FINNEGAN

US Patent Law: Year in Review

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by

Tom Irving, Paul Browning Ph.D., and Stacy Lewis[2,3]

2. Tom Irving is a partner at Finnegan, Paul Browning, Ph.D., is a partner at Finnegan, and Stacy Lewis is a law clerk at Finnegan.

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I. Supreme Court

A. *Thryv v. Click-to-Call*, 140 S. Ct. 1367 (April 20, 2020)[4]

On April 20, 2020, a divided Supreme Court held that a PTAB determination of whether an IPR petition is timely under 35 U.S.C. § 315(b) cannot be judicially reviewed.[5]

Thryv petitioned the Patent Trial and Board to institute inter partes review of Click-To-Call's patent. Click-To-Call argued that the petition was untimely under § 315(b) based on a lawsuit filed against Thryv's predecessor in 2001. The Board determined that Thryv's petition was timely, instituted review, and found 13 claims of Click-To-Call's patent unpatentable. Click-to-Call appealed the timeliness determination. On appeal, the Federal Circuit reversed the Board's § 315(b) determination. Thryv then petitioned for certiorari at the Supreme Court, which was granted.

The Court, in a 7-justice majority opinion by Justice Ginsburg, held that § 315(b) time bar determinations are not appealable, vacated, and remanded with instructions for the Federal Circuit to dismiss for lack of jurisdiction.

The majority opinion focuses on the language of 35 U.S.C. §§ 314(d) and 315(b), as well as the Court's earlier decision in *Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. ___, 136 S. Ct. 2131 (2016). Section 315(b) states that "[a]n inter partes review may not be instituted" if a petition "is filed more than 1 year after the date on which the petitioner, real party in interest, or privy of the petitioner is served with a complaint alleging [patent] infringement." Section 314(d) states that the USPTO Director's determination "whether to institute an inter partes review under this section shall be final and nonappealable." Relying on Cuozzo, the Court held that a "challenge to a petition's timeliness under § 315(b) . . . raises an 'ordinary dispute about the application of' an institution-related statute" and cannot be appealed because it is essentially "a contention that the agency should have refused 'to institute an inter partes review'" under § 314(d). Thryv, 590 U.S. at ___, slip op. at 8.

The majority supported its conclusion, in part, by looking to the congressional intent of the AIA.[6] The Court reasoned that IPR proceedings were designed to create a "more efficient and streamlined" system to challenge patent validity. *Id.* at 8. The Court reasoned that, if parties were allowed to appeal § 315(b) determinations, a successful appeal

challenge could vacate a finding of unpatentability without prevailing on the merits, thus "wasting the resources spent resolving patentability and leaving bad patents enforceable." *Id.* at 9.

The majority also determined that other AIA provisions compel the same conclusion because they "prioritize[] patentability over §315(b)'s timeliness requirement." *Id.* For example, the Court observed that, even if a petitioner is barred under § 315(b), it may still join a timely challenge by another petitioner under § 315(c). Allowing judicial review of timeliness determinations, the Court reasoned, could prevent streamlined resolution of patentability the AIA sought to achieve.

The majority also rejected Click-to-Call's narrower interpretation of § 314(d) that the appeal prohibition was limited solely to the Board's determination of a petitioner's "reasonable likelihood" of success under § 314(a). Thryv, 920 U.S. __, slip op. at 10-13. The majority considered the statutory language and determined that § 314(d) "sweeps more broadly" than just the likelihood of success determination because it does not refer to only subsection (a), but rather refers to "this section" and "encompasses the entire determination" whether to institute review. *Id.* at 11. The Court thus vacated the Federal Circuit's decision and remanded with instructions to dismiss for lack of jurisdiction.

Justice Gorsuch wrote a dissenting opinion, in which Justice Sotomayor joined. Justice Gorsuch's dissent criticizes the majority's decision as allowing the USPTO to revoke inventors' property rights without judicial

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4. Summary is reprint of Finnegan blog, https://www.finnegan.com/en/insights/blogs/america-invents-act/supreme-court-holds-pt-ab-time-bar-decisions-cannot-be-judicially-reviewed.html. *See also*, "SCOTUS Thryv Ruling Cracks Open Door on PTAB Joinder," Lionel M. Lavenue; Bradford C. Schulz; Bradley T. Edgington, https://www.finnegan.com/en/insights/articles/scotus-thryv-ruling-cracks-open-door-on-ptab-joinder.html, Aug. 5, 2020; and "How High Court IPR Time-Bar Ruling Affects PTAB Practice," Lionel M. Lavenue; Cory C. Bell; Max Mauldin, https://www.finnegan.com/en/insights/articles/how-high-court-ipr-time-bar-ruling-affects-pt-ab-practice.html, July 31, 2020.
5. The Court "[did] not decide whether mandamus would be available in an extraordinary case." Thryv, 590 U.S. at ___, slip op. at 8 n.4.
6. Section III(C) of the Thryv opinion, discussing congressional intent, was not joined by Justices Thomas and Alito.

reviewability of the timeliness of the challenges. The dissent questions how § 314(d) can prevent judicial review of an agency's mistaken interpretation of a different section of the statute—§ 315—and concludes that "[t]he answer is that it doesn't." *Thryv*, 590 U.S. at ___, Gorsuch, J., dissenting, slip op. at 6. Because § 314(d) only prevents review of "[t]he determination" made "under [that] section," the dissent argues that it does not preclude review of a determination made under § 315(b).

