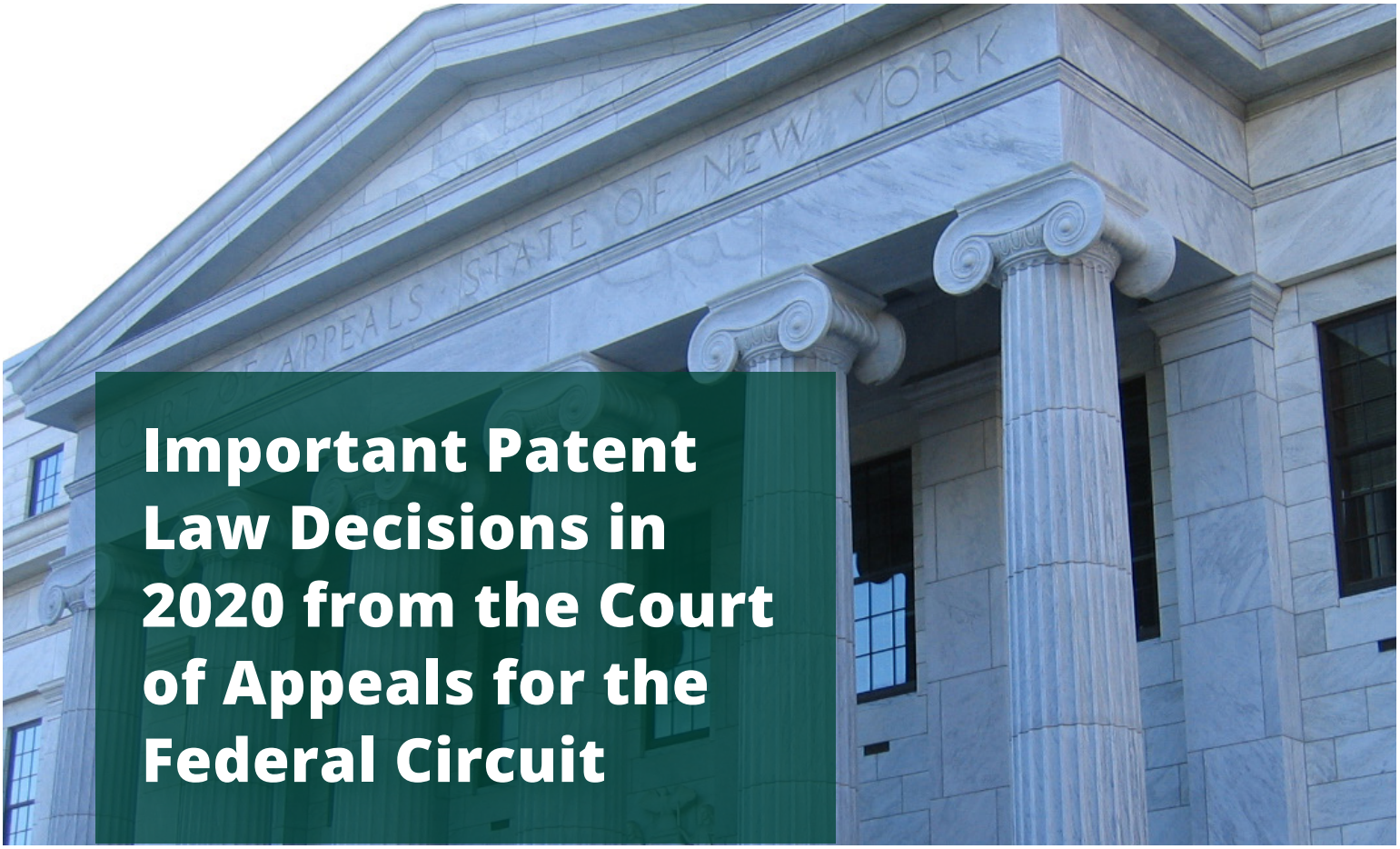

Important Patent Law Decisions in 2020 from the Court of Appeals for the Federal Circuit

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 and 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 2020.

- » LITIGATION
- » PATENT TRIAL AND APPEAL BOARD
- » CLAIM CONSTRUCTION
- » SECTION 101: PATENT-ELIGIBLE SUBJECT MATTER
- » VALIDITY
- » INVENTORSHIP

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Skinny Label Does Not Prevent Claim of Induced Infringement - Rehearing *en banc* granted February 9, 2021

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. 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."

On February 9, 2021, the Federal Circuit granted Teva's petition for rehearing and ordered that the appeal be reheard on the merits by the panel that decided the appeal. The oral argument, set for February 23, 2021, will be limited to the issue of "whether there is substantial evidence to support the jury's verdict of induced infringement during the time period from January 8, 2008 through April 30, 2011," which is prior to the date when Teva amended its label to include the use covered by the patent.

GlaxoSmithKline LLC v. Teva Pharmaceuticals USA, Inc., 976 F.3d 1347 (Fed. Cir. 2020).

Sovereign Immunity Precludes Coercive Joinder Under Rule 19(A)(2)

Gensetix, Inc. exclusively licensed certain patents from the University of Texas, an arm of the State of Texas. The exclusive license required Gensetix, at its own expense, to enforce any patent covered by the license. The University retained a secondary right to sue if Gensetix failed to file suit against a substantial infringer within six months knowledge of infringement.

When Gensetix instituted a patent infringement suit, it named the University as an involuntary plaintiff pursuant to Rule 19(a). The district court granted the University's motion to dismiss based on sovereign immunity and dismissed the lawsuit because the University was an "indispensable" party. The Federal Circuit held that sovereign immunity precluded joining the University as an involuntary plaintiff because the University did not voluntarily submit to federal court jurisdiction and the license agreement did not waive its sovereign immunity. A sovereign may not be joined as an involuntary plaintiff under Rule 19(a).

The Federal Circuit, however, reversed the district court's conclusion that the case could not proceed in the University's absence. Rule 19(b) provides that, where joinder of a required party is not feasible, "the court must determine whether, in equity and good conscience, the action should proceed among the existing parties or should be dismissed." The Federal Circuit concluded that the district court abused its discretion by not allowing the suit to proceed without the University and gave improper weight to the University's status as a sovereign in its analysis.

Potential implication for future cases:

Although the Federal Circuit determined that the exclusive licensee's claim could proceed in the absence of the joinder of the sovereign patentee, if possible a license agreement should specify that the patentee is required to join the litigation.

Gensetix, Inc. v. Board of Regents of the University of Texas System, 966 F.3d 1316 (Fed. Cir. 2020).

Non-Compliance with Marking Requirement Can Be Cured Only By Beginning to Mark or By Providing Actual Notice to the Infringer

A patentee who makes or sells patented articles can satisfy the notice requirement of 35 U.S.C. § 287 either by providing constructive notice (*i.e.,* marking its products) or by providing actual notice to an alleged infringer. The plaintiff's licensee, who had no obligation to mark under the parties' license, sold unmarked products until September 6, 2013, approximately one year before the plaintiff brought a patent infringement suit against another company. The Federal Circuit held that the cessation of selling unmarked product did not excuse non-compliance with the notice requirement of § 287 and thus the plaintiff could not recover damages between the date its licensee stopped selling unmarked products and the date it commenced the patent infringement action. Once unmarked products have been sold, the patentee must begin marking covered products or provide actual notice to begin to recover damages. Further, willful infringement of the asserted claims is insufficient to establish actual notice under § 287.

