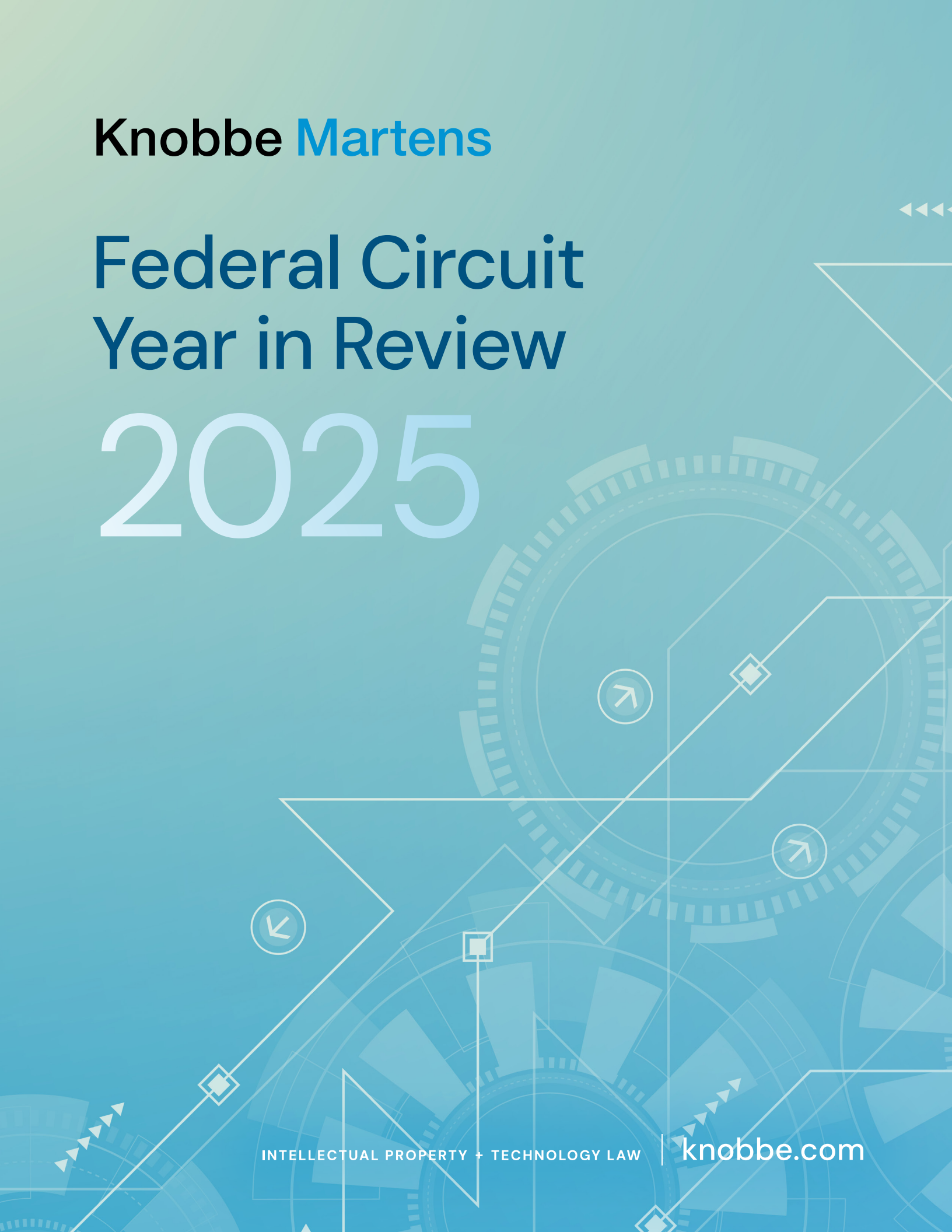
Knobbe Martens

Federal Circuit Year in Review

2025



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CONTENTS

Cases of Note

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Letter from the Litigation Chair

Dear Readers,

As Chair of the Litigation group at Knobbe Martens, I am pleased to share the second edition of our Federal Circuit Year in Review. This report offers insights into more than 50 of the Federal Circuit's most significant patent-related decisions from the past year, organized by central themes like claim construction, infringement, patentable subject matter, and PTAB developments.

2025 was another impactful year at the Federal Circuit, with opinions that established new precedent and offered practical guidance. A few broad trends emerged from the opinions covered in this report. First, the court's analysis of claim construction emphasized the importance of issue preservation and consistency. Second, new leadership at the USPTO and activity at the PTAB underscored evolving boundaries around estoppel, reliance on applicant-admitted prior art and petition strategy, particularly for inter partes reviews. Third, the court's decisions regarding patent eligibility under Section 101 continued to emphasize the importance of articulating technological detail in the claim language. Each of these themes resonated across multiple opinions this year, in addition to key rulings on other issues such as the role of expert witness testimony in damages cases and the domestic industry requirement for International Trade Commission proceedings.

In publishing this report, our aim is to provide IP professionals, in-house counsel, and business leaders with an overarching view of the patent litigation landscape, so you can act with confidence in the upcoming year. Inside, you'll find concise summaries and in-depth analysis from Knobbe Martens lawyers that can help inform robust, effective patent strategies and advance your business goals.

This publication reflects the collective effort of our litigation team, and I'm grateful for the care they brought to researching, writing, and editing the report. We hope our 2025 Federal Circuit Year in Review serves as a dependable reference for you as we navigate what will surely be an exciting year ahead in patent litigation.

Sincerely,

Sheila Swaroop
Chair, Firmwide Litigation Group
Knobbe Martens

The Federal Circuit in 2025: Key Takeaways

By Sean Murray and Jeremiah Helm

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The Federal Circuit's year in 2025 was notable for developments no one would have predicted in 2024. Foremost was the tug-of-war between the court and the Patent Office on *inter partes* review (IPR) proceedings. In prior years, the court and the Patent Office appeared to be on the same page with regard to IPRs. That changed in 2025. While the Federal Circuit issued a series of decisions that strengthened the hand of IPR petitioners, the Patent Office introduced new rules and policies that dramatically reduced the number of IPRs that were instituted compared to prior years.

Two Federal Circuit decisions exemplify the Federal Circuit's trend toward loosening restrictions on IPR petitioners. The court's April decision in *Sage Products v. Stewart* ruled that an IPR petitioner may prove anticipation using evidence beyond the prior art references raised in the petition. A petitioner arguing anticipation must show that every element of the challenged claim is disclosed in a single prior art reference. The prior art reference in *Sage Products* did not clearly disclose one of the claim limitations. The Federal Circuit nevertheless permitted the petitioner to rely on expert testimony and a confidential, non-public corporate document to prove that a skilled artisan would have understood the reference to disclose the disputed limitation.

The following month, the Federal Circuit weakened IPR estoppel in *Ingenico v. Ioengine*. The doctrine of IPR estoppel bars an IPR petitioner from asserting invalidity grounds in district court that it raised or could have raised in the IPR. The plaintiff in *Ingenico* argued the defendant was estopped from relying on a prior art device because the defendant's IPR was based on a substantively identical publication describing the device. The court held that the prohibition against relying on the same invalidity "ground" does not bar IPR petitioners from relying on a prior art reference in both an IPR and a district court case. Because petitioners may not rely on prior art physical devices or systems in an IPR ground, IPR estoppel does not bar invalidity theories that rely on physical prior art.

About the same time the Federal Circuit was making life easier for IPR petitioners, the Patent Office began implementing a series of rule changes that created new barriers for petitioners to surmount. First, Acting PTO Director Coke Morgan Stewart divided the institution analysis into two stages. Previously, the Patent Trial and Appeal Board decided both whether the PTO should exercise its discretion to deny institution and whether institution of an IPR was appropriate on the merits. Director Stewart decreed that the Director's office would first decide the discretionary denial issue, with the Board addressing the merits of institution only if the petition survived discretionary denial. This meant petitioners had to clear two hurdles to secure institution.

The Patent Office also expanded the grounds for discretionary denial. Most controversially, it decided that discretionary denial may be appropriate if the challenged patent has been in effect long enough to create "settled expectations" that the patent is valid. The PTO indicated that settled expectations presumptively exist about six years after the challenged patent issued.

The PTO also suggested it may exercise its discretion to deny institution unless the petitioner stipulates not to assert invalidity theories in district court that are substantively identical to unpatentability grounds asserted in the petition. This policy appears to be a direct response to the *Ingenico* decision, which limited IPR estoppel and expanded the permissible overlap between an IPR and a parallel district court proceeding.

These and other policy changes at the PTO cut the IPR institution rate in half. Several well-known companies, unhappy with the new rules and the denial of their IPR petitions, filed mandamus petitions in the Federal Circuit challenging the new discretionary-denial regime. In an interesting twist, the Federal Circuit uniformly denied those petitions. So while the Federal Circuit in 2025 made it easier for IPR petitioners to invalidate a patent in an IPR proceeding, it also firmly supported the PTO's discretion to implement policies that dramatically reduce the number of those proceedings.

Another interesting trend at the Federal Circuit developed in the latter part of the year. The court issued several decisions that revived the quasi-dormant debate about the written description requirement for patentability. Three decisions in particular strengthened the requirement, making it a more potent tool for defendants seeking to invalidate an asserted patent.

In August, the court issued a decision in *Mondis v. LG Electronics* that addressed an electronics-related claim requiring an identification number for identifying a type of display unit. The court held that the patent's discussion of a prior art monitor that used the phrase "type of display device" did not provide written description support for the invention because that discussion of the prior art could not be fairly read as describing a part of the patent's invention. The decision therefore limited the ability of patentees to rely on a patent's background section for written description support.

In October, the court decided *Brita v. ITC*, which explained that broad claims covering any filter media with a particular property did not satisfy the written description requirement because the specification did not explain in any detail which media might possess that property. In an unusual step, the court emphasized the inventors' testimony about the scope of their invention instead of focusing solely on the patent's disclosure.

Finally, the court's November decision in *Duke v. Sandoz* concluded there was insufficient written description support for claims to a genus of molecules. Although the specification disclosed the individual claim elements, the disclosure would not have led a skilled artisan to the specific combination of elements on which the claims relied to define the claimed genus. The court emphasized the need for "blaze marks": affirmative teachings in the specification that would lead an artisan to the claimed genus. Far from blazing a trail to the claimed invention, the specification contained teachings that would have led a skilled artisan

away from the claimed combination. The court rejected the plaintiff's argument that the inventors possessed the claimed genus merely because a skilled artisan could have picked the invention from a laundry list of many possible options disclosed in the specification.

While the Federal Circuit made 2025 a fascinating year in patent law, 2026 may prove even more interesting. The new year is off to a fast start with the Supreme Court granting *certiorari* in Hikma's "skinny label" patent case. Between the prospect of a Supreme Court decision on patent law, the evolving saga at the Patent Office, and the packed Federal Circuit docket, 2026 should be another year to watch.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

CASES OF NOTE

FEATURE CASE

Wash World Inc. v. Belanger Inc.

Forfeiting Claim Construction On Appeal

In *Wash World Inc. v. Belanger Inc.*, the U.S. Court of Appeals for the Federal Circuit considered the line between mere elaboration on an argument presented to the district court, which is properly raised on appeal, and a substantially new position, which is forfeited on appeal because it was not previously raised.

The court, in an opinion written by U.S. Circuit Judge Leonard Stark and joined by U.S. Circuit Judges Alan Lourie and Sharon Prost, specifically addressed the forfeiture issue in the context of claim construction.

During patent litigation, a key aspect of any case is determining the meaning of, or construing, disputed claim terms. That process typically occurs earlier in the litigation; by trial, any disputes as to the meaning of disputed claim terms are usually resolved.

The problem the Federal Circuit faced in *Wash World* was that the appellant and adjudged infringer, Wash World, presented a claim construction that differed from the claim construction it had advocated at the U.S. District Court for the Eastern District of Wisconsin.

The district court held that the claim terms "outer cushioning sleeve" and "predefined wash area," both were understandable under their plain and ordinary meaning. Thus, neither claim term required further construction.

In concluding that no construction was needed, the district court rejected Wash World's proposed construction for each term. At trial, a jury applied the plain and ordinary meaning of these claim terms and found Wash World infringed Belanger's patent.

After trial, Wash World moved for judgment as a matter of law, arguing that, instead of allowing the jury to apply the terms' plain meaning, "outer cushioning sleeve" should have been construed to require "a thick sleeve of extruded foam plastic," and "predefined wash area" should have been construed to require that the "spay arm move in a manner established by the location of the equipment."

The district court rejected Wash World's claim construction arguments and denied its motion seeking judgment as a matter of law.

On appeal, Wash World advocated a construction for "outer cushioning sleeve" that focused on the idea that the sleeve must be soft or resilient so that it can be compressed and spring back into shape. Wash World's proposed construction did not include the requirement that the sleeve be a thick sleeve of extruded foam plastic.

The Federal Circuit noted that Wash World had not previously presented the district court with a "soft and resilient" construction, and that the district court therefore could not have previously evaluated that position. Thus, the Federal Circuit held that Wash World forfeited that claim interpretation argument and could not pursue it on appeal.

The forfeiture analysis does not turn solely on whether the same words were presented to the district court. On appeal, a party may present new or additional arguments to support its claim construction so long as that claim construction reflects the parties' dispute, as it was developed over the course of the district court litigation.

The Federal Circuit acknowledged that Wash World had mentioned the idea that the cushioning sleeve needed to be soft, but the court found that Wash World never asked the district court to include the "soft and resilient" requirement in a claim construction of "outer cushioning sleeve."

The Federal Circuit held that ambiguous statements in the record, such as those cited by Wash World, would not suffice to preserve a claim construction argument on appeal.

Forfeiture may also be excused under exceptional circumstances. As the Federal Circuit explained, Wash World chose the construction to propose to the district court, was

FEATURE CASE

fully heard on that proposed construction, and never indicated the claim construction dispute required addressing the need for soft and resilient material.

The Federal Circuit noted that the case proceeded through trial without a construction imposing such a requirement, and emphasized the strong requirement of timely raising of distinct objections to jury instructions. Because Wash World's claim construction on appeal was not raised in a timely manner, no exceptional circumstances excused forfeiture.

The Federal Circuit also concluded Wash World had forfeited the construction of "predefined wash area" that it advanced on appeal because that construction was materially different from the construction presented to the district court.

Again, the Federal Circuit considered whether the argument presented to the district court was sufficient to put the court on notice of the construction advanced on appeal. The Federal Circuit concluded it had not put the court on notice because, among other things, Wash World's proposed construction on appeal added new requirements that were not the focus of the district court dispute. As a result, the construction presented on appeal was forfeited.

In contrast, the Federal Circuit concluded that Wash World had not forfeited its appellate argument that Belanger's damages award should have been reduced, even though Wash World never plainly and expressly requested a reduction of the specific damages amount or identified the lost profits per unit that it wanted deducted from the jury's verdict.

The Federal Circuit held that Wash World had preserved the issue for appeal by challenging the methodology and evidence used to calculate damages for certain sales. That challenge put the district court on notice that Wash World believed that lost profits damages were not warranted as to some specific sales.

In particular, Wash World's appeal requesting remittitur relied on the data cited in Wash World's judgment-as-a-matter-of-law brief at the district court. Thus, the Federal Circuit concluded Wash World's appellate argument, which specifically requested remittitur, was a proper elaboration on its prior arguments.

The Federal Circuit also concluded that exceptional circumstances would also have merited consideration of the remittitur argument. This is because Belanger, in opposing Wash World's judgment as a matter of law at the district court, specifically adopted its expert's testimony and calculations as the basis for the jury's damages award.

The Federal Circuit held Belanger was judicially estopped from arguing a different basis for the jury's damages award. Accordingly, the Federal Circuit concluded that the appeal presented an exceptional circumstance: Belanger's expert's testimony allowed the appellate court to discern the precise amount of damages improperly awarded by the jury.

The Federal Circuit's opinion in *Wash World* provides litigants with important guidance regarding the scope of arguments that can be made on appeal. Mere elaboration or recharacterization of a position presented to the district court, even if presented using different terms, is allowed. But the appellant must adequately preserve any arguments by presenting them to the district court and allowing the district court the opportunity to weigh in on the merits.

This is why the Federal Circuit rejected the modified claim constructions on appeal as forfeited. These new positions represented a shift in the core dispute from the corresponding positions presented at the district court, which unfairly prevented the district court from addressing the merits.

Wash World underscores that practitioners must present a complete set of arguments to the district court or be ready to explain, on appeal, why extraordinary circumstances prevented them from doing so.

Wash World also provides examples of acceptable elaboration that emphasize the role of fairness in the forfeiture analysis. When an appellant presented the factual

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basis for an argument to the district court and argued for the ultimate result sought on appeal — as Wash World did for reduced damages — forfeiture is less likely.

If an issue was fairly raised and considered by the district court, some refinement of the argument on appeal is likely acceptable, even if it involves using new words to further define a legal theory.

Wash World confirms the importance of fair notice to the district court when determining forfeiture of an argument on appeal. *Wash World* thus allows appellants to better gauge the appropriate framing of arguments that may be presented on appeal.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

IQRIS Technologies LLC v. Point Blank Enterprises, Inc

Pulling the Cord on Unstated Claims Limitations

In *IQRIS Technologies LLC v. Point Blank Enterprises, Inc.*, Appeal No. 23-2062, the Federal Circuit held that the district court erred in construing the term "pull cord" as a directly pulled cord that lacks a handle.

