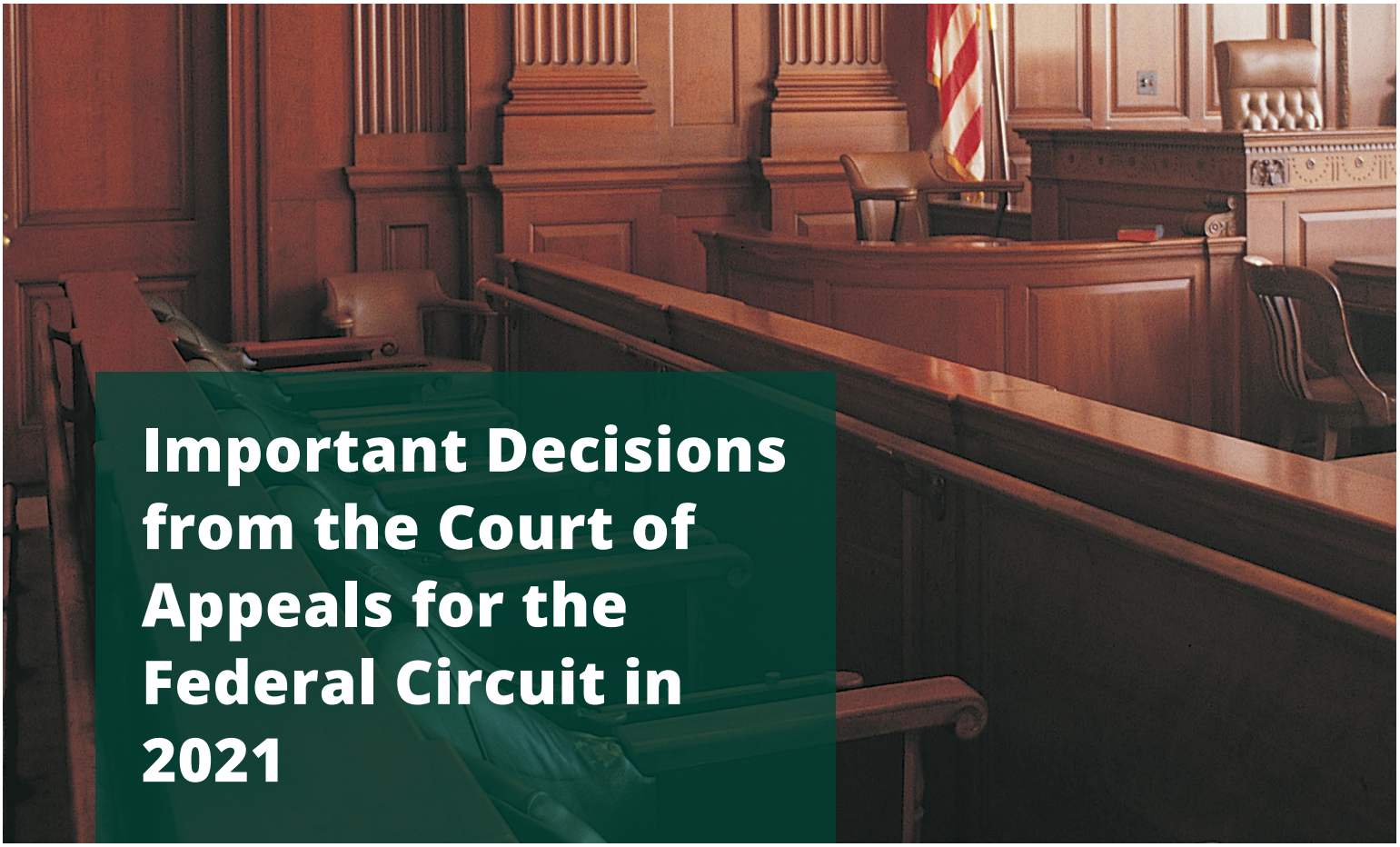

Important Decisions from the Court of Appeals for the Federal Circuit in 2021

Whether you are pursuing patents on your new technology, thinking about bringing patent infringement litigation or defending patent infringement claims in court, knowing the important developments in patent law will help you formulate strategy. Reviewing the major Federal Circuit decisions that have affected patent law over the past year can spark a change in your procedures or decision-making process.

Laura Smalley, partner with our Intellectual Property Law group, summarizes key judicial holdings in patent law from the Federal Circuit during 2021.

The following are several key judicial holdings from the Federal Circuit from 2021:

- » CLAIM CONSTRUCTION
- » WRITTEN DESCRIPTION/ ENABLEMENT
- » PATENT TRIAL AND APPEAL BOARD
- » ANTICIPATION/ OBVIOUSNESS
- » LITIGATION
- » DESIGN PATENTS
- » SUBJECT MATTER ELIGIBILITY

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Specification and Prosecution History Narrow the Plain Meaning of "0.001%."

The claim at issue included a concentration of 0.001% of PVP. The term's plain meaning is 0.001% within one significant figure (i.e., 0.0005% to 0.10014%). The Federal Circuit held that the term had a narrower meaning in light of the specification and prosecution history—"precisely 0.001% w/w PVP with only minor variations'" (i.e., 0.00095% to 0.00104%). As a matter of general construction and scientific convention, the term, expressed with only one significant figure, would encompass the larger range. The meaning of a claim term, however, is the meaning understood by one of ordinary skill in the art "after reading the entire patent." Here, because the written description and the prosecution history strongly emphasized the stability of the claimed formulations (with 0.001% w/w PVP) as compared to close variations, a narrower construction was warranted. The specification touted a formulation with 0.001% w/w PVP as the "most stable" and the formulation with 0.0005% was one of the least stable. Further, during prosecution, the claims were amended to delete a PVP range from "about 0.005% to about 0.05% w/w" to a claim with "0.001% w/w" of PVP without using the term "about". The inventors argued that data in the specification demonstrated that the range, as amended, was "critical".