Potential implication for future cases:

Any patent license should require the licensee to mark its products; the patent owner should monitor compliance with that requirement. If unmarked sales occur, the patent owner should begin marking covered products or send actual notice of its patent to competitors.

Artic Cat, Inc. v. Bombardier Recreational Prods., Inc., 950 F.3d 860 (Fed. Cir 2000).

Patentee Cannot Circumvent the Marking Requirement by Relying On Related Method Claims

Packet Intelligence owned patents teaching a method for monitoring packets exchanged over a computer network. The claims of the patents asserted in the district court describe apparatuses and methods for network monitoring. Before filing, Packet Intelligence licensed the asserted patents and its licensees were alleged to have produced unmarked, patent-practicing products.

An alleged infringer "bears an initial burden of production to articulate the products it believes are unmarked 'patented articles'. . . ." The initial burden is a "low bar" and the infringer need "only to put the patentee on notice that certain licensees sold specific unmarked products that the alleged infringer believes practice the patent." The patentee then has the burden of proving that the identified products do not practice the patent.

As the infringer, NetScout satisfied its preliminary burden of identifying unmarked products that it believed practiced the apparatus patent. Packet Intelligence failed to meet the resulting burden of demonstrating that those products did not practice the patent. The evidence, including testimony of a named inventor, did not satisfy its burden, particularly because the inventor was not qualified as an expert, did not provide an infringement opinion regarding the identified products, and failed to address what claim limitations were purportedly missing from the products. NetScout was entitled to judgment as a matter of law that it was not liable for pre-suit damages based on infringement of the apparatus patent because Packet Intelligence failed to present substantial evidence to the jury applying the limitations in any claim of the asserted patent to the features of the identified products.

Further, even if Packet Intelligence's proof that infringement of the method patents drove sales of the accused products were sufficient to recover damages, it was barred from recovering damages for pre-suit sales because it failed to comply with the marking requirement. "It cannot circumvent § 287 and include those products in its royalty base simply by arguing that [the] infringement of related method claims drove sales."

Packet Intelligence LLC v. NetScout Systems, Inc., 965 F.3d 1299 (Fed. Cir. 2020).

Assignor Estoppel Does Not Bar Reliance in District Court Litigation on PTAB Invalidation Of Claims – Certiorari Granted: Supreme Court to Review

The '183 and '348 patents, which relate to procedures and devices for endometrial ablation, were assigned by inventor Csaba Truckai to Nova-Cept. Cytyc Corporation then acquired Nova-Cept, including rights to patents and continuation patent applications, thereby acquiring the applications that issued as the '183 and '348 patents. Mr. Truckai left Nova-Cept and subsequently founded the accused infringer, Minerva. He and others at Minerva developed the Endometrial Ablation System ("EAS").

Hologic, which had acquired Cytyc, sued Minerva for patent infringement, accusing the EAS of infringing the '183 and '348 patents. Minerva filed petitions for *inter partes* review ("IPR") of both patents. The Patent Trial and Appeal Board ("PTAB") instituted review of the '183 patent but denied review of the '348 patent. Minerva requested that the district court dismiss the claims of infringement of the '183 patent as moot after the PTAB found the claims of the '183 patent unpatentable as obvious. The motion was denied because the PTAB's decision, which was on appeal, was not final. Hologic moved for summary judgment that the doctrine of assignor estoppel prevented Minerva from challenging the validity of the claims in district court. The district court granted the motion as to both patents.

After a jury found infringement and awarded damages on both patents, the Federal Circuit affirmed the PTAB's decision finding the '183 patent claims obvious. The district court then ruled that the Federal Circuit's affirmance of the PTAB's decision did not affect the jury verdict because the invalidation of those claims did not affect the finding of infringement of the '348 patent and the jury's damages award was adequately supported by the finding of infringement of that patent.

The Federal Circuit affirmed the district court, holding that assignor estoppel did not preclude Minerva from relying on the PTAB's decision to argue that the '183 patent claims are void *ab initio*. Although Minerva would have been estopped from challenging the validity of the '183 patent claims in district court, it was able to challenge their validity in an IPR proceeding and thereby circumvent the assignor estoppel doctrine. With respect to the '348 patent, the Federal Circuit affirmed the district court's application of assignor estoppel. Although assignor estoppel is not a "broad equitable device susceptible of automatic application," the equities weighed in favor of its application here where an inventor executed broad assignments to his employer, left his employer, founded a competing company, and was directly involved in the alleged infringement.

Notably, the Federal Circuit also affirmed the district court's decision to award damages to Hologic based on Minerva's infringement of claim 1 of the '348 patent alone, even though the jury verdict did not apportion damages between the '348 and '183 patents.

The Supreme Court has granted certiorari and will perhaps finally clarify the doctrine of assignor estoppel.

Hologic, Inc. v. Minerva Surgical, Inc., 957 F.3d 1256 (Fed.Cir. 2020), cert. granted, 208 L. Ed. 2d 510 (Jan. 8, 2021).

Patent Term Extension Only Includes Active Ingredient or a Salt or Ester of the Active Ingredient Of The Approved Product

Biogen holds a New Drug Application ("NDA") for the active ingredient dimethyl fumarate ("DMF"), which was approved by the Food and Drug Administration in 2013 as Tecfidera®. DMF is the dimethyl ester of fumaric acid. Upon administration to a patient, one of DMF's methyl ester groups is readily metabolized to a carboxylic acid group, becoming monomethyl fumarate ("MMF") before the compound reaches its pharmacological site of action. DMF contains two methyl groups; MMF is virtually identical, except that it has only one methyl ester group. The patent claim covered both the dimethyl ester and monomethyl ester forms.

The patent was originally set to expire on April 1, 2018, but its term was extended by 811 days under the provisions of 35 U.S.C. § 156 to compensate Biogen for the period during which the FDA reviewed its Tecfidera NDA. The Federal Circuit concluded that the monomethyl ester, covered by the claim, was not covered by the extension. Section 156 entitled the NDA holder to extend the term of only one patent for the corresponding approved product. Section 156 requires the applicant's approved NDA to be "the first permitted commercial marketing or use of the product," § 156(a)(5)(A), and defines "product" as "the active ingredient of … a new drug … including any salt or ester of the active ingredient." § 156(f)(2)(A). The scope of a patent term extension under 35 U.S.C. § 156 thus only includes the active ingredient of an approved product, or an ester or salt of that active ingredient.

Biogen International GmbH v. Banner Life Sciences LLC, 956 F.3d 1351 (Fed. Cir. 2020).

Attorneys Participated in Inequitable Conduct by Purposefully Evading Disclosure and Failing to Seek Out Relevant Information

The invention at issue was ready for patenting and the subject of a proposal in July 2003 to Agri-Energy, offering a no-risk trial of the oil recovery system. A provisional patent application was filed in August 2004. One of the inventors provided prosecution counsel with a signed copy of the July 2003 proposal. The inventors submitted an IDS attaching the proposal with a statement asserting that the claimed method "was 'never disclosed, carried out, or performed' more than one year before the filing date and that the July 2003 [p]roposal was irrelevant." After a third party stated that it had reason to believe the pending patent application was invalid due to an offer in violation of the on-sale bar, one of the inventors went to Agri-Energy to offer a royalty-free license for the ethanol oil recovery system. Prosecution counsel subsequently wrote Agri-Energy in attempt to confirm that the system proposed to Agri-Energy was for testing purposes. Prosecution counsel also provided a declaration from one of the inventors claiming that the July 2003 proposal had actually been delivered on August 18, 2003. The declaration omitted key documents, including testing results. During a deposition, the inventor admitted that the July 2003 proposal was possibly sent on August 1, 2003. In subsequent prosecution, the inventors filed a second declaration that did not correct the first declaration and did not explain the significance of the August 1, 2003 email that indicated a pre-critical date offer for sale.