IQRIS Technologies LLC sued Point Blank Enterprises, Inc. and National Molding, LLC alleging infringement of two of IQRIS's patents for tactical vests. The district court construed the claim term "pull cord" to mean cords directly pulled by a user that lack a handle. Point Blank and National Molding moved for summary judgment of non-infringement. The district court granted the motion because the accused product lacked a "pull cord" under the court's definition of the term. IQRIS appealed, arguing that the district court erred in its construction of "pull cord."

The Federal Circuit held that the district court erred in construing "pull cord." The Federal Circuit ruled that "pull cord" should be given its plain and ordinary meaning because the claim language did not limit who or what pulls the pull cord, and because the specification did not explicitly redefine the term or disavow the full scope of the term. The court held that the specification did not disclaim pull cords with handles by disparaging prior art devices with handles because that prior art was criticized for an unrelated reason, not because it had handles. The Federal Circuit therefore vacated the grant of summary judgment and remanded for further consideration.

Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.

No Takebacks: The High Bar for Departing from Patent Lexicography

In *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.*, Appeal No. 23-2357 the Federal Circuit held that once the high threshold for lexicography is met, there must be a clear and unmistakable reason to depart from that controlling definition.

Alnylam sued Moderna, alleging that Moderna's COVID-19 vaccine contained a lipid compound that infringed Alnylam's patents. The asserted claims were directed toward a lipid compound with a hydrophobic tail which includes "a branched alkyl." Moderna argued that Alnylam had acted as a lexicographer regarding "branched alkyl" based on the following sentence in the specification:

> Unless otherwise specified, the term[] "branched alkyl" ... refer[s] to an alkyl ... group in which one carbon atom in the group (1) is bound to at least three other carbon atoms and (2) is not a ring atom of a cyclic group.

In contrast, Alnylam proposed a different construction that it asserted to be the ordinary meaning. The district court agreed with Moderna and construed "branched alkyl" according to the definition in the specification and further reasoned that any departure from that lexicography needed to be clear and unmistakable. The parties stipulated to non-infringement under the court's construction and Alnylam appealed.

On appeal, the Federal Circuit agreed that Alnylam had acted as a lexicographer in defining "branched alkyl." Further, the Federal Circuit agreed with the district court that once the high threshold for lexicography has been met, a high threshold must also be met before finding a departure from that controlling definition. Alnylam's definition of "branched alkyl" included the phrase "unless otherwise specified," which Alnylam argued left room for a broader interpretation elsewhere in the patent. However, the Federal Circuit found no clear reason in the claims, specification, or prosecution history to depart from the definition. Thus, the Federal Circuit affirmed.

FMC Corp. v. Sharda USA, LLC

Deleted Specification Portions Undermine Claim Construction

In *FMC Corp. v. Sharda USA, LLC*, Appeal No. 24-2335, the Federal Circuit held that the district court erred by construing a claim term based on disclosures made in a provisional application and an unasserted patent in the same patent family.

FMC Corp. ("FMC") sued Sharda USA, LLC ("Sharda") for infringement of two patents related to insecticide. FMC moved for a preliminary injunction against Sharda. The district court construed the claim term "composition" as only extending to physically stable compositions, as opposed to unstable compositions. The district court based its reasoning on disclosures on the stability found in a related provisional application and in an unasserted patent family member. The patents-in-suit, however, removed the references to "stable," "stability," or variations thereof. The district court rejected Sharda's invalidity defenses based on its construction of "composition" and ultimately granted a preliminary injunction. Sharda appealed, and argued that the district court's construction of "composition" was erroneous because it improperly limited the scope of the claim to just stable compositions.

The Federal Circuit agreed with Sharda and vacated the district court's injunction order.

The Federal Circuit focused on the differences between the disclosure of the patents-at-issue and the respective disclosures of the provisional and unasserted family member. Regarding the provisional, the Federal Circuit reasoned that FMC chose to delete the disclosure pertaining to stability when drafting its asserted patent specifications. The Federal Circuit explained that a skilled artisan "would find that evolution meaningful." Accordingly, the prosecution history demonstrated that a skilled artisan would not have understood the claimed composition to be limited to only stable formulations. Regarding the related patent, the Federal Circuit noted that it typically applies a consistent meaning to claim terms within a patent family. But, the court explained, that presumption does not apply when, as here, the applicant materially alters the specification of some family members.

Because the Federal Circuit had found error with the district court's construction of "composition," it also found error in the lower court's validity analysis. Accordingly, the court vacated the preliminary injunction and remanded for further proceedings applying the correct claim scope.

Knobbe Martens was Hatch-Waxman Litigation Firm of the Year at the 2025 LMG Life Sciences Americas Awards.

Azurity Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.

Hard to Stomach: Things You Say to Prosecute a Patent Can and Will Be Used Against You

In *Azurity Pharmaceuticals, Inc. v. Alkem Laboratories Ltd.*, Appeal No. 23-1977, the Federal Circuit held that Arguments and amendments made during prosecution of a parent application can provide "clear and unmistakable" evidence of a disclaimer of claim scope in a continuation application.

Azurity Pharmaceuticals sued Alkem Laboratories alleging Alkem's Abbreviated New Drug Application ("ANDA") infringed a patent directed to drinkable drugs for treating colon infections. Azurity's patent was a continuation of another application ("'059 Application") that had been rejected numerous times during prosecution over a prior-art reference ("Palepu") which contained "a polar solvent including propylene glycol." The district court determined that Azurity's arguments and amendments during prosecution of the '059 Application "clearly and unmistakably" disclaimed propylene glycol from the claimed invention. Because Alkem's ANDA contained propylene glycol and Azurity's patent claims used the closed "consisting of" transition phrase, the district court found that Alkem's ANDA did not infringe Azurity's patent.

Further, the district court rejected Azurity's argument that a discovery stipulation overcame the disclaimer of propylene glycol. Specifically, Azurity's patent claims recited a "flavoring agent" and the parties had stipulated that "[s]uitable flavoring agents for use in the Asserted Claims include flavoring agents with or without propylene glycol." Azurity interpreted the stipulation to mean that products with flavoring agents that include propylene glycol could infringe regardless of the "consisting of" transition and disclaimer. However, the district court rejected that argument and found that the disclaimer of propylene glycol was dispositive.

The Federal Circuit affirmed. The Federal Circuit noted that during prosecution of the '059 Application, the examiner repeatedly cited Palepu as prior art and, at every opportunity, Azurity clearly and unmistakably distinguished its invention from Palepu by asserting the claimed formulations did not contain propylene glycol. Azurity also argued that it did not disclaim propylene glycol because during prosecution of another patent application ("'421 Application"), Azurity stated in an office action response that the '059 Application did not disclaim propylene glycol. The Federal Circuit did not consider that statement relevant because the '421 and '059 Applications were prosecuted in parallel with each other and Azurity made that statement after the claims at issue were allowed. Finally, the Federal Circuit affirmed the district court's conclusion that the parties' stipulation did not preclude the disclaimer. Alkem stated contended in the stipulation that it did not infringe due to the presence of propylene glycol and the Federal Circuit found it implausible that Alkem would have conceded infringement just several lines later.

Sierra Wireless, ULC v. Sisvel S.P.A.

Where Method Claim Steps Are Connected by "And," a Covered Method Must Perform Each Step

In *Sierra Wireless, ULC v. Sisvel S.P.A.*, Appeal No. 23-1059, the Federal Circuit held that the Board erred by finding method-claim steps connected by "and" to be conditional and by never explaining its reasoning for relying on the testimony of an expert who failed to meet the Board's definition of one of ordinary skill in the art.

Sierra Wireless and others petitioned for IPR challenging claims of Sisvel's patent as anticipated and obvious. The claims recited a wireless communication method with the following steps: 1[a] detecting a missed data block; 1[b] starting a timer; 1[c] stopping the timer when the missed data block is received while the timer is running; and 1[d] transmitting a status report after the timer expires. The Board defined the level of ordinary skill in the relevant art as requiring an electrical engineering degree. The Board then construed the claims to require either step 1[c] ***or*** step 1[d] because the timer cannot both be stopped while running (step 1[c]) and also expire without having been stopped (step 1[d]). Based on that construction, the Board found Sierra's prior art reference anticipated and rendered obvious some claims because it disclosed steps 1[a], 1[b], and 1[c]. The Board also found certain dependent claims unpatentable based on the testimony of Sisvel's expert witness, who lacked an electrical engineering degree.

The Federal Circuit rejected the Board's claim construction. The court held that because steps 1[c] and 1[d] are connected by "and," the plain language "requires that a method, to come within the claim, must perform both limitations 1[c] and 1[d] where their preconditions apply." The court also held that no substantial evidence supported the Board's finding that Sierra's prior art reference disclosed step 1[c]. For these two reasons, the court vacated the Board's anticipation and obviousness findings and remanded. The Federal Circuit also vacated and remanded the Board's finding that the dependent claims were unpatentable because the Board never explained its reasoning for relying on expert testimony from a witness who did not meet the Board's definition of the level of ordinary skill in the art.

Laboratory Corporation of America Holdings v. Qiagen Sciences LLC

Words Matter: "Identical" Does Not Mean "Identical to a Portion Of"

In *Laboratory Corporation of America Holdings v. Qiagen Sciences LLC*, Appeal No. 23-2350, the Federal Circuit reversed the district court's denial of judgment as a matter of law ("JMOL") of non-infringement, which rested on an incorrect construction of "identical" and was not supported by substantial evidence.

Labcorp sued Qiagen, alleging that Qiagen's DNA sample sequencing kits infringed two Labcorp patents related to methods of preparing DNA samples for sequencing. At trial, the jury found that Qiagen infringed one patent under the doctrine of equivalents and literally infringed the other patent. After trial, the district court denied Qiagen's motion for JMOL of non-infringement. Qiagen appealed.

The Federal Circuit reversed. For one asserted patent, the Federal Circuit first found the district court erred in denying JMOL of non-infringement by allowing the jury to conclude that the claim term "identical" could mean "identical to a portion." The court emphasized that such claim construction issues cannot be decided by the jury. The court also found "identical" cannot mean "identical to a portion of" because identical means "the same." The Federal Circuit also found the accused product did not infringe the patent under the doctrine of equivalents because it failed all three prongs of the function-way-result test. For the other asserted patent, the Federal Circuit agreed there was insufficient evidence to support a verdict of literal infringement. Specifically, the Federal Circuit found the district court relied on evidence that failed to satisfy two requirements of the claim terms as construed by the district court. The court also rejected Labcorp's argument that two components could in combination infringe the limitation in question, as the district court's construction required the claimed functions to be performed by one component. Accordingly, the Federal Circuit reversed and remanded to the district court with instructions to grant JMOL of non-infringement on both asserted patents.

Knobbe Martens was named a "Litigation Leader" in the 2026 edition of BTI's Litigation Outlook.

Focus Products Group International, LLC v. Kartri Sales Co., Inc.

Cooperation With a Restriction Requirement May Result in Disavowal of Claim Scope

In *Focus Products Group International, LLC v. Kartri Sales Co., Inc.*, the Federal Circuit held that repeatedly acquiescing to an examiner's restriction requirement and characterization of the claims without objection may result in disavowal of claim scope.

Focus Products Group sued Marquis Mills and Kartri Sales for infringement of patents relating to hookless shower curtains that used rings to receive the shower rod, as well as for trademark and trade dress infringement. The district court granted summary judgment that Marquis's and Kartri's accused products—shower curtains having incorporated rings with flat upper edges—infringed the patents.

On appeal, Marquis argued that the district court erred because Focus disavowed during prosecution shower curtains incorporating rings with flat upper edges. The Federal Circuit agreed. As originally filed, the patents' parent application contained claims covering several different types of shower curtain rings, including rings with flat upper edges. The examiner characterized the claims as directed to patentably distinct species and issued a restriction requirement. Focus elected rings with an offset slit and/or new finger configurations and added new claims directed to that species, including a claim that recited a ring with a "flat upper edge." However, the examiner stated that the "flat upper edge" claim was drawn to a non-elected species and was therefore withdrawn from consideration. Focus did not dispute the examiner's withdrawal of that claim and continued to prosecute the non-withdrawn claims. In a notice of allowance, the examiner gave Focus a final chance to challenge the withdrawal of the "flat upper edge" claim, but Focus did not do so. The Federal Circuit held that by cooperating with the examiner's repeated demands to exclude rings with a flat upper edge, in keeping with the original restriction requirement, Focus made it clear that it accepted the narrowed claim scope. Further, because there was no dispute that Marquis's accused products included flat upper edges, the Federal Circuit reversed the summary judgment of infringement.

Notably, although both Marquis's and Kartri's accused products had flat-topped rings, the Federal Circuit only reversed the infringement judgment as to Marquis. The two appellants originally filed separate, noncompliant briefs that incorporated arguments from one brief to the other. Kartri's brief focused on the trademark and trade dress issues while Marquis's brief focused on the patent issues. After the Federal Circuit struck the noncompliant briefs, Kartri and Marquis refiled their briefs with the incorporation-by-reference statements deleted. After closely reviewing the refiled briefs, the Federal Circuit held that Kartri waived its patent non-infringement arguments, as its treatment of the patent issue was too conclusory.

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Eye Therapies, LLC v. Slayback Pharma LLC

Transitional Phrases In Patent Claims

The U.S. Court of Appeals for the Federal Circuit's decision in *Eye Therapies LLC v. Slayback Pharma LLC* is an interesting opinion on a rarely addressed topic: transitional phrases in patent claims.

Patent claims typically have three portions: a preamble, a transitional phrase and the body of the claim. In a claim to "a chair comprising: a seat, a back, and three legs," the transitional phrase is the single word "comprising." It connects the preamble — "a chair" — with the body of the claim.

Preamble language is regularly disputed in patent litigation when one side can find a plausible argument that the preamble limits the scope of the claim. The body of the claim is almost always a bloody battlefield on which the parties wage full-scale war. The humble transitional phrase, however, is rarely the subject of a substantive dispute.

That was not the case in *Eye Therapies v. Slayback Pharma*. The case began when Slayback Pharma petitioned for *inter partes* review of Eye Therapies' U.S. Patent No. 8,293,742. The '742 patent teaches a method to reduce eye redness using a low-concentration dose of brimonidine.

Eye redness is often caused by dilation of the small blood vessels in the eye. Brimonidine was known to cause vasoconstriction, a narrowing of blood vessels.

The claims of the '742 patent recited specific low concentrations of brimonidine. But the claims contained the relatively uncommon transitional phrase "consisting essentially of." For example, Claim 1 recited: "A method for reducing eye redness consisting essentially of administering brimonidine to a patient" in specific concentrations.

The most common transitional phrase is the word "comprising." Use of "comprising" indicates that the claim covers anything with the expressly listed elements of the claim, even if it also has additional, unlisted elements.

In the chair example, our hypothetical claim would cover any chair with a seat, a back and three legs. Adding armrests, wheels or a fourth leg would not take the chair outside the scope of the claim.

By contrast, the transitional phrase "consisting of" does not permit the addition of any element beyond those expressly listed in the claim. If we substituted "consisting of" for "comprising" in our hypothetical claim, a chair with armrests would not infringe the claim.

The transitional phrase "consisting essentially of" occupies a middle ground. Claims with this transitional phrase allow the presence of additional, unclaimed elements provided those elements "do not materially affect the basic and novel properties of the invention."

The claims of the '742 patent should therefore have covered methods of treating eye redness that administered other medicaments in addition to brimonidine, so long as the administration of the other medicaments did not "materially affect the basic and novel properties of the invention."

During *inter partes* review, Slayback Pharma argued that the claims of the '742 patent were obvious over three prior art references. All three references taught administering compositions that contained active ingredients in addition to brimonidine.

The Patent Trial and Appeal Board concluded that the claims of the '742 patent were obvious over the prior art. In so doing, the Board found that the prior art's administration of additional active ingredients did not materially affect the basic and novel characteristics of the invention of the '742 patent.

Eye Therapies argued to the Board that the prosecution history of the '742 patent required that the claims be limited to administering brimonidine as the sole active ingredient. Eye Therapies pointed to a statement by the patentee that the claimed methods "do not require the use of any other active ingredients in addition to brimonidine."

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The Board rejected this argument because prohibiting the use of additional ingredients "would construe the semi-open-ended transition phrase 'consisting essentially of' to have the same scope as the closed transition phrase 'consisting of.'"

On appeal, the Federal Circuit reversed the Board's interpretation of the claims. The court held that the patentee's statements during prosecution had redefined the phrase "consisting essentially of." The Federal Circuit first relied, somewhat half-heartedly, on the patentee's statement that the claimed methods "do not require the use of any other active ingredients."

As Eye Therapies pointed out, though, this statement only means that the administration of brimonidine alone is sufficient to infringe the claim — no other active ingredient is required. The statement does not preclude the use of additional ingredients.

But the Federal Circuit did not rely solely on the patentee's statement about what the claimed methods "require." The patentee also distinguished the prior art from its own "methods consisting essentially of administering brimonidine (i.e., methods which do not include administering other active ingredients)."