› Practice Tip:

The best practice is to use the term "about" if possible and to quantify numerical values in the specification as falling within a specific tolerance or margin of error.

AstraZeneca AB v. Mylan Pharmaceuticals LP, No. 2021-1729, 2021 U.S. App. LEXIS 36127 (Fed. Cir. Dec. 8, 2021)

Claim Preamble Was Limiting Where Patentee Relied on Language in Preamble to Argue that the Claims Were Directed to Patent-Eligible Subject Matter

The patents at issue were directed to systems and methods for displaying and navigating three-dimensional electronic spreadsheets by implementing user-customizable "notebook tabs" on the spreadsheet interface. The specification touted that "the spreadsheet notebook of the present invention provides a 3-D interface which readily accommodates real-world information in a format the user understands." The preamble of the representative claim read: "In an electronic spreadsheet system for storing and manipulating information, a computer-implemented method of representing a three-dimensional spreadsheet on a screen display, the method comprising …"

During the litigation, Google filed a motion to dismiss under Fed. R. Civ. P. 12(c), asserting that the claims were patent-ineligible under 35 U.S.C. § 101. On appeal of the district court's dismissal of the claims, the plaintiff argued that the claims were patent-eligible under § 101, explaining that the claims solved a problem unique to three-dimensional spreadsheets. The Federal Circuit reversed the district court's judgment, finding that the claims were patent-eligible because they solved a known technological problem in a particular way—providing a highly intuitive, user-friendly interface with familiar notebook tabs for navigating the three-dimensional worksheet environment. The notebook tabs disclosed in the claims, held the Federal Circuit, were specific structures within the three-dimensional spreadsheet environment.

On remand, the district court reopened claim construction and construed the preamble as limiting and having patentable weight. The district court then granted Google summary judgment because its product did not "allow a user to define the relative position of cells in all three dimensions." The Federal Circuit affirmed the grant of summary judgment, holding that the district court's claim construction was correct. The plaintiff's argument for patent-eligibility relied on the improvement "being unique to three-dimensional spreadsheets." It could not now argue a different construction for infringement (the preamble recitation of three-dimensional spreadsheets was not limiting) than it argued for validity (relying on the improvement in three-dimensional spreadsheets).

Data Engine Technologies LLC v. Google LLC, 10 F.4th 1375 (Fed. Cir. 2021)

Specification Focus on Basic Research Fails to Support Specific Therapeutic Dose Claim

The Federal Circuit upheld the district court's finding that patent claims directed to a method of treating multiple sclerosis with about 480 mg per day of dimethyl fumarate (DMF) were invalid for lack of written description. Plaintiff Biogen International sold the treatment under the brand name Tecifidera®; defendant Mylan Pharmaceuticals filed an Abbreviated New Drug Application seeking to market a generic DMF product.

The specification contained only one paragraph regarding dosage levels for DMF monotherapy and the dosage levels were not linked to the treatment of any specific disease. The paragraph noted that an effective dose could be from about 480 mg/day to about 720 mg/day. Notably, the specification defined the term "effective amount" in therapeutic terms and the inventor testified that his research could be extrapolated to a clinical dose of DMF. The district court held that the specification did not reasonably convey to a person of ordinary skill in the art that the inventors had actually invented a method of treating multiple sclerosis with a therapeutically effective dosage of DMF as of the patent's filing date. The specification lacked a written description of the DMF dosage for treatment of multiple sclerosis because the identified range appeared at the end of one of a series of ranges. "The specification's focus on basic research and broad DMF-dosage ranges show that the inventors did not possess a therapeutically effective DMF480 dose at the time of filing in 2007" and expert testimony credited by the district court stated that "the paragraph containing the sole DMF480 reference fails to specifically link an effective dose of DMF to the treatment of MS."

The Federal Circuit stated that "a patent cannot be awarded for mere theoretical research without more" and that the "written-description requirement limits patent protection only to individuals who perform the difficult work of producing a complete and final invention featuring all its claimed limitations and publicly disclose the fruits of that effort."

Biogen International GmbH v. Mylan Pharmaceuticals Inc., No. 20-1933, 2021 U.S. App. LEXIS 35254 (Fed. Cir. Nov. 30, 2021)

Examples in Specification Did Not Provide Written Description Support for Bounded or Closed Ranges

The Federal Circuit affirmed the Patent Trial and Appeal Board's ("Board") determination that a patent specification did not provide written description support for range limitations in the challenged claims. The patent generally describes orally-dissolvable films containing therapeutic agents. The claims recited limitations specifying the amount of a water-soluble polymeric matrix, including "about 40 wt % to about 60 wt %", "about 48.2 wt % to about 58.6 wt %" and "about 48.2 wt %" of the matrix. These ranges were not expressly claimed or stated in the original application, and thus the question was whether a skilled artisan "could reasonably discern" a disclosure of each range from the specification. The language of the specification was ambiguous—it noted different permissible percentages and stated that the amount of polymeric material could vary. Tables in the specification detailed examples that fell within the claimed ranges, but the percentages were not disclosed expressly and needed to be calculated from the data in the tables.

The Federal Circuit stated that using these data points from examples in the specification to support the claimed ranges "amounts to cobbling together numbers after the fact." To satisfy the written description requirement, the specification must be a "statement of the invention," not invite the reader "to go on a hunting expedition to patch together after the fact a synthetic definition of the invention." The disclosure of examples that fell within the claimed ranges provided insufficient written description support for the ranges. Notably, the Federal Circuit did affirm the Board's interpretation that the disclosure supported a claim limitation of "about 48.2 wt %", even though the percentage was not explicitly set forth in the specification, because the limitation specified a particular amount, not a range.