After the patent issued, plaintiff CleanTech, the assignee, asserted the patents in litigation. The district court found as a matter of law that the on-sale bar invalidated the patents-in-suit because the July 2003 proposal was a commercial offer for sale and the method described in the patents-in-suit had been ready for patenting at that time. The district court also found that CleanTech committed inequitable conduct because the inventors had a complete lack of regard for their duty to the USPTO and attempted to hide the offer for sale from their lawyers and then the USPTO. The district court also found that prosecution counsel participated in the inequitable conduct by purposefully evading disclosure and failing to seek out relevant information.

The Federal Circuit affirmed the finding of inequitable conduct, finding that the infringer had proven by clear and convincing evidence that the patentee knew of the prior commercial sale, knew it was material and made a deliberate decision to withhold it. CleanTech knew the July 2003 proposal to Agri-Energy threatened its chances of patenting its ethanol oil recovery method, and it was aware of the on-sale bar and its requirements. The inventors and the prosecution attorneys withheld evidence of successful testing in 2003 and made false representations by implying that the invention was not reduced to practice until 2004. CleanTech and its attorneys "threatened" Agri-Energy to coerce its support regarding the critical date for the patents-in-suit. The inventors and their attorneys made a "patently false" statement in the first declaration submitted to the USPTO by claiming the July 2003 proposal was delivered to Agri-Energy after the critical date. The district court did not abuse its discretion in concluding that the "patently false" statement in the first declaration was material and the failure to correct the false declaration in subsequent prosecution was "strong evidence of intentional deceit."

GS CleanTech Corp. v. Adkins Energy LLC, 951 F.3d 1310 (Fed. Cir. 2020).

Concrete Plans Raising a Substantial Risk of Future Infringement Establish Standing to Appeal PTAB Decision

Raytheon and General Electric Company ("GE") vigorously compete in the market to supply propulsion engines to the commercial aviation industry. The Patent Trial Appeal Board ("PTAB") instituted *inter partes* review of the claims of Raytheon's patent to a two-stage high pressure turbine engine for commercial airplanes and found the claims non-obvious. GE appealed the PTAB's decision to the Federal Circuit. Raytheon moved to dismiss the appeal for lack of standing.

The Federal Circuit found that GE had standing to appeal because it alleged facts sufficient to establish that it was currently engaged in conduct creating a substantial risk of future infringement of the patent. Although Raytheon had never sued or threatened to sue GE for infringing the patent, the appellant need not face a specific threat of infringement litigation by the patentee to establish the requisite injury to appeal from a final written decision. The Federal Circuit found that GE met its requisite burden of production to show that it would likely engage in activity that would prompt an infringement suit. It had made concrete plans for future activity, including spending substantial sums in developing a geared turbo fan architecture and design. Its specific investment and continued development of this specific design for sale, including its informal offer of the engine to Airbus in an ongoing bidding process, established that GE would likely engage in the sale of this geared turbo fan engine design to customers. GE also established that such a sale would raise a substantial risk of an infringement suit.

Potential implication for future cases:

In order to establish standing to appeal a PTAB decision, the appellant needs to provide concrete facts showing that it is currently engaged in conduct creating a substantial risk of future infringement of the patent. While the appellant need not admit infringement, it needs to provide a sufficient evidentiary basis for allegations that it will likely engage in activity that would prompt an infringement suit.

General Electric Company v. Raytheon Technologies Corp., 983 F.3d 1334 (Fed Cir. 2020).

While Filing an ANDA is Not Required to Establish Standing to Appeal a PTAB Determination, the Appellant Must Provide Sufficient Proof that it Will Bear the Risk of an Infringement Suit or Incur Economic Harm

All petitioners in an appeal of an *inter partes* review proceeding settled except for Argentum. The Federal Circuit granted the motion to dismiss Argentum's appeal. To prove standing, Argentum had the burden of showing that it had: "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." The Federal Circuit found that Argentum had not established injury in fact because any ANDA that would be filed would be filed by Argentum's manufacturing and marketing partner, and because Argentum failed to provide evidence showing that it would bear the risk of any infringement suit or anything related to its involvement in the ANDA process. Further, Argentum failed to establish economic harm as an injury in fact. It failed to provide evidence that its investments would be harmed or that it invested in its partner's generic drug or ANDA. Its allegations of lost profits were conclusory and speculative. Finally, potential estoppel regarding patentability and validity issues did not suffice because Argentum did not establish a risk of an infringement suit.

Argentum Pharmaceuticals LLC v. Novartis Pharmaceuticals Corp., 956 F.3d 1374 (Fed. Cir. 2020).

Rights as Joined Party in IPR Apply to the Entirety of the Proceedings, Including Right of Appeal

Apple, Inc. filed a petition for *inter partes* review ("IPR") of claims 1-13 of the patent at issue. The Patent Trial and Appeal Board ("PTAB") granted the petition as to claims 1, 2, and 6-13. Thereafter, Fitbit filed a petition for *inter partes* review of claims 1, 2 and 6-13 and requested joinder with Apple's IPR, which was granted. Fitbit's separate petition was terminated. After the decision in *SAS Institute*, the PTAB reinstituted the Apple/Fitbit IPR to add claims 3-5 of the patent. The PTAB's Final Written Decision held that all of the claims, except claims 3-5, were unpatentable. Apple withdrew from the proceeding and Fitbit appealed the PTAB's decision. The Federal Circuit held that Fitbit had the right to appeal the PTAB's rulings on claims 3-5 even though its petition did not challenge those claims. Fitbit's rights as a joined party applied to the entirety of the proceedings and included the right of appeal, conforming to the statutory purpose of avoiding redundant actions by facilitating consolidation, while preserving statutory rights, including judicial review.

Fitbit, Inc. v. Valencell, Inc., 964 F.3d 1112 (Fed. Cir. 2020).

The PTAB Cannot Cancel Claims as Indefinite

This case presented the issue whether the Patent Trial and Appeal Board ("PTAB") could, after instituting *inter partes* review ("IPR") based on grounds authorized by statute, cancel claims based on indefiniteness under 35 U.S.C. § 112. The PTAB had initially instituted review to determine the obviousness of claim 11, but the institution decision was modified after *SAS Institute* to include all of the claims in the petition. The PTAB determined that the added claims were indefinite, but did not cancel the claims because the Petitioner had not established a reasonable likelihood that the claims were unpatentable under the asserted grounds. The Federal Circuit affirmed that portion of the PTAB's decision, ruling that the IPR statute does not authorize the PTAB to cancel claims as indefinite, even after it has instituted review on statutorily-authorized grounds.

Samsung Electronics America, Inc. v. Prisua Engineering Corp., 948 F.3d 1342 (Fed. Cir. 2020).

Decision that Patent Qualified for Covered Business Method Review Not Reviewable

The Patent Trial and Appeal Board ("PTAB") determined that SIPCO's patent was not excluded from covered business method review under the statutory "technological invention" exception. The Federal Circuit reversed the PTAB's decision and remanded for further consideration. The Supreme Court granted Emerson Electric's petition for certiorari and remanded to the Federal Circuit in light of *Thryv, Inc. v. Click-to-Call Technologies, LP**. On remand, the Federal Circuit held that, in light of *Thryv*, the threshold determination that SIPCO's patent qualifies for covered business method review is not appealable under 35 U.S.C. § 324(a). Thus, the Federal Circuit could not review the PTAB's decision that the patent qualified for covered business method review.