The dissent also argues that neither the majority's nor Thryv's arguments overcome the strong presumption favoring interpretations of statutes to allow for judicial review of administrative actions. In the dissent's view, § 315(b) is an express limit by Congress on agency authority and to hold otherwise requires a clear showing of Congressional intent, which the dissent argues the majority has not shown.

II. CAFC Decisions of PTAB Appeals

A. *Arthrex, Inc. v. Smith & Nephew, Inc.,* 941 F.3d 1320 (Fed. Cir. 2019), reh'g denied, 953 F.3d 760 (March 23, 2020 (with several concurring and dissenting opinions), pet. for cert. filed, June 2020

The Federal Circuit (MOORE, Reyna, and Chen) held that Patent Trial and Appeal Board ("PTAB") judges were unconstitutionally appointed under the Appointments Clause. The judges are not "inferior officers" and should have been appointed by the President and confirmed by the Senate.

The panel then "fixed" the problem by stripping out the part of the law that prevented the judges from being fired without cause. The PTAB decision was vacated and remanded for hearing before a new panel. Rehearing en banc was then denied with several concurring and dissenting opinions.[7]

Under a PTAB General Order, Arthrex remands held in abeyance until the Supreme Court acts on a petition for certiorari. Three petitions for certiorari were filed in June 2020.

B. F*acebook, Inc. v. Windy City Innovations, LLC*, 953 F.3d 1313 (Fed. Cir., Mar. 18, 2020), replaced 2020 U.S. App. LEXIS 28259 (Fed. Cir. Sept. 4, 2020)[8]

Windy City filed a patent infringement complaint against Facebook in district court. On the one-year anniversary of being served with that complaint, and before Windy City had identified the claims it was asserting in the district court action, Facebook filed petitions for inter partes review ("IPR") challenging some of Windy City's claims. The IPRs were instituted. Several months later, Windy City identified the claims it was asserting in district court. Facebook then filed two additional IPR petitions with motions for joinder to the already instituted IPRs. The Board instituted Facebook's new IPRs, granted the motions for joinder, and found in a Final Written Decision that some of the challenged claims—including some claims challenged only in the later IPR petitions—were unpatentable. The parties cross-appealed.

35 U.S.C. 315(c) allows the Director, in his discretion, "to join as a party [to an instituted IPR] any person." On appeal, Windy City argued that 315(c) does not allow a party to be "joined" to a proceeding where it was already a party and does not allow new issues to be added to an existing IPR through joinder, particularly issues that would be time-barred otherwise.

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7. MOORE, Circuit Judge, with whom O'MALLEY, REYNA, and CHEN, Circuit Judges, join, concurs in the denial of the petitions for rehearing en banc.
   O'MALLEY, Circuit Judge, with whom MOORE and REYNA, Circuit Judges, join, concurs in the denial of the petitions for rehearing en banc.
   DYK, Circuit Judge, with whom NEWMAN and WALLACH, Circuit Judges join, and with whom HUGHES, Circuit Judge, joins as to Part I.A, dissents from the denial of the petitions for rehearing en banc.
   HUGHES, Circuit Judge, with whom WALLACH, Circuit Judge, joins, dissents from the denial of the petitions for rehearing en banc
   WALLACH, Circuit Judge, dissents from the denial of the petitions for rehearing en banc.
8. Summary is excerpt of Finnegan blog, "The Impact of the Federal Circuit's Decision in *Facebook v. Windy City* on PTAB Practice: No Same Party or Issue Joinder and No Deference to POP Decisions on Statutory Interpretation," Brooke M. Wilner; Trenton A. Ward, Erika Harmon Arner, https://www.finnegan.com/en/insights/blogs/america-invents-act/the-impact-of-the-federal-circuits-decision-in-facebook-v-windy-city-on-ptab-practice-no-same-party-or-issue-joinder-and-no-deference-to-pop-decisions-on-statutory-interpretation.html, March 20, 2020 and "Court Upholds No Same-Party or New Issue Joinder for IPRs at the PTAB," Seth W. Bruneel, Caitlin E. O'Connell, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/court-upholds-no-same-party-or-new-issue-joinder-for-iprs-at-the-ptab.html (Sept. 11, 2020).

