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2025

# Federal Circuit IP Appeals

SUMMARIES OF KEY 2025 DECISIONS | 10TH EDITION

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# Introduction

This past year was an exciting one at the Federal Circuit. The court's decision in *EcoFactor v. Google* — concerning the standard for admissibility of expert testimony on damages — marks its first en banc decision in a utility patent case since 2018. In *Lashify v. International Trade Commission*, the court clarified the standard an ITC complainant must satisfy to meet the economic prong of the domestic industry requirement. In *Global Health Solutions v. Selner*, the court issued its first decision on review from an America Invents Act (AIA) derivation proceeding. And in *Shockwave Medical v. Cardiovascular Systems,* the court addressed the thorny issue of how applicant-admitted prior art may be used as part of an obviousness argument in an inter partes review (IPR). This edition of our Federal Circuit review covers these cases and more, canvassing over a dozen of this year's most impactful decisions in appeals from the Patent Trial and Appeal Board (PTAB), the Trademark Trial and Appeal Board (TTAB), district courts, and the ITC.

Turning to the statistics, the number of appeals from the U.S. Patent and Trademark Office (USPTO) and district courts fell in 2025, continuing a decade-long trend of fewer appeals from these most common origins. Median appeal pendency rose again this year, largely due to increased lag between submission of the joint appendix and calendaring of oral argument.

Appellate results continued to heavily favor appellees in appeals from all fora, especially the USPTO. Overall, the affirmance rate in 2025 was approximately 70%. The court affirmed USPTO decisions at a rate of nearly 80%. Rule 36 affirmance rates were substantially lower this past year (17% in 2025 versus approximately 30% in the years 2020-2024), with a corresponding increase in the rate of both precedential and nonprecedential opinions.

The summaries and statistics in this review are the results of a collaborative process. We want to thank our co-authors — Jacqueline Wright Bonilla, Jennifer Chagnon, Richard Crudo, Melissa Haapala, Kristina Caggiano Kelly, Anna Phillips, Trey Powers, Deirdre Wells, Ryan Kaiser, and Bridget Moore. We'd also like to thank Patrick Murray for his contributions to the data and statistics.

We appreciate your interest in this report, now in its 10th year. And we encourage you to explore our firm's other 2025 year-in-review reports and on-demand webinars, available at sternekessler.com or by request. Please feel free to reach out if you have questions about this report or wish to discuss the future of Federal Circuit appeals.

**William H. Milliken**
Director

**Michael Joffre**
Director

# Editor & Authors

## Editor

**William H. Milliken, Director**
wmilliken@sternekessler.com

## Authors

**Jacqueline W. Bonilla, Ph.D., Director**
jwrightbonilla@sternekessler.com

**Jennifer Meyer Chagnon, Director**
jchagnon@sternekessler.com

**Richard Crudo, Director**
rcrudo@sternekessler.com

**Melissa Haapala, Director**
mhaapala@sternekessler.com

**Michael Joffre, Director**
mjoffre@sternekessler.com

**Kristina Caggiano Kelly, Director**
kkelly@sternekessler.com

**Anna G. Phillips, Director**
aphillips@sternekessler.com

**R. Wilson "Trey" Powers III, Ph.D., Director**
tpowers@sternekessler.com

**Deirdre M. Wells, Director**
dwells@sternekessler.com

**Ryan N. Kaiser, Associate**
rkaiser@sternekessler.com

**Bridget Moore, Law Clerk**
bmoore@sternekessler.com

## Use of Applicant Admitted Prior Art (AAPA) in IPRs: *Shockwave Med., Inc. v. Cardiovascular Sys., Inc.*, 142 F.4th 1371 (Fed. Cir. 2025) (Lourie, Dyk, and Cunningham)

BY: JACKIE W. BONILLA

"Applicant admitted prior art," or AAPA, refers to when an applicant in a patent specification admits that certain subject matter is known in the prior art. The Federal Circuit decided cases in 2025 addressing the issue of how AAPA may be used as part of an obviousness argument in an inter partes review. Specifically, the Federal Circuit addressed whether and how IPR petitioners may use AAPA, along with prior art patents, in an unpatentability ground. 35 U.S.C. § 311(b) provides that a petitioner may raise a ground in an IPR only "under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications."

For example, *Shockwave* addressed an obviousness ground in an IPR petition that relied on a patent publication "as modified by AAPA" in combination with other prior art references. The Board found claims unpatentable after "relying on AAPA only as evidence of the background knowledge in the art."

The Federal Circuit affirmed. The petitioner in *Shockwave* did not expressly state that AAPA formed the "basis" of its ground, but instead used AAPA only to show that certain technology was well known in the prior art. Petitioner argued that this general background knowledge was sufficient to meet claim limitations relating to that technology.

The Federal Circuit stated that its "case law has long recognized numerous permissible uses for general background knowledge in an IPR such as, 'for example, furnishing a motivation to combine, or supplying a missing claim limitation.'" Applying that precedent, the court held that it is permissible for general knowledge, as evidenced in AAPA, to supply a missing claim limitation in a ground in an IPR petition. Here, the petitioner properly relied on general background knowledge to supply missing claim limitations (which the patent owner did not argue were novel to the invention) and used AAPA as evidence to establish that general background knowledge.

Interestingly, two weeks later, on July 31, 2025, the then-Acting U.S. Patent and Trademark Office (USPTO) Director issued a guidance memorandum on AAPA that superseded prior USPTO memoranda on the issue. The July 2025 memo states that AAPA, expert testimony, common sense, and other evidence "that is not 'prior art consisting of patents or printed publications' (collectively, 'general knowledge')" may not be used to supply a missing claim limitation. This statement appears to diverge from Federal Circuit decisions, including *Shockwave*, holding that general background knowledge, as evidenced by AAPA, for example, *can* supply a missing claim limitation.

The July 2025 memo further states that, going forward, the USPTO will not "waive" the requirements of 37 C.F.R. § 42.104(b)(4), which provides that an IPR petition "must specify where each element of the claim is found in the prior art patents or printed publications relied upon." The memo cites *Shockwave* in a footnote and states that "[w]hile Rule 104(b)(4), as applied in some cases, may be narrower than 35 U.S.C. § 311(b), enforcing Rule 104(b)(4) is the best course of action to provide certainty to the parties, the Board, and the public, and to allow for the efficient administration of the Office." The memo does, however, note that "general knowledge," which presumably includes that established by AAPA, may still be used in an IPR to support a motivation to combine or to demonstrate the knowledge of a skilled artisan.

## *Bayer Pharma Aktiengesellschaft v. Mylan Pharmaceuticals Inc.*, 152 F.4th 1400 (Fed. Cir. 2025) (Moore, Cunningham, Scarsi[1])

BY: BRIDGET MOORE

Pharmaceutical companies developing a method of treatment often simultaneously seek patent protection and U.S. Food and Drug Administration (FDA) approval for the method. Balancing clinical trials with the timing of the initial patent application is crucial, as publications describing the clinical trial protocol risk becoming prior art and invalidating the claimed method. That is what happened with Bayer's anticoagulant drug Xarelto (rivaroxaban).

Bayer's '310 patent described the results of a Phase III clinical trial evaluating the safety and efficacy of administering rivaroxaban with aspirin to prevent major adverse cardiovascular events among patients with cardiovascular disease. The clinical trial protocol and claimed regimen were published in an academic journal prior to conclusion of the study and filing of the patent application. The results of the study, however, were not in the prior art.

