be inequitable. Throughout 2025, settled expectations has become one of the USPTO's primary justifications for declining to institute IPRs. Here, too, the courts have deferred to the USPTO. In *In re Cambridge Industries*, the Federal Circuit denied a mandamus petition challenging a denial based on the doctrine of settled expectations (although the Federal Circuit pointed out that its decision was limited to the context in which it decided the issue, ie, a mandamus petition).

And perhaps most importantly, the idea of Director Review rather than the prior delegation of authority to the PTAB is based on at least four considerations identified by Director Squires. The announcement of this change pointed to a desire to eliminate the appearance of self-interest, removing a perceived "referral-signal bias", enhancing transparency and public trust, and re-aligning duties and responsibilities of the Director to be accountable for the threshold determination of institution. The Director expressed concern that there may be the appearance that the PTAB is incentivised to grant institution in order to fill out its own docket, indicating that the prior bifurcated process for preliminary consideration of discretionary denial "inadvertently produced extraordinarily high institution rates" in referred cases. He further stated that returning institution decisions to the Director "realigns [the USPTO's] procedures with the clear language and intent of the statute and returns accountability for such decisions to the Director just as the framework of the [statute] provides".

The future and the impact on patent litigation

These changes are expected to continue to develop in 2026. Although certain changes have already been in place for several months, the USPTO's proposed rule-making has not yet taken effect. And most of the court decisions rejecting challenges to changed procedures are from the last two months of 2025, so further challenges in the Federal Circuit are likely. But unless there is some dramatic change in the USPTO's approach, the early results suggest that far fewer IPRs will be instituted going forward compared to the historical average, as the rate of institution has dropped to around 50% for 2025 and somewhere between 0% and 10% for the final quarter of 2025.

Over the last 10 to 15 years, hundreds of decisions regarding the validity of patent claims were made at the PTAB. This was a change to the historical practice, in which patent challengers would need to rely

on district courts for their anticipation and obviousness arguments. It appears that the focus of invalidity arguments will again shift back to the courts because the USPTO will decline to institute many IPRs. Additionally, even if the Director were otherwise inclined to institute an IPR, that institution decision may hinge on the petitioner's willingness to forego certain rights. Most importantly, a petitioner will now need to agree to not only a *Sotera* stipulation, but a waiver of any and all arguments for anticipation and obviousness in parallel proceedings. For some patent challengers, this may be too much to give up, particularly if they believe they have a good system art or on-sale bar argument, and they may decide that litigation in district court is preferable to ever seeking institution of an IPR.

Whatever the exact balance of validity challenges in the PTAB and other venues, it appears inevitable that there will be fewer patents subject to parallel proceedings as patent challengers will be required to choose one venue and be bound by the results in that venue. The USPTO's focus on patents as property rights and the patent owner's interest in certainty are likely to result in efficiencies for all parties, whether they like it or not.

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