SIPCO, LLC v. Emerson Electric Co., 980 F.3d 865 (Fed. Cir. 2020).

***Note: It was not a Federal Circuit case, but on April 20, 2020, the Supreme Court held that 35 U.S.C. § 314(d) precludes judicial review of the agency's application of § 315(b)'s time prescription. In other words, the patent owner cannot appeal a determination of the Patent Trial and Appeal Board that a petition for inter partes review is not time-barred under § 315(b).**

Thryv, Inc. v. Click-to-Call Technologies, LP, 140 S.Ct. 1367 (2020)

Amendment Only Tangentially Related to the Accused Equivalent Bars Prosecution History Estoppel

The patents-in-suit are directed to systems and methods for using microscopic droplets of fluids to perform biochemical reactions. Microfluidic systems utilize chips that have "microfluidic channels," hair-width pathways through which cells and fluids flow. The patent claim at issue had limitations requiring "a microfluidic system comprising a non-fluorinated channel" and "a carrier fluid comprising a fluorinated oil and a fluorinated surfactant." During prosecution, the inventors amended the claims to overcome a prior art reference disclosing microchannels formed or coated with Teflon or other fluorinated oils. The inventors amended the claims to require non-fluorinated microchannels and a fluorinated surfactant. The surfactant and microchannels would not react with each other. The inventors distinguished the amended claims over the prior art disclosure which taught coating the microchannels with a fluorinated oil and using fluorinated surfactants in the carrier fluid, which could react with each other.

The accused products contained micro-channels with a coating resin containing negligible amounts of fluorine, which did not literally satisfy the "non-fluorinated micro-channels" limitation. The Federal Circuit affirmed that the tangentiality exception to prosecution history estoppel applied because the prosecution history established that the objectively apparent reason for adding the "non-fluorinated micro-channels" limitation was no more than tangentially-related to the equivalent at issue. The accused product, which had negligible quantities of fluorine that had no function in the product and did not react with the microchannels, could meet the non-fluorinated limitation under the doctrine of equivalents. The plaintiff was therefore not barred from asserting that microchannels containing negligible amounts of fluorine are equivalent to "non-fluorinated microchannels."

Potential implication for future cases:

The purpose and effect of a claim amendment are important. Even if an amendment was made to overcome prior art, prosecution history estoppel may not apply if the reason for the amendment only tangentially relates to the product alleged to be equivalent.

Bio-Rad Laboratories, Inc. v. 10X Genomics Inc., 967 F.3d 1353 (Fed. Cir. 2020).

Claim Reciting "At Least One" Binder or Disintegrant "Selected From the Group Consisting of" Various Excipients Does Not Foreclose the Presence of Additional Binders or Disintegrants

Claim 1 disclosed in relevant part: "A pharmaceutical composition comprising: (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg; (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof; (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof . . . ."

During prosecution, the applicant narrowed the claim to add the limitation on the amount of cinacalcet to "about 20 mg to 100 mg" and an examiner's amendment revised the binder and disintegrant limitations to a Markush group format.

The Federal Circuit held that neither Markush group foreclosed the use of unlisted binders or disintegrants. Although the phrase "consisting of" creates a "very strong" presumption that the claim element is closed and excludes other ingredients, the claim also recited that "at least one" binder or disintegrant was to be "selected from the group consisting of" various excipients. The plain language of the claim requires "at least one" of the Markush members to meet the specified weight-percentage requirements, but does not indicate that the *only* binders and disintegrants in the claimed formulation are those listed in the Markush groups. Further, the beginning of the claim used a "comprising" transition phrase, indicating that the claim does not foreclose additional binders or disintegrants.

Amgen Inc. v. Amneal Pharmaceuticals LLC, 945 F.3d 1368 (Fed. Cir. 2020).

Federal Circuit Defines "Antibody" and "Antibody Fragments"

In patent infringement litigation involving Genentech's Hemlibra® (emicizumb-kxwh) product used to treat the blood clotting disorder hemophilia, the Federal Circuit construed the term "antibody" as an "immunoglobulin molecule having a specific amino acid sequence comprising two heavy chains (H chains) and two light chains (L chains)" and the term "antibody fragment" as a "portion of an immunoglobulin molecule having a specific amino acid sequence comprising two heavy chains (H chains) and two light chains (L chains)."

The district court narrowly defined antibody as "an immunoglobulin molecule, having a specific amino acid sequence that only binds to the antigen that induced its synthesis or very similar antigens, consisting of large, identical heavy chains (H chains) and two light, also identical chains (L chains)."

The Federal Circuit rejected this narrow construction, finding that: (1) the plain language of the claim did not limit the term to monospecific antibodies or to antibodies that only bind the antigen that induced their synthesis; (2) the district court's construction excluded claimed embodiments, such as bispecific antibodies and humanized antibodies; (3) statements in the specification did not limit the claims; and (4) there was no "clear and unmistakable" disavowal of claim scope by replacing the term "antibody derivatives" with "antibody fragment" to resolve an enablement rejection. The term "antibody derivative" was not commonly used in the art and thus it was unclear whether the amendment to "antibody fragment" surrendered claim scope.

Potential implication for future cases:

While the definition of claim terms will necessarily depend on how they are used in the specification and claims, this decision gives guidance on what the Federal Circuit believes is the plain meaning of these important biotechnology terms.

Baxalta Inc. v. Genentech, Inc., 972 F.3d 1341 (Fed. Cir. 2020).

Broadest Reasonable Construction of "Human Antibody" Includes "Humanized" Antibodies

The patent at issue was directed to antibodies that bind to the human interleukin-4 ("IL-4") receptor, the resulting inhibition of which is significant for treating various inflammatory disorders, such as arthritis, dermatitis and asthma. Claim 1 disclosed "[a]n isolated human antibody that competes with a reference antibody for binding to human IL-4 interleukin-4 (IL-4) receptor . . . ." As the court described, antibodies are roughly Y-shaped, made of four chains—two "heavy" and two "light." Each chain has a "variable region" and a "constant region," with each variable region containing three "complementarity-determining regions" (CDRs) situated at the tips of the Y. The remainder of the variable regions are the "framework regions." In "chimeric" antibodies, the constant regions tend to be human in origin, and the variable regions, including the CDRs, tend to be nonhuman. In "humanized" antibodies, only the CDRs are nonhuman. Fully human antibodies can be made in which even the CDRs are human in origin. The specification disclosed "partially human" (chimeric and humanized) and "completely human" embodiments.

The Federal Circuit affirmed the Patent Trial and Appeal Board's construction of "human antibody" as including "fully human" and "partially human antibodies," rejecting the patent owner construction of the term as limited to "fully human" antibodies. Neither the claims nor the specification specifically defined "human antibody," but the use of the term in the specification made clear that "human antibodies" is a broad category encompassing both partially and completely human antibodies. Further, the use of two different terms—"human" and "fully human"—in the prosecution history demonstrated that "human" had a different meaning than "fully human." Lastly, the court considered extrinsic evidence—how a person of ordinary skill in the art would interpret the term. The PTAB found the extrinsic evidence consistent with its interpretation of "human antibody." Even if the extrinsic evidence had supported a different definition, however, the Federal Circuit stated that the definition found in the intrinsic evidence would nevertheless control.

