Sterne Kessler
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2025

PTAB Year in Review

ANALYSIS & TRENDS | 6TH EDITION

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Introduction

In 2025, the Patent Trial and Appeal Board (PTAB) experienced significant procedural and substantive changes. Under new leadership at the U.S. Patent and Trademark Office (USPTO), a series of developments reshaped pre-institution practice, culminating in a shift in institution authority that now rests with the USPTO Director. Additionally, the USPTO proposed and solicited comments on broad changes to the rules governing inter partes review (IPR) proceedings. At the same time, we observed an increase in ex parte reexamination filings before the USPTO's Central Reexamination Unit (CRU), reflecting a shift in strategic considerations in parallel with the changes at the PTAB.

Early in 2025, the PTAB introduced a new bifurcated pre-institution briefing process that carved out separate briefing for discretionary considerations, followed by detailed guidance on how parties should engage. Additional process and policy changes culminated with centralized institution decisions, with the USPTO Director taking the lead in consultation with a group of senior PTAB judges. These changes reflect a broader effort by the USPTO's leadership to manage PTAB workload, sharpen institutional discretion, and align America Invents Act (AIA) trials with evolving policy objectives.

Against this backdrop, practitioners are realigning their strategy to address the evolving patent landscape, as the contours of post-grant practice continue to shift in real time. Now, perhaps more than ever, it is imperative for patent owners and patent challengers alike to understand the interplay, shifting dynamics, and complex inner workings at the PTAB and CRU to guide strategic post-grant challenge decisions.

This Year in Review report recaps the most significant PTAB developments that we covered throughout the year, and provides updated analysis and practical takeaways for both patent owners and petitioners. We also offer a preview of what 2026 may hold, informed by the perspectives of some of our key PTAB team members — three former Administrative Patent Judges at the PTAB — who provide insight into how the developments of 2025 may shape post-grant practice in 2026.

Thank you to our authors and our entire Post-Grant Proceedings team for making this publication possible. We appreciate your interest in this report and welcome the opportunity to discuss post-grant matters and how they may impact your business. If you have questions or topics you would like to see us cover in 2026, please do not hesitate to contact us directly to start the conversation.

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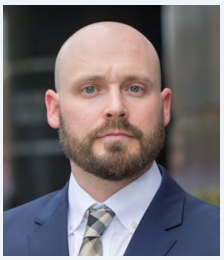

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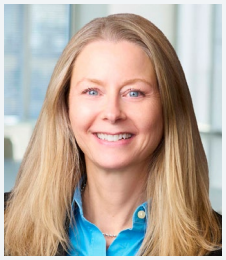

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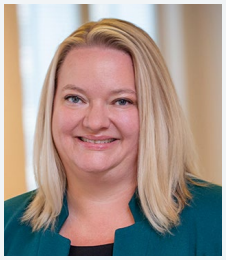

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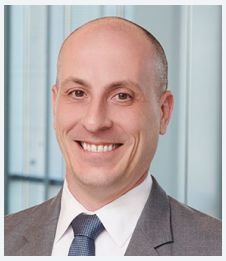

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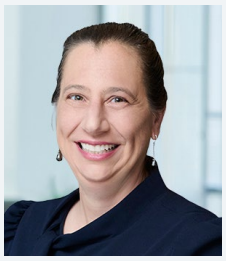

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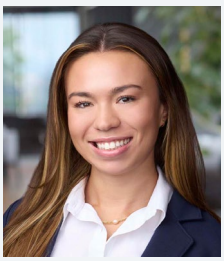

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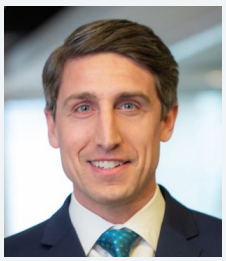

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USPTO Rescinds Memo Addressing PTAB Discretionary Denial Procedures and Issues Memo on *Fintiv* Analysis Changes

BY: JENNIFER MEYER CHAGNON AND MIKE D. WEBB

In February 2025, the United States Patent and Trademark Office (USPTO) rescinded its June 2022 Interim Procedure governing Patent Trial and Appeal Board (PTAB) discretionary denials under *Fintiv*, which had imposed structured guidance on how the PTAB should weigh parallel district court litigation when deciding whether to institute inter partes reviews (IPRs) and post-grant reviews (PGRs). Within a month of rescinding the *Fintiv* memo, the PTAB issued a clarifying guidance memo instructing members of the PTAB on how to analyze *Fintiv* going forward. Together, these actions signaled a return to case-by-case, holistic discretionary analysis, rooted in precedential PTAB decisions rather than following the 2022 memo's narrower rules.

The rescission eliminated prescriptive rules related to *Sotera* stipulations, compelling merits, and parallel U.S. International Trade Commission (ITC) proceedings, but indicated that median time-to-trial statistics should still be considered. The PTAB memo confirms that *Fintiv* remains good law but must be applied flexibly, with all relevant factors weighed based on the record in each case.

Key Takeaways

- No More Bright-Line Rules: The PTAB now applies the multifactor *Fintiv* discretionary denial analysis rather than the bright-line directives of the rescinded 2022 memo.
- Greater Uncertainty: Without prescriptive guidance, unpredictability in discretionary denials has increased.
- *Sotera* and Timing — Still Relevant but Less Predictive: Stipulations not to pursue overlapping grounds are helpful but no longer guarantee avoidance of discretionary denial; timing and projected litigation outcomes matter.
- Merits Strength Matters, but "Compelling Merits" Is Not Determinative: Strong invalidity arguments are one factor among many.

Best Practices for Practitioners and Parties

- As petitioner:
  - File Early and Strategically: Early petitions reduce the weight of *Fintiv* timing considerations and minimize risks associated with parallel litigation.
  - Strategically Tailor Stipulations: Draft them carefully considering litigation strategy as a whole, but pair them with strong explanations of efficiency and fairness in the discretionary briefing.
- As patent owner:
  - Include *Fintiv* Arguments: Be sure to include *Fintiv* arguments anytime there is a parallel litigation; chances of success of denial under *Fintiv* are higher with the rescission of the 2022 memo.
  - Consider *Fintiv* in Deciding Assertion Forum: Consider filing in a traditionally faster forum or the ITC to argue for discretionary denial under *Fintiv*.
- Both parties:
  - Develop a Complete *Fintiv* Narrative: Address all factors cohesively rather than relying on a single argument (e.g., stipulations or merits).
  - Substantiate Timing Arguments: Use objective data such as court statistics, not merely docketed trial dates.

Read the original alerts:

USPTO Rescinds Memo Addressing PTAB Discretionary Denial Procedures (March 3, 2025)

PTAB Issues Memo on *Fintiv* Analysis Changes (March 25, 2025)

New Pre-Institution Discretionary Briefing Framework and the Director's Expanded Role in Institution Decisions

BY: JENNIFER MEYER CHAGNON AND MIKE D. WEBB

On March 26, 2025, the USPTO issued an *Interim Processes for PTAB Workload Management* memorandum introducing a bifurcated decision-making process at the institution stage of America Invents Act (AIA) trials. On October 17, 2025, the United States Patent and Trademark Office (USPTO) issued a *Director Institution of AIA Trial Proceedings* memorandum, updating this process whereby the authority for institution decisions now centrally resides with the USPTO Director. Both of these memos mark major procedural changes in how the Patent Trial and Appeal Board (PTAB) handles institution of inter partes review (IPR) and post-grant review (PGR) proceedings.