Mylan, Teva, and Invagen jointly challenged the '310 patent in an inter partes review, relying in part on the prior art disclosure of the clinical trial protocol. The relevant claim recited a method of administering rivaroxaban and aspirin in amounts that are "clinically proven effective" for reducing the risk of adverse cardiac events and further specified a regimen of 2.5 mg rivaroxaban twice daily and 75–100 mg aspirin daily.

Bayer argued the "clinically proven effective" language distinguished the claims from the clinical trial protocol because the results of the study were not known in the prior art. The Patent Trial and Appeal Board (PTAB) disagreed, finding that the "clinically proven effective" element was nonlimiting and was, in any event, inherently disclosed by the prior art disclosure of the protocol.

The Federal Circuit affirmed on alternative grounds. The court declined to decide if the phrase "clinically proven effective" was limiting or inherently anticipated and instead held that it was "a functionally unrelated limitation that fail[ed] to make the claims patentable." The court expressed concern that a contrary holding would create the potential for "indefinite patenting of known methods through the addition of novel, yet functionally unrelated limitations." In reaching this conclusion, the court relied on *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010), which held that an otherwise anticipated method of treatment was not made patentable by the addition of an instructional limitation requiring informing the patient about the treatment. The "clinically proven effective" limitation, the court found — like the "informing" step in *King* — could not make the claims patentable because it lacked a new and nonobvious functional relationship with the remaining steps of the claimed method. In other words, the limitation in question "in no way transform[ed] the process of taking the drugs at the amounts and frequencies expressly recited in the claims." The court also observed that the "clinically proven effective" limitation was no different in substance from a limitation specifying an accolade like "Best Drug of 2026."

Given that conclusion, the court also rejected Bayer's reliance on unexpected results as a secondary consideration of nonobviousness. Bayer had argued that the success of the clinical trial was unexpected. But, because the "clinically proven effective" limitation was not entitled to patentable weight, that evidence lacked any nexus to "the merits of the claimed invention."

1 Honorable Mark C. Scarsi, District Judge, United States District Court for the Central District of California, sitting by designation.

## *Bayer Pharma Aktiengesellschaft v. Mylan Pharmaceuticals Inc.*, 152 F.4th 1400 (Fed. Cir. 2025) (Moore, Cunningham, Scarsi) *continued*

**Related:**

***Top Brand LLC v. Cozy Comfort*, 143 F.4th 1349 (Fed. Cir. 2025)** (applying prosecution history disclaimer to narrow claims of design patent on an enlarged oversized garment with a marsupial pocket because applicant had focused on specific design features in response to examiner's rejection and thereby clearly surrendered claim scope).

***Maquet Cardiovascular LLC v. Abiomed Inc.*, 131 F.4th 1330 (Fed. Cir. 2025)** (declining to find prosecution history disclaimer in construing claims related to positioning a lumen within an intravascular blood pump because, while the patentee had disclaimed claim scope when prosecuting the patent's parent application, the claims at issue were not "sufficiently similar" to the parent claims "such that the prosecution history of the latter would be relevant when construing the former").

***In re Xencor, Inc.*, 130 F.4th 1350 (Fed. Cir. 2025)** (holding that the preamble to a Jepson claim must be supported with adequate written description in the specification, and affirming the PTAB's finding that the Jepson claim preamble at issue lacked written description support).

## *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333 (Fed. Cir. 2025) (en banc) (Moore)

BY: ANNA G. PHILLIPS

*EcoFactor* — the Federal Circuit's first en banc decision in a utility patent case since 2018 — addressed the standard for admissibility of expert testimony on damages.

In June 2024, a split panel (Judges Lourie and Reyna, with Judge Prost dissenting) had affirmed the district court's denial of Google's motion for a new trial on damages. Google petitioned for rehearing en banc. It argued that the opinion of EcoFactor's damages expert, David Kennedy, which arrived at a per-unit royalty rate based on settlement agreements between EcoFactor and three competitors, was unreliable and therefore inadmissible. The court granted Google's petition and ordered briefing limited to "the district court's adherence to Federal rule of Evidence 702 and *Daubert* … in its allowance of testimony from EcoFactor's damages expert assigning a per-unit royalty rate to the three licenses in evidence in this case."

As an initial matter, the Federal Circuit (applying Fifth Circuit law) held that the district court abused its discretion in failing to explain its reasoning for rejecting Google's *Daubert* challenge to Mr. Kennedy's opinion. The court went on to conclude that the trial court also failed to satisfy its Rule 702 "gatekeeping role" by admitting Mr. Kennedy's damages opinion because "the relevant evidence [was] contrary to a critical fact upon which the expert relied."

Mr. Kennedy had offered a reasonable royalty opinion based on a hypothetical negotiation under the well-accepted *Georgia Pacific* framework, which "attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began." Mr. Kennedy considered three lump-sum settlement licenses involving the asserted patents between EcoFactor and licensees Daikin, Schneider, and Johnson, and concluded that the lump-sum amounts in those three licenses reflected an $X per unit rate applied to each of the licensee's sales.

The en banc majority concluded that these licenses were insufficient to support Mr. Kennedy's conclusion. For one, each of the licenses recited only that "*Ecofactor represents* that it has agreed to the payment set forth in this Agreement based on what *Ecofactor believes* is a reasonable royalty calculation of $[X] per-unit for estimated past and [licensee's] projected future sales of products accused of infringement in the Litigation." The Daikin and Schneider licenses also stated that "[s]uch [a lump-sum] amount is not based upon sales and does not reflect or constitute a royalty," and the Schneider license further stated that "nothing in this clause should be interpreted as agreement by Schneider that $[X] per unit is a reasonable royalty." The Federal Circuit concluded that these latter passages "directly contradict[] any claim that the lump-sum is based upon any particular royalty rate or even that it is based upon sales volume" and that none of the licenses reflected the *licensees*' agreement to pay the $X royalty rate.

The court rejected EcoFactor's argument that other record evidence supported Mr. Kennedy's opinion. EcoFactor's CEO Shayan Habib had testified that the lump-sum payment for each license was based on the licensee's past and future projected sales using the $X per unit rate. Mr. Habib had not seen any licensee sales data but explained that his conclusion was based on his "general understanding" of the relevant industry. The majority dismissed Mr. Habib's testimony as "an unsupported assertion from an interested party" that could not serve as a "sufficient factual basis for Mr. Kennedy to provide a reliable opinion that the licensees agreed to pay the $X rate." EcoFactor had also relied on the Johnson license, which applied the $X rate and lacked the language disavowing the $X rate from the lump sum amount. But the court dismissed this argument too because Mr. Kennedy relied on the three licenses collectively to provide a royalty rate,

## *EcoFactor, Inc. v. Google LLC*, 137 F.4th 1333 (Fed. Cir. 2025) (en banc) (Moore)

*continued*

not any of the licenses individually. When evaluating the sufficiency of an expert's opinion, the majority reasoned, a court must examine the evidence on which the expert relied, not the record evidence as a whole.

The majority also found that the admission of Mr. Kennedy's testimony was not harmless error. The $X rate was "crucial to Mr. Kennedy's damages analysis," as (in his telling) it was both the starting point and end point of the parties' hypothetical negotiation.

Judges Reyna and Stark both filed dissents on the damages issue (each of which the other joined).

Judge Reyna, who had authored the panel decision, believed the majority had exceeded the scope of the court's grant of en banc review by focusing exclusively on contract interpretation. This changed approach deprived EcoFactor of notice and the opportunity to be heard. Judge Reyna also disagreed with the majority's harmless-error analysis, reasoning that Mr. Kennedy's opinion, even if inadmissible, was "wholly duplicative of properly admitted evidence," such as Mr. Habib's unobjected-to testimony regarding the $X rate as EcoFactor's "baseline policy," his understanding that each of the licensees accepted the $X rate, his testimony regarding the parties' relative market share, and the licenses themselves. Finally, Judge Reyna contended that the entirety of Mr. Kennedy's opinion need not be struck because the majority disagreed with but one portion of Mr. Kennedy's overall analysis: *Georgia-Pacific* factor one, "[t]he royalties received by the patentee for the licensing of the patent in suit." And the majority had acknowledged that the licenses showed the rate that EcoFactor sought as a willing licensor.