› Practice Tip:

The determination of whether a claimed range is supported by the specification is fact-specific, so this decision might not be controlling in all situations. In drafting a patent application, however, numerous variations of potential ranges should be explicitly stated, including variations that enclose all examples as well as variations that enclose discrete subsets of the examples in the specification. As in all cases of written description, the more examples the better.

Indivior UK Ltd. v. Reddy's Labs. S.A., Nos. 2020-2073, 2020-2142, 2021 U.S. App. LEXIS 34959 (Fed. Cir. Nov. 24, 2021)

A Specific Threat of Litigation is not Necessary to Establish the Requisite Injury to Appeal

While there is no standing requirement for a petitioner to request inter partes review by the Board, in order to appeal a Board decision, the putative appellate must have: (1) suffered an injury in fact; (2) that is traceable to its challenged conduct; and (3) that is likely to be redressed by a favorable judicial decision. Moderna, seeking to appeal, established that there was a substantial risk that the patent-holder would assert the patent subject to the Board proceeding in an infringement suit targeting Moderna's COVID-19 vaccine. Moderna submitted a declaration describing how the patent holder's statements and actions created a "substantial risk" of an infringement action against Moderna's COVID-19 vaccine, citing the patent-holder's public statements regarding its patent coverage and its position that Moderna needs a license to its patent.

As noted by the Federal Circuit, a specific threat of litigation is not necessary to establish the requisite injury to appeal—an appellant may demonstrate that "it has engaged in, is engaging in, or will likely engage in 'activity that would give rise to a possible infringement suit.'" Here, Moderna demonstrated sufficient risk of an infringement suit to establish standing.

Moderna TX, Inc. v. Arbutus Biopharm Corp., Nos. 2020-1184, 2020-1186, 2021 U.S. App. LEXIS 35472 (Fed. Cir. Dec. 1, 2021)

Remote Possibility of Future Financial Impact Insufficient to Establish Standing to Appeal

In another appeal from a Board decision in an inter partes review, the Federal Circuit found that Moderna did not have standing to appeal the Board decision and dismissed the appeal. As the party seeking to appeal, Moderna had the burden of demonstrating the requisite injury to establish standing. Moderna did not rely on the threat of an impending infringement lawsuit, but its status as a current licensee of the challenged patent. The potential financial impact of the case established standing, Moderna argued. There were, however, no recent milestone payments or the reasonable prospect of another such payment.

The Federal Circuit found that Moderna lacked standing when the appeal was filed, because the evidence of financial burden from the license was too speculative. Not only was the possibility of a future payment remote, but the patent was only one of many licensed patents. Further, termination of the licensed development program may have meant that Moderna did not have standing continuously during the appeal.

ModernaTx, Inc. v. Arbutus Biopharm Corp., No. 20-1184, 2021 U.S. App. LEXIS 35471 (Fed. Cir. Dec 1, 2021)

Standing Requires that Validity of the Patent Affect Contract Rights

The Federal Circuit held that Apple lacked standing to appeal a Board decision in an inter partes review. Before the appeal, Apple and Qualcomm had settled all litigation between the parties. As part of the settlement, the parties entered into a six-year license agreement that included a license to the patents at issue before the Board. Apple claimed it had standing because: (1) the license had ongoing payment obligations; (2) it could be sued for infringement of one of the patents after the license agreement expired; and (3) potential estoppel effects. The Federal Circuit rejected the argument regarding the licensed patents because Apple did not allege that the validity of the patent at issue would affect its contract rights, which was fatal to standing. The license agreement involved "tens of thousands" of patents and Apple did not identify any contractual dispute that relates to, or could be resolved through, determination of the validity of the patents at issue. The allegations regarding a possible patent infringement suit were too speculative because Apple did not set forth any plans to engage in activity that might lead to an infringement suit after the license expired. Finally, estoppel does not provide an independent basis for standing.

Apple Inc. v. Qualcomm Inc., 992 F.3d 1378 (Fed. Cir. 2021), petition for cert. filed Sept. 03, 2021

Patent Office Should Have Denied Ex Parte Reexamination Where Prior Inter Partes Review Proceedings Addressed the Same Prior Art

The Patent Office must find a "substantial new question of patentability" to order reexamination of a patent, 35 U.S.C. § 303(a), and may deny reexamination when "the same or substantially the same prior art or arguments" were previously "presented to the Office." 35 U.S.C. § 325(d). In this case, Vivint sued Alarm.com for infringing four patents. Alarm.com filed fourteen inter partes review ("IPR") petitions, three of which challenged the claims of U.S. Patent No. 6,717,513. The Patent Office declined to institute IPR on the claims of the '513 patent. Over a year later, Alarm.com requested ex parte reexamination of all claims of the '513 patent. Its arguments repeated arguments made in other IPR proceedings but substituted a new reference in rearguing two other previously-presented grounds. The IPR petitions were denied due to abusive filing practices.

Nevertheless, the Patent Office granted the request for reexamination, finding a substantial new question of patentability. Vivint petitioned the Patent Office under 37 C.F.R. § 1.81 seeking dismissal of the ex parte reexamination. The Patent Office dismissed the Petition, determining that it had no authority to consider petitions filed after reexamination, and explaining how the grant of ex parte reexamination was not inconsistent with denying IPR given the different statutory frameworks used to make each decision. And, even if the IPR was denied based solely on § 325(d) considerations, the differences between ex parte reexamination and IPR could justify the different outcome. The examiner issued a final rejection for all of the claims of the '513 patent, and the Board affirmed.