Potential implication for future cases:

While this case suggests that the courts will find that the plain meaning of the term "human antibody" includes "partially human" (humanized and chimeric) antibodies, the best practice is to define the terms explicitly in the specification and/or claims with an eye towards the state of the prior art.

Immunex Corp. v. Sanofi-Aventis, 977 F.3d 1212 (Fed. Cir. 2020).

An Unwarranted Expansion of Section 101?

The *American Axle* decision was originally issued in October 2019 and was modified and reissued in 2020 after a petition for rehearing was filed by American Axle. The Federal Circuit found some of the asserted claims ineligible under 35 U.S.C. § 101. The patent generally related to a method for manufacturing driveline propeller shafts ("propshafts") with liners designed to attenuate vibrations transmitted through a shaft assembly. Because these propshafts are typically made of a "relatively thin-walled steel or aluminum tubing," they will vibrate in response to various driveline excitation sources. The propeller shafts can vibrate in three modes which correspond to different frequencies and cause undesirable noise. Methods using prior art weights, dampers, and hollow liners designed to attenuate each of the three vibration modes individually already existed and were well-known in the art. The patent identified "a need in the art for an improved method for damping various types of vibrations in a hollow shaft" and disclosed the tuning of a liner in order to produce frequencies that dampen two different modes simultaneously.

At step 1 of the *Mayo/Alice* analysis, the district court concluded that the asserted claims, "considered as a whole," were "directed to the mere application of Hooke's law." Hooke's law "is an equation that describes the relationship between an object's mass, its stiffness, and the frequency at which the object vibrates." The claims' direction to tune a liner to attenuate different vibration modes amounted to merely "instruct[ing] one to apply Hooke's law to achieve the desired result of attenuating certain vibration modes and frequencies" without providing a specific means of crafting the liner and the propshaft to achieve that result.

Following the Supreme Court's two-step *Mayo/Alice* test, the Federal Circuit determined that independent claim 22, and the claims dependent on it, were subject-matter ineligible because the claims simply applied Hooke's law to tune a propshafts liner to dampen vibrations. The claim did not specify the method of reaching the attenuation goal, but merely claimed a result. They did not recite the finite element analysis models and experimental analysis which the patentee noted may be required to tune a liner and did not contain physical structure or steps for achieving the result stated in the claim. The Federal Circuit stated that a claim directed to "a result that involves application of a natural law without limiting the claim to particular method of achieving the result," is patent-ineligible because it is directed to a natural law. Further, nothing in claim 22 qualified as an "inventive step" sufficient to render the claim patent-eligible. The argument that the claims were directed to tuning propshafts liners to dampen two different vibration modes simultaneously did not constitute an inventive step, but simply pointed to the achievement of a certain result.

The dissent argued that the decision was an unwarranted expansion of § 101 and that, under the majority's decision, claims are now ineligible if their performance would require an application of a natural law. The dissent characterizes the claims at issue as providing a "specific, concrete solution (inserting a liner inside a propshaft) to a problem (vibrations in propshafts)," claims which have been historically patentable. Thus, the majority's decision expands the idea that a claim is "directed to" an abstract idea or natural law to cover claims relating to industrial processes that have been historically eligible for patent protection.

Potential implication for future cases:

In drafting patent applications, include a range of claims with varying levels of detail regarding the specific steps and methods for achieving the result stated in the claim.

American Axle & Manufacturing, Inc. v. Neapco Holdings LLC, 967 F.3d 1285 (Fed. Cir. 2020).

Improvement to a Method of Sorting Particles Using Flow Cytometry Technology is Patent-Eligible Subject Matter

An invention is not rendered patent-ineligible simply because it involves an abstract concept. "Applications" of abstract concepts "to a new and useful end" are eligible for patent protection. The claims are considered in their entirety to determine whether they are, as a whole, directed towards ineligible subject matter.

XY's patent claims were directed to an improved method of flow cytometry resulting in enhanced discrimination between populations of particles, such as separating X from Y bearing sperm. The improved method reconfigured data to enhance separation between data points by geometric transformation. For example, embodiments of the claimed invention "may involve rotating data to increase a separation of data from male determining cells to female determining cells." The claimed process, however, included the physical steps of establishing a fluid stream in the flow cytometry apparatus with detectors and entraining particles from the sample in the fluid stream in the apparatus.

The Federal Circuit determined that XY's patent claims, as a whole, were not directed to a mathematical equation, but were directed towards an improved method of operating a flow cytometry apparatus to classify and sort particles. The Federal Circuit analogized XY's invention to the claims held patent-eligible in *Diamond v. Diehr*, where the Supreme Court held that claims to a method of operating a rubber-molding press using a computer and the well-known Arrhenius equation were patent eligible. Although the claims in *XY, LLC* used mathematical formulae "to improve classification and separation of individual particles," that abstract idea improved the prior art separation method "only when combined with the specific detectors and other flow cytometry limitations in the claims."

XY, LLC v. Trans Ova Genetics, Inc., 968 F.3d 1323 (Fed. Cir. 2020).

Methods of Separating DNA are Patent-Eligible Subject Matter

The patents at issue discussed the natural phenomenon that cell-free fetal DNA exists in maternal plasma and serum. Although it was known that cell-free fetal DNA existed in the mother's bloodstream, there was no known way to distinguish and separate the tiny amount of fetal DNA from the vast amount of maternal DNA. The inventors discovered that the majority of the circulatory extracellular fetal DNA has a relatively small size of approximately 500 base pairs or less, whereas the majority of circulatory extracellular maternal DNA in maternal plasma has a size greater than approximately 500 base pairs. Additionally, 70% of all DNA fragments smaller than 300 base pairs were fetal. The claimed methods, which solved the problem of separating fetal DNA from maternal DNA, included size discrimination of the DNA based on size parameters that the inventors selected to balance the need to remove enough longer maternal DNA fragments to enrich the sample but also leave behind enough shorter fetal DNA fragments to allow for testing.

The Federal Circuit, characterizing the claims as a method of preparation rather than a method of treatment or diagnosis, characterized the natural phenomenon at issue as the fact that cell-free fetal DNA is shorter than cell-free maternal DNA in maternal plasma and serum. The claims, however, were not directed to that natural phenomenon but were directed to a patent-eligible method using that phenomenon to prepare a fraction of cell-free DNA that is enriched in fetal DNA. The method included specific, physical process steps to increase the amount of fetal DNA relative to maternal DNA in the sample using human-chosen size parameters to optimize the process. The process steps changed the composition of the mixture. Although the techniques for size discrimination and selectively removing DNA fragments in the claims were well-known and conventional, they were used in unconventional ways.

Illumina, Inc. v. Ariosa Diagnostics, Inc., 967 F.3d 1319 (Fed. Cir. 2020).

PTAB May Consider § 101 Challenge to Substitute Claims in an IPR

During *inter partes* review ("IPR"), the patent owner may file a motion to amend the patent by cancelling any challenged patent claim and by proposing a reasonable number of substitute claims for each challenged claim. 35 U.S.C. § 316(d)(1). When an IPR is completed, the Patent Trial and Appeal Board ("PTAB") is required to "issue a final written decision with respect to the patentability of any patent claim challenged by the petitioner and any new claim added under 316(d)." *Id.* § 318(a).