Judge Stark wrote to emphasize the narrow scope of the majority's holding and to reiterate that it is within the jury's purview to decide disputed facts. He explained that the majority's holding is limited to situations where "the relevant evidence is *contrary to a critical fact* upon which the expert relied." Judge Stark stated that, if an expert relies on *disputed* facts in rendering an opinion, that opinion is not necessarily insufficient — it merely shows that there is a factual dispute that requires resolution by the "proper factfinder."

Judge Stark also disagreed that the district court's failure to provide its rationale for admitting Mr. Kennedy's testimony was an abuse of discretion. And Judge Stark believed that, even if the district court had erred on that front, Judge Stark believed that the proper remedy "would be to vacate and remand for a better explanation from the district judge, not order him to conduct a new trial."

### Related:

***Rex Medical, L.P. v. Intuitive Surgical, Inc.*, 156 F.4th 1289 (Fed. Cir. 2025)** (excluding damages expert's testimony about a license for failure to apportion and affirming nominal damages award because the record lacked evidence to support the jury's award).

## *Global Health Sols. LLC v. Selner*, 148 F.4th 1363 (Fed. Cir. 2025) (Stoll, Stark, Goldberg[1])

BY: JENNIFER MEYER CHAGNON

The America Invents Act (AIA) changed the U.S. patent system from a first-to-invent system to a first-to-file system. Thus, under the AIA, a first inventor is generally not entitled to a patent if a second inventor files his application first. However, a first-inventor second-filer may still obtain a patent if the first filer derived the invention from the second filer. These challenges are pursued at the Board in a new proceeding created by the AIA called a "derivation proceeding." *Global Health Solutions* (GHS) was the Federal Circuit's first review of a Patent Trial and Appeal Board (PTAB) decision in such a proceeding.

GHS filed a derivation petition against Selner's U.S. patent application. The claims at issue were directed to methods of preparing a wound treatment ointment. Selner was the first filer. GHS contended that its inventor, Burnam, was the first inventor, and that Selner derived the invention from Burnam. The PTAB determined that Burnam conceived the invention and communicated it to Selner via email by the afternoon of Feb. 14, 2014, but that Selner had proven earlier conception of the invention because he had sent an email to Burnam earlier that day describing the invention. The PTAB thus ruled in Selner's favor.

The Federal Circuit affirmed. It first clarified the similarities and differences between pre- and post-AIA derivation claims. Prior to the AIA, a party asserting derivation had to establish (1) conception prior to the adverse claimant's conception and (2) communication to the adverse claimant. In an AIA derivation proceeding, a petitioner also must show prior conception and communication, but the inquiry "centers on whether the petitioner conceived and communicated the invention before the respondent *filed his application*." A "respondent can overcome the petitioner's showing by proving independent conception prior to having received the relevant communication from the petitioner." The respondent does *not* need to prove conception prior to the petitioner's *conception*. This is because "under the AIA ... the inventor who files first will retain patent rights as long as he did not derive his claimed invention from another." The court also noted in a footnote that it was not deciding what burden of proof applies in addressing these questions because neither party raised the issue on appeal.

The PTAB, the Federal Circuit explained, had incorrectly focused on whether Selner was the first to invent rather than whether his conception was independent. But this was harmless error because "in finding Selner was the *first*-to-invent, the Board also indirectly determined that he *independently* conceived and, thus, did not derive his invention from Burnam."

The court addressed but rejected the arguments GHS made on appeal. First, the court rejected GHS' argument that there was insufficient corroboration of Selner's claim of inventorship. A "rule of reason test is used to determine whether an alleged inventor's testimony is sufficiently corroborated." The court agreed with the PTAB that the emails retrieved from Selner's web-based AOL email account were "documentary evidence generated contemporaneously with the inventive process" that sufficiently corroborated Selner's claim. The court found that the "emails, whose authenticity is not challenged, do not require independent corroboration," and that in any event the email metadata was "independent of Selner's own statements and documents" and thus independently corroborative.

Second, the court rejected GHS' argument that the PTAB improperly shifted the burden to GHS to disprove Selner's conception. The PTAB, the court concluded, considered the evidence, determined that Selner had proven conception, and did not shift the burden to GHS to prove otherwise.

1 Honorable Mitchell S. Goldberg, District Judge, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

## *Global Health Sols. LLC v. Selner*, 148 F.4th 1363 (Fed. Cir. 2025) (Stoll, Stark, Goldberg) *continued*

Third, the court rejected GHS' argument that the PTAB erred by not requiring Selner to prove that he had reduced the invention to practice. The court found that substantial evidence supported the PTAB's factual findings that Selner was "able to define [the invention] by its method of preparation" and had formed "a definite and permanent idea of the complete and operative invention." Namely, Selner's email "explained the invention in detail to Burnam" and was sufficient to prove conception without a showing of reduction to practice.

Finally, the court determined that GHS had not preserved its alternative request that inventorship be corrected to name Burnam as a joint inventor because it had not followed the procedures required by the PTAB to do so.

**Related:**

***Regents of the U. of California v. Broad Inst., Inc.*, 136 F.4th 1367 (Fed. Cir. May 12, 2025)** (in an appeal from an interference proceeding, holding that the PTAB legally erred by conflating the distinct legal standards for conception and reduction to practice, that proving conception does not require proof that the inventor knows the invention will work, and that the PTAB erred by "failing to consider routine methods or skill" for achieving reduction to practice).

## *In re Brunetti*, 151 F.4th 1367 (Fed. Cir. 2025) (Lourie, Dyk, Reyna)

BY: DEIRDRE M. WELLS

Erik Brunetti filed intent-to-use trademark registration applications seeking registration of the standard character mark FUCK on the principal register. The applications were initially refused on the ground that the proposed mark consisted of "immoral" or "scandalous" matter. Brunetti successfully challenged the basis for one of the initial rejections before the Supreme Court, which held the U.S. Patent and Trademark Office's (USPTO) bar on registering immoral or scandalous matter unconstitutional. *Iancu v. Brunetti*, 588 U.S. 388, 390 (2019).

On reexamination, the examining attorney refused the trademark applications on the ground that FUCK is a slogan or term that does not function to indicate the source of Brunetti's goods or services or to distinguish them from others' goods or services. The examining attorney explained that FUCK is a commonplace term or expression that is widely used by a variety of sources and merely conveys an ordinary, familiar, well-recognized concept or sentiment. Brunetti appealed the examining attorney's rejection to the Trademark Trial and Appeal Board (TTAB), which affirmed the refusals to register because the applied-for term failed to function as a trademark.

Brunetti appealed to the Federal Circuit. He made a variety of arguments, most of which the Federal Circuit rejected. However, the Federal Circuit ultimately vacated and remanded because it concluded that the TTAB failed to articulate a satisfactory explanation for its action.

## *In re Brunetti*, 151 F.4th 1367 (Fed. Cir. 2025) (Lourie, Dyk, Reyna) *continued*

Quoting the Lanham Act — which governs the registrability of trademarks — the Federal Circuit noted that it is a threshold requirement of registrability that an applied-for mark "identify and distinguish" the goods and services of the applicant from those of others, as well as "indicate the source" of those goods and services. The court stated that to distinguish one's goods or services from another's — and thus be a registerable trademark — the proposed mark must therefore be distinctive, either inherently or through the acquisition of secondary meaning.