The use of "i.e." showed that the patentee intended to define the phrase "methods consisting essentially of administering brimonidine" to mean "methods which do not include administering other active ingredients." The patentee therefore adopted a special definition of "consisting essentially of."

Because the Board's determination of obviousness was based on prior art references that administered other active ingredients in addition to brimonidine, the Federal Circuit vacated the obviousness determination and remanded so that the Board could consider whether it would have been obvious to modify the prior art to employ a method that administered no active ingredient other than brimonidine.

Although it was vacated, the Board's decision was interesting because it addressed an ambiguity in the law. In finding obviousness under the traditional interpretation of "consisting essentially of," the Board found that the prior art's use of additional ingredients did not "materially affect the basic and novel characteristics of the invention."

Like brimonidine, some of the additional ingredients in the prior art had the effect of reducing eye redness. That is, they arguably bolstered and augmented the basic and novel characteristic of the invention: reduction of eye redness.

The Board's determination appears to implicitly hold that augmenting the novel benefit of the invention does not materially affect the novel characteristics of the invention.

The Federal Circuit's opinion in *Eye Therapies* provides some useful lessons for attorneys prosecuting patents. First and foremost, attorneys should be very careful when using "i.e." or when otherwise restating claim language. Doing so may be considered a redefinition of the claim language in subsequent litigation.

More importantly, the patentee in *Eye Therapies* had no need to distinguish the prior art so broadly. The prior art cited by the Patent Office achieved vasoconstriction by administering two active ingredients: brimonidine and brinzolamide. The patentee could have claimed treating eye redness by administering brimonidine without administering brinzolamide. The resulting claims would have covered compositions with any active ingredient other than brinzolamide.

Better still, the patentee could have claimed administering brimonidine in a concentration sufficient to reduce eye redness. It could then have argued that the prior art did not disclose a composition in which the brimonidine alone reduced eye redness. The resulting claims would then have covered compositions with multiple active ingredients that acted independently of one another.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

FEATURE CASE

Barrette Outdoor Living, Inc. v. Fortress Iron, L.P.

Spotlight On Wording Beyond Patent Claims

A company's patent attorney plays a central role in the development of its patent portfolio. When it comes time to enforce the company's patents, the specific words used by the patent attorney are critical and often disputed. The wording of the patent's claims is the quintessential example. The claims are the rock stars of patent litigation—they typically receive the lion's share of attention from both the parties and the courts. And rightly so. Virtually every issue of liability and damages depends on the scope of the asserted claims.

Sometimes, however, the focus of a litigation can shift away from the claims to the words the attorney used in the patent's specification or in communications with the Patent Office. A pertinent example is *Barrrette Outdoor Living, Inc. v. Fortress Iron, L.P.*, a dispute the Federal Circuit addressed in a recent decision.

Barrette provides useful guidance on specification disclaimer and prosecution disclaimer, doctrines often used by defendants to narrow the scope of patent claims and avoid infringement. Familiarity with the decision will help patent prosecutors know how they can disparage the prior art in a patent's specification without triggering specification disclaimer, and when they should refrain from making arguments to the Patent Office that could lead to prosecution disclaimer.

Barrette sued Fortress for infringement of four patents directed to fencing used on sloped surfaces. The fencing's pickets and rails rotate relative to one another so that the pickets can all remain vertical even as the rails are angled to extend generally parallel to the sloped ground below them. Barrette's patents teach that the rails and pickets are rotatably connected using connectors with bosses that are inserted into holes in the pickets. Figure 5 shows a segment of the fencing with rails 30 and vertically oriented pickets 20:

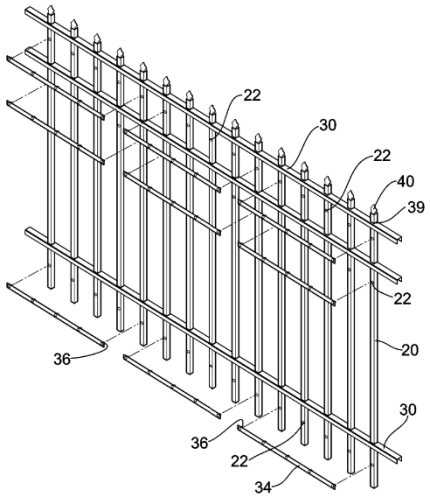

FIG. 5

During prosecution, the Patent Office granted the first two patents, but then rejected the third patent over a patent application to Shers-tad. In response, Barrette argued that Sherstad disclosed conventional rail-picket connectors, in which a loose pin extended into the picket's hole, not connectors with "the claimed integral boss." However, Barrette's decision to narrow the claim to integral bosses was ineffective. The Patent Office maintained the rejection because it found that Sherstad disclosed both non-integral and integral bosses.

The Patent Office ultimately allowed Barrette's third patent, but only because Barrette cancelled all of the rejected claims and added new claims with language similar to the two previously granted patents. But Barrette's success proved to be a pyrrhic victory. In the litigation with Fortress, the district court found that Barrette's prosecution argument about Sherstad disclaimed non-integral bosses, limiting the claims of all four asserted patents to connectors with integral bosses.

The district court also found that Barrette's statements in the patents' shared specification disclaimed connectors that used fasteners to attach the bosses to the pickets. The court focused on language criticizing

FEATURE CASE

prior art fencing with such fasteners as "time consuming to install." The district court ruled that this was a disclaimer of bosses with fasteners, limiting the patent claims to fastener-less bosses. The district court then entered judgment of non-infringement, as it was undisputed that Fortress's bosses were neither integral nor fastener-less.

On appeal, the Federal Circuit disagreed with the district court's ruling that specification disclaimer limited the claims to fastener-less bosses, but agreed that prosecution disclaimer limited the claims to integral bosses.

In addressing specification disclaimer, the Federal Circuit noted that the specification criticized the prior art not only for being slow to install, but also for allowing only limited rotation between the rails and pickets, a feature known in the industry as "racking." Because bosses with fasteners could solve one of the two problems in the prior art, i.e., poor racking, the specification's criticism that fasteners make installation slow did not disclaim all bosses with fasteners. The court stressed that every embodiment of the patented invention need not embody every advance over the prior art.

Turning to prosecution disclaimer, the Federal Circuit agreed with the district court's conclusion that Barrette disclaimed non-integral bosses when it distinguished Sherstad's connectors from "the claimed integral boss." Relying on *Ecolab, Inc. v. FMC Corp.* (Fed. Cir. 2009) and its progeny, Barrette argued that it made no clear and unmistakable disclaimer of claim scope because the examiner was unpersuaded by Barrette's attempt to distinguish Sherstad, and Barrette later abandoned the argument by cancelling the pending claims.

The Federal Circuit was unpersuaded. Unlike in *Ecolab*, where the examiner rejected the patent applicant's argument about the scope of the claims, in this case the examiner determined that Sherstad disclosed both integral and non-integral bosses and therefore invalidated the pending claims even under Barrette's narrow construction that limited the claims to integral bosses. Because Barrette's narrow construction was not rejected by the examiner, Barrette was bound by its disclaimer even though it subsequently cancelled its claims.

Finally, the Federal Circuit agreed with the district court that Barrette's disclaimer during prosecution of its third patent applied to all other patents in the family with the same claim term, even the two patents that issued *before* Barrette made its argument about Sherstad.

The *Barrette* decision offers many insights for patent prosecutors. First, it provides clear guidance on how to avoid specification disclaimer: the specification should discuss multiple insufficiencies in the prior art, not just one. This approach is superior to avoiding all criticism of the prior art. That ultra-conservative strategy makes it difficult for the patent to show that its invention is an advance in the field. And describing such an advance is, of course, important for persuading the Patent Office and juries that the claimed invention is patentable.

Barrette is also a cautionary tale about the risks of prosecution disclaimer. It is hazardous to distinguish prior art with an argument that limits the claims unless the prosecuting attorney is certain the argument will overcome the examiner's rejection. Attorneys should never be content to narrow pending claims in a way that merely distinguishes the prior art reference's preferred embodiment or figures. If the narrowed claims are disclosed by any embodiment in the prior art, even one only mentioned in passing in the written description, the examiner could accept the proposed narrow construction of the claims and still maintain the rejection.

The *Barrette* decision is another reminder that prosecuting attorneys must choose their words carefully, and not just when drafting the all-important language of the claims.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

Fraunhofer-Gesellschaft v. Sirius XM Radio Inc.

Equitable Estoppel: Misleading Silence Not Enough Unless It Was Relied on And Caused Prejudice

In *Fraunhofer-Gesellschaft v. Sirius XM Radio Inc.*, Appeal No. 23-2267, the Federal Circuit held that the defense of equitable estoppel requires showing that the patentee engaged in misleading conduct that the accused infringer relied on, resulting in prejudice.

Fraunhofer sued Sirius XM (Sirius), alleging patent infringement. Fraunhofer had previously collaborated with Sirius's predecessor, XM, to develop satellite radio technology. To do so, XM obtained a sublicense to the patents at issue from Fraunhofer's exclusive third-party licensee, who later went bankrupt. Years later, Fraunhofer sued Sirius for patent infringement, arguing that all patent rights had reverted to Fraunhofer during the bankruptcy. Before the district court, Sirius moved for summary judgment that Fraunhofer's claims were barred by equitable estoppel because Fraunhofer collaborated with Sirius's predecessor to create the accused features of Sirius's satellite radio system and Fraunhofer had waited more than five years to raise Sirius's alleged infringement. The district court agreed, granting summary judgment on the basis of equitable estoppel.

On appeal, the Federal Circuit reversed. While the Federal Circuit agreed with the district court's finding that Fraunhofer's conduct was misleading by staying silent for more than five years before filing suit against Sirius, the Federal Circuit did not agree that Sirius presented sufficient evidence to show it relied on Fraunhofer's silence when deciding to incorporate the accused features into its radio system. Because Sirius failed to prove reliance, the Federal Circuit held that Sirius could not show it was prejudiced by relying on Fraunhofer's silence. However, the Federal Circuit also explained that, if Sirius could establish at trial that it relied on Fraunhofer's misleading silence, then it could adequately show it was prejudiced by that reliance because Sirius clearly decided to migrate to the accused system rather than pursue a viable, non-infringing alternative.

IGT v. Zynga Inc.

No Shenanigans: IPRs and Interference Estoppel

Knobbe Martens was recognized nationally and regionally for PTAB Litigation, Patent Disputes, and Trademark Litigation in the 2025 Managing IP "IP STARS" guide.

In *IGT v. Zynga Inc.*, Appeal No. 23-2262, the Federal Circuit held that interference estoppel does not apply when the interference was terminated due to a threshold issue.

Zynga petitioned for *inter partes* review (IPR) of an IGT patent after having attacked the same patent via an interference proceeding. IGT opposed, arguing interference estoppel under 37 C.F.R. § 41.127(a)(1). Because the interference proceeding was terminated on a threshold issue and the IPR petition relied on a combination of prior art references not used in the interference proceeding, the PTAB declined to apply interference estoppel. The PTAB ultimately concluded that IGT's claims were obvious. IGT appealed.

The Federal Circuit affirmed, finding that the decision not to apply interference estoppel was related to the decision to institute the IPR and therefore unreviewable. The court reasoned that the PTO Director is afforded discretion regarding whether to institute an IPR. The decision to institute an IPR is generally unreviewable unless the PTO has violated legal constraints or engaged in other "shenanigans."

The Federal Circuit found the PTAB's reasoning for not applying interference estoppel sufficient to support a finding of no "shenanigans," and that no exceptions applied to the general bar on reviewability of institution determinations. The court further affirmed the PTAB's finding on obviousness.

In re Riggs

Portions of a § 102(e) Prior-Art Reference That Do Not Find Support in its Provisional Application Are Not Afforded the Provisional Application's Filing Date

In re Riggs, Appeal No. 22-1945, the Federal Circuit held that a reference that qualifies as prior art under pre-AIA 35 U.S.C. § 102(e) is afforded the filing date of its provisional patent application only for portions of the reference that find written description support in the provisional.

Several individuals (the "named inventors") filed a patent application. An examiner rejected the patent application over a U.S. patent application publication to Lettich ("Lettich"). The examiner found Lettich was prior art under pre-AIA § 102(e). Lettich published after the priority date of the named inventors' patent application but claimed priority to a provisional patent application that published before that priority date (the "Lettich Provisional"). The named inventors appealed the rejection to the Patent Trial and Appeal Board. After a series of decisions, a request for rehearing, multiple appeals, and remand, the Board affirmed the subject rejection. In doing so, the Board found that Lettich qualified as prior art under § 102(e) because one of its claims found written description support in the Lettich Provisional. The named inventors appealed to the Federal Circuit.

The Federal Circuit vacated the Board's decision that Lettich qualifies as prior art under § 102(e). It announced that "the provisional application must . . . provide written description support for the specific portions of the patent specification identified and relied on in the prior art rejection." The court found the Board had not completed this analysis for the subject rejection. Therefore, the Federal Circuit remanded for the Board to determine whether the Lettich Provisional provides written description support for the specific disclosures in Lettich that the examiner identified and relied on in the subject rejection.

Novartis Pharmaceuticals Corporation v. Torrent Pharma Inc.

Later-Existing State of The Art Can Not "Reach Back" to Invalidate Claims

In *Novartis Pharmaceuticals Corporation v. Torrent Pharma Inc.*, Appeal No. 23-2218, the Federal Circuit held that patent was not required to include written description of later-discovered chemical complexes, even though claims were construed to arguably cover those later-discovered complexes.

Patentee Novartis sued Defendants, including Appellee MSN, for infringement of a patent claiming a pharmaceutical composition. At claim construction, the parties disputed the claim term "wherein said [valsartan and sacubitril] are administered in combination." MSN argued that the term limited to claim to administration of valsartan and sacubitril as two separate components rather than a complex, because MSN's product included valsartan and sacubitril as a complex. The district court rejected MSN's position, instead construing the term based on its plain and ordinary meaning, because the intrinsic record was "silent on whether sacubitril and valsartan must be separate (and not complexed)." MSN stipulated to infringement under this construction and the case proceeded to a bench trial on invalidity. The district court determined that the patent was invalid for lack of written description on valsartan and sacubitril complexes, which were not known at the time the patent was filed

On appeal, the Federal Circuit reversed the district court's finding of lack of adequate written description. The Federal Circuit criticized the district court for conflating the issues of patentability and infringement, emphasizing that the written description inquiry is about the invention that is specifically claimed, rather than what the claim is construed to cover. Here, the claim recited a combination of valsartan and sacubitril, which was described throughout the specification. The court reasoned that the fact that the patent did not describe the complexed form of valsartan and sacubitril did not affect the validity of the patent, because the complex was not "what is claimed."

In re Xencor, Inc.

Jepson Claim Preamble Requires Written Description Support for Conventional Aspects of the Invention

In re Xencor, Inc., Appeal No. 24-1870, the Federal Circuit held that to provide adequate written description for a Jepson claim, the applicant must establish that what is claimed to be well known in the prior art is, in fact, well known in the prior art.

Xencor filed a U.S. patent application with a Jepson claim and a method claim. Both claims have preambles that recite "treating a patient by administering an anti-C5 antibody." The patent examiner rejected both claims for lack of written description. After a series of appeals within the U.S. Patent Office and the Federal Circuit, the Appeals Review Panel of the Patent Trial and Appeal Board affirmed the examiner's rejection. Xencor appealed the ARP's decision to the Federal Circuit.

The Federal Circuit affirmed. It noted a Jepson claim uses the preamble to recite elements or steps of the claimed invention that are conventional or known. Xencor had agued those conventional or known aspects do not require written description support. The Federal Circuit rejected that argument and noted adequate written description for a Jepson claim requires the applicant to establish that what is claimed to be well known in the prior art is, in fact, well known in the prior art. The court found substantial evidence that Xencor did not do so for the "anti-C5 antibody" claimed in the preamble of its Jepson claim. For Xencor's method claim, the Federal Circuit affirmed that the preamble term "treating a patient" limits the claim and that Xencor's patent application lacks written description for that term.

Mondis Technology Ltd. v. LG Electronics Inc.

Examiner's Allowance Not Enough: Lack of Written Description for Claim Amendment Upends Infringement Verdict

In *Mondis Technology Ltd. v. LG Electronics Inc*. Appeal No. 23-2117, the Federal Circuit reversed a jury verdict of infringement because a claim limitation amended during prosecution lacked written description support.

Mondis Technology Ltd. sued LG Electronics Inc. for infringement of claims 14 and 15 of Mondis's '180 patent directed to a system for controlling a specific display unit based on an identification number stored in the display unit's memory. During prosecution, claim 14 was amended from reciting "an identification number for identifying said display unit" to reciting "an identification number for identifying at least a type of said display unit." At trial, LG argued the claims were invalid because, while the specification supported the original claim language, it did not support the amended language of identifying a type of said display unit. Although Mondis did not present a rebuttal case on written description during trial, the jury found the claims not invalid and that LG infringed. The district court also denied LG's motion for judgment as a matter of law on written description and LG appealed.