Under the new process, the decision whether to institute a trial is bifurcated into two phases:

1. **Discretionary Denial Phase** — Where the Director in consultation with at least three PTAB judges, decides whether to discretionarily deny a petition based on a range of policy and discretionary factors.
2. **Merits/Statutory Phase** — If discretionary denial is not appropriate, the petition proceeds to an assessment of the merits and statutory requirements for institution. When the bifurcated process was first implemented, this assessment was referred to a three-judge PTAB panel. Beginning October 20, 2025, this assessment is now done by the Director himself, in consultation with at least three PTAB judges.

To support this bifurcated decision making, a new separate briefing process on discretionary considerations (distinct from the merits briefing in the Petition and Patent Owner Preliminary Response) was also implemented. The bifurcated briefing timeline is as follows (including procedural updates implemented subsequent to the March 26 memo):

- A patent owner may file a brief arguing why discretionary denial is warranted. Patent owner's brief is limited to 20 pages and is due within two months of the Notice of Filing Date Accorded (NFDA).
- A petitioner may file an opposition to patent owner's discretionary denial brief. Petitioner's brief is likewise limited to 20 pages and is due within three months of the NFDA.
- Additional limited discretionary briefing may be authorized for good cause, but is not available as of right.
- The standard preliminary response deadline remains unchanged (i.e., within three months of the NFDA).

The March 26 memo highlighted additional discretionary factors (beyond traditional ones from *Fintiv*, *General Plastic*, and *Advanced Bionics*) that the Director may consider, including prior validity adjudications, changes in law, strength of unpatentability challenges, reliance on expert testimony, settled expectations, and broader policy concerns like economic/public health interests and PTAB resource management. A set of FAQs released by the USPTO to clarify aspects of the new process provided additional guidance, including that petitioners should file any stipulations "as soon as practicable" so that the patent owner can address their impact in the discretionary briefing, and that the Director would consider whether such stipulations materially reduce overlap between proceedings. Regarding expert testimony, the FAQs suggested that heavy reliance on expert testimony — or reasonable expert disputes on dispositive issues — may signal that issues are better suited for Article III courts, potentially weighing against institution.

The October 17 memo indicated that the Director will typically issue summary notices granting or denying institution, unless "detailed treatment of issues is appropriate."

New Pre-Institution Discretionary Briefing Framework and the Director's Expanded Role in Institution Decisions

continued

Key Takeaways

- Bifurcated Decision Making: Discretionary denial is evaluated first by the Director; merits are addressed only if discretionary denial is declined.
- Separate Discretionary Briefing: Patent owners now have a stand-alone briefing window early in the proceeding to press discretionary denial arguments. Petitioners must respond strategically, addressing patent owner's arguments and also providing reasons why institution is appropriate.
- Expanded Discretionary Factors: Beyond *Fintiv*, *General Plastic*, and *Advanced Bionics*, the Director may consider prior adjudications, changes in law, strength of the challenge, reliance on expert testimony, settled expectations, public interest concerns, and other equitable factors.
- Director-Led Institution Decisions: The Director generally issues a summary grant or denial of institution, referring matters to PTAB judges only when detailed treatment is warranted.
- Summary Notices: Institution decisions will most often be issued as summary notices without extensive reasoning, increasing uncertainty for stakeholders about decision rationales.

Best Practices for Practitioners and Parties

- Treat Discretionary Denial as a Stand-Alone Advocacy Phase: Develop focused, evidence-driven arguments tailored to the Director's broader discretion.
- Prepare for Discretionary Briefing Early:
  - Petitioners should analyze discretionary considerations even prior to filing their petition. A strong story about why institution is an appropriate use of Board resources is necessary to get past the discretionary denial phase. A showing of Office error under § 352(d) has evolved as one strong argument for petitioners. In some cases, ex parte reexamination may be a more attractive option than an IPR, particularly for older patents.
  - Patent owners should plan discretionary denial briefs immediately upon receiving notice of a petition, focusing not just on traditional *Fintiv* factors but also on new considerations like prior adjudications and policy impacts. Settled expectations has evolved as a strong argument for patent owners where a patent issued over six years ago.
- Coordinate Strategy Across Briefs: Ensure consistency between discretionary briefing and merits positions without duplicating arguments.
- Strategically Align With PTAB Priorities: Both sides should align arguments with PTAB's workload management and broader institutional goals — e.g., efficiency, avoidance of duplicative reviews, and resource constraints — to strengthen their positions.

Read the original alerts:

Latest PTAB Memo Bifurcates Pre-Institution Briefing; Creates New Separate Briefing on Discretionary Considerations (March 27, 2025)

PTAB Issues Additional Information on New Pre-Institution Discretionary Briefing (April 29, 2025)

USPTO Proposes New IPR Rules; Director to Handle Institution Decisions (October 17, 2025)

IP Hot Topic: More Details About Director Institution of AIA Trials — USPTO Hour Webinar Update (October 30, 2025)

Key Takeaways — USPTO Proposes New IPR Rules

BY: JENNIFER MEYER CHAGNON AND MIKE D. WEBB

In October 2025, the U.S. Patent and Trademark Office (USPTO) issued a Notice of Proposed Rulemaking (NPRM) concerning changes to inter partes review (IPR) procedures under the AIA. Along with issuing the NPRM, the USPTO withdrew an earlier April 2024 rule proposal about discretionary denial of institution.

The proposed rules in the NPRM would restrict IPR availability by limiting institution or maintenance of IPRs in certain circumstances:

- "Super" Stipulation Requirement: Institution barred unless petitioner files broad stipulation not to pursue invalidity challenges under 35 U.S.C. § 102 or § 103 in other forums.
- Bars Based on Prior Validity Upholding: Institution barred if another forum (e.g., a court or ITC) has upheld claims under § 102 or § 103, or if the Federal Circuit reverses unpatentability findings. This proposed rule also applies where an ex parte reexamination proceeding upholds the claims.
- Bar if Adjudication Likely Elsewhere: Institution may be barred if it is "more likely than not" that another proceeding (district court or ITC) will occur before the final written decision.

Public comments on the proposed rules were due on December 2, 2025. A USPTO webinar regarding the NPRM has been postponed until 2026.

Key Takeaways

- Potential Limits on IPR Accessibility: Proposed rules could significantly limit IPR use (e.g., requiring "super" stipulations; bars based on prior forum outcomes), potentially making IPRs less available in certain cases.
- Parties should continue to monitor status of the NPRM.

Read USPTO Proposes New IPR Rules; Director to Handle Institution Decisions (October 17, 2025)

Significant PTAB Decisions in 2025

BY: MELISSA A. HAAPALA

2025 was a particularly active year at the Patent Trial and Appeal Board (PTAB) for Director Review and the designation of new precedential and informative decisions. The decisions selected below span a broad range of subject matter and reflect noteworthy PTAB policy on key issues.