Brunetti argued that the USPTO was acting arbitrarily by allowing registrations of some all-purpose word marks while denying registration of others, including his registrations for the word FUCK, without any explanation as to the difference. He pointed, for example, to the USPTO's registration of marks with other common words, such as LOVE and even other marks using the term FUCK.

While the Federal Circuit agreed with the USPTO that it need not reconcile all past cases with the case under consideration, the court concluded that the decision here was insufficiently reasoned to permit judicial review under the Administrative Procedure Act. In particular, the TTAB had failed to articulate a coherent rule regarding failure-to-function refusals that took account of past decisions on this issue. Instead, it had adopted an "'I know it when I see it' approach to failure-to-function refusals." The court therefore vacated the TTAB's decision and remanded for a clearer explanation of the basis for its decision.

Judge Lourie dissented. While he agreed with the majority that there were shortcomings in the TTAB's analysis of the failure-to-function issue, he did not view this case as a close call. Judge Lourie reasoned that, "[b]ecause of its ubiquity, consumers cannot specifically associate the word [FUCK] with Brunetti's brand."

## *In re Entresto*, 125 F.4th 1090 (Fed. Cir. 2024) (Lourie, Prost, Reyna)

BY: RICHARD A. CRUDO

Novartis markets and sells Entresto, a combination therapy of valsartan and sacubitril for treating heart failure. After MSN Pharmaceuticals and others sought U.S. Food and Drug Administration (FDA) approval to sell generic versions of the drug, Novartis sued them for infringement of a patent directed to a pharmaceutical composition of valsartan and sacubitril administered "in combination."

MSN initially sought a construction of the phrase "in combination" excluding a valsartan-sacubitril "complex" — i.e., a noncovalently bonded form of the two compounds, which had not been discovered until four years after the patent's priority date (and which was covered by Novartis' later-filed patents). The district court rejected that construction, holding that "in combination" should receive its plain and ordinary meaning. Based on that construction, MSN stipulated to infringement since its generic drug comprised a valsartan-sacubitril complex. Following a bench trial, the district court held that the patent claims were invalid for lack of written description since the specification does not describe a complex. But the district court rejected MSN's enablement challenge, reasoning that valsartan-sacubitril complexes were not

## *In re Entresto*, 125 F.4th 1090 (Fed. Cir. 2024) (Lourie, Prost, Reyna) *continued*

known as of the priority date and that patentees need not enable after-arising technology.

The Federal Circuit reversed the district court's written-description ruling and affirmed its enablement ruling. As to written description, the court noted that Novartis need only show written description of that which is claimed, not that which the claims "cover" for purposes of infringement. The claims recite a "combination," not a "complex," and so valsartan-sacubitril complexes "need not have been described" in the patent. By holding otherwise, the district court "erroneously conflated the distinct issues of patentability and infringement, which led it astray in evaluating written description."

The Federal Circuit then determined that Novartis' patent adequately discloses a "combination" of valsartan and sacubitril since the patent describes both compounds and explains that they can be combined in a "composition." The court thus found that the "patent has an adequate written description of what is claimed."

As to enablement, the Federal Circuit employed a similar analysis, noting that "a specification must only enable the *claimed* invention," which, here, is simply a "combination" of valsartan and sacubitril. The court also agreed with the district court that valsartan-sacubitril complexes constitute after-arising technology that need not have been enabled in Novartis' patent. Thus, regardless of whether such complexes are covered by the claims, they "cannot be used to 'reach back' and invalidate the asserted claims." Accordingly, because the patent "does not expressly claim complexes, and because the parties did not otherwise dispute that the … patent enables that which it does claim," the Federal Circuit concluded that MSN failed to show lack of enablement.

**Related:**

***Regeneron Pharms., Inc. v. Mylan Pharms. Inc.*, 127 F.4th 896 (Fed. Cir. 2025)** (affirming that claims directed to a protein formulation with an upper bound range of stability had adequate written description, citing expert testimony indicating that a skilled artisan would have understood the stability to be limited by what was understood to be workable).

***Duke University v. Sandoz Inc.*, 160 F.4th 1305 (Fed. Cir. 2025)** (reversing after finding a patent's written description (1) failed to describe a representative number of species of a subgenus of prostaglandin analogs recited in a method, and (2) failed to provide sufficient blaze marks or structural features common to the subgenus because the specification did not identify how the disclosed features were unique to the claimed subgenus, as opposed to the entire genus).

***Seagen Inc. v. Daiichi Sankyo Co.*, 2023-2424, 160 F.4th 1322 (Fed. Cir. 2025)** (reversing a jury verdict of willful infringement after finding an earlier patent application failed to provide written description, e.g., blaze marks, for an 81-member subgenus of peptide linkers recited in an antibody-drug conjugate claim based on disclosure of a broad genus encompassing over 47 million peptides, and finding the application failed to enable a broad functional limitation of cleaving a drug from an antibody).

## *Ingenico Inc. v. IOENGINE, LLC*, 136 F.4th 1354 (Fed. Cir. 2025) (Dyk, Prost, Hughes)

BY: R. WILSON "TREY" POWERS III, PH.D.

*Ingenico* provided a definitive resolution to a decade-long split among district courts regarding the scope of inter partes review (IPR) estoppel. The court's ruling centers on a technical but vital distinction between a legal "ground" of invalidity and the evidence used to prove the ground.

IOENGINE accused Ingenico of infringing several patents directed to portable USB-type communication devices. While Ingenico successfully invalidated many claims through IPR proceedings at the Patent Trial and Appeal Board (PTAB), several claims survived to a jury trial in the District of Delaware.

At trial, Ingenico argued that the remaining claims were invalid based on a prior art system, the DiskOnKey, that was in "public use" or "on sale" before the patent's priority date. IOENGINE sought to block this invalidity defense under the IPR estoppel statute, 35 U.S.C. § 315(e)(2). That statute provides that the petitioner in an IPR that results in a final written decision "may not assert" in district court that any claim challenged in the IPR "is invalid on any ground that the petitioner raised or reasonably could have raised during" the IPR. IOENGINE argued that the DiskOnKey's features were fully described in manuals and "Readme" files — which are printed publications — and that therefore Ingenico was estopped from relying on the DiskOnKey *device* in district court because it could have used the *underlying documents* in its IPR. The district court rejected this argument and allowed Ingenico to present this defense.

The Federal Circuit affirmed, holding that estoppel did not apply to the DiskOnKey "system art." The court clarified that a "ground" under 35 U.S.C. § 315(e)(2) refers to a legal theory of invalidity, not the prior art itself. The Federal Circuit explained that "[g]rounds are the theories of invalidity available to challenge a claim under §§ 102 and 103," whereas prior art is "evidence of a ground" and "not coextensive with [the] ground."

The Federal Circuit also relied on 35 U.S.C. § 311(b), which restricts IPRs to challenges based on "prior art consisting of patents or printed publications." Because "public use" and "on-sale" grounds cannot be raised in an IPR, the court held that a party cannot be estopped from raising these distinct invalidity theories later in district court. Significantly, the Federal Circuit held that a party may use the exact same documents from an IPR in district court so long as it uses them as evidence of a *different* invalidity ground: "IPR estoppel … does not preclude a petitioner from relying on the same patents and printed publications as evidence in asserting a ground that could not be raised during the IPR."

Previously, some district courts had estopped defendants from using physical devices if they were "materially identical" to printed publications describing the devices. This test is now effectively dead. Instead, the inquiry centers on whether the specific ground of invalidity at issue could have been raised in an IPR. If not, it is fair game in district court.