Patent owner Unlioc filed a motion to amend to enter substitute claims for certain independent claims if the PTAB found the latter unpatentable. The PTAB's Final Written Decision explained why the challenged original claims were unpatentable, and denied Uniloc's motion to amend the claims, concluding that the Petitioner had shown by a preponderance of the evidence that the substitute claims were directed to non-statutory subject matter under 35 U.S.C. § 101. The PTAB concluded that, under the statutory IPR provisions, it is permitted to review and deny proposed substitute claims during IPR proceedings for patent ineligibility pursuant to § 101. The Federal Circuit affirmed, holding that the PTAB is not limited by § 311(b) in its review of proposed substitute claims in an IPR, and that it may consider § 101 eligibility. The determination is supported by the text, structure, and history of the statute, which "indicate[s] Congress's unambiguous intent to permit the PTAB to review proposed substitute claims more broadly than those bases provided in § 311(b)." The legislative history "also confirms that the PTAB is permitted to review proposed substitute claims for patentability outside of anticipation and obviousness." "Proposed substitute claims in an IPR proceeding have not undergone a patentability review by the [US]PTO and thus the 'substantial new questions of patentability' that 'have not previously been considered by' the USPTO include all patentability questions, including § 101 patent eligibility."

Uniloc 2017 LLC v. Hulu LLC, 966 F.3d 1295 (Fed. Cir. 2020).

An Abstract Idea That Lacks Any Inventive Concept or Meaningful Application of the Idea is Patent-Ineligible

The patent-in-suit, entitled "System and Method for Creating Intelligent Simulation Objects using Graphical Process Descriptions," concerned making object-oriented simulations easier and more accessible by letting users build simulations with graphics instead of programming. The district court held the asserted claims patent-ineligible under the 35 U.S.C. § 101 and dismissed the complaint for failure to state a claim upon which relief could be granted. The independent claim recited a computer-based system for developing simulation models on a physical computing device. The claim included a limitation disclosing "an executable process to add a new behavior directly to an object instance of the one or more object instances without changing the object definition and the added new behavior is executed only for that one instance of the object." That limitation involved changing a particular object's behavior without changing the object's overall definition in the simulation.

The Federal Circuit analyzed patent-eligibility under *Alice*'s two-step framework. First, the court determined that the claim was directed to an abstract idea. The key advance of the patent, using graphics instead of programming to create object-oriented simulations, was the focus of the independent claim. Using graphical processes to simplify simulation-building had been done since the 1980s and 1990s. Simply applying the already-widespread practice of using graphics instead of programming to the environment of object-oriented simulations constitutes an abstract idea. Further, neither improving a user's experience while using a computer application nor the improved speed or efficiency inherent in applying an abstract idea on a computer sufficed to render the claims patent-eligible as an improvement to computer functionality.

Because it determined that the claim represented an abstract idea, the court addressed *Alice* step two, looking for an "inventive concept" in the claims that rendered the claims "significantly more" than a patent on the abstract idea. The executable-process limitation did not provide the necessary inventive concept because it was conventional and known in object-oriented programming. The claim was directed to using graphics instead of programming to create object-oriented simulations, which presented an arguably new idea, but the claim lacked any inventive concept or meaningful application of the idea. Thus, the claim was patent-ineligible.

Potential implication for future cases:

When drafting claims for an invention that could be seen as an abstract idea, do not rely on limitations that are arguably conventional to supply the inventive concept.

Simio, LLC v. Flexsim Software Products, 983 F.3d 1353 (Fed. Cir. 2020).

The Court Cannot Read Elements from the Specification into the Claims to Find an "Inventive Concept"

The patent at issue generally claimed a method and system for limiting and controlling access to resources and describes "a system and method for controlling access to a platform for a mobile terminal for a wireless telecommunications system." The field of the invention was described as "securing mobile phones against improper access by apps." The Federal Circuit found that the claims were patent-ineligible subject matter under the two-step *Mayo/Alice* test. It determined that the claims were "directed to the abstract idea of controlling access to, or limiting permission to, resources." All of the components recited in the claims "collapse into simply 'an access controller for controlling access' by 'receiving a request' and then 'determining if the request should be granted.'" The process of controlling access is abstract because it can be performed in the human mind or by a human using a pen and paper.

The Federal Circuit further found that that the claims lacked an "inventive concept." The claims were not limited to a specific technological environment, such as mobile phones or a "resource-constrained" environment. Neither claim recited any "any particular architecture at all," including the "three layered architecture" or "software stacks or units" alleged to be novel. The court refused to import these details from the specification into the claims because "the § 101 analysis must always yield to the claim language."

Potential implication for future cases:

When drafting claims for an invention that could be seen as an abstract idea, ensure that the claims are, if appropriate, limited to a particular technological environment and recite the novel structure or aspect of the invention. Resist the temptation to claim too generally.

Ericsson Inc. v. TCL Communication Technology Holdings Ltd., 955 F.3d 1317 (Fed. Cir. 2020).

An Old Method of Administration of an Old Product Made by a New Process is Not Novel

The patent at issue was directed to a method of treating a viral condition, a viral disease, cancers or tumors by administration of a pharmaceutically effective amount of a recombinant polypeptide related to human interferon-β ("IFN-β"). IFN-β is naturally produced by the human immune system in small amounts. The amino acid sequences of the claimed recombinant IFN-β and the prior art native IFN-β are identical.

After a jury determined that the patent claims were anticipated by prior art references teaching the use of native IFN-β to treat viral diseases, the district court granted Biogen judgment as matter of law on anticipation. The district court held that the claims were not anticipated because the identified prior art did not disclose treatment with a "recombinant interferon-β polypeptide produced in a 'non-human host' that had been 'transformed by a recombinant DNA molecule.'" The Federal Circuit reinstated the jury's determination that the claimed method was anticipated, holding that "an old product is not patentable even if it is made by a new process." A claim to recombinant DNA is not novel over the identical native DNA. Production "by recombinant technology" is not a structural limitation and does not distinguish over the prior art. That the claim is directed to a method of treatment is immaterial—the process by which the therapeutic product is made cannot confer novelty.

Potential implication for future cases:

In seeking to patent methods using a product in the prior art, the use must be new or the new process of manufacture must impart differences in structure or properties to the old product.

Biogen MA, Inc. v. EMD Serono, Inc., 976 F.3d 1326 (Fed. Cir. 2020).

Knowledge or Use That is Not Publicly Accessible Does Not Qualify As Prior Art Under § 102(A)

In this case, the district court concluded that a process performed by a third party, Celanese Corporation's "Sanwet® Process," evidenced prior art knowledge and use of the patented invention within the meaning of 35 U.S.C. § 102(a), and further constituted both a public-use bar and an on-sale bar to the patented invention under 35 U.S.C. § 102(b). In 1985, Sanyo and Celanese entered into a license agreement that provided Celanese with an exclusive license to make, use, and sell certain of Sanyo's superabsorbent polymers in the Americas. In addition, Sanyo furnished Celanese with extensive technical information about the Sanwet Process, and dispatched technical personnel to assist Celanese with plant start-up. Celanese was obligated to protect the secrecy of Sanyo's confidential information for 10 years and was only allowed to disclose such information to its employees and subcontractors to the extent necessary to build and operate the plant. These employees and subcontractors were required to sign confidentiality agreements.