The Federal Circuit reversed, holding that no reasonable jury could find written description support for the "type of said display unit" limitation. Mondis argued because the examiner allowed the claim amendment without objection, it was entitled to an "especially weighty presumption of correctness." But the Federal Circuit rejected that argument, explaining that an examiner's allowance of claims by itself does not provide substantial evidence that the claims comply with the requirements of § 112. The Federal Circuit found that the claim limitation was unsupported by the application, which consistently described only identifiers tied to specific devices and never to a *type of* device. Moreover, Mondis's expert testified that the specification "[did] not expressly recite an identification number for identifying a type of display unit" and Mondis never redirected its expert on this testimony. Thus, there was no evidence in the record that would allow a reasonable jury to determine that a person of ordinary skill in the art would have understood that the patent disclosed the "type" limitation.

FEATURE CASE

Duke University v. Sandoz Inc.

Looking for Patent 'Blaze Marks'

The Federal Circuit's November 2025 decision in *Duke University v. Sandoz Inc.* addresses a fundamental question in patent law: Can a patent applicant pick and choose from different pieces of the disclosure when crafting a claim to the invention? In *Duke*, the Federal Circuit suggests that some degree of mixing-and-matching might be acceptable, but serves as a warning to patentees that the specification must provide some reason to take the path that ultimately led to the claimed invention. If the patent discloses many different possibilities but does not provide sufficient guidance for a skilled artisan to arrive at the claimed invention, the claim lacks support and is invalid.

The patent at issue in *Duke*, U.S. Patent No. 9,579,270 (the '270 Patent), relates to Latisse®, a drug marketed by Allergan to increase eyelash growth. According to its marketing materials, Latisse® will result in fuller, longer, and darker lashes. The active ingredient in Latisse® is bimatoprost, an analog of a molecule called prostaglandin F. The '270 Patent claims a method of growing hair by administering an active ingredient selected from a genus of prostaglandin F analogs. This claimed genus includes a common structural core but allows substitution with different chemical moieties at different positions on the core. The specific compound bimatoprost falls within the scope of the genus recited in the claimed method of treatment.

During the jury trial, Sandoz argued that there was not sufficient disclosure to meet the written description requirement of 35 U.S.C. § 112(a). The written description requirement represents a part of the quid pro quo of patent law. A patent applicant must disclose an invention with sufficient detail and specificity to demonstrate to those of skill in the art that the inventors had possession of the claimed invention when the application was filed. This requirement prevents the patent applicant from claiming something that was neither invented nor contemplated in the disclosure. A description that does not support the claims leads to invalidity because the claims are not directed to the applicant's invention.

Written description is a factual inquiry. Sandoz argued that the '270 Patent claimed a genus that included thousands of different compounds as active ingredients without a corresponding description of any specific embodiments of the claimed genus or sufficient common structural features that would have led a person of ordinary skill in the art to the claimed genus of compounds. The jury considered Sandoz's evidence and found that Sandoz had failed to prove a lack of written description by clear and convincing evidence.

The Federal Circuit came to a different conclusion. In holding that the '270 Patent claims did not have adequate written description support, the court repeatedly referred to "blaze marks," a concept that comes from forestry, not patent law. The idea of blaze marks in a patent's description was introduced into patent law by Judge Giles Rich, one of the most prominent American patent law jurists. In his 1967 opinion, *In re Ruschig*, Judge Rich wrote for the Federal Circuit's predecessor court and explained the link between forestry and patent law:

> It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared — or have not yet been made, which is more like the case here — to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none

Judge Rich's analogy between trailblazing and the adequacy of a patent's disclosure lay largely dormant for several decades until the Federal Circuit increased judicial focus on the written description requirement as an independent basis for invalidity. Now, Judge

FEATURE CASE

Rich's blaze marks analogy is a crucial articulation of the written description requirement.

The *Duke* decision reinforces that a patent must guide the reader, almost inevitably, to the claimed invention and is inadequate if it leaves an incomplete or confusing trail of possible twists and turns. In *Duke*, the Federal Circuit explained, the patent specification disclosed billions of potential compounds that included the claimed backbone structure but it did not provide a clear path to the specific modifications in the later-claimed genus of mere thousands of compounds; the blaze marks were insufficient to direct a skilled artisan to the more specific variations that were ultimately claimed. The patentee argued that there were a relatively small number of variations claimed at specific positions, but the court disagreed, explaining that even a small number of branching possibilities gave rise to yet more branches, resulting in a vast number of options.

The *Duke* court focused on the totality of the specification's disclosure, and not just the isolated pieces that arguably supported each individual claim element. Thus, the court considered that the patent taught "preferred" or "more preferred" options that were not included within the scope of what was claimed. The court explained this would have led an artisan on a path away from the one needed to arrive at the claimed genus of active ingredients. This demonstrated that the inventors did not possess what was eventually claimed as the invention. In effect, these teachings placed blaze marks on trees that would inevitably guide the skilled artisan to a different invention, not the one ultimately claimed. In the court's view, the specification provided a maze-like path, not a direct route, to the invention. Thus, the court indicated, the specification was more reasonably viewed as a "laundry list" of possibilities and therefore was insufficient to satisfy the written description requirement.

Duke is notable because it addresses the not-unusual situation where a patentee revises claims during prosecution by selecting from lists of disclosed elements. The court focused on the claimed combination of different elements and compared the narrowed claims to the billions of possibilities disclosed in the specification. The court overturned the jury verdict because the specification did not provide the reader with sufficient blaze marks to differentiate the claimed sub-genus (of thousands of compounds) from the disclosed genus (of billions of compounds) in a way that would ultimately arrive at the claimed invention. This approach of comparing the claimed combination of elements to the disclosure, as a whole, provides an important limit on retrospective claim drafting and re-emphasizes *In re Ruschig*'s requirement that the specification provide a clear path to the specific claimed invention, and not just the individual claimed elements in isolation. Moving forward, *Duke* will likely provide patent challengers with a potent tool to attack claims revised during prosecution to recite a subgenus not specifically disclosed in the patent.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

Knobbe Martens was nationally recognized as a Tier 1 firm for Intellectual Property Litigation in the 2026 edition of Benchmark Litigation's "USA Guide".

Colibri Heart Valve LLC v. Medtronic Corevalve, LLC

Cancellation of a Closely Related Claim During Prosecution Can Trigger Prosecution History Estoppel

In *Colibri Heart Valve LLC v. Medtronic Corevalve, LLC, Appeal No*. 23-2153, the Federal Circuit reversed a $106 million infringement verdict, holding that Colibri's doctrine-of-equivalents arguments were barred by prosecution history estoppel because it cancelled a related claim during prosecution.

Colibri sued Medtronic, a manufacturer of replacement heart valves, for infringement of a patented method for implanting an artificial heart valve that gives the surgeon a second chance to get the positioning of the valve right. During prosecution of its patent, Colibri pursued two closely related independent claims reciting the do-over method. The first claim recited "pushing" the valve out from the delivery device, while the second claim covered "retracting" an outer sheath to expose the valve. The examiner rejected the "retracting" claim for lack of written description and Colibri cancelled it.

In the district court, Medtronic argued that its product deployed the valve by retracting, not pushing. Colibri responded that the "pushing" claim covered Medtronic's procedure under the doctrine of equivalents. The jury agreed and awarded Colibri more than $106 million in damages. Medtronic moved for judgment as a matter of law (JMOL) on the grounds that Colibri's doctrine-of-equivalents theory was barred by prosecution history estoppel. The district court denied the JMOL motion because the "pushing" and "retracting" claims were separate independent claims and Colibri did not amend the "pushing" limitation during prosecution.

The Federal Circuit reversed the district court's denial of JMOL. The court explained that when evaluating prosecution history estoppel, a court considers closely related claims, not just the amended claim. Because of the close substantive relationship between the "pushing" claim and the "retracting" claim, Colibri's cancellation of the "retracting" claim gave rise to prosecution history estoppel as to the "pushing" claim.

Magēmā Technology LLC v. Phillips 66

Bait, Switch, and Retrial: Federal Circuit Rebukes Trial Arguments That Reneged on Prior Representations

In *Magēmā Technology LLC v. Phillips 66*, Appeal No. 24-1342, a district court abused its discretion by permitting a defendant to argue to a jury that actual testing was required to show infringement, after the same party successfully opposed a motion to compel by representing such testing was not necessary.

Magēmā sued Phillips for infringement of its patent directed to a low-sulfur heavy marine fuel oil ("HMFO")—a fuel used in large, ocean-going cargo ships. The asserted claims required that, before a process called hydroprocessing, the HMFO must have a flashpoint of at least 140°F. During discovery, Magēmā moved to compel Phillips to produce actual flashpoint testing data. However, Phillips successfully opposed the motion to compel, arguing that actual testing would be too dangerous and representing that Magēmā could instead rely on a generally accepted formula to estimate the flashpoint temperature. But on the eve of trial, Magēmā learned that Phillips, contrary to its representations, planned to argue that actual testing was required and that formula estimates were insufficient to prove infringement. Magēmā objected to Phillips presenting its actual-testing theory at trial, but the district court overruled the objection. At trial, Phillips repeatedly argued that actual testing was required to demonstrate the flashpoint limitation. The jury returned a non-infringement verdict. Magēmā then moved for a new trial, which the district court denied. Although the district court acknowledged Phillips' actual-testing argument was "improper and prejudicial," the district court found it was harmless error because the jury could have found non-infringement based on other claim limitations.

On appeal, Magēmā argued that the district court abused its discretion in denying the motion for new trial. The Federal Circuit agreed that Phillip's actual-testing argument was both improper and prejudicial, but did not agree that it was harmless error. The Federal Circuit found that Phillips "sandbagged Magēmā right before trial with a bait-and-switch" by reneging on its prior representations that actual testing was not required and that formula estimates were sufficient. Further, the Federal Circuit determined that the error was not harmless because the case was submitted to the jury on a general verdict and the Federal Circuit could not determine whether the jury based its verdict on the improper actual-testing argument or on a different issue. Thus, the Federal Circuit reversed the district court's denial of the motion for new trial and remanded for a new trial.

Finesse Wireless LLC v. AT&T Mobility LLC

Expert Testimony Fails to Support Jury's Infringement Verdict

In *Finesse Wireless LLC v. AT&T Mobility LLC*, Appeal No. 24-1039, unclear and internally inconsistent expert testimony was not substantial evidence that supported a jury's infringement verdict.

Finesse sued AT&T alleging AT&T's use of Nokia radios infringed two of Finesse's patents: the '134 patent and the '775 patent. Nokia intervened. A jury found all asserted claims in Finesse's patents were valid and infringed, and awarded damages. AT&T and Nokia moved for judgement as a matter of law (JMOL) of non-infringement, JMOL on damages, and a new trial. The district court denied those motions. AT&T and Nokia appealed.

The Federal Circuit reversed. It held that the jury's infringement verdict was not supported by substantial evidence. With respect to the '134 patent, the Federal Circuit found Finesse's expert testimony was unclear and contradictory as to whether the accused radios' receiver sampled both "signals of interest" and "interference generating signals." With respect to the '775 patent, the Federal Circuit held that no reasonable jury could have found the accused radios perform seven multiplications, as claimed, when a document Finesse's expert relied on showed only three multiplications. The Federal Circuit reversed the denial of JMOL of non-infringement and vacated the damages award.

Lashify, Inc. v. ITC

Distribution and Marketing May Satisfy the Economic Prong of the Domestic-Industry Requirement

In *Lashify, Inc. v. ITC,* Appeal No. 23-1245, the Federal Circuit held that warehousing, quality control, distribution, sales, and marketing expenses may constitute "significant employment of labor or capital" under 19 U.S.C. § 1337(a)(3)(B) to satisfy the economic prong of the domestic-industry requirement in ITC cases.

Lashify filed a complaint before the ITC alleging that multiple importers were importing products that infringe Lashify's patents pertaining to eyelash extensions and related accessories. The ITC declined to consider Lashify's expenditures for warehousing, quality control, distribution, sales, and marketing of its products. Accordingly, determining that Lashify had not established domestic industry because Lashify failed to satisfy the economic-prong requirement, the ITC denied relief. Lashify appealed.

Lashify argued that the ITC's holdings were contrary to the statutory language and the Federal Circuit agreed. The ITC reasoned that large expenditures for domestic employment of labor or capital are insufficient when the labor or capital is used for sales or marketing alone, and when the labor or capital is used for warehousing, quality control, and distribution if the products are not domestically manufactured and no additional steps are taken in the U.S. to make them saleable. However, the Federal Circuit determined that these limitations have no basis in the statute and, in fact, "clause (B) covers significant use of 'labor' and 'capital' without any limitation on the use within an enterprise to which those items are put[.]" Thus, the Federal Circuit vacated and remanded to the ITC for reconsideration under the proper standard.

Restem, LLC v. Jadi Cell, LLC

Limits of Inherent Anticipation in Product-by-Process Claims

In *Restem, LLC v. Jadi Cell, LLC*, Appeal No. 23-2054, the Federal Circuit held that inherency in product-by-process claims requires the prior art to inevitably produce the claimed product—not merely disclose similar process steps.

Jadi Cell's patent covers isolated stem cells produced from mammalian umbilical cord tissue by a process with two key steps: (1) placing the subepithelial layer (SL) of the umbilical cord tissue in direct contact with a growth substrate, and (2) culturing the SL to produce cells with a specific marker expression profile. Restem sought *inter partes* review. In a final written decision, the Board found that while the prior art references cited by Restem disclosed similar process steps for culturing umbilical cord-derived stem cells, they did not necessarily result in the claimed product—that is, the prior art did not necessarily produce cells with the precise marker expression pattern recited in Jadi Cell's claims.

Restem appealed, arguing that the prior art inherently anticipated the claims because it used comparable or identical isolation and culturing techniques, and therefore, once the process steps are met by the prior art, the product is necessarily present. In other words, Restem argued inherency is automatic for product-by-process claims and the Board erred in finding that the prior art did not inherently anticipate the challenged claims. However, the Federal Circuit rejected this argument, explaining that inherency in product-by-process claims is not satisfied merely because a prior art process is similar, or even identical—the end result must inevitably include the claimed product. The Federal Circuit affirmed the Board's decision because substantial evidence showed that different culturing conditions and cell-to-cell interactions could influence cell marker expression, meaning the prior art did not necessarily yield the claimed cell population.

Honeywell International Inc. v. 3G Licensing, S.A.

Motivation to Modify Under Obviousness Standard Does Not Need to Align with Patentee's Goal

In *Honeywell International Inc. v. 3G Licensing, S.A.*, Appeal No. 23-1354, the Federal Circuit held that under the obviousness standard of 35 U.S.C. § 103, the motivation to modify prior art does not need to be the same as the patentee's motivation.

Honeywell filed a petition for *inter partes* review challenging claims of a patent owned by 3G Licensing, arguing that the claims were obvious in view of two prior art references. The Board ruled in favor of 3G Licensing, finding that Honeywell failed to demonstrate sufficient motivation for a person of ordinary skill in the art to modify the first reference or to combine the approaches described in the two references.

The Federal Circuit reviewed the Board's determination *de novo* and reversed its decision, identifying several errors. The Federal Circuit reiterated that the motivation to modify prior art does not need to align with the patentee's specific motivations, and therefore, it was an error to rely on the patentee's goal in determining obviousness. Further, the Federal Circuit also relied on unrebutted expert testimony from Honeywell to find that the Board's conclusion that a person of ordinary skill in the art would not understand certain modifications to the reference was unsupported by substantial evidence. The Federal Circuit also found that the Board applied the wrong standard by conflating obviousness with anticipation. Finally, the Federal Circuit found that the Board erred by failing to recognize that the claimed modification needed only to be desirable in light of the prior art and not the "best" or "preferred" approach. The Federal Circuit, therefore, reversed the Board's decision.

In dissent, Judge Stoll argued that the Federal Circuit exceeded its appellate role by reweighing evidence and making factual determinations, contending the proper remedy was to vacate and remand the Board's decision for further review rather than outright reversal.

HD Silicon Solutions LLC v. Microchip Technology Inc.

Every Word Counts: Specification Naming Conventions Can Limit Claim Scope

In *HD Silicon Solutions LLC v. Microchip Technology Inc.*, Appeal No. 23-1397, the Federal Circuit held that all but one patent claim were invalid as obvious because the claimed material, as properly construed, was disclosed by the asserted prior art reference.

Microchip Technology filed an IPR, arguing all claims of HD Silicon Solutions' patent were invalid. The challenged patent is directed to a method of forming local circuit interconnects that requires "depositing a second film ... comprising tungsten." The Board construed "comprising tungsten" to mean any form of tungsten, including elemental tungsten and tungsten compounds. Based on that construction, the Board held all but one claim invalid as obvious.

The Federal Circuit disagreed with the Board's construction of "comprising tungsten" but affirmed the Board's holding under the proper construction of that term. The court emphasized that patent's claims and specification consistently used the term "tungsten" alone, and the specification described the material properties of elemental tungsten. The court also noted the specification's convention of using open-ended modifiers (e.g., chlorine-based etchants) when referencing materials that include both elements and compounds. Based on this naming convention, the court concluded the claimed "tungsten," without any modifiers, refers to elemental tungsten only. Because Microchip's asserted prior art reference disclosed elemental tungsten, the court affirmed the Board's obviousness holding.