### Related:

***Kroy IP Holdings, LLC v. Groupon, Inc.*, 127 F.4th 1376 (Fed. Cir. 2025)** (holding that a PTAB finding of unpatentability in an IPR does not collaterally estop a patent owner from asserting different, even "immaterially different," claims of the same patent in district court, because the burden of proof in an IPR is lower than the burden of proof for invalidity in district court).

## *Lashify, Inc. v. Int'l Trade Comm'n*, 130 F.4th 948 (Fed. Cir. 2025) (Prost, Taranto, Chen)

BY: MICHAEL JOFFRE

A complainant who seeks relief at the International Trade Commission (ITC) for patent infringement by an imported good must meet the "domestic industry requirement" of 19 U.S.C. § 1337(a)(3). Courts have interpreted this provision to contain a "technical prong," which requires that a domestic industry article practice the patent, and an "economic prong," which can be satisfied by (among other things) a showing that there is — with respect to the article — a "significant employment of labor or capital." *Id.* § 1337(a)(3)(B).

In this case, Lashify brought a complaint at the ITC against multiple companies for infringing its patents. Lashify argued that it imported and then sold goods that practiced its patents. After a hearing, the administrative law judge (ALJ) held that Lashify had not satisfied the economic prong. In analyzing Lashify's domestic investments, the ALJ excluded Lashify's U.S. expenses related to warehousing, quality control, and distribution of the articles because there were "no additional steps required to make the products saleable" upon arrival in the United States and because the quality control measures were "no more than what a normal importer would perform." The ALJ also excluded expenses related to sales and marketing because Lashify had not established significant qualifying expenses in other areas.

On review of this issue, the ITC split, with the majority affirming the ALJ but noting that such expenses might apply if some additional activities were present. The dissenting commissioners would have held that there was no statutory basis to exclude these expenses in determining whether the economic prong was met.

On appeal, the Federal Circuit disagreed with the ITC majority. The court held that the language of the statute did not carve out "employment of labor or capital" related to sales, marketing, warehousing, quality control, or distribution. And the court held that the language did not require U.S. manufacturing or other U.S. activities for such expenses to be counted in the economic-prong analysis. The court similarly concluded that nothing in the legislative history suggested that these expenses would not count under the statute. Finally, the court held that its prior decision in *Schaper Manufacturing Co. v. ITC*, 717 F.2d 1368 (Fed. Cir. 1983), did not address this issue and analyzed an earlier version of the statute regardless.

The Federal Circuit accordingly remanded the case to the ITC to take into account Lashify's domestic expenses related to sales, marketing, warehousing, quality control, or distribution in determining whether Lashify satisfied the domestic industry requirement.

## *Lynk Labs, Inc. v. Samsung Elecs. Co.*, 125 F.4th 1120 (Fed. Cir. 2025) (Lourie, Prost, Stark)

BY: MELISSA A. HAAPALA

Samsung filed an IPR petition challenging claims of Lynk Labs' patent related to light emitting diode (LED) lighting systems used for general lighting and decoration. Six of the alleged grounds of unpatentability relied on a U.S. patent application to Martin, which was filed before the priority date of the challenged patent but published after the priority date. Lynk Labs appealed the Patent Trial and Appeal Board's (PTAB) determination that the claims were unpatentable for obviousness and argued that Martin could not be used as prior art in the IPR.

The Federal Circuit rejected Lynk Labs' argument and affirmed. 35 U.S.C. § 311(b) limits IPR challenges only to "a ground that could be raised under section 102 or 103 and only on the basis of prior art consisting of patents or printed publications." The court observed that Lynk Labs' argument that Martin is not a *prior art* printed publication relied on cases that analyzed books and articles under §§ 102(a) or (b). Prior art under those subsections must be publicly accessible before the relevant date — here the priority date of the challenged patent. However, the court found those cases inapposite because Congress created "a special rule" for published patent applications in § 102(e). Under that subsection, published patent applications — like Martin — are "deemed prior art as of their filing date." Thus, the court concluded that "the plain language" of §§ 311(b) and 102(e) permit IPR challenges based upon published patent applications that were filed before the patent's priority date because published patent applications are a specific type of printed publication deemed prior art as of their filing date (rather than their date of publication).

The court found this result supported by the historical context behind § 311(b). The phrase "patents or printed publications" first appeared in 1980 in the newly created procedures for ex parte reexamination. Congress limited those proceedings to "prior art consisting of patents or printed publications" — the same phrase used in § 311(b) — to provide a cheaper and faster alternative to challenge patent validity on grounds normally handled by patent examiners, while leaving challenges on other, more evidence-intensive grounds (e.g., public use or sale) to the courts. This same phrase also appeared in the 1999 statute that limited challenges of the newly created inter partes reexamination procedure on the same basis and also, for the first time, provided for the publication of patent applications.

With that context, the court was unpersuaded by Lynk Labs' argument that a reference is a "prior art printed publication" only if it is *published* before the relevant date (which would exclude applications treated as prior art under § 102(e)). The court observed that much of the case law relied on by Lynk Labs predated the publication of patent applications and so did not inform the definition of "prior art printed publication" vis-à-vis published patent applications. The court determined that the term "printed publication" "does not have its own, baked in temporal requirement, and that instead whatever temporal requirement exists is drawn from the other [statutory] language" (i.e., §§ 102(a), (b), and (e)(1)). Thus, published patent applications are afforded "*a prior-art effect*," under § 102(e)(1), different from the effect given to printed publications in §§ 102(a) and (b). The court found its interpretation consistent with the congressional purpose to limit IPRs to printed documents because they are the types of references "normally handled by patent examiners" and do not require substantial discovery or factfinding. Therefore, the court concluded the PTAB properly deemed Martin prior art.

Lynk Labs has petitioned the Supreme Court for certiorari. That petition remains pending as of the publication of this review.

## *Lynk Labs, Inc. v. Samsung Elecs. Co.*, 125 F.4th 1120 (Fed. Cir. 2025) (Lourie, Prost, Stark) *continued*

**Related:**

***In re Riggs*, 131 F.4th, 1377 (Fed. Cir. 2025)** (holding that a non-provisional application is prior art under § 102(e) as of its provisional application's filing date, provided it is entitled to the priority date of the provisional application).

***Merck Serono S.A. v. Hopewell Pharma Ventures, Inc.*, 159 F.4th 10 (Fed. Cir. 2025)** (holding that any difference between the inventive entity between inventors of a prior art reference and inventors of a patent claim, regardless of whether inventors are added or subtracted, renders the prior disclosure by "another" and available as prior art under § 102(e)).

## *Recentive Analytics, Inc. v. Fox Corp.*, 134 F.4th 1205 (Fed. Cir. 2025) (Dyk, Prost, Goldberg)

BY: KRISTINA CAGGIANO KELLY

*Recentive* held that the application of machine learning to new tasks and contexts cannot render an invention patent-eligible under 35 U.S.C. § 101.

Recentive's claims recited iteratively training a machine-learning model to identify relationships between different event parameters and desired outcomes for the events, generating a schedule for future events based on user-defined event parameters and desired outcomes, and updating the generated schedule based on real-time changes to event parameters. In other words, the patents claimed various machine-learning-generated network maps and schedules for TV broadcasts and live events.

The district court dismissed Recentive's infringement case against Fox, holding that the patents at issue were directed to ineligible subject matter under the two-step *Alice* inquiry. Under step one, the court found that the claims were "directed to the abstract ideas of producing network maps and event schedules, respectively, using known generic mathematical techniques." Under step two, the court found no "inventive concept" because the machine learning techniques described were "broad, functionally-described, well-known techniques" that did not amount to significantly more than a patent on the abstract concept itself.