The Federal Circuit found that the Patent Office acted arbitrarily and capriciously in granting ex parte reexamination. A "substantial new question of patentability is a question that had not been "considered and decided on the merits." The grounds in the reexamination were "new" because the Patent Office never addressed the patentability of the claims in light of the new reference, and because the Patent Office declined to institute an IPR for reasons unrelated to patentability. Denying the petition to dismiss the reexamination, however, was arbitrary and capricious because the Patent Office relied primarily on its alleged lack of authority to terminate an ex parte reexamination. That ground was incorrect—the Patent Office has authority to reconsider its decision ordering ex parte reexamination based on § 325(d). Additionally, the Patent Office's grant of reexamination and denial of the petition to terminate were arbitrary and capricious because the earlier IPR petitions were dismissed as similar, serial challenges to the same patent and the ex parte reexamination request was another such filing.

In re: Vivint, Inc., 14 F.4th 1342 (Fed. Cir. 2021)

Federal Circuit Has Mandamus Jurisdiction Over Denial of Institution

The Board denied institution of a Janssen patent pursuant to its discretion to decline institution under Apple v. Fintiv, based on substantial overlap between the issues raised in the IPR Petition and two co-pending district court actions. Mylan appealed the denial and also sought mandamus relief.

The Federal Circuit dismissed the direct appeal, holding that it does not have jurisdiction over an appeal from a decision denying institution under 35 U.S.C. § 314(d).

The Federal Circuit held that judicial review is available in "extraordinary circumstances" by petition for mandamus. "To protect [its] future jurisdiction," the court has "jurisdiction to review any petition for a writ of mandamus denying institution of an IPR."

The Federal Circuit, however, denied Mylan's petition, finding that Mylan failed to identify a clear and indisputable right to relief, or a colorable constitutional claim. Mylan challenged the Patent Office's adoption of the Fintiv standard through a precedential decision, rather than through notice-and-comment rulemaking. It also argued that Fintiv impermissibly shortened the statute of limitations to initiate IPR proceedings, and that the Fintiv standard is unconstitutional as applied. Because the scope of the review over a decision denying institution is "very narrow," the mandamus standard will be "especially difficult to satisfy" in challenging such a decision. The Director is not compelled to institute an IPR and no petitioner has a right to institution. Denial of institution is thus not reviewable except when the petition presents a colorable constitutional claim.

Mylan Labs, Ltd. v. Janssen Pharmaceutica, N.V., 989 F.3d 1375 (Fed. Cir. 2021)

Presumption of Obviousness for Overlapping Ranges Not Applicable Where Prior Art Does Not Teach the Overlapping Range

The patent claim at issue disclosed a nucleic acid lipid particle comprised of (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 4 mol % to 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.

Moderna petitioned for inter partes review of the patent, asserting that the claims were obvious because the prior art disclosed all of the ranges for the components of the claimed lipid particle and a presumption of obviousness applied. While Moderna could point to expressly disclosed ranges in the prior art for three of the four components, the prior art did not expressly disclose a range for the phospholipid portion. Moderna instead argued that, based on the ranges of other components, the range of the phospholipid could be calculated and could be obtained through routine optimization in any event.

The Federal Circuit declined to determine the issue of whether the presumption arises where the prior art does not expressly, but only inherently, discloses the range. It held that Moderna had failed to show that the range was actually taught or suggested by the prior art. It was impermissible to adjust the amount of the components across the different ranges and then subtract from 100 to get the percentage of phospholipid. Further, the assumption necessary to derive the implicit overlapping range was undermined by the unpredictable interactivity between the components. Moderna also failed to provide sufficient evidence to demonstrate that the amount of phospholipid could be derived through routine optimization because it failed to show that the range was a result-effective variable and because optimizing four interdependent components would not have been routine.

Moderna TX, Inc. v. Arbutus Biopharm Corp., No. 20-2329, 2021 U.S. App. LEXIS 35472 (Fed. Cir. Dec. 1, 2021)

The General Working Conditions in the Prior Art Must Encompass the Claimed Invention to Apply Authority Regarding Prior Art Ranges

It is black-letter law that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." A prima facie case of obviousness exists where the ranges of a claimed composition overlap ranges found in the prior art. Here, the patent claim involved a method of treating Cushing's syndrome by co-administering mifepristone and a strong CYP3A inhibitor. The claimed dosage of the mifepristone was 600 mg. The prior art limited the co-administration of mifepristone in combination with a strong CYP3A inhibitor to 300 mg per day. The challenger, Teva, relied on monotherapy doses above 300 mg per day to argue obviousness. Those dosages did not create an overlap with the claimed range because the general conditions of the claim (combination therapy) were different from those in the prior art (monotherapy).

Teva Pharmaceuticals USA v. Corcept Therapeutics, Inc., No. 21-11360, 2021 U.S. App. LEXIS 36045 (Fed. Cir. Dec. 7, 2021)

Patent Trial and Appeal Board Determination of "Reasonable Expectation of Success" Must Be Supported by Substantial Evidence

The Federal Circuit reversed a decision of the Patent Trial and Appeal Board ("Board") finding a patent on a method of disinfection obvious. The reversal was based in part on a finding that the Board's determination—that there was a "reasonable expectation of success" in combining the teachings of two prior art references—was not supported by substantial evidence.

The patent had claims directed to a method for photoinactivating antibiotic-resistant bacteria, such as methicillin-resistant Staphylococcus aureus ("MRSA") and other Gram-positive bacteria, using a photosensitizing agent. The inventors had found that wavelengths in the 400–500 nm region, particularly 400-420 nm, provided a high rate of MRSA inactivation. Illustrative claim 1 disclosed a method for disinfecting air, contact surfaces, or materials by exposing the Gram-positive bacteria to visible light without using a photosensitizer where a portion of the visible light is in the range 400-420 nm.