The Federal Circuit reversed the district court's determination, holding that knowledge or use that is not publicly accessible, such as that protected by confidentiality obligations, does not qualify as prior art under § 102(a). Because confidentiality agreements applied to both the technical information Sanyo provided Celanese concerning the Sanwet® Process and Celanese's performance of that process in its plant, neither was available as evidence of prior art knowledge or use. Where the prior user has successfully concealed the work from the public, such prior knowledge or use is unavailable as prior art. Both the existence of relevant confidentiality agreements and the degree to which they were honored are evidence of whether prior knowledge and use were accessible to the public, but are not necessarily conclusive. Because there were disputes as to the extent to which Sanyo's technical information and the performance of the Sanwet Process at the Celanese plant were actually subject to confidentiality restrictions, there were genuine issues of material fact as to whether the Sanwet Process was "known or used" within the meaning of § 102(a).

The public-use bar of § 102(b) does not apply to a third party's secret commercial use. The public-use bar applies to uses of the invention "not purposely hidden." A use that is successfully concealed or hidden and therefore inaccessible to the public is not a public use. Further, a third party's commercial exploitation of a secret process does not create a public-use bar to another inventor.

BASF Corp. v. SNF Holding Co., 955 F.3d 958 (Fed. Cir. 2020).

Admission of Lay Witness Testimony on Obviousness An Abuse Of Discretion

The patents at issue were directed to methods and devices for controlling an oxygen-generating system, which is used to sustain and manage airflow for torch glass artists who use surface mix glass torches. At trial, defendant Oxygen Frog argued that the claims were obvious in view of a combination of two prior art references: a post on a glass blowing internet forum depicting an oxygen system used for glass blowing, and a video that was posted online by Tyler Piebes, a glass blowing artist. Mr. Piebes was not qualified as an expert witness, but provided deposition testimony as a fact witness, most of which was played at trial before the jury. He opined that modifying the prior art oxygen system to support two circuits was obvious. Admission of Mr. Piebes' testimony opining that it would be "obvious" to modify a prior art system in a particular way that would match the claimed invention was improper.

Obviousness is analyzed from the perspective of a person of skill in the art. It is an abuse of discretion to permit a witness to testify as an expert on the issues of non-infringement or invalidity unless that witness is qualified as an expert in the relevant art. The prohibition of unqualified witness testimony extends to the ultimate conclusions of infringement and validity as well as to the underlying technical questions. Piebes' testimony, which was directed to the conclusion of obviousness and its underlying technical questions, was the province of qualified experts, not lay witnesses. The error in admitting this testimony was not harmless and the Federal Circuit therefore granted a new trial.

HVLPO2 v. Oxygen Frog, LLC, 949 F.3d 685 (Fed. Cir. 2020).

Specification References to Publicly-Available Databases or Deposits Can Satisfy the Written Description Requirement for a Biological Drug

The accused product was a biosimilar version of Immunex's Enbrel®, a biologic drug for reducing the signs and symptoms of moderately to severely active rheumatoid arthritis. The patents-in-suit disclose the fusion protein etanercept, the active ingredient in Enbrel®, and methods of making etanercept. "Etanercept is made by combining a portion of a 75 kilodalton ("kDa") human tumor necrosis factor receptor protein with a portion of immunoglobulin G1 ("IgG1")." The claims at issue covered a p75-IgG1 fusion protein. Sandoz claimed that the priority applications did not include written description support for (1) the full-length p75 DNA sequence; and (2) the claimed p75-IgG1 fusion protein.

The Federal Circuit held that the claimed fusion protein had adequate written description support where the specification referenced publicly-available databases or deposits containing the full sequences, and the evidence demonstrated that the full sequences were known to a person of ordinary skill in the art at the time of the invention.

The Federal Circuit also found that the p75 protein sequence used in entanercept had adequate written description. Although the specification disclosed a truncated p75 DNA sequence, the sequence was known in the prior art. The sequence identification numbers were set forth in the specification, and a person of ordinary skill in the art would know to find the complete sequence in Gen-Bank, a well-known genetic sequence database. The specification also disclosed a prior art publication that referenced the sequence's availability in Gen-Bank, demonstrating that the p75 sequence was known to a person of ordinary skill in the art at the time of the invention. The specification also explained that the inventors had isolated the 75 kDa full-length p75 TNFR.

With respect to the fusion-protein claim, Sandoz again argued that the p75 sequence was truncated and that, to arrive at the claimed invention, a person of ordinary skill in the art would have had to select the "never-referenced" full sequence identified in the prior art. The district court found that the specification identified four preferred fusion proteins, including the claimed p75-IgG1 fusion protein, and provided the steps required to make those proteins. The specification referenced deposited vectors, which provided adequate written description "of the precise IgG1 sequence to be used in the claimed fusion proteins."

Immunex Corp. v. Sandoz, Inc., 964 F.3d 1049 (Fed. Cir. 2020).

Functional Terms Do Not Necessarily Render System or Device Claims Indefinite

The asserted patents were directed to high-frequency spinal cord stimulation therapy for inhibiting an individual's pain. The specification noted that conventional spinal cord stimulation systems deliver electrical pulses to the spinal cord to generate sensations, such as tingling or paresthesia, that mask or otherwise alter the patient's pain. The claimed invention purportedly improved conventional spinal cord stimulation therapy by using waveforms with high frequency elements or components, which are intended to reduce or eliminate side effects. Several of the asserted claims were directed to embodiments of the claimed invention in which "therapy-induced paresthesia is not a prerequisite to achieving pain reduction." Specifically, the claims at issue recited systems or devices comprising a means for generating therapy signals that are "paresthesia-free." The district court held the asserted "paresthesia-free" system and device claims indefinite because infringement of those claims depended upon the effect of the system on a patient, and not a parameter of the system or device itself.

The Federal Circuit reversed, holding that the term "paresthesia-free" is definite. The term is not inherently indefinite because it is a functional term, "defined by what it does rather than what it is." Functional language can "promote[] definiteness because it helps bound the scope of the claims by specifying the operations that the [claimed invention] must undertake." Whether a functional claim term is definite is highly dependent on context, such as the specification and the knowledge of a person of ordinary skill in the relevant art. Such claims are not indefinite where the patent "provides a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine the scope of the claims." The patents provided reasonable certainty about the claimed inventions' scope by giving detailed guidance and examples of systems and devices that generate and deliver paresthesia-free signals with high frequency, low amplitude, and other parameters.

Nevro Corp. v. Boston Scientific Corp., 955 F.3d 35 (Fed. Cir. 2020).

It is Obvious to Substitute One Well-Known Design Choice in The Prior Art for Another

The patent at issue was generally directed towards exchanging location information between mobile devices and describes a "Buddy Watch application" that allows a mobile device user to add other mobile device users to her "Buddy List." The user can share her location with her Buddies through the application and then press a "Mapit" button to see the locations of all of her buddies displayed on a map. The purported novelty of the invention was in this "two way position information sharing," the creation of such location sharing "groups," and "temporary location sharing" that "automatically expires."

At issue was the claim limitation "software responsive to a request from the first individual to obtain a map, to obtain a last known position for multiple users identified by the buddy list, and to plot the last known location of at least two of the multiple users on the map, and to transmit the map with plotted locations to the first individual." The limitation requires a server to first plot certain known locations on a map, and then, only after plotting, to "transmit the map with plotted locations" to a user's mobile device. The first prior art reference disclosed such "server-side" plotting. The second prior art reference did not expressly disclose server-side plotting, but instead disclosed "terminal-side" plotting, wherein the user's mobile device first receives a map and only then, on the mobile device, are the locations of other users plotted on the map.