The Federal Circuit affirmed. Recentive had argued that its claims were patent-eligible because they involved a "unique application of machine learning to generate customized algorithms, based on training the machine learning model, that can then be used to automatically create … event schedules that are updated in real-time." The Federal Circuit rejected this argument, concluding that iterative training using updated data is "incident to the very nature of machine learning" and "do[es] not … mak[e] machine learning better." The court explained that the claimed systems and methods simply applied conventional machine-learning techniques to a new data environment.

Under *Recentive*, the process of using artificial intelligence (AI) to perform tasks previously done manually or using more basic computer processing (like sorting through

## *Recentive Analytics, Inc. v. Fox Corp.*, 134 F.4th 1205 (Fed. Cir. 2025) (Dyk, Prost, Goldberg) *continued*

large amounts of sequencing data to find patterns or using a generic large language model to generate a compound that binds to a target of interest) is unpatentable. But the court stated that patent protection should remain available for inventions that improve AI itself, such as machine learning tools that provide a new technological advantage. *Recentive* held "only that patents that do no more than claim the application of generic machine learning to new data environments, without disclosing improvements to the machine learning models to be applied, are patent ineligible under § 101."

*Recentive* carries forward several § 101 jurisprudential concepts into the AI space. In particular, field-of-use limitations (for example, using AI in a new data environment) do not transform an abstract idea into a patentable improvement. And increased speed and efficiency relative to human performance of a task are also not sufficient for eligibility. The decision thus shows that the court views AI and machine learning similarly to general-purpose computing for purposes of patentability.

Going forward, patent applications for AI innovations would be well served to include robust disclosure of how a claimed invention provides a technical solution to a technical problem (for example, a novel training process or novel data preprocessing technique). Surface-level claiming of "iteratively training" models to improve accuracy will likely not be sufficient.

## *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898 (Fed. Cir. 2024) (Prost, Taranto, Hughes)

BY: RYAN N. KAISER

Amneal applied for U.S. Food and Drug Administration (FDA) approval to market a generic version of Teva's ProAir HFA drug — a combination product of albuterol sulfate (the active ingredient), a propellant, ethanol, and an inhaler. Teva sued Amneal for infringement under the Hatch-Waxman Act. Amneal counterclaimed, alleging that Teva had improperly listed certain patents in the FDA's Orange Book.

By way of background, the Orange Book is an FDA publication where brand-name drug manufacturers can list patents that, according to the brand, cover a particular branded drug. To qualify for listing, the patent must, as relevant here, "claim the drug for which the applicant submitted the application." When a generic drug company applies for approval to market a generic version of the branded drug, it must make one of four certifications with respect to the listed patents. As relevant here, if a listed patent has not yet expired and the generic company wishes to market its product before expiration, it must submit a "paragraph IV" certification stating that the patent is invalid or will not be infringed by the generic company's drug product. The brand company may then initiate litigation under the Hatch-Waxman Act. If the brand company does so, the FDA will not finally approve the generic company's application for at least 30 months.

The FDA does not substantively review patent information for accuracy before publishing it in the Orange Book. So, if a brand company improperly lists a patent, the generic company has no recourse with the agency. However, if

## *Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of New York, LLC*, 124 F.4th 898 (Fed. Cir. 2024) (Prost, Taranto, Hughes) *continued*

the brand sues the generic applicant, the generic can file a "delisting" counterclaim on the ground that the patent listed in the Orange Book "does not claim … the drug for which the application was approved."

In this case, Teva had nine nonexpired patents listed in the Orange Book for its ProAir HFA product. Five of those patents were directed to dose counters, which tell the user of the inhaler product how many doses remain in the inhaler's canister. Amneal moved the district court to order Teva to delist those patents from the Orange Book because they "contain[ed] no claim for the active ingredient at issue, albuterol sulfate," and were instead "directed to components of a metered inhaler device." In other words, they did not "claim the drug for which the applicant submitted the application." The district court agreed with Amneal, and Teva appealed.

The Federal Circuit affirmed, finding that Teva's inhaler-device patents did not "claim the drug for which the applicant submitted the application" because they did not claim the active ingredient. The court rejected Teva's three contrary arguments.

First, the court rejected Teva's argument that a patent's claim scope "is effectively coterminous with the products that infringe a patent." In finding that argument "defective," the court explained that the Hatch-Waxman Act's "listing" provision "identifies infringing and claiming as two distinct requirements." Under the statute, the court explained, a patent may be listed in the Orange Book only if it "claim[s] the drug" and would "be infringed by the NDA product." The court further relied on distinctions in the Patent Act and Federal Circuit case law between a claim — which "particularly point[s] out and distinctly claim[s] the subject matter" of the invention — and *infringement*, which "occurs when others make, use, or sell the invention without authorization."

Second, the court rejected Teva's argument that its patents were listable so long as they claimed any part of Teva's inhaler product. This argument synthesized two definitions of "drug" in the applicable statute to mean "any part of something used to treat a disease," including device parts. While the court saw "some superficial appeal" in that argument, it found that when viewing the statute as a whole and "looking at how the FDA approves the many different medical products it regulates, it is apparent that a product regulatable and approvable as a drug contains an active ingredient." The court contrasted the regulatory approval pathways for drugs and devices and noted that the "touchstone of the distinction between drugs and devices is that the former are 'composed of complex chemical compounds or biological substances' and the latter are 'characterized more by their purely mechanical nature.'" Thus, to claim a drug, a patent must claim at least the active ingredient.

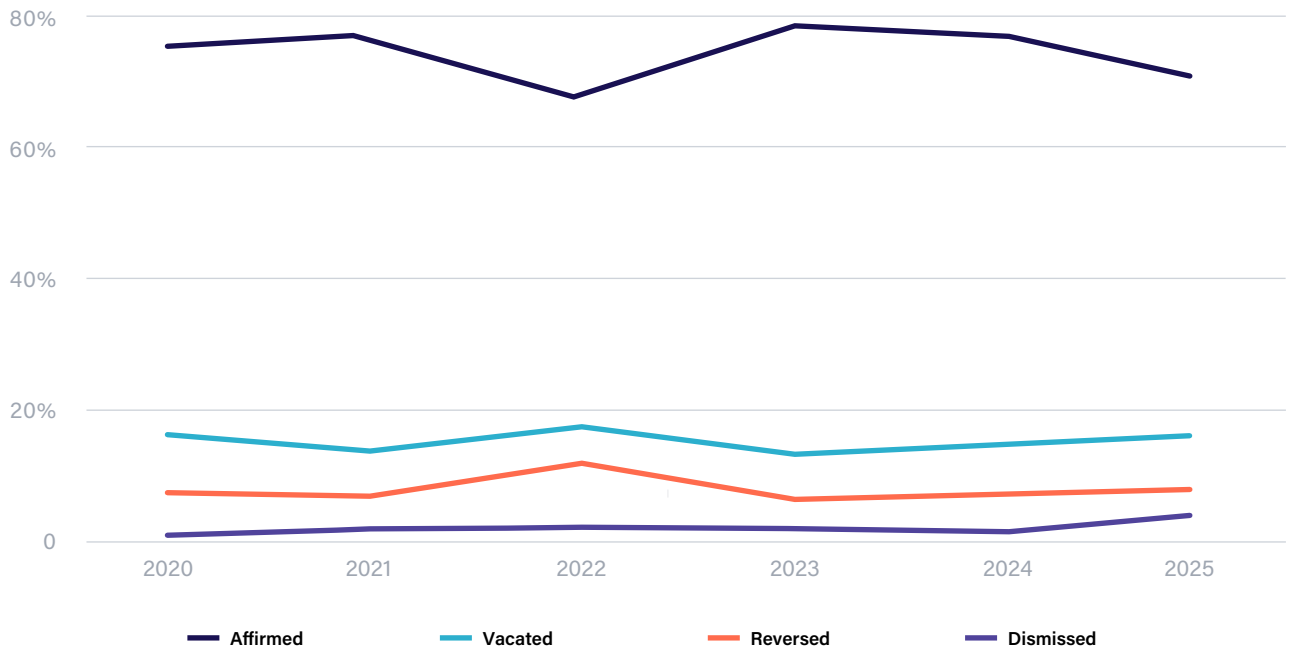
Finally, the court rejected Teva's argument that the patents do in fact claim the active ingredient. For purposes of its analysis, the court assumed that the claims require the presence of "an active drug." But that broad construction, the court said, allows "the presence of any active ingredient in any form." Since, even under that construction, the patents did not "particularly point out and distinctly claim what was approved—the ProAir® HFA with albuterol sulfate as the active ingredient" — the patents were not eligible for listing in the Orange Book.