The Board found the illustrative claim obvious over two prior art references. The primary dispute was whether the prior art taught exposing bacteria to light without using a photosensitizer. The Federal Circuit concluded that the Board erred in finding that the two references taught or suggested all of the limitations of the illustrative claim, and specifically that the "combined teachings" of the references disclosed exposing bacteria to light without using a photosensitizer. Because neither reference taught or suggested "inactivation of any bacteria without using a photo-sensitizer," the court failed "to see why a skilled artisan would opt to entirely omit a photo-sensitizer when combining these references."

Further, the Federal Circuit also disagreed with the Board's conclusion that a person of ordinary skill in the art would have had a reasonable expectation of successfully combining the references. Neither reference achieved inactivation of any bacteria without using a photosensitizer and one of the references detailed a failed attempt to inactivate bacteria under that condition. The Federal Circuit found that the references lacked evidence, data or "other promising information" showing successful inactivation of any bacteria without using a photosensitizer. The Board's finding of likelihood of success was therefore not supported by substantial evidence.

Practice Tip: In litigating obviousness in court or before the Board, remember that it is not enough to identify all of the claim limitations in the cited prior art references. The facts (which may include expert testimony) must demonstrate that "that a person of ordinary skill in the art would have been motivated to combine or modify the teachings in the prior art and would have had a reasonable expectation of success in doing so."

Univ. of Strathclyde v. Clear-Vu Lighting LLC, No. 2020-2243, 2021 U.S. App. LEXIS 32872 (Fed. Cir. Nov. 4, 2021)

Patent Holder Fails to Show Nexus Between the Challenged Claims and Commercial Embodiments Because the Broad, Functional Claims Did Not Have a Nexus to a Specific Product

Calcitonin gene-related peptide (CGRP) was known to be potentially connected to vasomotor symptoms, including vascular headaches such as migraines. Thus, prior to the disclosed inventions, treatments were being informed by the possible connection between CGRP as a vasodilator and the pathology of migraines. The patents at issue were directed to humanized antagonistic antibodies that antagonize CGRP and thereby inhibit its activity in the body by targeting and binding to the CGRP ligand.

Teva provided proof of secondary considerations of non-obviousness based on its and the defendant's commercial products, both of which were antibodies that fell within the scope of the claims. The Board found that Teva failed to show a nexus between the challenged claims and the commercial products covered by the claims. Generally, "a patentee is entitled to a rebuttable presumption of nexus between the asserted evidence of secondary considerations and a patent claim" where the evidence is "tied to a specific product and that product 'embodies the claimed features and is coextensive with them.'" In determining whether the presumption applies, the finder of fact must consider the unclaimed features of the products and determine the impact on the correspondence between the claim and the products.

In this case, the Board found that no presumption of nexus applied. The Federal Circuit agreed, finding that the claims at issue were defined by their function (ability to bind to the CGRP ligand) rather than structure (amino acid sequence). Because the claims are broad, the unclaimed features, such as the amino acid sequences (which affect binding affinity), were critical to the function of the products as humanized anti-CGRP antagonist antibodies. Teva therefore failed to demonstrate that the presumption of nexus applied.

› Note:

This decision presents another potential difficulty in enforcing antibody patents or other biotech patents with genus claims. Even if the patentee's commercial product falls within the genus claim, the patentee may not be able to show a nexus between the claim and the proffered secondary considerations. If the patentee's product is covered by a claim to an embodiment with a specific amino acid sequence, then the claim may not cover the alleged infringer's product.

Teva Pharm. Int'l GmbH v. Eli Lilly and Co., 8 F.4th 1349 (Fed. Cir. 2021)

No Absolute Requirement for Reference to Be Self-Enabling to Establish Obviousness

The Federal Circuit held that a reference used to demonstrate obviousness need not be self-enabling "so long as the overall evidence of what was known at the time of the invention establishes that a skilled artisan could have made and used the claimed invention." A reference that does not include an enabling disclosure for a claim limitation may furnish the motivation to combine and be combined with, another reference that is enabled. If a reference is not self-enabling and no other evidence (such as a prior art reference) would have enabled the skilled artisan to make the invention, then the claimed invention is not obvious.

The Raytheon patent disclosed gas turbine engines and generally claims a geared gas turbine engine with two turbines and a specific number of fan blades, turbine rotors and/or stages. The novel feature of the claims was a "power density" range that the patent describes as being "much higher than in the prior art."

In the inter partes review, the Board found two claims unpatentable as obvious, finding that the prior art reference ("Knip") discloses the claimed power density limitation for a geared gas turbine engine. Raytheon, however, had submitted unrebutted evidence establishing that Knip's disclosure of highly aggressive performance parameters for a futuristic turbine engine was based on the use of composite materials that did not exist. General Electric provided no evidence suggesting a skilled artisan could have made a turbine engine with the cited power density. The Federal Circuit reversed, holding that the Board's finding was legal error because the relied-upon prior art fails to enable a skilled artisan to make and use the claimed invention.

Raytheon Technologies Corp. v. General Electric Co., 993 F.3d 1374 (Fed. Cir. 2021)

Venue in Hatch-Waxman Litigation Requires Defendant to Commit Acts of Infringement and Have a Regular Place of Business in the Chosen Venue

To establish venue, the plaintiff must demonstrate that the defendant "resides" in the district of suit or that it "has committed acts of infringement and has a regular and established place of business there."

Submitting an ANDA that seeks approval to market a drug while that drug is on-patent (e.g., an ANDA containing a paragraph IV certification) is patent infringement. Thus, under the Hatch-Waxman Act, submission of the ANDA is the sole act of infringement at issue in establishing venue. Venue is proper where the ANDA-filer submits its ANDA to the FDA, not where the proposed generic drug will be distributed. Relevant acts for establishing venue include those acts involved in the preparation and submission of the ANDA. Sending the paragraph IV notice letter, although required by the Act, is not an act of infringement and thus cannot be used as a basis for venue.