Parallel District Court or ITC Proceedings

Hulu, LLC v. Piranha Media Distribution, LLC, IPR2024-01252, Paper 27 (PTAB Apr. 17, 2025) (informative).

Patent owner requested, on Director Review, that the panel institution decision be reversed because the district court entered final judgment that the challenged claims were invalid under 35 U.S.C. § 101. The Acting Director held, in this informative decision, that "the efficiency and integrity of the patent system is best served by denying institution" where a district court has already found the challenged claims invalid.

Motorola Solutions Inc. v. Stellar, LLC, IPR2024-01205, Paper 19 (PTAB Mar. 28, 2025).

This Director Review decision issued soon after the USPTO rescinded the 2022 *Fintiv* memo under which the PTAB did not deny institution if a petitioner filed a stipulation not to pursue in the parallel proceeding the same grounds or any other ground that could have been reasonably raised before the PTAB (*Sotera* stipulation). The Acting Director vacated the panel decision granting institution and determined that Petitioner's *Sotera* stipulation did not outweigh the other *Fintiv* factors, because the stipulation was not likely to moot the more expansive invalidity contentions in district court, which included combinations of prior art with unpublished system art.

Claim Construction

Revvo Tech., Inc. v. Cerebrum Sensor Tech., Inc., IPR2025-00632, Paper 20 (PTAB Nov. 3, 2025) (precedential).

On *sua sponte* Director Review, the Director determined the Board erred by limiting considerations of different claim construction positions to instances that implicate means-plus-function. This precedential decision explains that a petitioner taking alternative positions before the Board and a district court should, at a minimum, explain why the alternative positions are warranted.

Tesla, Inc. v. Intellectual Ventures II LLC, IPR2025-00340, Paper 18 (PTAB Nov. 5, 2025) (informative).

In this Director Review decision, designated informative, Director Squires held that a petitioner's statement that it cannot raise indefiniteness challenges in an IPR is not a sufficient explanation for taking inconsistent claim construction positions before the Board and district court.

Cambridge Mobile Telematics, Inc. v. Sfara, Inc., IPR2024-00952, Paper 12 (PTAB Dec. 13, 2024) (informative).

The Acting Director designated as informative this Board decision that denied institution because Petitioner failed to comply with 37 C.F.R. § 42.104(b)(3). Petitioner argued claim terms should be construed as means-plus-function in district court and argued for plain and ordinary meaning at the PTAB. Under these facts, the Board determined that § 42.104(b)(2) requires the Petition to "identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function." At a minimum, the Board held that the Petition should have explained why the inconsistent positions were warranted or set forth an alternative means-plus-function construction.

Significant PTAB Decisions in 2025 *continued*

§ 325(d)

Ecto World, LLC v. RAI Strategic Holdings, Inc., IPR2024-01280, Paper 13 (PTAB May 19, 2025) (precedential as to § A).

This precedential Director Review decision clarifies the application of 325(d) when a petition relies on asserted prior art submitted on an Information Disclosure Statement (IDS) but not applied by the examiner. Such asserted prior art is sufficient to satisfy the first part of the *Advanced Bionics* two-part framework used by the PTAB for evaluating whether denial under 35 U.S.C. § 325(d) is warranted. The decision then resolves a prior dispute among prior Board panels on the level of analysis required to satisfy part two of the framework and holds that a petitioner must explain, with reference to the precedential *Becton Dickinson* factors, how the examiner erred in overlooking the prior art.

Parallel Petitions

CrowdStrike, Inc. v. GoSecure, Inc., IPR2025-00068, Paper 25 (PTAB June 25, 2025) (informative).

On Director Review, the Acting Director found the Board abused its discretion in granting institution of two petitions challenging the same claims. When a petitioner files two parallel petitions to advance two different claim constructions, the Board should construe the claim term and institute review of, at most, one of the petitions.

314(a) Institution Discretion

Tessel, Inc. v. Nutanix, Inc., IPR2025-00298, Paper 17 (PTAB Aug. 22, 2025).

This Director Review decision determines, under the discretion authority granted by 35 U.S.C. § 314(a), that it "is not an efficient use of Office resources to institute an IPR on a patent where the inventors of that patent now advocate for its unpatentability."

Real Parties in Interest

Corning Optical Comm. RF, LLC v. PPC Broadband, Inc., IPR2014-00440, Paper 68 (PTAB Aug. 18, 2015) (precedential, except for § II.E.1).

This 2015 decision was designated precedential after Director Squires removed the precedential designation from *SharkNinja* — a decision under which the PTAB did not conduct a real party in interest (RPI) analysis unless there was a potential statutory one-year time bar or estoppel that would prevent review. In *Corning Optical*, the Board determined that the petition failed to name all RPIs and, on that basis, granted a motion to dismiss, vacated the institution decision, and terminated the IPR. The Board stated that under 35 U.S.C. § 312(a)(2), "an IPR petition may be considered 'only if' it identifies 'all' real parties-in-interest." Director Squires also issued a memorandum explaining his rationale for the shift in policy, including to prevent misuse of AIA proceedings by foreign adversaries.

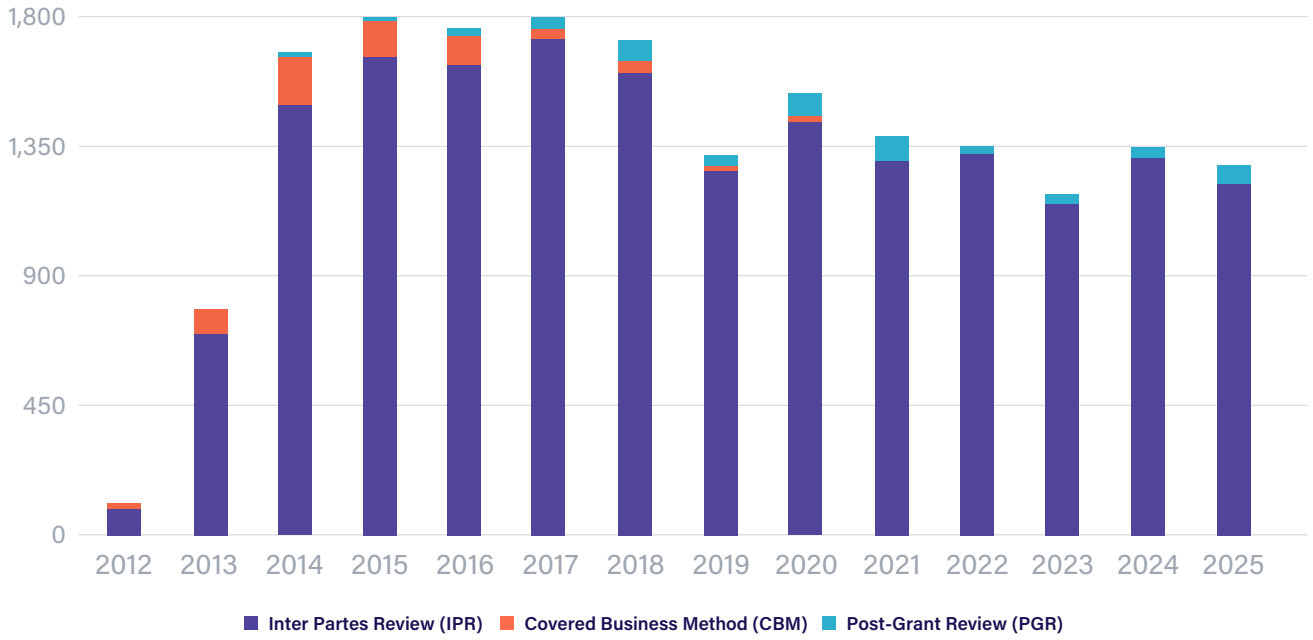
Section 101 & Artificial Intelligence

Ex parte Desjardins, 2024-000567 (PTAB Sept. 26, 2025) (precedential).