The Patent Trial and Appeal Board ("PTAB") concluded that the combination of the two references did not render obvious the server-side plotting limitation of claim 1 because such a combination "represents impermissible hindsight." Further, because the first reference sufficiently taught the implementation of plotting the locations of group members on a map on its mobile terminal, substituting the "server-side" plotting of the second reference would be "a wholesale modification" of the first reference.

The Federal Circuit reversed and remanded for further consideration. The two prior art references and the patent all attempt to solve the same problem — "helping one user view and track the location of other users." A person of ordinary skill in the art would have recognized server-side plotting and terminal-side plotting as the two available methods for displaying a map with plotted locations. Server-side plotting and terminal-side plotting thus represent "a finite number of identified, predictable solutions" to a design need that existed at the relevant time. The PTAB erred when it determined that a person of ordinary skill in the art would not have been motivated to combine the teachings of the first reference with the reference disclosing server-side plotting to render obvious the limitation "software . . . to transmit the map with plotted locations to the first individual." A person of ordinary skill would have had two predictable choices for when to perform plotting, providing such a person with a simple design choice as to whether to plot server-side or terminal-side.

Uber Technologies, Inc. v. X One, Inc., 957 F.3d 1334 (Fed. Cir. 2020).

Inventor Need Not Know that an Invention Will Work for its Intended Purpose in Order for Conception to be Complete

The Federal Circuit affirmed the district court's decision after a bench trial to add Dr. Gordon Freeman and Dr. Clive Wood as inventors to the patents at issue, which claimed a method of treating cancer by administering antibodies targeting specific receptor-ligand interactions on T cells. The patent claims recite uses of antibodies that target either the PD-1 receptor or its PD-L1 ligand, blocking the receptor-ligand interaction, and thereby in effect stimulating immune response against tumor cells that would otherwise have been hidden by their expression of the PD-L1/L2 ligands.

It was undisputed that Drs. Freeman and Wood collaborated with the named inventor Dr. Tasuku Honjo. Ono, Dr. Honjo's assignee, argued that conception was in October 2000 when Dr. Honjo discussed the possible use of PD-1 for treating cancer in light of earlier knockout mice experiments performed by a graduate student on PD-1 at Dr. Honjo's request. Dr. Honjo had discovered the PD-1 receptor in the early 1990s, isolated its DNA sequence and began working with the protein in mouse models with a colleague. The two researchers discovered that mice without PD-1 showed symptoms typical of auto-immune disease, suggesting that the receptor was involved in immune-system inhibition. Dr. Honjo began working with a graduate student in mid-1998 to conduct studies on PD-1 with knockout mice and human tumor cell lines. This study showed binding of the PD-1 protein in a variety of cells, including in tumor cells, but did not identify the molecule that was binding to the receptor.

Dr. Wood disclosed to the collaborators in October 1999 that PD-1 and CTLA-4 had similar structures and that PD-L1 antibodies inhibited the PD-1/PD-L1 interaction. Dr. Freeman disclosed that the amino acid sequence he was investigating was from a human ovarian tumor and that PD-L1 shares 20% of its amino acid sequence with B7-1 and B7-2 but does not bind to either CD28 or CTLA-4. At Dr. Freeman's direction, other researchers tested both normal and tumor tissues and found high PD-L1 expression in tumors. Drs. Honjo, Freeman, and Wood worked on a journal article documenting their discoveries concerning PD-L1, and, in a final round of edits, Dr. Freeman added a sentence to the paper stating that PD-L1 was also expressed in cancers and that some tumors may use PD-L1 to inhibit an antitumor immune response. In March 2000, Drs. Wood and Honjo presented results of their PD-1/PD-L1 collaborative research at a conference. By May 2000, Drs. Wood, Freeman, and Honjo were discussing their development of anti-PD-L1 antibodies and the possible use of those antibodies in treating cancer. In 2018, Dr. Honjo won the Nobel Prize in Physiology or Medicine, and in his acceptance speech, he credited Dr. Freeman as a major collaborator in his work.

The district court held that Drs. Freeman and Wood made significant contributions to the conception of the invention, crediting them with significant discoveries, such as the discovery of the PD-L1 ligand and that anti-PD-1 and anti-PD-L1 antibodies can block the pathway's inhibitory signal. The defendant, Dr. Honjo's assignee, argued that the finding was error because Dr. Freeman and Dr. Wood's contributions were made public and thus were prior art prior to conception of the invention. Further, experiments performed independently of Drs. Freeman and Wood on the use of PD-1 for cancer led directly to the conception of the claimed inventions.

The Federal Circuit rejected the idea that once a contribution is made public, it "no longer qualifies as a significant contribution to conception." It noted that, to be a joint inventor, one must: (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art. Individuals may be joint inventors even though their type and amounts of contribution differ and they need not physically work on the invention together or at the same time, and even though each does not make the same type or amount of contribution. Thus, even though Drs. Freeman and Wood did not participate in certain experiments that led to the conception of the claimed invention, they were still inventors due to their overall contributions throughout their collaboration with Dr. Honjo.

Further, the alleged speculative nature of the collaboration prior to the 2000 knockout mice studies did not negate joint inventorship, which relies on conception. An inventor need not know that an invention will work for its intended purpose in order for conception to be complete: verification that an invention actually works is part of its reduction to practice and *in vivo* verification is not required for a conception to be definite and permanent. Further, joint inventorship does not depend on whether a claimed invention is novel or nonobvious over a particular researcher's contribution. Collaboration and concerted effort are what result in joint inventorship. Inventorship of a complex invention may depend on partial contributions to conception over time. Publication of a portion of a complex invention does not necessarily defeat joint inventorship of that invention.

Potential implication for future cases:

When the invention involves collaborative research, identify and evaluate the contribution of potential inventors and resolve inventorship issues early in the process.

Dana-Faber Cancer Institute, Inc. v. Ono Pharmaceutical Co., Ltd., 964 F.3d 1365 (Fed. Cir. 2020).

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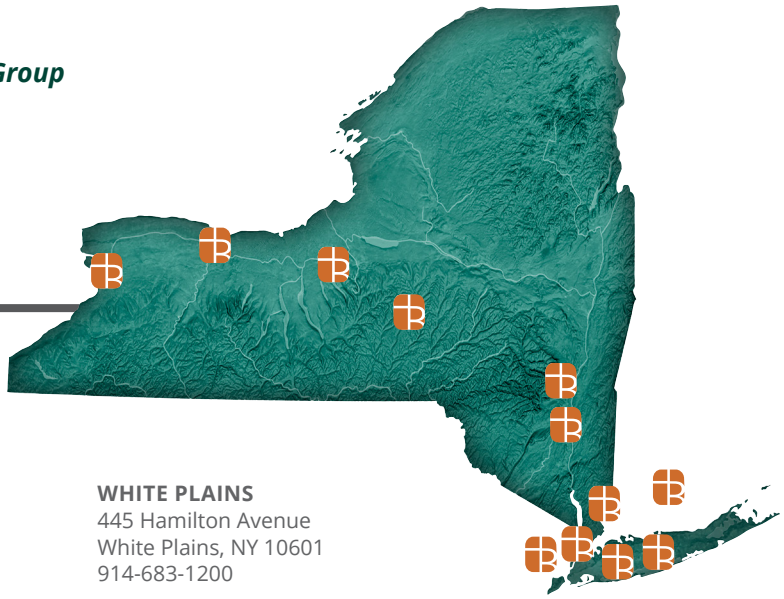

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