Celgene Corp. v. Mylan Pharm. Inc., No. 21-1154, 2021 U.S. App. LEXIS 32996 (Fed. Cir. Nov. 5, 2021)

Forum Selection Clause in NDA Did Not Prohibit Inter Partes Review

Kannuu and Samsung entered into a non-disclosure agreement as part of exploring a business arrangement. The agreement contained a forum selection clause providing that "Any legal action, suit, or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby must be instituted exclusively in a court of competent jurisdiction, federal or state, located within the Borough of Manhattan, City of New York, State of New York and in no other jurisdiction." The parties did not consummate a deal such as a license or sale of Kannuu's technology.

Kannuu filed suit six years later for breach of the NDA and patent infringement. Samsung filed petitions for inter partes review of the asserted patents. Review was instituted for two of the five patents. Kannuu sought a preliminary injunction to compel Samsung to dismiss the instituted IPRs. The Federal Circuit upheld the district court's denial of an injunction dismissing Samsung's petitions for inter partes review at the Patent Trial and Appeal Board. The Federal Circuit agreed with the trial court that the plain meaning of the forum selection clause in the NDA did not compass the IPR proceedings because those proceedings do not "relate" to the agreement or transactions contemplated by the Agreement. The agreement governed the confidentiality rights of the parties, not their intellectual property rights. The district court did not err in concluding that the inter partes review proceedings did not fall within the scope of the NDA's forum selection clause.

Kannuu Pty. Ltd. v. Samsung Elec. Co., Ltd., 15 F.4th 1101 (Fed. Cir. 2021)

Skinny Label Does Not Prevent Claim of Induced Infringement

Carvedilol, marketed by GlaxoSmithKline with the brand name Coreg®, was initially approved by the FDA for the treatment of hypertension. The FDA eventually approved three indications for carvedilol: hypertension, left ventricular dysfunction following a myocardial infarction, and congestive heart failure. After the patent on carvedilol expired on March 5, 2007, the only use covered by a patent was for the treatment of congestive heart failure.

Teva launched its generic carvedilol in 2007 with a label listing the indications of left ventricular dysfunction following myocardial infarction and hypertension, but omitting the patented indication of treating congestive heart failure. Teva's press releases and marketing materials, however, marketed its generic as equivalent to Coreg®, stating that its carvedilol is "an AB Rated generic of Coreg® Tablets." Teva amended its label in 2011 to include the indication for treatment of heart failure based on the FDA's requirement that the label be "identical in content" to the approved Coreg® labeling.

The jury found that Teva induced infringement of the asserted claims both before and after amending its label. On appeal, the Federal Circuit found that substantial evidence existed to support the jury's verdict. Induced infringement is established when the provider of an identical product knows of and markets the same product for intended direct infringing activity. Although Teva's label carved out the indication of treatment for heart failure, the jury received evidence that, among other things, Teva's promotional materials referred to Teva's carvedilol tablets as AB rated equivalents of Coreg® tablets. Literature placing Teva's carvedilol tablets next to Coreg® tablets using the phrase "AB rating," would lead a doctor to believe that the drugs are "therapeutically interchangeable."

The Federal Circuit granted rehearing en banc to clarify that its holding did not extend liability to generic drug makers for merely marketing and selling under a "skinny label" omitting all patented indications or where the label indicated that the FDA had found the product therapeutically equivalent to a brand-named drug. Generic manufacturers, however, can be liable for infringement if they market a drug with a label bearing patented indications or if they take "active steps" to encourage use of the drug in an infringing manner. Under this statement of the law, Teva actively induced infringement by marketing a drug with a label "encouraging a patented therapeutic use" and by disseminating marketing materials that encouraged physicians to prescribe carvedilol in an infringing manner.

GlaxoSmithKline LLC v. Teva Pharm. USA, Inc., 7 F.4th 1320 (Fed. Cir. Aug. 5, 2021)

Infringement Action May be Dismissed at the Pleading Stage Where the Patentee Pleads Facts Inconsistent with its Claims

After the plaintiff filed suit, the case was transferred and the plaintiff filed an amended complaint. The district court granted defendant's motion to dismiss most of the patent infringement claims and denied leave to file a second amended complaint. The district court granted summary judgment on the remaining patent infringement claim.

The Federal Circuit affirmed the dismissal of two of the patent infringement claims, but reversed the dismissal of two other patent infringement claims. It also affirmed the district court's denial of leave to file a second amended complaint and the grant of summary judgment on the fifth patent claim under 35 U.S.C. § 101.

To state a claim, the complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Patentees need not prove their case at the pleading stage, and a plaintiff is not required to plead infringement on an element by element basis (i.e., include claim charts). The allegations in the complaint, however, must show that the plaintiff has a plausible claim for relief and provide "sufficient factual content" to show an entitlement to relief. "The level of detail required in any given case will vary depending upon a number of factors, including the complexity of the technology, the materiality of any given element to practicing the asserted claim(s), and the nature of the allegedly infringing device." Conclusory allegations merely reciting the claim elements and asserting that the accused product has those elements are insufficient.

While the plaintiff's allegations in this case were sufficiently detailed, its "kitchen sink" approach to pleading demonstrated a fatal inconsistency in its allegations regarding one of the patents. The pleading alleged that the claimed "authentication program" was stored on the PS4 motherboard, whereas the claim language required the program to be stored on a separate board. Thus, plaintiff's allegations of infringement were not plausible. The Federal Circuit also upheld the dismissal with regard to a second patent infringement claim because, while the complaint pointed to several different storage components, it failed to allege which of those components satisfied a "mutual authentication" limitation.