An Appeals Review Panel (ARP), consisting of Director Squires, Acting Commissioner Wallace, and Vice Chief Administrative Patent Judge Kim, was convened to review a PTAB panel's decision in an ex parte appeal in which the panel had entered a new ground of rejection under 35 U.S.C. § 101. In a precedential decision that vacated the Board's new ground of rejection, the ARP found the claims were patent eligible because they recited improvements in how a machine learning model operates. The ARP provided guidance that examiners and PTAB panels should not evaluate claims directed to artificial intelligence at such a high level of generality to essentially equate any machine learning with an unpatentable algorithm without adequate explanation.

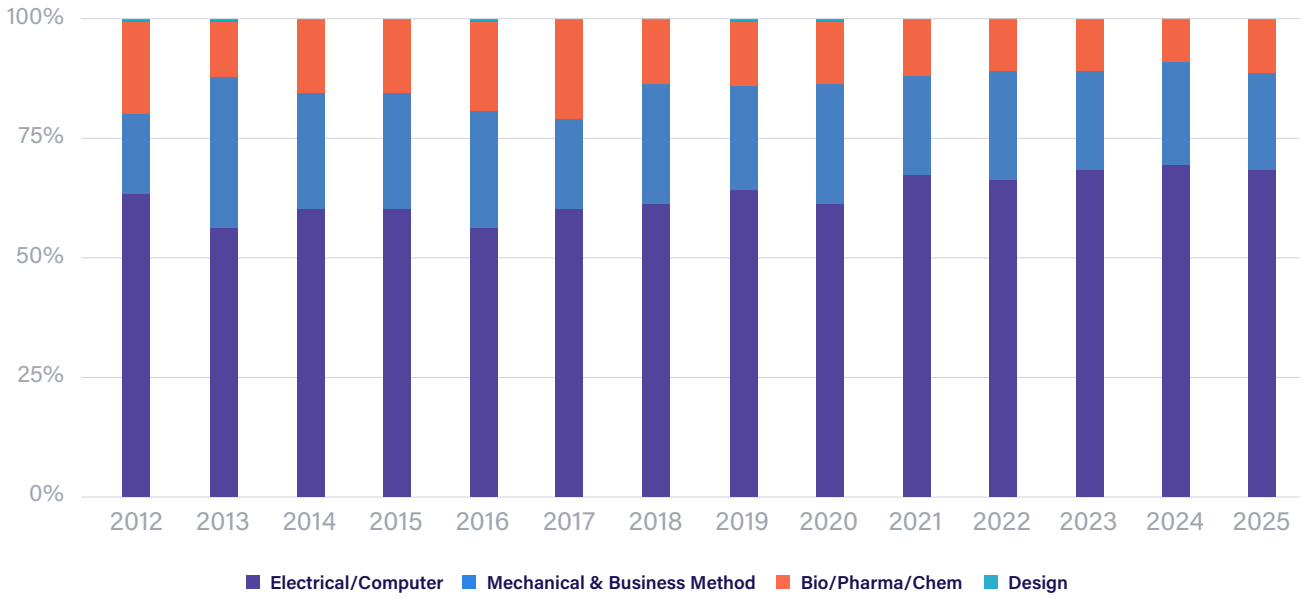
Key 2025 PTAB Statistics

Petitions Filed by Year



1,280 petitions were filed in 2025, but fewer than 200 were filed in Q4, representing a nearly 50% decline from the average number filed in the first three quarters of 2025.

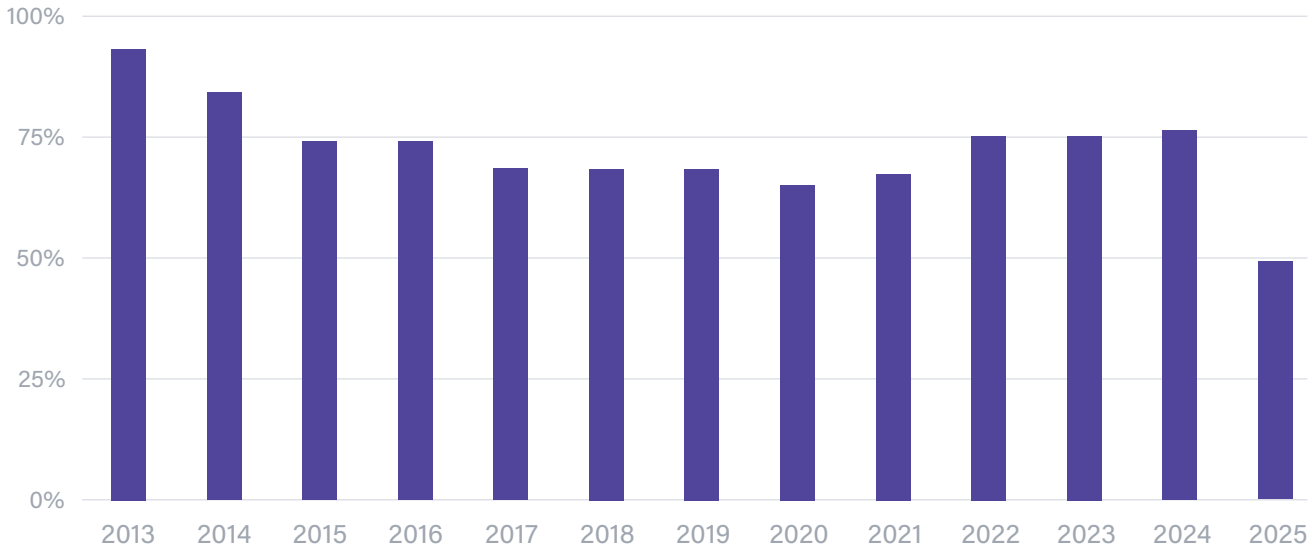
Challenged Patents by Technology



The technology breakdown of challenged patents remained stable in 2025, with 68% of petitions targeting electronics patents, 20% mechanical and business methods patents, 12% life sciences patents, and fewer than 1% challenging design patents.