Knobbe Martens was ranked Tier 1 nationwide for Intellectual Property Litigation in the 2026 U.S. News – Best Lawyers "Best Law Firms" guide.

Immunogen, Inc. v. Stewart

An Obvious Solution to an Unknown Problem

In *Immunogen, Inc. v. Stewart*, Appeal No. 23-1762, the Federal Circuit held that even if the specific problem solved by an inventor were unknown in the art, the claimed solution to the problem could still be found obvious.

ImmunoGen filed a civil action in district court under 35 U.S.C. § 145 to obtain a patent directed to a cancer treatment method using an immunoconjugate drug known as IMGN853. The applied-for claims recited a specific dosage of 6 mg/kg of the patient's adjusted ideal body weight (AIBW), which the patent explained could avoid the negative side effect of ocular toxicity. After a bench trial, the district court found the claims were obvious over ImmunoGen's own prior art that disclosed dosing IMGN853 based on total body weight (TBW) in view of prior art disclosing dosing based on AIBW. The district court also held the claims were indefinite because the application did not define how to calculate AIBW, when there were multiple known formulas to do so.

On appeal, ImmunoGen argued that the district court erred in analyzing motivation to combine because it was undisputed that at the time of the invention, a person of ordinary skill in the art would not have known that IMGN853 caused ocular toxicity in humans. The Federal Circuit explained, however, that even if the specific problem the inventors purported to solve via the dosing regimen was unknown, that did not necessarily mean that the dosing regimen itself was not obvious. The Federal Circuit found no error in the district court's analysis because although IMGN853 was not known to cause ocular toxicity, ocular toxicity was a well-known side effect of administering immunoconjugates that contain a drug known as DM4. And because IMGN853 contains DM4, a person of ordinary skill would therefore have understood the potential risk of ocular toxicity and monitored for it when testing IMGN853. Moderating the dosage to avoid the problem therefore would have been obvious.

ImmunoGen also argued that it would not have been obvious to base the dosage on the patient's AIBW, as opposed to using the patient's TBW. But the Federal Circuit rejected that argument because the prior art disclosed a dose of 6 mg/kg TBW, and for some patients, their AIBW is the same as their TBW. Thus, the Federal Circuit affirmed the district court's decision that the claims were obvious and did not reach ImmunoGen's arguments regarding indefiniteness.

Amp Plus, Inc. v. DMF, Inc.

To Support a Finding of Unpatentability, Each Claim Limitation Should Be Discussed

In *Amp Plus, Inc. v. DMF, Inc.*, Appeal No. 23-1997, the Federal Circuit held that substantial evidence supported the Board's determination that the appellant failed to show the unpatentability of a claim because its supporting documents did not discuss a claim element.

ELCO petitioned for IPR challenging claims of DMF's patent as anticipated and obvious. ELCO argued that one claim was obvious in view of two brochures directed towards light fixtures for marine applications. On remand, the Board concluded that ELCO failed to show the unpatentability of the claim because it presented "no analysis" of a portion of a limitation. ELCO appealed.

ELCO argued that the Board erred in not finding the claim anticipated because the Board had previously found that a similar claim was anticipated. The Federal Circuit rejected this argument because ELCO's petition argued the challenged claim was obvious, not anticipated. ELCO also argued that the Board's determination was unsupported by substantial evidence. Noting that ELCO's petition and the supporting documents did not discuss a claim requirement, the Federal Circuit ruled that this omission constituted substantial evidence supporting the Board's determination that ELCO had failed to show the unpatentability of the claim.

The Federal Circuit noted that "ELCO's position boils down to an invitation for this court to comb through other sections of its petition and find support for its obviousness argument," and that "the law of obviousness does not require the court, or the Board, to develop arguments for a limitation that the petition simply did not make." The Federal Circuit affirmed.

Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.

Combination Dosing Regimen Not Obvious Despite Overlapping Prior-Art Ranges

In *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, Appeal No. 25-1228, the Federal Circuit found that claims reciting a dosing regimen with unequal loading doses were not obvious and that a presumption of obviousness based on overlapping ranges did not apply.

Janssen sued Teva for infringing patent claims directed to dosing regimens for an injectable form of paliperidone palmitate. Teva stipulated to infringement and challenged validity on grounds of obviousness and indefiniteness. In a prior appeal, the Federal Circuit affirmed the district court's rejection of the indefiniteness challenge but vacated its obviousness ruling. On remand, after a bench trial, the district court held that Teva had not proved any of the asserted claims invalid for obviousness or indefiniteness.

The Federal Circuit affirmed. First, it declined to apply the presumption of obviousness despite an overlap in the claimed and prior-art dosage ranges. It found the claimed combination included a novel dosing sequence with a higher first dose followed by a lower second dose. The Federal Circuit explained that the presumption typically applies when a single variable overlaps with prior-art ranges and when the skilled artisan could optimize it through routine experimentation. The Federal Circuit also upheld findings by the district court that Teva failed to show a motivation to combine the cited references. It agreed with the district court that a skilled artisan would not have expected success with the claimed regimen due to missing safety data and differing drug behavior in the prior art.

Merck Serono S.A. v. Hopewell Pharma Ventures, Inc.

Identical Inventor Required to Exclude Prior Art

In *Merck Serono S.A. v. Hopewell Pharma Ventures, Inc.*, the Federal Circuit held that an earlier reference is available as prior art "by another" unless it involved the same inventive entity.

Hopewell requested inter partes review of two Merck patents directed to methods of treating multiple sclerosis (MS). The Board found each one unpatentable as obvious over two prior art references: Bodor and Stelmasiak. Merck argued that, under pre-AIA 35 U.S.C. § 102, Bodor was not prior art "by another" because the named inventors on the challenged patents contributed to the portion of Bodor's disclosure that the Board relied on. The Board rejected Merck's argument, finding that Merck failed to establish that Dr. De Luca, one of the named inventors, made significant contribution to the cited disclosure in Bodor. Merck appealed.

The Federal Circuit affirmed the Board's decision. The court explained that, to establish a reference was not "by another," a portion of the reference's disclosure must be the "collective work of the same inventive entity identified in the patent." The court explained that, to remove portions of a cited reference as prior art, the patentee must demonstrate that the relevant disclosure in the prior art reference reflects the collective work of the same inventive entity as the challenged patent. That showing can be made even if fewer than all the inventors are named on the alleged prior art. But if fewer than all the inventors are named, the patentee must establish that the disclosure actually reflects the joint work of all the inventors named on the challenged patent, including those not named on the alleged prior art. Otherwise, the disclosure will be deemed "by another" and thus prior art against the later filing. The showing that a disclosure in the prior art was by the same inventive entity requires evidence that each inventor made a significant contribution – merely having "some unspecified involvement" is insufficient. The court affirmed the Board's finding that Merck failed to establish that Dr. De Luca made a significant contribution to the cited disclosure in the Bodor reference. Therefore, Bodor was "by another" and constituted prior art.

US Synthetic Corp. v. International Trade Commission

Claims Reciting Material Properties of a Claimed Composition Withstand § 101 Scrutiny

In US Synthetic Corp. v. International Trade Commission, Appeal No. 23-1217, the Federal Circuit found claims reciting magnetic properties of a claimed composition were not directed to an abstract idea where the specification expressly correlated the recited magnetic properties to physical characteristics of the claimed composition.

US Synthetic Corp. (USS) filed a complaint with the U.S. International Trade Commission alleging several entities violated § 337 of the Tariff Act by importing products that infringed U.S. Patent No. 10,508,502 (the '502 patent) and four other USS patents. The '502 patent claims a composition known as a polycrystalline diamond compact (PDC), which is used in drilling tools and machining equipment. Representative claims recite the claimed PDC's constituent elements such as diamond, its dimensional information such as grain size, and its magnetic properties. The Commission instituted an investigation. In a final initial determination, an administrative law judge determined the asserted claims of the patent were patent ineligible under 35 U.S.C. § 101 as directed to an abstract idea. The Commission reviewed and affirmed that determination. USS appealed.

The Federal Circuit reversed the Commission's patent ineligibility ruling and remanded. According to the court, the parties' dispute centered around the magnetic properties recited in the '502 patent. It found the patent's specification expressly correlated the recited magnetic properties to physical characteristics of the claimed PDC composition. The Federal Circuit held the disclosed correlation was "sufficient for § 101, where we are trying to ascertain as a matter of law whether a patent claim is directed to a specific implementation of an idea or merely just the idea itself." The court explained that "no perfect proxy is required between the recited material properties and the structure of the PDC." It found the described correlations to be "concrete and meaningful, rather than something that is merely speculative." The Federal Circuit therefore concluded that the asserted claims of the '502 patent are not directed to an abstract idea under *Alice* step one.

Block Holding, Inc. v. iFit, Inc.

Can § 101 Carry the Weight?

In *Block Holding, Inc. v. iFit, Inc.*, Appeal No. 24-1177, the Federal Circuit held that under step one of the *Alice* test, claims should be considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter.

PowerBlock Holdings (PowerBlock) sued iFit for patent infringement and unfair competition. iFit filed a motion to dismiss under 35 U.S.C. § 101, arguing that the claims were directed to the abstract idea of automated weight stacking. iFit argued that the patent claimed a weight selection and adjustment system consisting of generic components, without adding significantly more to the abstract idea. The district court agreed, found all but one claim ineligible under § 101, and granted iFit's motion to dismiss. PowerBlock appealed.

The Federal Circuit reversed, holding that the claims at issue were not directed to an abstract idea under step one of the *Alice* test. The court held that the claims recited meaningful structural limitations, not just generic components, that provided a specific implementation of automatic weight stacking. Further, the Federal Circuit rejected iFit's attempts to read out or ignore limitations merely because they could be found in the prior art, because step one of *Alice* should involve consideration of the claims in their entirety to ascertain whether their character as a whole is directed to excluded subject matter. Failing to do so can improperly conflate the separate novelty and obviousness inquires under 35 U.S.C. §§ 102 and 103 with the eligibility inquiry under § 101. Accordingly, the Federal Circuit reversed and remanded.

FEATURE CASE

Bayer Pharma Aktiengesellschaft v. Mylan Pharmaceuticals Inc.

The Printed Matter Doctrine Expands

On Sept. 23, 2025, the U.S. Court of Appeals for the Federal Circuit decided *Bayer Pharma Aktiengesellschaft v. Mylan Pharmaceuticals Inc.*, which involved an issue that often arises in patents directed to pharmaceutical products.

To obtain U.S. Food and Drug Administration approval for a new drug product, an applicant must provide clinical testing to demonstrate the safety and efficacy of the drug product. The results of such testing are submitted to the FDA in support of the drug's approval. Often, pharmaceutical companies seek patents based on those clinical testing results, including claims drawn to the clinical effects, or side effects, observed in the clinical trials.

Bayer involved one such patent directed to findings made during a clinical trial. The patent in *Bayer* was based on the results of a Phase III clinical trial that evaluated the safety and efficacy of administering a drug, rivaroxaban, either with or without aspirin, for the prevention of major adverse cardiac events.

The claims at issue were directed to a method of reducing the risk of myocardial infarction, stroke or cardiovascular death by administering the two drugs "in amounts that are clinically proven effective in reducing" those risks. The claims also recited a specific amount of rivaroxaban and a specific range of amounts of aspirin.

The amounts of rivaroxaban and aspirin were known, at least because the clinical trial protocols were published long before the patent application was filed. Mylan, and others, challenged Bayer's patent in an *inter partes* review proceeding at the U.S. Patent and Trademark Office's Patent Trial and Appeal Board.

Bayer defended against the patentability challenge by arguing the "clinically proven effective" requirement distinguished the prior publications of the clinical trial protocols because the protocols, unlike the patent, did not include the ultimate result demonstrating clinical efficacy. The Board rejected that argument, and so did the Federal Circuit on appeal.

The Federal Circuit, however, did not adopt the Board's reasoning and instead reached its conclusion by extending a line of prior cases related to instructions and written words. That line of cases involves what is sometimes referred to as the printed matter doctrine. Under that doctrine, simply adding new words to an existing product or method will not support patentability unless there is a functional relationship between the new words and the underlying substance of the claim.

In *King Pharmaceuticals Inc. v. Eon Labs Inc.*, a 2010 Federal Circuit decision that the *Bayer* panel discussed, the court found unpatentable claims directed to a known method of treatment that also added a step of informing the patient about a property of the drug. The court in *King* analogized those "informing" claims to similar issues raised by the printed matter doctrine. Even though the claims in *King* did not specifically involve printed matter, such as written instructions, the court applied the same printed matter doctrine analysis: whether the added instructional limitation has a "new and unobvious functional relationship" with the known method of administration.

The claims in *Bayer*, in contrast, did not merely inform the patient of effectiveness. Nevertheless, the Federal Circuit recognized that allowing the words "clinically proven effective" to determine patentability would have resulted in a pernicious situation where "one could claw back from the public domain an anticipated method of treatment merely by adding a limitation that the method subsequently performed well in a clinical trial."

In *Bayer*, the court reasoned, the limitation did not impose a functional restriction on the composition; instead, the limitation merely indicated that the composition had been proven to have clinical efficacy, i.e., it performed well

FEATURE CASE

in clinical trials. Under the court's reasoning, like *King*, the added limitation merely provided information about the underlying drug.

Bayer represents an extension of the printed matter doctrine beyond *King*'s holding. Unlike *King*, which expressly involved informing the patient of the information, the relevant claim language in *Bayer* was "administering" the drugs "in amounts that are clinically proven effective in reducing the risk" of various conditions. That limitation would appear to be somewhat functionally related to the underlying method of administering the two drugs to achieve a clinical effect, and thus beyond the mere instruction to patients addressed in *King*.

Nevertheless, the Federal Circuit held the "clinically proven effective" limitation in *Bayer* "cannot breathe patentability into the challenged claims as a functionally unrelated limitation."

Many pharmaceutical patents include a limitation requiring the method of treatment or administration to be effective, and the Federal Circuit distinguished one of those in its *Bayer* analysis: *Allergan Sales LLC v. Sandoz Inc.* In that 2019 decision, the Federal Circuit considered a claim that required a method of treatment using two drugs, twice a day, be as effective as the administration of one drug three times a day, and also required the claimed method reduce the incidence of at least one adverse event.

Facially, the claims in *Allergan* seem very similar to those in *Bayer* because both are related to the safety and efficacy of a method that recites administering a drug. The patent in *Allergan*, like *Bayer*, also involved the results of a clinical trial. The Federal Circuit, however, distinguished *Allergan* because in *Allergan* the effectiveness limitation was found in a "wherein" clause.

The court explained that the wherein clause served to directly link the method of administration to meeting the safety and efficacy benchmarks. Accordingly, the efficacy requirement excluded methods that did not meet those benchmarks. That was enough to create a functional relationship between the result and the method and thus distinguish *Allergan* and *Bayer*.

The line between *Bayer* (no functional relationship) and *Allergan* (sufficient functional relationship) is unclear. In the short term, patent challengers, particularly in the abbreviated new drug application context, should consider raising arguments asserting that a claimed result of a clinical trial does not actually limit the underlying method, and therefore does not have the required functional relationship to breathe patentability into the claim.

Patent holders should be mindful of establishing that the claimed results do provide a meaningful limitation on the claim's scope and be prepared to articulate that limitation as early as claim construction.

Moving forward, it will be interesting to see whether the Federal Circuit continues to apply the "functionally related" analysis, derived from the printed matter doctrine, in new contexts. For now, however, litigants should be aware that the functional relationship analysis extends beyond its traditional scope.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

Recentive Analytics, Inc. v. Fox Corp.

Applying Established Methods of Machine Learning to a New Environment does not Render Claims Patent Eligible Under § 101

In *Recentive Analytics, Inc. v. Fox Corp.*, Appeal No. 23-2347, the Federal Circuit held that claims that do no more than apply established methods of machine learning to a new data environment are patent ineligible under § 101.

Recentive sued Fox, alleging infringement of four patents. Two of the patents were the "Machine Learning Training" patents, which concerned the scheduling of live events. The other two patents were the "Network Map" patents, which concerned the creation of network maps for broadcasters. Fox moved to dismiss on the grounds that the patents were ineligible under § 101. The district court applied the *Alice* two-step inquiry, finding that the asserted claims were directed to the abstract ideas of live event scheduling and network map creation, and that the claims were not directed to an "inventive concept." Accordingly, the district court granted Fox's motion to dismiss. Recentive appealed.

The Federal Circuit affirmed. Under step one of *Alice*, the Federal Circuit noted the patents relied on generic machine learning to carry out the claimed methods. Furthermore, Recentive had conceded that it was not claiming machine learning itself nor a method for improving machine learning. There was no technological improvement to the machine learning. As such, the Federal Circuit reasoned that the claims only disclosed use of machine learning in a new environment and further rejected Recentive's argument that its claimed methods are patent eligible because they apply machine learning to a new field of use. The Federal Circuit also rejected the argument that the claimed methods are patent eligible for increasing the speed and efficiency of a task previously undertaken by humans. Accordingly, the Federal Circuit held that the district court correctly held that the patents were directed to abstract ideas at step one of Alice.