BOT M8 LLC v. Sony Corp. of Am., 4 F.4th 1342 (Fed. Cir. 2021)

LITIGATION

Jury Permitted to Select Royalty Rate Within Range Posited by Expert; Right to Jury Trial Does Not Attach to Award of Pre-Verdict Supplemental Damages

The patent at issue is directed to recombinant forms of human factor VIII (or FVIII), useful in the treatment of hemophilia A. The claims were directed to an improved form of FVII with an increased half-life, which therefore required less-frequent administration. Bayer sued Baxalta for patent infringement based on its recombinant PEGylated FVIII product, which was used to treat hemophilia A. The jury found that the claims were enabled and infringed, and awarded a reasonable royalty. The district court denied judgment as a matter of law or a new trial on the issues of infringement, enablement and damages.

The district court excluded the testimony of the plaintiff's expert regarding a specific royalty percentage, which was the midpoint of his bargaining range. The expert selected the midpoint based on the Nash Bargaining Solution. The district court, however, allowed the expert to testify to the range, which was derived from the incremental profits the defendant would expect to earn from the product (maximum) and the profits the plaintiff would lose by granting a license (minimum). The Federal Circuit held that the district court did not err in admitting the range testimony. No precedent requires an expert to provide a single proposed royalty rate. The expert considered and discussed the appropriate Georgia-Pacific factors in determining the range of reasonable royalties. The amount of damages, based on a 17.78% royalty rate, was within the range in the record and the plaintiff's expert provided the jury with sufficient guidance on selecting the rate.

The jury calculated the royalty rate, royalty base and total damages through November 30, 2018. The trial court awarded pre-verdict supplemental damages for the time period between the jury's verdict and entry of judgment based on the royalty rate awarded by the jury and the actual sales data. As noted by the Federal Circuit, "[c]alculating pre-verdict supplemental damages in this case merely required applying the jury's royalty rate to the undisputed actual infringing sales base." The district court did not abuse its discretion in awarding pre-verdict supplemental damages, and the award did not violate defendant's right to a jury trial.

Bayer Healthcare LLC v. Baxalta Inc., 989 F.3d 964 (Fed. Cir. 2021)

DESIGN PATENTS

Design Patent Claims Are Limited to the Article of Manufacture Identified in the Claim

The design patent application at issue claimed an "ornamental design for a lip implant…" The examiner rejected the claim as anticipated by a catalog disclosing an art tool that had substantially the same shape as the claimed lip implant. The Patent Trial and Appeal Board affirmed, holding that the claimed design is not limited to the particular article of manufacture identified in the claim. The Federal Circuit held that a "design claim is limited to the article of manufacture identified in the claim; it does not broadly cover a design in the abstract." Because the Board's finding that the design claim was anticipated rested on an erroneous interpretation of the claim's scope (that it was not limited to implants), the Federal Circuit reversed.

In re SurgiSil, L.L.P., 14 F.4th 1380 (Fed. Cir. 2021)

Claims that Disclose a Technical Solution to a Security Problem in Networks and Computers are Patent-Eligible

The patent-in-suit disclosed an authentication method both low in complexity and high in security. The inventors claimed to improve on conventional mobile phone authentication methods by making the authentication function normally inactive but activated by the user for the transaction and then deactivated by the second channel. The method is simple because it only requires detection that the authentication function is active, but high in security because a fraudulent user would only succeed if the true user "happens to activate the authentication function of his mobile phone device in just the right moment."

The Supreme Court's subject-matter eligibility test in Alice has two steps: (1) first, the court determines whether the claims at issue are directed to a patent-ineligible concept such as an abstract idea; and (2) if the answer to the first step is "yes," the court considers the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application of the concept. The Federal Circuit held that the patent claims were patent-eligible under Alice step two because they recite a specific improvement to a particular computer-implemented authentication technique. The patent claims and specification recited a specific improvement to authentication that increased security, prevented unauthorized access by a third party, was easily implemented, and could advantageously be carried out with mobile devices of low complexity. The arrangement of the claimed steps provided a technical improvement over conventional authentication methods.

Cosmokey Solutions GmbH & Co. KG v. Duo Security LLC, 15 F.4th 1019 (Fed. Cir. 2021)

Claims Involving Authentication Technology Were Not Subject-Matter Eligible

The patents at issue were directed to securing electronic payment transactions. The Federal Circuit held that all asserted claims of three patents are directed to an abstract idea and that the claims contain no additional elements that transform them into a patent-eligible application of the abstract idea.

The Federal Circuit noted that "in cases involving authentication technology, patent eligibility often turns on whether the claims provide sufficient specificity to constitute an improvement to computer functionality itself." The three patents disclosed: (1) an identification system enabling a person to be verified or identified without providing any personal information by use of a Universal Secure Registry to which access is gained by various electronic devices, such as a phone or watch; (2) combined use of a user device (e.g., cell phone), a point-of-sale (POS) device, and a universal secure registry to facilitate financial transactions; and (3) a system for authenticating identities of users, including a first handheld device configured to transmit authentication information and a second device configured to receive the authentication information.

The Federal Circuit held that the claims of the patents at issue were directed to abstract ideas. While the rationale was slightly different for each patent, in general the claims "'simply recite[d] conventional actions in a generic way' (e.g., receiving a transaction request, verifying the identity of a customer and merchant, allowing a transaction) and 'do not purport to improve any underlying technology.'" The claims failed to disclose a specific technical solution.

As to Alice step two, the claims lacked an inventive concept that would transform the abstract idea into patentable subject matter. The claims are directed to a combination of known authentication techniques that yield expected results. Thus, the claims did not recite patent-eligible subject matter.