### Related:

***Jazz Pharm., Inc. v. Avadel CNS Pharm., LLC*, 136 F.4th 1075 (Fed. Cir. 2025)** (reversing injunction prohibiting generic manufacturer from initiating new clinical trials for drug because that activity was permitted under the safe harbor of 35 U.S.C. § 271(e)(2), and remanding to district court to consider, in the first instance, whether submitting an ANDA or "paper NDA" for a drug claimed in any patent — as opposed to only patents listed in the Orange Book — is an act of infringement under 35 U.S.C. § 271(e)(2)).

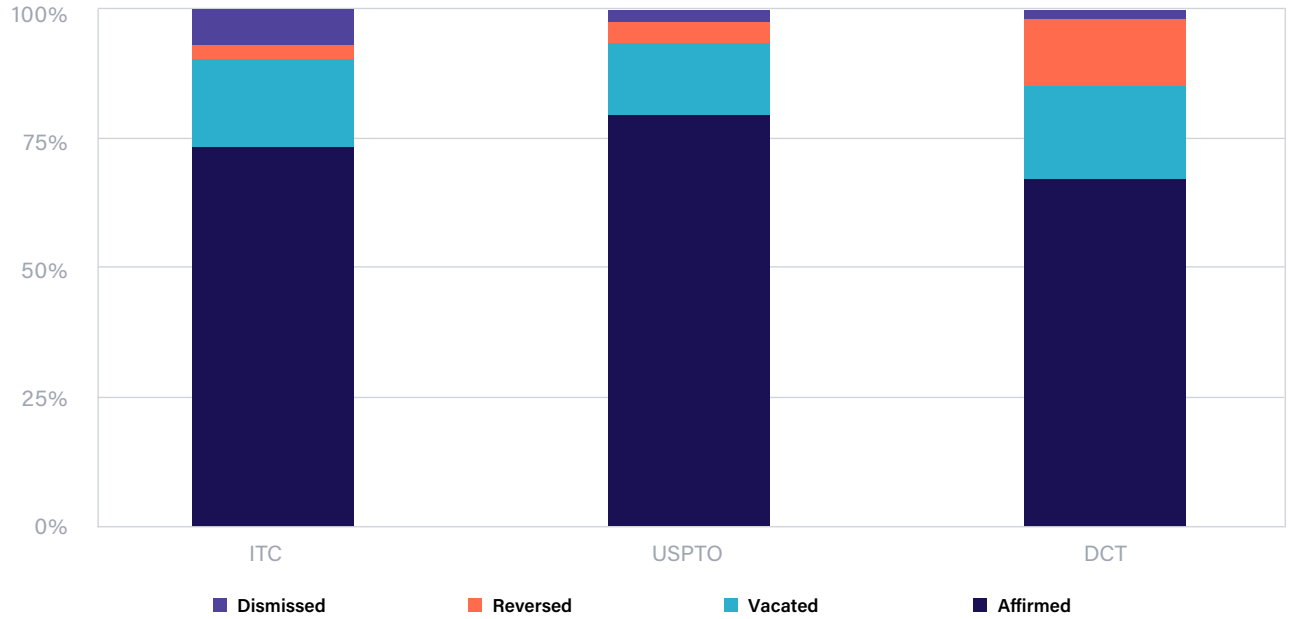
## Data and Trends: IP Appeals to the Federal Circuit *(USPTO, District Court, and ITC)*

### Appeal Outcomes by Year




70% of USPTO, district court, and ITC appeals were affirmed in 2025. 16% of appeals were vacated and remanded, 9% were reversed, and about 5% were dismissed.

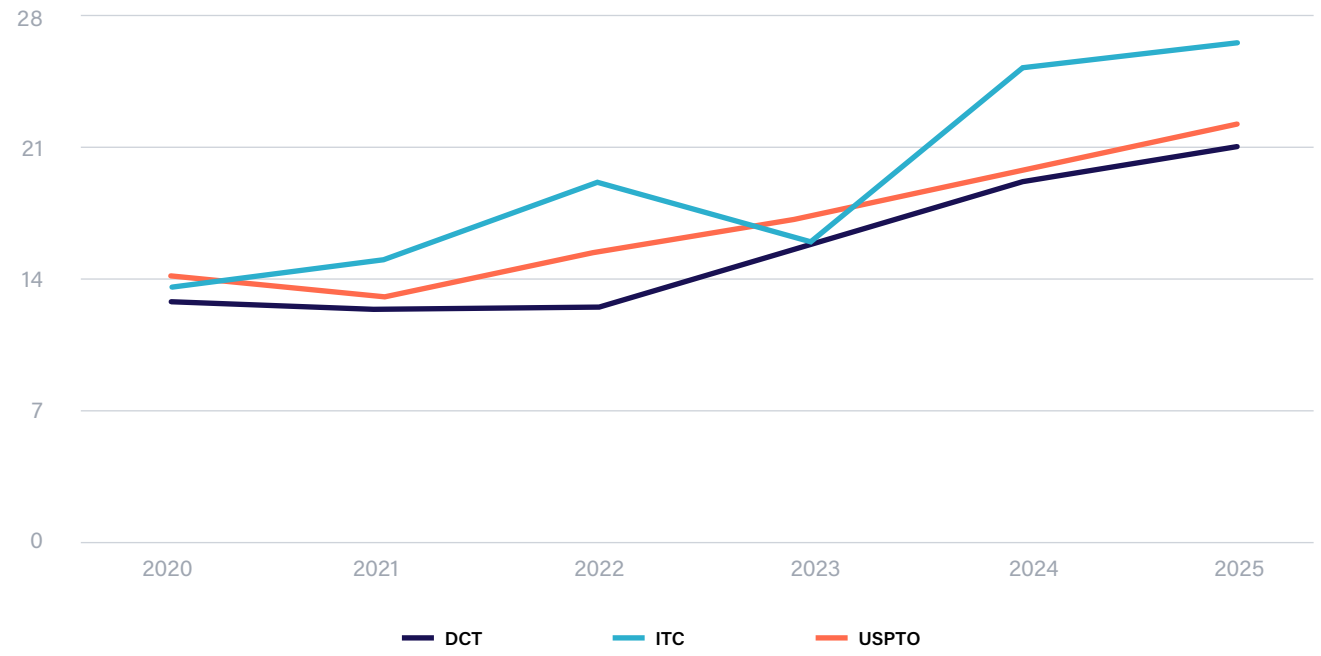
### Appeal Outcomes by Origin (2020–25)




District court appellants have been somewhat more successful than USPTO or ITC appellants since 2020. That said, the affirmance rate in district court appeals is around two-thirds of cases.