Under step two of *Alice*, Recentive claimed that the inventive concept was "using machine learning to dynamically generate optimized maps and scheduled based on real-time data and update them based on changing conditions." The Federal Circuit found that the district court correctly held that this did no more than claim the abstract idea and thus the claims were not directed to an "inventive concept" sufficient to transform the claims to patent-eligible subject matter at step two of *Alice*.

United Services Automobile Association v. PNC Bank N.A.

Inventive Concepts Must Be Included in the Claim Language

In *United Services Automobile Association v. PNC Bank N.A.*, the Federal Circuit held that a claim that merely recites a system for conducting routine steps without providing sufficient specificity as to the technical improvement behind the claimed invention is patent-ineligible subject matter.

United Services Automobile Association (USAA) sued PNC Bank (PNC) alleging infringement of USAA's patent describing a system for allowing a customer to deposit a check to a mobile banking application using a handheld mobile device and reviewing the deposited check for errors using optical character recognition (OCR). Both USAA and PNC filed for summary judgment motions seeking, respectively, judgement that the claim was or was not patent eligible under 35 U.S.C. § 101. The district court granted USAA's motion and denied PNC's, holding that the asserted claim was patent eligible under § 101. The district court concluded that the claim was not directed to an abstract idea and therefore did not meet the first step in the *Alice* analysis.

On appeal, the Federal Circuit reversed. First, the Federal Circuit held that the claim was directed to an abstract idea under Alice step one. The Federal Circuit explained the claim was directed to the abstract idea of depositing a check using a mobile device. The Federal Circuit reasoned that the steps for depositing a check using a mobile device were routine data collection and analysis steps (e.g., depositing checks, reviewing for errors, storing the data, etc.). The court further noted that, even if the implementation required the development of "non-obvious algorithms," the claim required no particular configuration for the otherwise abstract steps. Thus, including a handheld device to carry out conventional steps without additional details did not make the claim any less abstract.

The district court never reached *Alice* step two. But, because the § 101 analysis is a matter of law, the Federal Circuit did not remand the case and instead moved on to step two of *Alice*. In the step two analysis, the Federal Circuit concluded there was no inventive concept sufficient to support patent eligibility. The Federal Circuit reasoned that the claim as a whole did not improve how the mobile device functions, nor did it claim any new or unknown functions. Additionally, particular claim elements such as OCR, remote deposit applications, and the use of a mobile device were well known and conventional. Therefore, the Federal Circuit concluded that the claim was patent-ineligible under § 101.

FEATURE CASE

Kroy IP Holdings, LLC v. Groupon, Inc.

Lessons On Cases With Many Patent Claims

In February 2025, the U.S. Court of Appeals for the Federal Circuit issued a decision that will make life harder for defendants accused of infringing patents containing numerous claims.

In *Kroy IP Holdings LLC v. Groupon Inc.*[1], the Federal Circuit considered a defendant's use of the doctrine of collateral estoppel to challenge the validity of patent claims in the U.S. District Court for the District of Delaware, based on the Patent Trial and Appeal Board's earlier invalidation of other claims in the same lengthy patent.

The Federal Circuit ruled that collateral estoppel was inapplicable because, while the Board found unpatentability by a preponderance of the evidence during *inter partes* review of Kroy's patent, the district court was required to establish invalidity by clear and convincing evidence.

The dispute began when Kroy sued Groupon in the District of Delaware for infringing U.S. Patent No. 6,061,660, a patent directed to providing incentive programs over a computer network. Kroy IP Holdings appears to be a non-practicing entity whose business is acquiring and asserting IP rights.

Kroy's '660 patent spanned 56 pages and contained 115 claims. Kroy's initial complaint alleged that Groupon infringed 13 exemplary claims. Under the notice-pleading system of the Federal Rules of Civil Procedure, Kroy was not required to identify in its complaint each claim of the '660 patent that it intended to assert in the district court case. Groupon therefore could not have known which of the patent's 115 claims it would ultimately face in the litigation.

Groupon selected 21 claims to challenge in two petitions for *inter partes* review of the '660 patent. The Board granted the petitions and found all 21 challenged claims unpatentable in two final written decisions. Kroy appealed to the Federal Circuit, which affirmed the Board's decisions.

After the Federal Circuit's affirmance, Kroy filed an amended complaint in the district court. The amended complaint alleged infringement of 14 claims of the '660 patent that Groupon had not challenged in the IPR proceedings.

Groupon moved to dismiss the amended complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure, arguing that the 14 new claims were immaterially different from the 21 invalidated claims and that the Board's IPR rulings collaterally estopped Kroy from asserting the new claims. The district court granted the motion and dismissed the case

On appeal, the Federal Circuit reversed the district court's dismissal.

The appellate court did not disagree with the collateral estoppel standard applied by the district court. Collateral estoppel — also known as issue preclusion — applies in a later proceeding if (1) the identical issue was litigated in an earlier proceeding; (2) the issue was actually litigated; (3) the previous determination of the issue was necessary to the decision in the earlier proceeding; and (4) the party being precluded from relitigating the issue was fully represented in the earlier proceeding.

In the patent context, validity issues are considered to be identical if the subsequent proceeding involves (1) the same prior art asserted in the earlier proceeding, and (2) patent claims that are immaterially different from claims asserted in the earlier proceeding.

The Federal Circuit did not find fault with the district court's analysis of the four collateral-estoppel factors. But the court noted that the doctrine of collateral estoppel is subject to several exceptions.

One such exception, established in the U.S. Supreme Court's 2015 decision in *B&B Hardware Inc. v. Hargis Industries Inc.*[2], applies when the two proceedings involve different legal standards.

FEATURE CASE

Because the Board's unpatentability determinations were made under the preponderance-of-the-evidence standard that applies in IPRs, while the district court was required to establish invalidity under the higher clear-and-convincing-evidence standard, the Federal Circuit ruled that collateral estoppel did not apply. In so ruling, the court relied on its 2024 decision in *ParkerVision Inc. v. Qualcomm Inc*[3], an appeal involving very similar facts

Groupon argued that the case should be governed not by *ParkerVision*, but by the Federal Circuit's 2018 decision in *XY LLC v. Trans Ova Genetics LC*.[4]

According to Groupon, the *XY* decision recognized that a PTAB unpatentability determination can trigger collateral estoppel in a subsequent district court case

But the Federal Circuit read *XY* differently. The two proceedings addressed in *XY* involved the very same claims, not claims that were immaterially different. *XY* merely stands for the proposition that a patent claim invalidated in an IPR proceeding no longer exists and therefore cannot be asserted in a subsequent district court action.

In reversing the district court's dismissal order, the Federal Circuit did not mention that Kroy's patent contained 115 claims. But this fact lies at the heart of Groupon's dilemma. How could Groupon meaningfully address all 115 claims during *inter partes* review when IPR petitions are limited to 14,000 words?

Challenging a subset of the patent's claims did not work for Groupon. Though Groupon succeeded in invalidating all 21 of the claims it challenged in the Patent Office, Kroy was left with almost 100 other claims to assert in the district court litigation.

Patent challengers like Groupon can, of course, attempt to identify the right subset of claims to challenge in IPR proceedings by serving the patentee with an interrogatory asking for a list of the asserted claims.

The local rules of many district courts also require the patentee to identify the asserted claims relatively early in the case. But interrogatory responses can always be amended or supplemented after IPR deadline, and even court-mandated disclosures often can be amended in view of discovery or after claim construction.

Patent challengers can also opt to file two parallel IPR petitions. However, it is far from certain the Board will institute both IPRs. The Board's trial practice guide states that parallel petitions challenging the same patent "may place a substantial and unnecessary burden on the Board" and "are not necessary in the vast majority of cases."[5]

Even when parallel IPRs are instituted, this might not suffice to meaningfully address a patent containing 115 claims. Indeed, Groupon filed two petitions to challenge just 21 of the '660 patent's 115 claims.

For patent owners, the *Kroy* decision highlights the benefit of seeking patents with many claims. According to the USPTO's current rate schedule, the fee is $200 for each claim in excess of the first 20 claims. That amounts to almost $20,000 in additional fees for a patent applicant that wants 115 claims.

Seeking a large number of claims will also likely increase prosecution costs, as more time will be required of the prosecuting attorney. But for a patent that is likely to prove commercially valuable, the litigation benefit might well be worth the extra expense.

Some might view the assertion of patents with numerous or long claims as an attempt to circumvent the *inter partes* review system that Congress created in enacting the America Invents Act.

Congress enacted the AIA in part to address concerns that certain nonpracticing entities were asserting large numbers of weak patents in federal court. The IPR regime was intended to eliminate questionable patents quickly and efficiently, without recourse to lengthy and costly district court actions. Asserting a patent with too many claims to be effectively addressed in *inter partes* review could be viewed as a tactic to insulate a weak patent from PTAB scrutiny.

FEATURE CASE

The USPTO could help address these concerns by providing more guidance on how the PTAB should handle patents with numerous or lengthy claims. For example, it could state that parallel IPR proceedings challenging such patents should generally be permitted, or that IPR word limits should generally be relaxed in such cases.

One thing is certain: IPR petitioners will not be able to challenge a subset of a patent's claims in the Patent Office and then rely on collateral estoppel to invalidate the rest.

[1] 127 F.4th 1376 (Fed. Cir. 2025).

[2] 575 U.S. 138, 148 (2015).

[3] 116 F.4th 1345, 1349 (Fed. Cir. 2024).

[4] 890 F.3d 1282, 1294 (Fed. Cir. 2018).

[5] Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), available at www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=TrialPracticeGuideConsolidated.

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Knobbe Martens was ranked highly for patent litigation across multiple jurisdictions in the 2025 IAM "Patent 1000" guide.

Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.

Personal Jurisdiction Exists Based On aBLA filing and Nationwide Distribution Channels

In *Regeneron Pharmaceuticals, Inc. v. Mylan Pharmaceuticals Inc.*, Appeal No. 24-1965, the Federal Circuit held that the district court could exercise personal jurisdiction over a foreign defendant based on its Biologics License Application (aBLA) filing and elaborate distribution agreement that did not carve out specific jurisdiction.

Regeneron owns patents covering EYLEA—a brand-name therapeutic product for treating eye disease. Samsung Bioepis ("SB") filed an abbreviated aBLA with the FDA, seeking approval to market its EYLEA biosimilar. Regeneron sued SB in the Northern District of West Virginia for patent infringement. The district court concluded that it had personal jurisdiction over SB and granted Regeneron's motion for a preliminary injunction. SB appealed.

SB, a South Korean company without any facilities or employees in the United States, argued that the district court lacked personal jurisdiction over SB because it would not distribute, market, or sell its biosimilar product in West Virginia. SB highlighted its distribution agreement with Biogen, which gave Biogen the exclusive rights to commercialize SB's biosimilar in the United States. Thus, SB argued that it would sell its biosimilar to Biogen in a state *other than* West Virginia, and Biogen would then distribute the product. SB also argued that there was no evidence that West Virginia was specifically targeted.

The Federal Circuit rejected SB's arguments, finding that SB's aBLA filing with the FDA was evidence of SB's plan to market its biosimilar product throughout the United States. The Federal Circuit also emphasized that the distribution agreement between SB and Biogen did not carve out West Virginia from the market. The Federal Circuit also concluded that there is no reason under the constitutional standard to require singling-out evidence when there is persuasive evidence of nationwide targeting without a carve-out. Therefore, the exercise of personal jurisdiction was proper.

Finally, the Federal Circuit affirmed the district court's grant of a preliminary injunction against SB because SB failed to present a substantial question of validity.

Dolby Laboratories Licensing Corporation v. Unified Patents, LLC

No Injury, No Appeal: Patent Owners Must Show Actual Injury for Article III Standing

In *Dolby Laboratories Licensing Corporation v. Unified Patents, LLC,* Appeal No. 23-2110, the Federal Circuit held that a patent owner lacks Article III standing to appeal an *inter partes* review decision on patentability when it cannot demonstrate concrete and actual injury as a result of the Patent Trial and Appeal Board's ruling.

Unified Patents initiated an IPR challenging claims in Dolby's patent and identified itself as the sole real party in interest (RPI). Dolby identified other entities it believed should have been named as RPIs. While the Board determined that the challenged claims were not anticipated and obvious, it refused to adjudicate whether there were other RPIs. The Board explained that there was no evidence that any of the alleged RPIs was estopped from bringing an IPR or that Unified purposely omitted potential RPIs to gain an advantage. Dolby appealed the Board's refusal to adjudicate the RPI issue, and Unified and the PTAB challenged Dolby's standing on appeal.

On appeal, the Federal Circuit held that Dolby lacked Article III standing. The court explained that, to establish Article III standing, an appellant must show an injury in fact, that is, a concrete and actual invasion of a legally protected interest. Dolby argued it had standing because (1) it was a "dissatisfied" party under 35 U.S.C. § 319; (2) its statutory right to information had been violated; and (3) it was injured because RPIs may have been breaching license agreements, there may have been conflicts of interest with alleged RPIs, alleged RPIs might not be properly estopped in future proceedings, and Unified might be disincentivized from filing IPRs if it must identify its members as RPIs.

The court rejected Dolby's arguments. First, the AIA's "dissatisfied" party provision does not supersede the requirement for Article III standing. Second, even if patent owners have a right to have RPI disputes adjudicated in the context of IPR proceedings, they have no free-standing right to information. Finally, Dolby's allegations of harm were too hypothetical and speculative to establish an injury in fact. The court therefore dismissed Dolby's appeal.

Knobbe Martens was nationally ranked in 2025 for Patent Litigation and Trademarks (Litigation), and noted as a "Firm to Watch" in ITC Litigation, by The Legal 500 U.S. Guide

Ingenico Inc. v. Ioengine, LLC

Finding Common Ground? — Federal Circuit Clarifies IPR Estoppel

In *Ingenico Inc. v. Ioengine, LLC*, Appeal No. 23-1367, the Federal Circuit held that IPR estoppel does not preclude reliance on public-use evidence that is substantively identical to printed publications that could have been raised in the IPR.

Ingenico filed a declaratory judgment action against IOENGINE, alleging invalidity. Before trial, Ingenico also filed IPR petitions challenging the validity of IOENGINE's patents, which led to final written decisions. At trial, Ingenico introduced evidence of prior art systems, alleging invalidity based on public use. The jury found the claims invalid as anticipated and obvious.

On appeal, IOENGINE argued Ingenico should have been estopped from introducing its public-use evidence. IOENGINE argued that Ingenico's prior art systems were cumulative of substantively identical printed publications that reasonably could have been raised in IPR, including the system's Readme instruction document. The Federal Circuit disagreed. The court noted that IPR estoppel prohibits a petitioner from asserting grounds that were raised or reasonably could have been raised in an IPR. The Federal Circuit held that "grounds" in this context refers to theories of invalidity rather than the prior art itself. Because theories of invalidity based in part on a public use cannot be raised in an IPR, they are not subject to estoppel in district court. Accordingly, the Federal Circuit affirmed the district court's decision.

Accorda Therapeutics, Inc. v. Alkermes PLC

Federal Circuit Lacked Jurisdiction Over a Patent Royalty Dispute

In *Accorda Therapeutics, Inc. v. Alkermes PLC*, Appeal No. 23-2374, the Federal Circuit held that it lacked jurisdiction over an appeal of an arbitral award regarding patent royalties because the appeal did not necessarily raise an issue of federal patent law.

Acorda licensed a patent owned by Alkermes. After the patent expired, Acorda continued paying royalties. Acorda sought a declaration from the American Arbitration Association (the "tribunal") that the royalty provision in the license was unenforceable after the patent expired. Acorda further sought a return of royalties Acorda had paid after expiration. The tribunal agreed the royalty provision became unenforceable upon patent expiration but concluded that Acorda was entitled to recover only those post-expiration payments it made under formal protest.

Acorda filed a petition in district court under the Federal Arbitration Act. The petition sought to confirm the tribunal's award except to modify its denial of the request to recoup unprotested payments. The district court affirmed the tribunal's ruling. Acorda appealed to the Federal Circuit.

The Federal Circuit held that it lacked jurisdiction over the appeal. First, it found there was no patent-law cause of action in the case, as it was brought solely under provisions of the Federal Arbitration Act after arbitration. Second, the court found Acorda's right to relief did not necessarily raise a patent-law issue. In doing so, it looked not to the underlying claims made in the arbitration but only to the petition that initiated the district-court action. The court found that, to obtain confirmation of the tribunal's award, Acorda was not required to plead and prove the correctness of the tribunal's rulings. The court also found that, to modify the tribunal's award, the district court had no need to address federal patent law because Acorda presented an alternative basis for recoupment that did not rest on federal patent law. Finding it lacked jurisdiction, the court transferred the case to the Second Circuit Court of Appeals.

Mitek Systems, Inc. v. United Services Automobile Association

Did They Want to Infringe? – Federal Circuit Denies Declaratory Judgment When Party at No Risk of Lawsuit

In *Mitek Systems, Inc. v. United Services Automobile* Association, Appeal No. 23-1687, the plaintiff could not seek declaratory judgment (DJ) of non-infringement because (i) its product did not meet all the limitations of the asserted claims and (ii) the DJ proceeding could not have resolved the issue of whether the plaintiff must indemnify customers who modified the product.