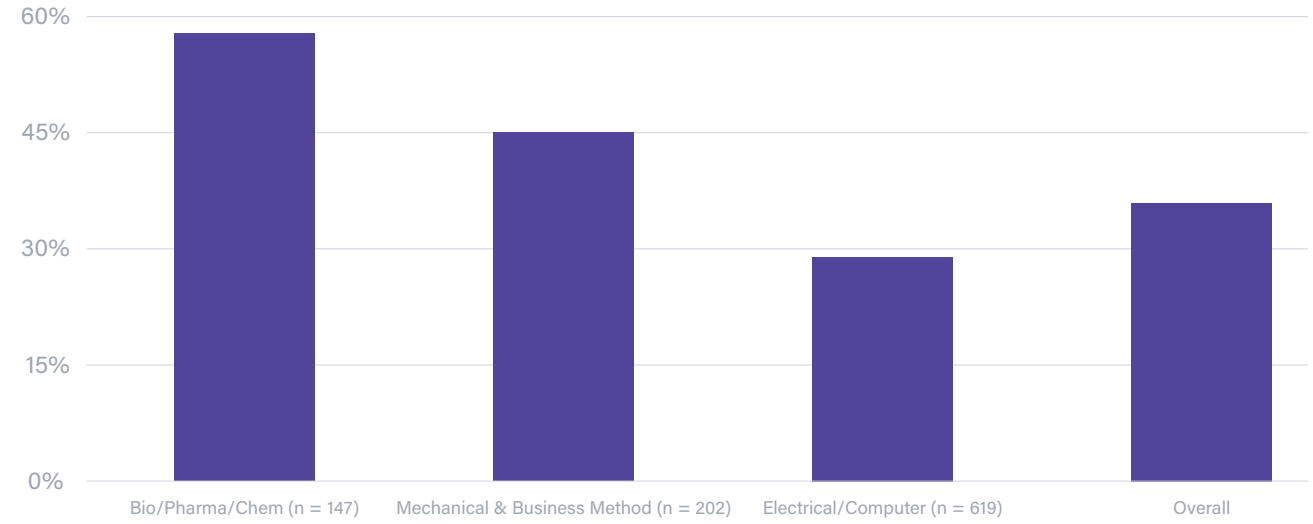
Key 2025 PTAB Statistics *continued*

Proceeding Institution Rate



USPTO policy changes sent institution rates tumbling to an all-time low in 2025. 44% of decisions instituted trial over the course of the year. The institution rate was 37% for the period following the first announcement of changes in late March.

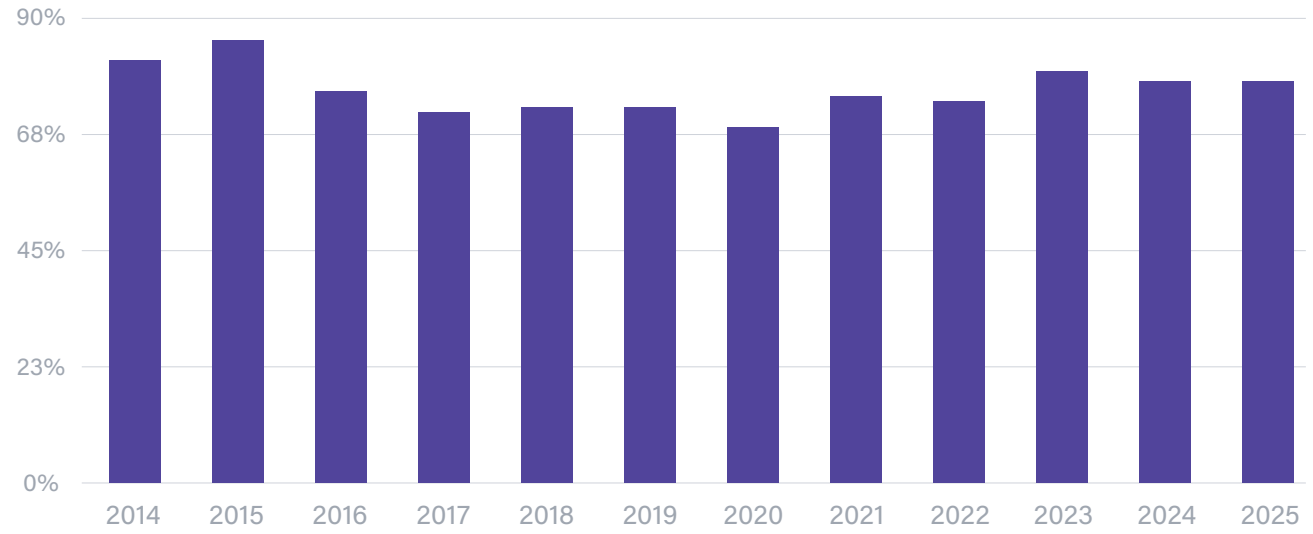
Institution Rate by Technology (March 2025 – December 2025)



Petitions challenging patents in electrical and computer technologies faced the stiffest headwinds to institution after the policy changes in March 2025. Institution outcomes for life sciences petitions were least affected.

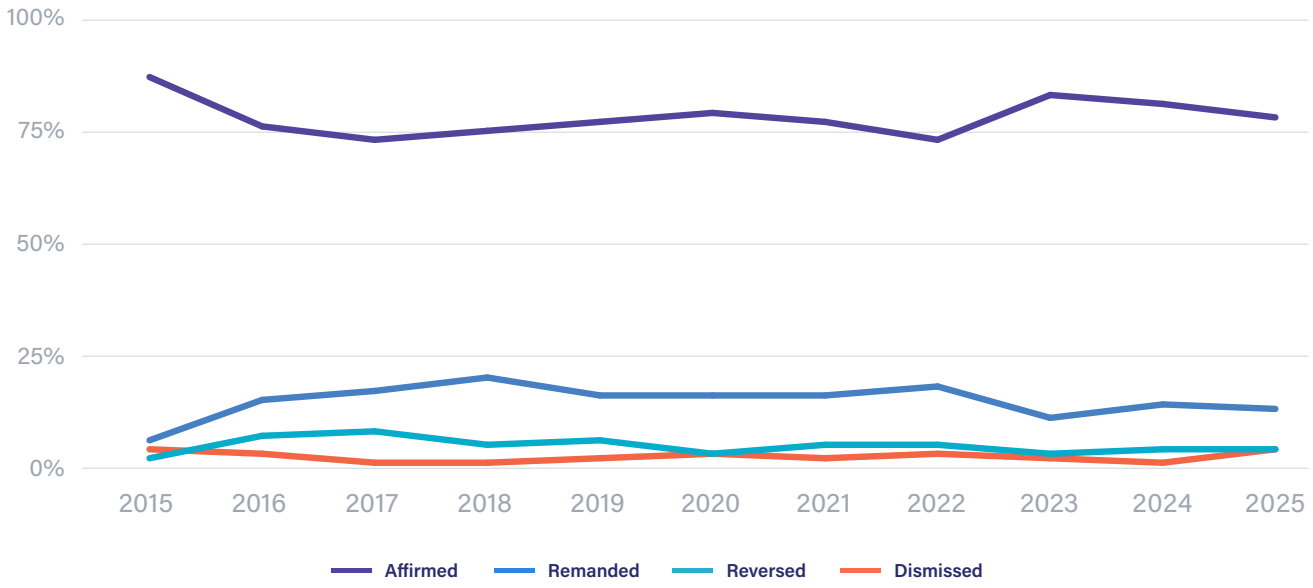
Key 2025 PTAB Statistics *continued*

Claim Cancellation Rate in Final Written Decisions



Unlike the significant changes for institution outcomes, the claim cancellation rate in final written decisions held steady in 2025.