Universal Secure Registry LLC v. Apple Inc., No. 10 F.4th 1342 (Fed. Cir. Aug. 26, 2021)

Claims to an Improved Digital Camera Directed to an Abstract Idea

The Federal Circuit affirmed the district court's decision that the patent claims at issue were invalid under 35 U.S.C. § 101. The patent claimed an improved digital camera with two image sensors, two lenses and circuitry to digitize a first and second image, store the images and enhance the first image with the second image. The Federal Circuit agreed with the district court that the claim was "directed to the abstract idea of taking two pictures (which may be at different exposures) and using one picture to enhance the other in some way." The practice of using multiple images to enhance each other is an old concept, and all of the components of the claim (lenses, etc.) are "well-known and conventional" and perform their basic functions. The claims also had "a high degree of generality." The court did not believe that the particular configuration of the lenses and the image sensors in the claims changed their abstract nature, particularly because the specification touted the benefit of a four lens configuration, while the claim at issue only required two lenses.

Further, the claims did not contain an "inventive concept sufficient to transform the claimed abstract idea into a patent-eligible invention." The claims had a "high level of generality" and only recited routine and conventional components. Even the allegedly novel digital camera configuration was insufficient to render the claims patent-eligible because the claimed configuration did not add "sufficient substance" to the abstract idea.

Yanbin Yu v. Apple Inc., 1 F.4th 1040 (Fed. Cir. 2021)

Claims Directed to Computerized Statistical Methods for Determining Haplotype Phase Are Abstract

The Federal Circuit affirmed the final rejection of claims to computerized statistical methods for determining haplotype phase. Haplotype phasing is a process for determining the parent from whom alleles—i.e., versions of a gene—are inherited. The application is directed to methods for inferring haplotype phase in a collection of unrelated individuals.

In analyzing the claims under the Supreme Court's test in Alice, the Federal Circuit determined that the claims of the application are directed to patent-ineligible abstract ideas—the use of mathematical calculations and statistical modeling. "[M]athematical algorithms for performing calculations, without more, are patent ineligible under § 101." The method steps, including "building a data structure describing an [HMM]," and then "repeatedly randomly modifying at least one of the imputed initial haplotype phases" to automatically recompute the parameters of the HMM until the parameters indicate that the most likely haplotype phase is found," are generic steps of implementing and processing calculations with a regular computer. They do not change the character of the claim from an abstract idea into a practical application. Further, an alleged increase in haplotype prediction accuracy did not render the claim a practical application rather than an abstract idea. "The different use of a mathematical calculation, even one that yields different or better results, does not render patent eligible subject matter."

Under Alice step two, the Federal Circuit determined that the claims did not contain an inventive concept that transformed the abstract idea into patent-eligible subject matter. The recited steps of receiving, extracting, and storing data amount to well-known, routine, and conventional steps taken when executing mathematical algorithms on a computer.

In re: Board of Trustees of the Leland Stanford Junior University, 1 F.4th 1040 (Fed. Cir. 2021), petition for cert. filed, Nov. 29, 2021

Claims Directed to Mathematical Calculations and Statistical Models for Determining Haplotype Phase Are Abstract, Particularly Because the Hardware Limitations Are "Generic"

The Federal Circuit affirmed the final rejection of claims to mathematical calculations and statistical models for determining haplotype phase. Haplotype phasing is a process for determining the parent from whom alleles—i.e., versions of a gene—are inherited. The application is directed to methods for determining haplotype phase. In analyzing the claims under the Supreme Court's test in Alice, the Federal Circuit determined that the claims of the application are directed to the patent-ineligible abstract ideas. "[M]athematical algorithms for performing calculations, without more, are patent ineligible under § 101." Although the process allegedly yielded a greater number of haplotype phase predictions, it at most constituted a new or different use of a mathematical process, not an improved technological process. With respect to Alice step two, the claim was not transformed into patent-eligible subject matter because it did not recite steps that practically apply the claimed mathematical algorithm; the claim ends at storing the haplotype phase and "providing" it "in response to a request," and recited only "generic" hardware elements.

In re: Board of Trustees of the Leland Stanford Junior University, 991 F.3d 1245 (Fed. Cir. 2021)

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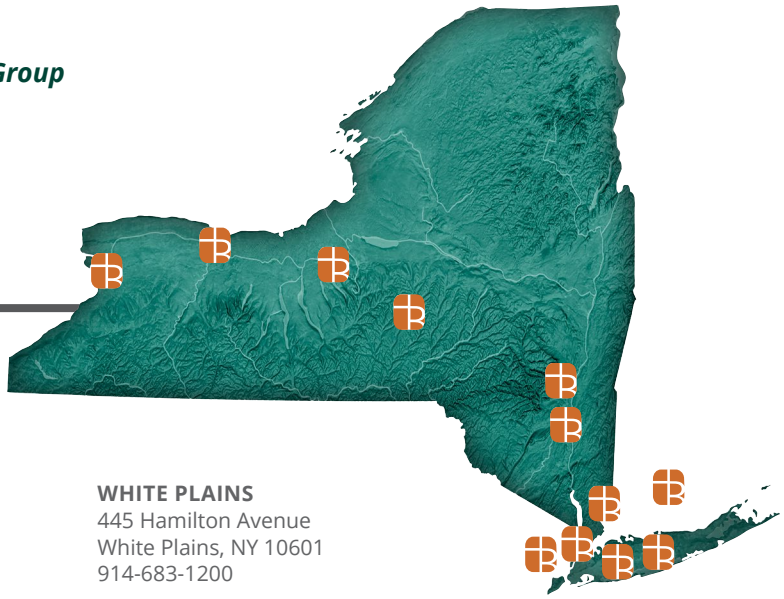

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