Mitek Systems, Inc. (Mitek) sought declaratory judgment that its software product did not infringe three United Services Auto Association (USAA) patents. Mitek claimed two bases for declaratory judgment jurisdiction: 1) Mitek's potential liability for infringement and 2) the possibility of indemnity demands made by Mitek's licensees after USAA sent letters proposing licenses to the USAA patents. Mitek argued that, due to the customizability of its software, an end user could utilize Mitek's product in a way that infringed USAA's patents. After an initial remand, the district court found that Mitek had no reasonable apprehension of direct or indirect infringement liability. After reviewing the letters USAA sent to Mitek's licensees and Mitek's indemnification agreements, the district court also concluded that there was no reasonable risk that Mitek would need to indemnify its customers.

The Federal Circuit affirmed the district court's decision. Accepting without deciding that the mere capability of Mitek's software to infringe the patents could be grounds for a direct infringement action, the Federal Circuit noted that the asserted claims in USAA's patents also involved hardware limitations that could not be met by modification. Similarly, there was no potential for inducement infringement because Mitek had never encouraged performance of the remaining limitations. A claim of contributory infringement would also fail because Mitek's software was capable of substantial non-infringing uses. As to Mitek's second basis for declaratory judgment, the Federal Circuit explained that the agreements with its customers contained indemnity carveouts that eliminated any reasonable risk that Mitek would be found liable for its customers' modification of the product. Thus, Mitek could not establish subject matter jurisdiction over its declaratory judgment claims.

Finally, in the alternative, the Federal Circuit held that, even if the district court did have jurisdiction over the declaratory judgment claims, it nevertheless did not err by declining to exercise that jurisdiction in this case. The district court found that the "best" way for Mitek to defend its software would be to intervene in another litigation brought by USAA against a Mitek customer. The district court found that intervening would provide Mitek the avenue to obtain the relief it sought via declaratory judgment. In addition, the district court found that any litigation of the issue of indirect infringement via declaratory judgment would require extensive involvement of the end users of Mitek's software. A declaratory judgment suit between Mitek and USAA – without the participation of the end users – could not resolve issues of infringement for such modified products. The Federal Circuit explained that it previously approved discretionary decisions that declined to exercise jurisdiction if the declaratory judgment action would not address the uncertainty giving rise to the proceeding in the first place. Thus, the Federal Circuit concluded that, even if subject matter jurisdiction did exist, it would not have been an abuse of discretion for the district court decline to exercise that jurisdiction.

Incyte Corporation v. Sun Pharmaceutical Industries, Inc. (District Court)

A Patent Does Not Guarantee the Patent Owner Will Be First to Market

In *Incyte Corporation v. Sun Pharmaceutical Industries, Inc.*, Appeal No. 25-1162, a district court erred in issuing a preliminary injunction against an alleged infringer under a theory that the patentee would have been first to market, when it was inevitable that the alleged infringer would have been first to market.

Sun Pharmaceuticals secured FDA approval in July 2024 for a drug used to treat auto-immune disorders and was set to launch the drug in October 2024. Before the launch, Incyte Corporation sued Sun for patent infringement and moved for a preliminary injunction. The district court granted the preliminary injunction based on its finding that, but for Sun's drug, Incyte's patent would allow it to be the first to market, and thus Incyte would be irreparably harmed absent an injunction.

On appeal, the Federal Circuit held that the district court's finding of irreparable harm was clearly erroneous because (1) Sun was prepared to launch, (2) Incyte's patent expires in December 2026, and (3) Incyte would not launch its product, under the best-case scenario, until several years after the expiration of its patent. Thus, an injunction would only shorten an otherwise inevitable head start for Sun's allegedly infringing product. Accordingly, the Federal Circuit reversed the district court's grant of the preliminary injunction.

FEATURE CASE

Shockwave Med., Inc. v. Cardiovascular Sys., Inc.

Instability In IPR Requirements

When an *inter partes* review challenges an issued patent before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board, it must be based on prior art consisting of patents or printed publications.

Despite that seemingly straightforward statutory requirement, more than a decade after IPR challenges were created, the USPTO and the U.S. Court of Appeals for Federal Circuit are still debating what evidence may be used in an IPR challenge.

The Federal Circuit's July 14, 2025 decision in *Shockwave Medical v. Cardiovascular Systems* provided an important, albeit short-lived, clarification to the role played by admissions made in the challenged patent, itself, to support an IPR challenge.

In many instances, patents discuss what was already known in the field. Such a discussion is often referred to as "applicant admitted prior art," or AAPA. Because a challenged patent is not prior art against itself, there has been confusion as to whether, and how, AAPA may be used in an IPR challenge.

Shockwave owns U.S. Patent No. 8,956,371, which is generally directed to treating atherosclerosis using a process called intravascular lithotripsy. Known treatments for atherosclerosis included balloon angioplasty, which used a balloon catheter to widen a blood vessel thereby increasing blood flow.

One common type of balloon catheter was known as an over-the-wire balloon catheter. Lithotripsy is a technique used in the treatment of kidney stones and involves using sonic waves, produced by an electrical charge or a laser, to break up the stones. The claims of the '371 patent were directed to an angioplasty catheter comprising both a pulse generator and an over-the-wire angioplasty balloon carrier.

Cardiovascular petitioned for IPR of the '371 patent. Its primary prior art publication, Levy, described using laser generated pulses to disintegrate plaque in blood vessels.

The petition also cited the '371 patent's discussion of what was already known in the field, specifically its AAPA discussion of "typical prior art over-the-wire angioplasty balloon catheters." Cardiovascular argued the claims of the '371 patent would have been obvious based on Levy as modified by the AAPA.

In July 2020, the Board held most of the challenged claims unpatentable as obvious. In its decision, the Board applied the AAPA as prior art under the statute. Soon after the Board's decision, however, the USPTO issued binding guidance indicating that AAPA cannot constitute prior art consisting of patents and printed publications, as required by the statute.

The Board instituted rehearing and, in 2023, published a new decision that relied on the AAPA only as evidence of the background knowledge that would have been known to a person of ordinary skill in the art. In the new decision, the Board again held most of the claims unpatentable as obvious.

Shockwave appealed and argued that the Board had improperly relied on the AAPA as a basis for its petition. A few months before the *Shockwave* decision, the Federal Circuit issued an opinion in *Qualcomm v. Apple* holding that AAPA cannot form the basis for a petition, so it might have seemed that Shockwave's appeal was on good footing.

The Federal Circuit, however, explained that the petition in *Shockwave* was quite different from the petition in *Qualcomm*. In *Qualcomm*, the petitioner "expressly labeled AAPA as the 'basis' for its challenge"; this was an impermissible use of AAPA because only a patent or printed publication — and

FEATURE CASE

not AAPA — may form the basis for an IPR challenge.

In contrast, the petition in *Shockwave* used AAPA merely to demonstrate that the over-the-wire balloon catheter was well known. The Federal Circuit explained that AAPA may be used to establish general background knowledge, and such general background knowledge can supply a missing claim limitation.

Thus, the court held that the general background knowledge, as demonstrated by the AAPA, was appropriately used to establish the claims' limitations related to over-the-wire configurations.

Shockwave also argued that the Board, in its decision on patentability, characterized the use of AAPA as a basis for the challenge and that AAPA cannot form the basis for an IPR challenge.

The Federal Circuit rejected this argument because the Board's characterization was not controlling. Instead, as the court explained, the IPR petition itself defines the scope of the challenge. And unlike the petition in *Qualcomm*, Cardiovascular's petition did not clearly indicate that the AAPA was a basis for the obviousness arguments.

The *Shockwave* case appeared to provide a simple rule for practitioners: Cite AAPA as background knowledge when using it to supply a missing claim limitation and do not identify AAPA as the basis for the petition.

But *Shockwave* is not the end of the story. On July 31, 2025, the USPTO issued a memorandum to the Board; this memorandum, nominally based on *Qualcomm*, indicated that the Board would no longer be permitted to use general knowledge to satisfy a missing claim limitation.

Such general knowledge includes AAPA, expert testimony, common sense and other evidence that is not prior art consisting of patents or printed publications. Notwithstanding the prohibition, the Board could still use general knowledge to support a motivation to combine or to demonstrate the knowledge of a skilled artisan.

The Patent Office indicated that it would implement the change by strictly enforcing Title 37 of the Code of Federal Regulations, Section 4,104(b)(4), which requires a petitioner to identify in the petition where each claim element is found in prior patents or printed publications.

The Patent Office cited *Shockwave* in a footnote and acknowledged that the requirement to find every claim element in a prior art patent or printed publication "as applied in some cases, may be narrower" than the corresponding statutory requirement. Nonetheless, the office concluded that its revised approach was being adopted because it would "allow for the efficient administration of the Office."

Shockwave illustrates the ongoing interplay between the USPTO and the Federal Circuit as they define and redefine the appropriate bases for IPR proceedings.

The initial Board decision in *Shockwave* was modified on rehearing in response to the USPTO's binding guidance on AAPA. *Qualcomm* had clarified one situation where AAPA might not be permissible.

Shockwave, in turn, limited *Qualcomm*'s applicability and endorsed the use of background knowledge to supply missing claim limitations. Following *Shockwave*, the Patent Office almost immediately narrowed the use of AAPA by indicating its intent to strictly enforce its own rules.

The USPTO's memorandum may be challenged in future litigation. For now, practitioners must account for both Federal Circuit precedent and the USPTO's guidance when citing AAPA in an IPR petition.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

Qualcomm Incorporated v. Apple Inc.

IPRs Cannot Use Applicant Admitted Prior Art as Part of the Basis of Invalidity

In *Qualcomm Incorporated v. Apple Inc.*, Appeal No. 23-1208, the Federal Circuit held that applicant Admitted Prior Art ("AAPA") cannot be the basis of an invalidity ground in an IPR under 35 U.S.C. §311(b).

Apple filed *inter partes* review (IPR) petitions challenging the validity of a patent owned by Qualcomm. Some of the invalidity grounds in the IPR petitions relied upon AAPA, i.e., disclosure from the specification of the challenged patent on the prior art. Qualcomm argued that this ground violated 35 U.S.C. §311(b), which requires that an IPR petition may request to cancel claims as unpatentable "only on the basis of prior art consisting of patents or printed publications." The Board initially determined that the use of AAPA complied with §311(b) because the AAPA is from the challenged patent and is thus "prior art consisting of patents or printed publications." Qualcomm appealed. In February 2022, the Federal Circuit held that to form the "basis" of an invalidity ground, the "prior art consisting of patents or printed publications under §311(b) does not encompass AAPA, and remanded for the Board to determine whether the AAPA in Apple's petitions formed the basis of the invalidity ground.

On remand, consistent with guidance from the USPTO Director, the Board ruled that AAPA does not form the basis of an invalidity ground if the ground relies on the AAPA in combination with prior art patents or printed publications. The Board then determined that the AAPA in Apple's petitions did not violate §311(b) because the AAPA did not form the basis of the invalidity ground because the AAPA was combined with prior art patents. Qualcomm appealed.

The Federal Circuit reversed, holding that the Board erred in interpreting §311(b). The Federal Circuit determined that the plain meaning of the statute clearly limits "the basis" to "prior art consisting of patents or printed publications." And AAPA is not a prior art patent or printed publication as previously held. Thus, from the plain meaning of the statute, §311(b) does not permit the basis of an invalidity ground to include AAPA. The Board's interpretation doesn't exclude the situations when the AAPA is actually used as part of the basis. Accordingly, the Federal Circuit concluded that the Board failed to properly interpret §311(b).

The Federal Circuit also reversed the Board's finding that Apple's IPR petition complied with §311(b). Apple admitted in its petitions that the AAPA is included in the basis of its invalidity grounds. Thus, the Federal Circuit concluded that Apple's statements established that the AAPA is part of the basis of the invalidity grounds, thereby violating §311(b). The Federal Circuit reversed the Board's finding that the challenged claims are unpatentable.

Lynk Labs, Inc. v. Samsung Electronics Co., Ltd.

A Published Patent Application Is IPR Prior Art as of its Filing Date

In *Lynk Labs, Inc. v. Samsung Electronics Co., Ltd.*, Appeal No. 23-2346, the Federal Circuit held that in an IPR, a patent application is considered a "printed publication" as of the application's filing date, not its publication date.

Samsung filed a petition for IPR of a Lynk Labs patent, challenging various claims as obvious. Several of Samsung's asserted grounds of unpatentability relied on a patent application which was filed before, but published after, Lynk Labs' priority date. Lynk Labs argued that an IPR can only be instituted based on prior art "printed publications," and that the reference was not a "printed publication" in the prior-art period because it published afterward. The Patent Trial and Appeal Board found the challenged claims unpatentable for obviousness based on the published patent application reference. Lynk Labs appealed.

The Federal Circuit affirmed. The court noted the parties agreed the published patent application reference was a printed publication and was thus a type of reference that can be used as the basis of an IPR challenge under 35 U.S.C. § 311(b). The Federal Circuit further noted that, under 35 U.S.C. § 102(e)(1), a published patent application is deemed prior art as of its filing date. The court held that reading these two provisions together, in an IPR, a published patent application can be deemed a printed publication as of its filing date.

FEATURE CASE

Sage Products, LLC v. Stewart

Introducing New Evidence During IPR

In its decision in *Sage Products LLC v. Stewart*, the U.S. Court of Appeals for the Federal Circuit gave a boost to patent challengers seeking to invalidate patents in *inter partes* review proceedings. The case is notable because the court upheld the decision of the Patent Trial and Appeal Board to allow a petitioner to rely on case-dispositive evidence beyond the prior art references raised in the petition.

Inter partes review Background

Congress created the *inter partes* review process to provide a streamlined procedure for canceling invalid patents. Unlike in district court, where any ground for invalidity may be raised, an IPR petitioner may only assert theories of anticipation or obvious, and only based on paper prior art such as patents and publications.

The rationale for the new IPR procedure was compelling: If the invalidity of a patent can be determined just by looking at a handful of documents, an accused infringer should not be required to spend a small fortune litigating in federal court until, years later, it finally gets the opportunity to present its invalidity case to a judge or jury.

The IPR process is streamlined because it generally does not attempt to resolve factual disputes about what occurred in the real world. District court litigation is more expensive and time-consuming because it addresses many such questions.

District court litigants conduct extensive discovery and adduce evidence to resolve real-world disputes such as whether the defendant induced others to infringe, whether the defendant's alleged infringement was willful, whether the named inventors derived their invention from a third party, whether the plaintiff obtained by the patent by perpetrating a fraud on the U.S. Patent and Trademark Office, and whether the alleged infringement caused harm to the plaintiff.

Certain validity theories also require proof about what happened in the real world. For example, a patent may be invalidated in district court by proving that the invention was publicly known or in public use before the plaintiff's invention date or patent application.

But such invalidity theories have never been permitted in IPR proceedings. An IPR petitioner can invalidate a patent only by showing (1) that the patent is anticipated because all the elements of a challenged patent claim are disclosed in a single prior art document; or (2) that the elements are disclosed in a handful of documents and combining them would have been obvious.

The Sage Products Dispute

The *Sage Products decision* is significant because the Federal Circuit approved the Board's decision to rely on evidence beyond the prior art references themselves, including confidential corporate documents that were not published and therefore could not possibly qualify as prior art.

The dispute began when Becton Dickenson & Co. filed two petitions seeing *inter partes* review of two patents owned by Sage. Sage's patents related to sterilized chlorhexidine products, such as applicators filled with an antiseptic composition for disinfecting skin. The challenged patent claims all required that the claimed chlorohexidine products be sterilized.

BD's primary prior art reference was the ChloraPrep public assessment report, a publication of the U.K. government approving the sale of ChloraPrep, an antiseptic solution containing chlorohexidine. BD argued that the public assessment report anticipated the challenged patent claims because it disclosed each element of those claims.

In its patent owner response, Sage argued that the public assessment report did not disclose that ChloraPrep was sterilized, only that it was sterile. Sage pointed out

FEATURE CASE

that nothing in the public assessment report stated that the ChloraPrep product had been subjected to a sterilization process.

With its petitioner's reply, BD submitted documents and expert testimony to prove that a person of ordinary skill in the field would have understood that ChloraPrep was sterilized.

One of these documents was the British standard for the sterilization of medical devices. BD also submitted a declaration by its expert in which the expert opined that a person of ordinary skill in the field would have understood that ChloraPrep was subject to the British sterilization standard and therefore would have been sterilized.

The Board accepted BD's argument. It found that a person of ordinary skill in the field would be familiar with the differing regulatory regimes in the U.S. and the U.K., and consequently would have interpreted the public assessment report in view of the British sterilization standard. The Board therefore found that a person of ordinary skill would have understood the public assessment report to disclose a sterilized ChloraPrep product.

The Board's sterilization finding allowed it to conclude that Sage's patent claims were anticipated because all of the claim elements were disclosed in a single prior art reference.

This is significant because, to reach this conclusion, the Board had to rely on another document: the British sterilization standard. Normally, when the elements of a patent claim are disclosed by a combination of prior art documents, the claim can only be invalidated under an obviousness theory.