PTAB Trial Appeal Outcomes



The Federal Circuit affirmance rate of IPR and PGR appeals stayed above 75% for the third straight year.

PTAB Trends in 2025: Life Sciences and § 112 at the PTAB

BY: DAVID H. HOLMAN, CHRISTOPHER M. GALLO, AND HANNAH JANKUNIS

In 2025, the Patent Trial and Appeal Board (PTAB) addressed more than 20 post-grant reviews (PGRs) and over 100 ex parte appeals involving issues under 35 U.S.C. § 112 in the life sciences field.[1] This article presents a summary of representative cases.

1. *BeOne Medicines USA, Inc. v. Pharmacyclics LLC*, PGR2024-00009

In April 2025, the Board issued a final written decision in *BeOne Medicines USA, Inc. v. Pharmacyclics LLC*, finding that all challenged claims of U.S. Patent No. 11,672,803 (the '803 patent) were unpatentable due to lack of written description. The challenged claims recited a method for treating chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in an individual comprising administering a therapeutically effective amount of an irreversible inhibitor of Bruton's tyrosine kinase (BTK). *See* PGR2024-00009, Paper 51, at 6-8. In particular, the BTK inhibitors of the claimed methods required certain structural features (e.g., a hydrophobic moiety, piperidine linker, and a generic Z'-structure consisting of a 5:6 heterocyclic ring) and functional features (e.g., administering a "therapeutically effective amount" that results in lymphocytosis). *Id*. at 29-30.

The Board concluded that "the claims encompass a very large number of possible species in light of the various optional substitutions of the Z'-structure." *Id.* at 30. And during trial, Pharmacyclics conceded that the specification did not disclose a representative number of species of BTK inhibitors and argued that "this is a common structural features case." *Id.* The Board, therefore, found that while the '803 patent claimed a broad genus of BTK inhibitors defined by both structural and functional features, the specification did not adequately describe common structural features of the genus. *Id.* According to the Board, even with the claimed structural limitations, the scope of the claims could encompass a "very large" number of species, and the specification had insufficient blaze marks to guide a person of ordinary skill in the art (POSITA) from the disclosed generic structures to the full scope of the Z'-structures that could satisfy the functional limitations of the claims. *Id.* at 30-31, 35.

In reaching its conclusions, the Board also determined that the facts were analogous to those in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019). According to the Board, the '803 patent specification "discloses thousands of potential Z'-structures, but does not explain what makes them effective, or why." Paper 51, at 35-36 (quoting *Idenix* at 1164). The Board also further compared the '803 patent to the patent at issue in *Idenix*, where the accused product arose after the filing date of the patent at issue, because the Z'-structure of Pharmacyclics' later-arising BTK inhibitor, zanubrutinib, was "conspicuously absent" from the '803 patent specification. *Id.* The evidence also showed that "compounds that satisfy the Structural Limitations will not necessarily satisfy the Functional Limitations of the claims." *Id.* at 43.

2. *Charles River Laboratories, Inc. v. Seikagaku Corporation*, PGR2025-00023

In September 2025, the Board instituted a PGR filed by Charles River Laboratories (CRL) against Seikagaku's U.S. Patent No. 11,959,109 (the '109 patent). The '109 patent is directed to "recombinant factor C and method for producing the same, and method for measuring endotoxin," and the challenged claims recite "a method for producing an endotoxin assay agent comprising a horseshoe crab Factor C, Factor B, and Pro-clotting enzyme." PGR2025-00023, Paper 14, at 7. CRL's petition argued that the challenged claims were not entitled to their priority date due to lack of written description and enablement support in the patent's priority applications. With

1 While the PTAB addressed § 112 issues in many other decisions in 2025, this article highlights cases in the life sciences.

PTAB Trends in 2025: Life Sciences and § 112 at the PTAB *continued*

a severed priority claim, CRL argued that the challenged claims were unpatentable as anticipated by an intervening prior art reference. CRL's petition also raised grounds that the challenged claims themselves were unpatentable for lacking written description and enablement in the '109 patent specification.

In its institution decision, the Board concluded that CRL's petition only challenged § 112 support of the '109 patent claims in the '109 patent specification as of the *2013 claimed priority date*, and did not assess written description or enablement as of the *2023 filing date* of the application that led to the '109 patent. *Id.* at 11-14. Relying on *Ariad*, the Board noted that "the person of ordinary skill in the art [in 2013] is not the same as in 2023." *Id.* at 12 (citing *Ariad* at 1351). The Board similarly concluded that the petition "focuses on whether the [priority] application would have enabled a 2013 POSITA to practice the invention," rather than a 2023 skilled artisan. *Id.* at 14. The Board accordingly concluded that the petition did not meet the threshold for institution based on the § 112 patentability challenges. *Id.* at 12-14.

The Board, however, did find that the petition's priority challenge had merit, and that the intervening art reference may anticipate the challenged claims. The Board found that the challenged claims lacked written description and enablement as of 2013 because claim 1 of the '109 patent included proteins from *Limulus polyphemus*, but the gene and sequence information for the Factor C, B, and Pro-clotting enzymes from *L. polyphemus* were not disclosed as of the claimed 2013 priority date. *Id.* at 24. Despite concerns of evidentiary admissibility, even a declaration that recited there was "no reason to believe that *L. polyphemus* Factor C would be difficult to express" was overcome by the fact that Seikagaku's previous efforts to obtain recombinant cascade proteins from *L. polyphemus* had failed. *Id.* at 27-28. Accordingly, the Board determined that Seikagaku failed to meet its burden of production, thus it is preliminarily more likely than not that the '629 publication is prior art over the challenged claims. This PGR is currently awaiting a final written decision, currently due in September 2026.

3. *Ex parte Skiöldebrand,* Appeal No. 2025-000232

In *Ex parte Skiöldebrand*, the Board affirmed the examiner's written description rejections of the pending claims of U.S. Appl. No. 16/309,708 (the '708 application). The '708 application was directed to "compeptide and antibodies thereto for diagnosing osteoarthritis." Pending claim 17 of the '708 application, the only claim on appeal, recited a method of diagnosing early osteoarthritis in a horse comprising contacting an antibody that specifically binds to a nine amino acid-long N-terminal peptide of the horse protein COMP comprising the sequence SGPTH. *See* '708 application File Wrapper, PTAB Decision, issued July 30, 2025, at 2.