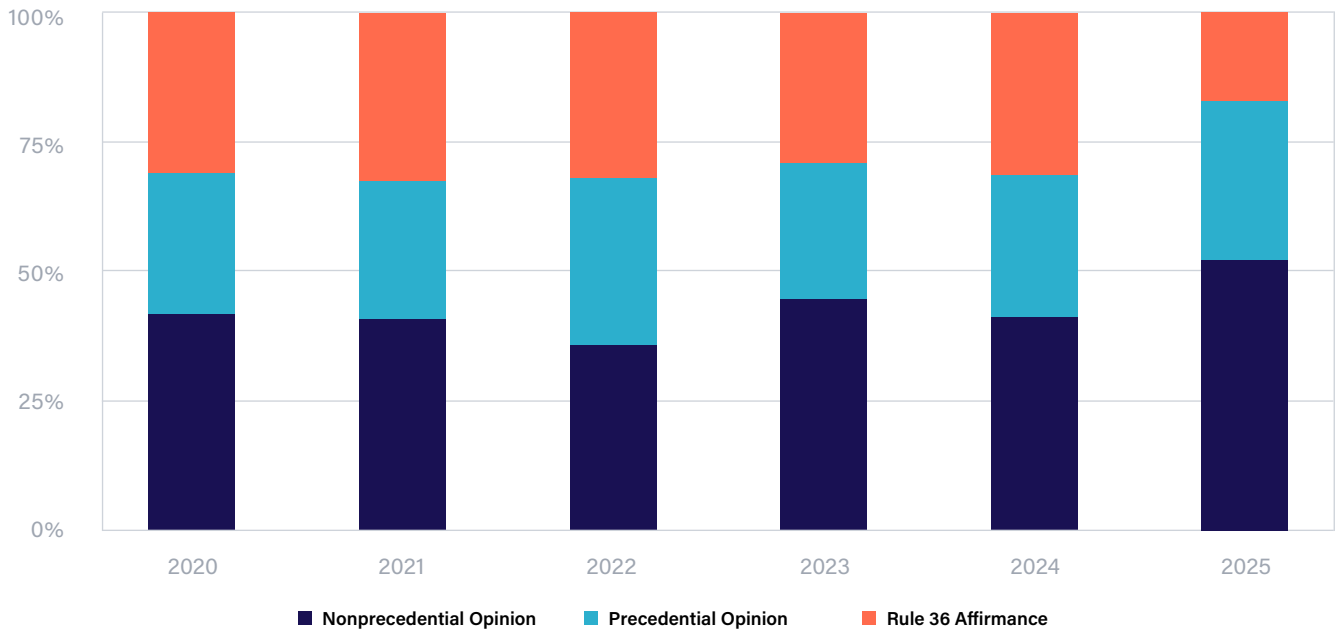
## Data and Trends: IP Appeals to the Federal Circuit *(USPTO, District Court, and ITC)*

### Median Appeal Pendency in Months



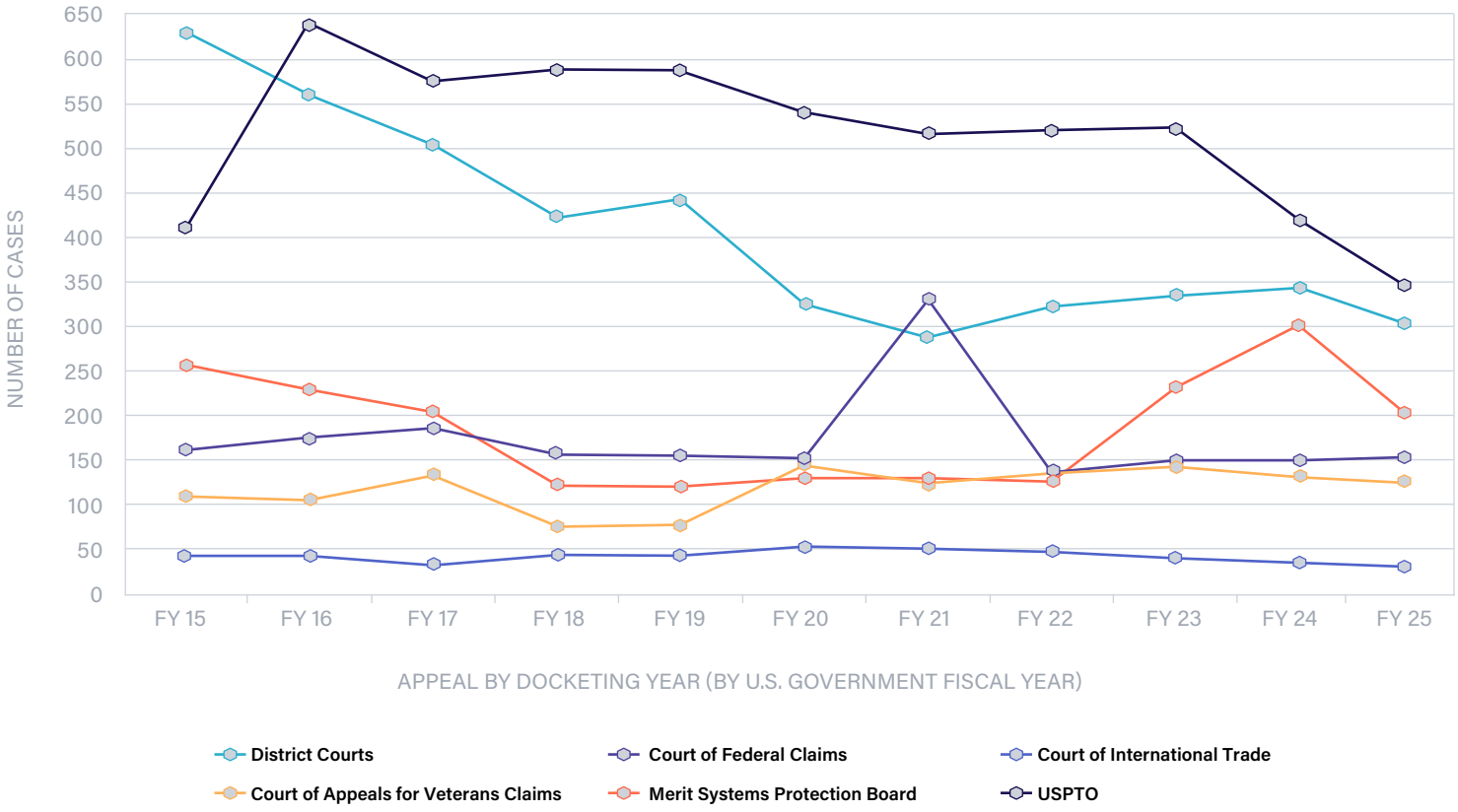

Median appeal pendency continued to climb in 2025, with time to decision for district court and USPTO appeals exceeding 20 months. ITC appeals took even longer, but these are subject to sample size fluctuations.

### Appeal Disposition Types




Rule 36 affirmances shrunk to their lowest level since 2020, making up just 17% of decisions, down from around 30% in past years.

## Data and Trends: IP Appeals to the Federal Circuit *(USPTO, District Court, and ITC)*




New appeals from both district courts and the USPTO declined in FY25, continuing a decade-long trend of fewer appeals from these most common origins.

Source: CAFC

## 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.

For more information about the firm and our services, visit sternekessler.com or follow us on LinkedIn to get the latest news and updates in IP.


**Sterne, Kessler, Goldstein & Fox PLLC**

1101 K Street NW, 10th Floor

Washington, DC 20005