The Federal Circuit Decision

On appeal, the Federal Circuit affirmed the Board's final written decisions invalidating Sage's patents, including the Board's finding that the public assessment report anticipated both patents. The court ruled that substantial evidence supported the Board's findings about the background knowledge that a person of ordinary skill in the field would possess.

Interestingly, the Federal Circuit was not concerned that the Board found anticipation — which requires that everything in the patent claim be disclosed in a single prior art reference — by looking to multiple documents. The court ruled that there was "nothing improper in the Board relying on evidence outside of the PAR to make findings as to what the skilled artisan would understand the PAR to be disclosing."

This ruling was essential to BD's IPR challenge to Sage's patents. The Board could not have found the patents obvious in view of the combination of the public assessment report and the British sterilization standard, because BD did not assert this obviousness theory in its IPR petitions. So instead, the Board and the Federal Circuit treated the British standard not as a prior art reference, but as evidence of how the PAR would be understood.

In its opinion, the Federal Circuit downplayed the significance of the case. The court cited two cases to show it had previously approved the use of expert testimony to determine how an allegedly anticipating reference would be understood.

But those cases involved claims of inherent anticipation. When a patent challenger argues that a claim element not mentioned in a reference is inherently disclosed by the reference, expert testimony is necessary to prove that the element would necessarily be present. BD did not argue that ChloraPrep was necessarily sterilized or that the sterilized element was inherently disclosed by the public assessment report.

Conclusion

Despite the Federal Circuit's attempt to frame its *Sage Products* decision as a mere application of earlier precedent, the decision has real significance for intellectual property practitioners. The court's ruling affords petitioners in IPR proceedings greater latitude in the type of evidence they may present and when they may present it. Petitioners do not need to anticipate — at the time they file their petitions — all of the prior art documents they will need to prove invalidity.

FEATURE CASE

If the patent owner responds to the petition by arguing that a claim element is not disclosed by the petitioner's prior art, the petitioner can introduce new evidence in its reply to show that one of its prior art references would be interpreted to disclose the missing element. The *Sage Products* decision is therefore a boon to those seeking to invalidate a patent in an IPR proceeding.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

Knobbe Martens and multiple firm partners are ranked highly in Chambers USA for patent litigation.

CQV Co., Ltd. v. Merck Patent GMBH

The Board Must Provide Reasoned Explanation When Discarding Material, Unrebutted Evidence

In *CQV Co., Ltd. v. Merck Patent GMB*H, Appeal No. 23-1027, the Federal Circuit held that the Board erred by failing to explain why it discarded material and unrebutted evidence that a reference constitutes prior art.

CQV petitioned for PGR challenging claims of Merck's patent, which is directed to transparent alumina flakes used as effect pigments in paints and coatings. The specification of Merck's patent explains that effect pigments based on alumina flakes are common and commercially available under the name Xirallic. CQV alleged that various claims were obvious based on a particular lot of Xirallic called "Sample C" in combination with other references. The Board found CQV failed to show Sample C qualifies as prior art and thus failed to show the unpatentability of any claim.

On appeal, the Federal Circuit held that the Board erred by failing to consider the whole record. The court found that CQV presented "highly material and unrebutted evidence" that Sample C qualified as prior art, which the Board improperly "discarded without explanation." The court rejected Merck's attempt to explain why the Board may have discarded such evidence because Merck's arguments, while plausible, were not findings the Board made and there was no basis in the Board's decision to infer the Board's reasoning. Because the Board never explained its reasoning for disregarding relevant and unrebutted evidence, the court noted "we cannot reasonably discern whether the Board followed a proper path." Thus, the Federal Circuit vacated and remanded, instructing the Board to carefully consider and explain whether the evidence, taken together, shows Sample C constitutes prior art.

In re Kostic

Reissue Applications Are Bound by the Scope of the Claims as Written, Not as Intended

In *In re Kostic*, Appeal No. 23-1437, the Federal Circuit held that when considering whether a reissue claim broadens the scope of the original patent, the PTAB determines the actual scope of the original claim, not the scope the inventors intended.

Kostic filed a reissue application for their patent directed to a method of selling online advertising, which had issued more than two years before. Independent claim 1 of the patent recited a step of conducting a trial process, and dependent claim 3 recited the method of claim 1 "without a trial process." The reissue application attempted to rewrite dependent claim 3 in independent form, making the trial process optional. The examiner rejected the reissue for impermissibly broadening the claims beyond the two-year limit. The PTAB affirmed the examiner's rejection, and Kostic appealed.

On appeal, Kostic argued that the proper inquiry was not whether the scope of the reissue claim was broader than the actual scope of the original claim, but whether the scope of the reissue claim was broader than the intended scope of the original claim. The Federal Circuit disagreed, holding that the claims are to be construed as written, not as the patentee intended. Because reissue claim 3, which recited a trial process as optional, would be broader than the original claims, which required a trial process, the reissue application was barred.

Incyte Corporation v. Sun Pharmaceutical Industries, Inc. (PTAB)

Speculative Plans Are Insufficient to Establish Standing in PTAB Appeals

In *Incyte Corporation v. Sun Pharmaceutical Industries, Inc.,* Appeal No. 23-1300, the Federal Circuit held that speculative plans for potentially infringing activity are insufficient to establish Article III standing to appeal the Board's decision.

Incyte filed a petition for post-grant review of Sun's patent covering a compound for treating hair loss. The PTAB found Incyte failed to prove unpatentability. Incyte appealed, and argued that it had standing based on potential infringement liability and the competitor standing doctrine.

The Federal Circuit held Incyte failed to establish an injury in fact sufficient to confer standing. Regarding potential infringement liability, the court found that Incyte failed to demonstrate concrete plans to develop and market a product that would create a substantial risk of future infringement. Rather, Incyte's development plans were too speculative. For example, the amount of money spent was small and was spread across several related products, some of which would not create a risk of infringement, and Incyte did not identify what portion of its allocated funding was directed toward developing a product covered by the claims. The court also rejected Incyte's competitor-standing argument because that doctrine also requires a showing of concrete injury.

FEATURE CASE

Global Health Solutions LLC v. Selner

A Framework For AIA Derivation Disputes

Rarely does an appellate court review the outcome of an entirely new type of legal proceeding. In its decision in *Global Health Solutions LLC v. Marc Selner*, the U.S. Court of Appeals for the Federal Circuit did just that.

For the first time, the court reviewed a final written decision by the Patent Trial and Appeal Board in an America Invents Act derivation proceeding. This is a new type of Patent Office proceeding created by the AIA, similar to *inter partes* review and post-grant review proceedings.

The GHS decision is important because it establishes a legal framework for addressing derivation challenges under the AIA. In particular, it describes the relationship between derivation claims in pre-AIA interference proceedings and in AIA-created derivation proceedings. It also explains to what extent the well-developed law of patent interferences is applicable in the new AIA proceedings.

The dispute began when GHS filed a petition challenging a patent issued to inventor Marc Selner. Selner's patent is directed to a method of preparing a wound treatment ointment without using an emulsifier to mix the ointment's two main ingredients: an aqueous biocide and petrolatum jelly.

The founder of GHS, Bradley Burnam, worked with Selner on the emulsifier-free ointment until the two parted ways. They then separately developed the patented method, which involves heating the two ingredients separately to different temperatures before mixing them together. GHS and Selner both filed patent applications on the method, but Selner filed first and obtained the patent.

Selner obtained his patent thanks to the first-to-file system created when the AIA went into effect in March 2013.

Previously, when two inventors independently conceived the same invention, the Patent Office awarded the patent to the applicant who invented first. In many cases, the first inventor could only be determined by conducting an interference proceeding: a full-fledged litigation in the Patent Office, complete with document production, depositions, expert discovery, motion practice and trial.

The AIA was passed to bring the U.S. in line with the rest of the world, which had long eschewed expensive and lengthy interference proceedings in favor of first-to-file systems. Under the AIA's first-to-file system, the second person to invent can obtain the patent by winning the race to the Patent Office. However, the AIA also provides that the issued patent can be invalidated by another inventor who proves that the named inventor derived the invention from the patent challenger.

As in the better-known IPR proceedings, an AIA derivation proceeding begins with a petition to cancel the challenged patent. Patent office regulations provide that a petitioner has standing if they own or applied for a patent claim that is "substantially the same" as the invention claimed in the challenged patent

GHS had standing because it had unsuccessfully applied for a patent on the same invention Selner patented.

While the requirements for standing are set forth in the regulations, neither the statute nor any court decision explained what a petitioner must prove to prevail in a derivation proceeding. The Federal Circuit was faced with the ultimate case of first impression.

The PTAB, grappling with the same issue, looked to pre-AIA interference proceedings for a substantive derivation standard. In interference proceedings, the first party to file a patent application enjoyed a presumption that it was the first inventor. In many cases, the second filer attempted to overcome this presumption by arguing that the first filer derived its invention from the second filer.

The Federal Circuit decided that pre-AIA derivation cases can provide "helpful guidance" and ruled that the AIA did not change

FEATURE CASE

the required elements of a derivation claim, except as necessary to adapt the standard to a first-to-file system. Under the pre-AIA standard, an inventor asserting a derivation claim had to prove (1) it conceived the invention prior to the other party, and (2) it communicated the invention to that party.

But who conceived first is irrelevant under a first-to-file system. An AIA petitioner cannot obtain patent rights in the invention by showing it conceived first — it can only invalidate the respondent's patent.

The Federal Circuit therefore held that, to establish a *prima facie* showing of derivation, an AIA petitioner need only prove: (1) it conceived the invention at some point, and (2) it communicated the invention to the respondent before the respondent filed its patent application. The named inventor can then rebut this *prima facie* showing by proving that it independently conceived the invention before the relevant communication from the petitioner.

Applying this standard to the facts found by the PTAB, the Federal Circuit affirmed the Board's rejection of GHS' derivation challenge.

GHS' petition alleged that Burnam communicated the invention to Selner in an email sent at 4:04 p.m. on Feb. 14, 2014. However, based on an email Selner sent earlier that day at 12:55 p.m., the PTAB determined that Selner conceived the invention no later than 12:55 p.m. Selner therefore could not have derived the invention from Burnam's 4:04 p.m. email.

Although the Federal Circuit affirmed the PTAB's decision, it held the Board erred — albeit harmlessly — by focusing on whether Burnam or Selner was the first to invent. In fact, who invented first was irrelevant to the Federal Circuit's analysis.

Selner did not prevail because he showed he invented first — the AIA awards patent rights to the first filer. But by showing he conceived the invention before Burnam communicated it in the 4:04 p.m. email, Selner proved that his invention was independent, not derived from Burnam. Because Selner's invention was independent, Selner would have prevailed even if Burnam had invented months earlier than Selner.

The *GHS* decision is important because it provides an analytical framework for future derivation cases under the AIA. Interference case law and the legal standards that prevailed in interference proceedings will be applicable in AIA derivation proceedings, though those standards may need to be adjusted to reflect the AIA's first-to-file system.

For example, in concluding that the PTAB reasonably relied on Selner's testimony that he invented before 12:55 p.m., the Federal Circuit applied the traditional rule-of-reason test for assessing the credibility of an inventor's testimony. That test required the PTAB to consider all pertinent evidence and determine whether the inventor's story was credible.

The Federal Circuit also applied the venerable rule that an inventor's testimony must be corroborated, preferably by contemporaneous documentary or physical evidence. The court affirmed the PTAB's reliance on Selner's 12:55 p.m. email to conclude that Selner's testimony was both credible and corroborated.

Practitioners considering bringing a derivation challenge under the AIA will find the *GHS* decision very useful. It unlocks the entire corpus of pre-AIA derivation jurisprudence, allowing the petitioner's attorney to predict the legal principles the PTAB and the Federal Circuit would likely apply to the petitioner's derivation claim.

Before the *GHS* decision, it was difficult to assess a potential derivation challenge's odds of success. It will now be much easier to determine whether such a challenge is worth the petitioner's time and resources.

The above summary was originally published in Law360 as part of an ongoing column on recent noteworthy Federal Circuit decisions.

Ecofactor, Inc. v. Google LLC

Running In Place: When a Running Royalty is Actually a Lump Sum License

In Ecofactor, Inc. v. Google LLC, Appeal No. 23-1101, the Federal Circuit held that a district court's denial of a motion for a new trial on damages was an abuse of discretion because the expert opinion was not based upon sufficient facts or data.

EcoFactor sued Google for infringement of their patent relying on an expert opinion to calculate the damages. The expert opinion used the "willing licensor-willing licensee" framework in combination with three licenses that EcoFactor had previously negotiated to calculate a hypothetical running-royalty agreement as the basis for damages and testimony from EcoFactor's CEO. Upon a jury finding in favor of EcoFactor, Google filed a motion for a new trial on damages, under the theory that EcoFactor's expert testimony should have been excluded because it was unreliable. The district court denied this motion.

On appeal, the Federal Circuit held that district court abused its discretion in denying a new trial on damages because the existing licenses and CEO testimony that formed the basis of the expert testimony were insufficient. The existing licenses could not be a sufficient basis for the testimony because (1) there is a fundamental difference between a running-royalty agreement and a lump sum license, (2) the unilateral assertion of a running-royalty agreement in the existing licenses was contradicted within each license, and (3) the existing licenses were lump sum licenses. The Federal Circuit further explained that testimony from EcoFactor's CEO could not provide a factual basis for the expert testimony, because it amounted to an unsupported assertion from an interested party due to the absence of evidence. The Federal Circuit further found that the admission of the expert testimony was not a harmless error. Accordingly, the Federal Circuit reversed the district court's denial of Google's motion for a new trial and remanded the case for a new trial on damages.

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Rex Medical, L.P. v. Intuitive Surgical, Inc.

$10 Million to $1: Exclusion of Damages Expert Results in Nominal Damages for Surgical Stapler Patent Infringement

In *Rex Medical, L.P. v. Intuitive Surgical, Inc.*, damages testimony was excluded for failing to apportion the value of the patent portfolio to isolate the value of the asserted patent.

Rex sued Intuitive alleging Intuitive's surgical stapler infringed one of Rex's patents: the '650. A jury found the asserted claim in Rex's patent was valid and infringed and awarded damages of $10 million. Intuitive moved for judgement as a matter of law (JMOL) on infringement, invalidity, and damages. The district court denied the motion as to infringement and invalidity but granted the motion as to damages and reduced the award to $1. Rex appealed.

The Federal Circuit affirmed. It held that the district court properly excluded Rex's expert. Rex's expert relied on a comparable lump-sum license agreement covering a portfolio of patents, including the '650 patent and eight other patents, seven U.S. applications, and nineteen patents or applications from outside the U.S. But the expert failed to apportion the value attributable to the '650 patent. The court emphasized that damages experts must reliably allocate value among licensed patents when using portfolio licenses. The court found that the expert's methodology was "untethered to the facts of this case." With no other evidence presented, the jury was unable to reasonably infer a royalty for the '650 patent alone. Thus, the Federal Circuit held that any damages award would be speculative and affirmed the district court's decision to award only nominal damages.

Jazz Pharmaceuticals, Inc. v. Avadel Cns Pharmaceuticals, LLC

Invoking the Hatch-Waxman Safe Harbor Does Not Necessarily Require Factual Development That Such Activities Fall Within its Scope

In *Jazz Pharmaceuticals, Inc. v. Avadel Cns Pharmaceuticals, LLC,* Appeal No. 24-2274, the Federal Circuit held that injunctions prohibiting the initiation of new clinical trials for paper NDA drugs before patent expiration violate the Hatch-Waxman Act's safe harbor provision and are therefore "unlawfully broad."

Jazz Pharmaceuticals, the maker of FDA-approved drugs Xywav® and Xyrem® for treating Idiopathic Hypersomnia ("IH"), sued competitor Avadel, which filed a paper NDA for its once-nightly IH treatment Lumryz. Jazz asserted the '782 patent against Avadel, even though Xywav and Xyrem did not practice the patent. After finding the '782 patent valid and infringed, the Delaware District Court issued a permanent injunction preventing Avadel from (1) initiating new clinical trials for Lumryz, (2) offering open-label extensions (OLEs) in ongoing clinical trials, and (3) applying for FDA approval of Lumryz for IH.

Avadel appealed, and the Federal Circuit reversed-in-part, vacated-in-part, and remanded. On point (1), the court held that the injunction was unlawful on its face because 35 U.S.C. § 271(e)(3) specifically prohibits injunctions on this kind of activity—namely, making, using, or selling a drug solely for uses reasonably related to developing and submitting information to the FDA. While Avadel had not factually developed its reliance on the safe harbor defense (e.g., that each use of Lumryz in each future clinical trial qualifies for safe harbor protection), the Federal Circuit ruled in its favor because the challenge was purely a legal invocation of the safe harbor requiring no factual development.

On point (2), the Federal Circuit reversed and remanded for the district court to consider whether Avadel's use of an OLE period falls within the safe harbor and whether the eBay factors for injunctive relief are satisfied. On point (3), the court vacated and remanded to determine whether Avadel's paper NDA filing for Lumryz constituted infringement under § 271(e)(2). If so, injunctive relief would be improper because § 271(e)(4) does not permit courts to enjoin an adjudicated infringer from applying for additional FDA approvals of a patented drug. On the other hand, if the filing was not an act of infringement, then the district court was to consider the eBay factors before imposing any injunction.

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