The Board agreed with the examiner's finding that the method "requires the use of an antibody defined solely by the antigen it binds." *Id.* at 3. The Board found that the specification thus described a functional genus of antibodies useful in the claimed method "including polyclonal, monoclonal, Fab, Fab, F(ab')2, Fv, and single-chain antibodies, encompassing a variety of different isotypes and specific functional characteristics … that may be produced … using an antigen that is a COMP peptide fragment of at least nine amino acids in length." *Id*. at 5. Because of that, the Board found that even though the appellant's claims were to a method and not to the antibody itself or a genus of antibodies, the '708 application still needed to provide an adequate written description of the genus of antibodies to be used in the claimed method. *Id*. at 6-7.

PTAB Trends in 2025: Life Sciences and § 112 at the PTAB *continued*

Relying on *Ariad v. Eli Lilly*, the Board stated that the '708 application needed to demonstrate possession of species sufficient to support the functionally defined genus. *Id.* at 5 (citing *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1349 (Fed. Cir. 2010) (en banc)). And the Board found that the '708 application failed to do so because the application only identified the structure of the antigen and not sufficient species of antibodies encompassed by the claimed genus. The Board thus emphasized that an applicant must describe the invention itself to meet the written description requirement, and an applicant cannot simply claim a genus of antibodies by describing the antigen to which it binds. *Id*. at 6-7.

4. *Ex parte Krause*, Appeal No. 2025-000513

In *Ex parte Krause*, the Board affirmed the examiner's written description rejection of the pending claims of U.S. Appl. No. 15/639,765 (the '765 application). The claims of the '765 application were directed to methods of cell-based therapy that comprised using pluripotent stem cells (PSCs) comprising a suicide gene under control of a cell-cycle dependent promoter. *See* '765 application File Wrapper, PTAB Decision, issued Oct. 27, 2025, at 2. The examiner initially rejected the claims as lacking written description because, according to the examiner, the specification "discloses a limited number of exemplary genes which may be used as a 'cell cycle dependent promoter' and that the limited number was not representative of the genus." *Id*. at 6.

The Board relied on *Ariad* and focused its analysis on whether the '765 application's specification provided disclosure of a sufficient number of species to support the claimed genus. *Id*. at 8. The Board found that, while the appellant argued that the 70 genes disclosed in the specification constituted a sufficient number of species to fulfill the written description requirement, those 70 genes were not representative of the genus of claimed promoters because the art taught that cell cycle-dependent expression in one type of cell was not predictive of activity in another cell type. *Id*. at 8. Thus, while cell cycle-dependent promoters were well known in the art, the appellant could not rely on that fact because a skilled artisan could not predict whether a given promoter would achieve the claimed function across various cell types. *Id*. at 8-10.

The Board, therefore, ultimately found that the appellant's claim scope outsized the breadth of description in the specification, given the hundreds of potential promoters in the art subsumed by the term "cell-cycle dependent promoters" and the unpredictability in expression between cell types. *Id*.

Conclusion

The foregoing cases represent only a snapshot of PTAB decisions addressing § 112 in patents and applications directed to the life sciences. Despite the swath of recent case law from the Federal Circuit and Supreme Court addressing § 112, the Board still routinely applies cases like *Ariad* and *Idenix* when assessing genus claims, and considers whether the specification discloses a representative number of species or common structural features among the members of the claimed genus. Parties should also be mindful of the critical date for assessing § 112 support in a specification as a priority challenge (measured from the priority date) or as a challenge to patentability (measured from the application's effective filing date).

Strategic Considerations for Post-Grant Challenges at the USPTO Under the New Landscape

BY: JASON EISENBERG, LESTIN KENTON, DOHM CHANKONG, AND PATRICK MURRAY

Acting Director Stewart and new Director Squires have changed the landscape of post-grant practice at the U.S. Patent and Trademark Office.

Several new rules and procedures packages and memos have been circulated since March 2025 that have dramatically affected post-grant strategy by imposing new gates to institution for inter partes and post-grant reviews alongside leadership and procedural changes at the Central Reexamination Unit (CRU). These changes are directed at curtailing the number of Patent Trial and Appeal Board challenges that have resulted in a dramatic decrease in both the number of filings and the success of those filings, while at the same time encouraging an increase in the number of filings at the CRU for reexamination proceedings.

We have captured the substance of these changes in two articles: Does Your Office Post-Grant Strategy Account for the Rise of Serial Challenges Flowing From the PTAB to the CRU? and Part II: Does Your Patent Office Post-Grant Strategy Account for the Rise of Serial Challenges Flowing From the PTAB to the CRU?

These articles provide an overview of the changes and practical strategy decisions that need to be made by patent owners and challengers to optimally navigate the new rules and procedures in place today.

Finally, we captured the statistical view of these changes in a recent article, Reexamination and Central Reexamination Unit — By the Numbers 2025 (Including Reflections on Related PTAB and District Court Proceedings), that shows year-over-year and month-over-month trends of filings and success for all post-grant proceedings at the USPTO.

In the end, PTAB challenges are obtainable for challengers for the right patents and sets of circumstances, and petitioners and patent owners alike need to maintain focus on what those gates are for litigation and defense strategy. Additionally, the CRU has embraced being the main department handling a broad spectrum of challenges and has set up a system to quickly assess the substantial new questions and patentability issues in view of the increased workload for the unit.

Perspectives From Three Former APJs: PTAB's Shifting Landscape in 2025 and Outlook for 2026

BY: JACQUELINE WRIGHT BONILLA, JENNIFER MEYER CHAGNON, AND MELISSA A. HAAPALA

As has been discussed throughout this publication, 2025 was a year of unprecedented change at the Patent Trial and Appeal Board (PTAB). This article discusses the impacts of a few major changes in 2025 from the perspective of three former Administrative Patent Judges (APJs) and offers an outlook for 2026.

A Few Major Changes in 2025

Changes in USPTO Leadership

The year opened with a change in leadership at the top of the U.S. Patent and Trademark Office (USPTO), beginning with the appointment of an Acting Director on January 20, and the swearing in of Director John Squires on September 22. Since February 2025, leadership has implemented, at an unprecedented level, sweeping personnel changes at the executive level throughout the USPTO, including at the PTAB, with nearly no former USPTO executives remaining from December 2024. This loss of institutional knowledge has the potential to cause cascading disruptive effects across the agency in 2026.

Changes to Discretionary Denial Processes and Considerations Have Led to Significantly Lower Institution Rates in AIA Proceedings

In February, the USPTO rescinded a prior 2022 memo related to *Fintiv*,[1] a precedential decision that considers whether to discretionarily deny institution of an inter partes review (IPR) or post-grant review (PGR) based on when a related parallel court may complete its trial.[2] With rescission of the memo, more cases were immediately subject to discretionary denial, including those with parallel ITC proceedings or those in which the petitioner had entered a *Sotera*[3] stipulation.

In March, the USPTO issued a memorandum[4] that bifurcated the process of determining whether to institute an AIA trial. In a first phase, the Director, in consultation with PTAB judges behind the scenes, determined whether discretionary denial was appropriate. Only if not appropriate, in a second phase, a Board panel determined whether to institute based on the merits and other nondiscretionary considerations. The memo discussed discretionary denial considerations generally, including those already existing, but most notably introduced a number of new ones, including, for example, "[s]ettled expectations of the parties, such as the length of time the claims have been in force."[5] Under the new process, overall institution rates decreased to well below historical numbers seen at any time since 2012.[6]

In October, Director Squires issued an "Open Letter"[7] and Guidance Memorandum[8] indicating that he himself, in consultation with PTAB judges behind the scenes, will make all decisions on institution, evaluating both discretionary considerations and the merits. Since that time, the Director has issued decisions in the form of summary notices. At first, the notices merely indicated "thumbs up" or "thumbs down" in a paper listing case numbers.[9] In November, the Director slightly modified the notices to indicate whether cases (1) were discretionarily denied, (2) would be reviewed on the merits, (3) were denied on the

1 Available at: https://www.uspto.gov/about-us/news-updates/uspto-rescinds-memorandum-addressing-discretionary-denial-procedures.

2 *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 (PTAB May 13, 2020) (precedential).

3 *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential as to § II.A).

4 Available at: https://www.uspto.gov/sites/default/files/documents/InterimProcesses-PTABWorkloadMgmt-20250326.pdf ("Interim Process Memo").

5 Interim Process Memo, 2; see also *iRhythm Tech. v. Welch Allyn, Inc.*, IPR2025-00363, Paper 10 (determining patent owner's settled expectations favored denial based on the time the patent had been in force).

6 *See e.g.*, PTAB Trial Statistics, 5 (Nov. 2025), available at: https://www.uspto.gov/sites/default/files/documents/Trial_Stats_November_2025.pdf.

7 Available at: https://www.uspto.gov/sites/default/files/documents/open-letter-and-memo_20251017.pdf.

8 Available at: https://www.uspto.gov/sites/default/files/documents/Director_Institution_of_AIA_Trial_Proceedings.pdf.

9 *See, e.g.*, October 31, 2025, Notice of Decisions on Institution, available at IPR2025-01014, Paper 14 (Squires Oct. 31, 2025), amended at Paper 15 (Squires Nov. 20, 2025).

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merits, or (4) were instituted.[10] The USPTO has indicated the Director may issue more fulsome decisions if they relate to "novel or important" issues; thus far, few such decisions have issued.[11] Again, institution rates under this process have stayed well below historical numbers.

For example, statistics as of December 31, 2025, show that, under this Director-led process, approximately 43% of cases have been discretionarily denied, 6% of cases await review on the merits, 18% of cases have been denied on the merits, and 33% of cases have been instituted. In 2026, we may see institution rates tick up slightly as we reach a steady state of decisions coming out of the new process.

Regardless, this new Director-led process represents a significant change. Prior to 2025, for over 13 years, PTAB panels determined whether to institute in detailed decisions that provided substantial reasoning and information. The current process may leave many parties with minimal insight as to what to do in the aftermath. For example, a summary notice to institute a trial gives both parties minimal insight to inform strategy, e.g., in terms of the Office's views on claim construction, the strength or weakness of certain grounds, evidence, and the applicability of prior art. A patent owner also may lack enough information to decide whether to file a motion to amend, or to perhaps request reexamination or file a reissue application. Summary notices also provide no information as to how parties should best prepare a request for Director Review of a decision on institution.

Pending Notice of Proposed Rulemaking (NPRM) on IPR Institution

In October, the Office issued an NPRM[12] proposing new rules that, if implemented as proposed, represent a fundamental change to institution criteria that will significantly restrict the availability of IPRs. Comments were due on December 2, 2025, and the USPTO received more than 11,400 comments, with over 2,800 of them being unique. Consideration of those comments and the rulemaking process will continue into 2026.

Outlook for 2026

Looking ahead to 2026, if the USPTO maintains its current trajectory of policies, the availability of IPRs as a vehicle to challenge patent validity is likely to be more limited than has historically been the case. Even so, IPRs and PGRs will remain an important strategic consideration — from the viewpoint of both patent owners and potential patent challengers.

Petitioners can likely expect continued hurdles at the discretionary denial stage. They may want to move quickly when there is a parallel proceeding and to consider potential responses to discretionary arguments early, even before filing an IPR petition. If institution appears unlikely, petitioners may want to consider alternative routes to challenge patent claims, such as ex parte reexamination. In the right circumstances, however, there is a path to institution.

Patent owners can likely expect continued success in winning challenges at the PTAB early. The Office has been receptive to new types of arguments, so patent owners should continue to be creative in presenting reasons why institution should be denied. Patent owners also should anticipate that defendants may challenge the validity of

10 *See, e.g.*, December 11, 2025, Notice of Decisions on Institution, available at IPR2025-01170, Paper 14 (Dec. 11, 2025).

11 *See, e.g.*, *Ford Motor Co. v. AutoConnect Holdings LLC*, IPR2025-01342, Paper 10 (Squires Dec. 4, 2025); *Caption Health, Inc. v. The Univ. of British Columbia*, IPR2025-01422, Paper 15 (Squires Dec. 18, 2025).

12 Revision to Rules of Practice Before the Patent Trial and Appeal Board, 90 Fed. Reg. 48335, available at: https://www.govinfo.gov/content/pkg/FR-2025-10-17/pdf/2025-19580.pdf.

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claims in ex parte reexamination, either after a denial of institution or in the first instance.

The full impact of many of the changes implemented in 2025 is yet to be seen. For example, new mandatory prehearing conferences will start occurring later in 2026 as trials implemented under the new process get to the hearing stage. And it remains to be seen how final written decisions will be impacted in many cases where the briefing and arguments are made by parties that had no early guidance from the panel or Director.

In addition, because IPRs may remain limited (at least in the near term), parties can likely expect an increase in both district court and ITC litigation and challenges to claim validity in those forums.

The only certainty in our outlook for 2026 is that more change will come. It is critically important now more than ever for stakeholders to remain up to speed on the ever-changing procedures and guidance coming out of the PTAB. Over the past 13 years, the pendulum has continued to swing regarding policies related to PTAB and AIA practice. We expect it will continue to do so in 2026, and parties should be prepared to navigate shifting landscapes, especially because the full impact of many of the 2025 changes is yet to be seen. That said, we are hopeful that the Office will provide transparency, consistency, and predictability to stakeholders as processes and procedures continue to evolve.

About Sterne, Kessler, Goldstein & Fox

Based in Washington, D.C., Sterne Kessler is one of the world's leading intellectual property law firms, specializing in the full range of IP services globally. We are passionate about IP law, with a unique combination of legal acumen and technical experience across both prosecution and litigation. With more than 200 attorneys, patent agents, and technical specialists across the firm, we are committed to delivering practical, business-driven solutions that support our clients' innovation and long-term objectives. For over 45 years, we have been a trusted partner to the world's most innovative companies and inventors, helping them protect, enforce, and maximize the value of their IP around the globe.

Our highly integrated IP practice focuses on patent prosecution and strategic counseling, post-grant proceedings, litigation in federal district and appellate courts and before the International Trade Commission, and trademark prosecution and enforcement. Our clients include Fortune 500 companies, entrepreneurs, start-ups, inventors, venture capital firms, and universities that are making discoveries, building brands, and creating inventions that impact our daily lives.

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