The Federal Circuit agreed, ruling that the unambiguous text of 315(c) does not authorize same-party or new issue joinder. By allowing Facebook to join its later IPR proceedings with the earlier one, the Board had essentially authorized the joining of two proceedings, not the joining of a party to a proceeding. The Federal Circuit held that this same-party joinder was prohibited by the clear text of 315(c), which allows the Director to join a person "as a party." The Court noted its disagreement with the POP's decision in *Proppant Express Investments, LLC v. Oren Techs., LLC*, IPR2018-00914, Paper 38 (P.T.A.B. Mar. 13, 2019), explaining that the POP decision turned on the Board's incorrect interpretation of the phrase "any person." The Court held that while "any person" has an expansive meaning, its range is limited by the ordinary legal meaning of "person," which would not allow for a party to join a proceeding in which it is already a party. The Federal Circuit thus disagreed with Proppant and held that 315(c) does not authorize new-party joinder.

315(c) also does not authorize the joinder of new issues, the Federal Circuit held. On appeal, Facebook argued that the statute does not expressly prohibit new-issue joinder. The Court held that, despite lacking an express prohibition, the language of 315(c) was not ambiguous. A person may join as a party to an already-instituted IPR, the Court explained, the scope of which is confined to the claims and grounds challenged in the original petition. In other words, a party joined to an IPR under 315(c) cannot bring new issues, claims, or grounds that were not already raised in the original IPR.

After oral argument, the Federal Circuit invited the Director to file a brief expressing his views on "what, if any, deference should be afforded to decisions of a Patent Trial and Appeal Board Precedential Opinion Panel ('POP')." Additional Views, slip op. 5. Because the majority opinion found the statutory text to be clear and unambiguous, it did not address what level of deference would be owed to the USPTO's own interpretation of 315(c) if the statute were ambiguous. Chief Judge Prost and Judges Plager and O'Malley (the same judges on the majority panel) wrote separately to provide additional views on the deference issue. The panel explained that even if the statutory language was ambiguous, no deference should be due to the USPTO's interpretation of 315(c) in the POP decision. Additional Views, slip op. 15. The Judges noted that deference can only be applied to an agency's implementation of a statutory provision when "Congress delegated authority to the agency generally to make rules carrying the force of law," and "the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). The AIA granted authority to the USPTO Director to promulgate regulations that govern the conduct of IPRs, including joinder under section 315(c). The Director's authority does not extend to interpreting statutory provisions through adjudicatory POP opinions, so those opinions are entitled to no deference according to the panel's views.

In *Facebook, Inc. v. Windy City Innovations, LLC*, No. 2018-1400 (Fed. Cir. Sept. 4, 2020), the Federal Circuit denied Appellant's petition for rehearing en banc but granted their petition for panel rehearing in order to withdraw and replace the original March 18, 2020 opinion. The Court maintained its holding that the text of 35 U.S.C. § 315(c) does not authorize same-party or new issue joinder to an existing IPR but modified the opinion to further expand on the Court's authority to review the Board's joinder decision.
The Court explained that, while 35 U.S.C. § 314(d) provides that the Director's determination to institute an IPR is "final and nonappealable," this does not preclude review where the agency has exceeded its statutory authority. The Court explained that the joinder decision does not concern whether the petition warrants institution or whether the petitioner is likely to succeed on the merits, which the Court is precluded from reviewing under § 314(d). Rather, the joinder decision is a separate decision made after institution regarding the manner in which the IPR will proceed. Thus, the Court held that it has the authority to review the Board's decision to determine whether it exceeded the statutory authority provided to it under 35 U.S.C. § 315(c).

C. *Samsung Electronics America v. Prisua Eng'g Corp.*, 948 F.3d 1342 (Fed. Cir. 2020)

The PTAB held claim 11 unpatentable as obvious but could not analyze patentability of claims 1-4 and 8 because those claims were indefinite.

The Federal Circuit affirmed with respect to claim 11 but reversed and remanded with respect to claims 1-4 and 8; the statute does not authorize PTAB to cancel challenged claims for indefiniteness.

According to the Court:

[T]he proper course for the Board to follow, if it cannot ascertain the scope of a claim with reasonable certainty

for purposes of assessing patentability, is to decline to institute the IPR. It would not be proper for the Board to cancel claims on a ground that is unavailable in an IPR.

Id. at 1353.

On remand, the Board should address Samsung's argument that the Board may analyze the patentability of a claim even if that claim is indefinite. Even though the validity of the challenged claims may be subject to question for IPXL-type indefiniteness, that is simply another ground on which the claims might be challenged in an appropriate forum (other than the Board). It does not necessarily preclude the Board from addressing the patentability of the claims on section 102 and 103 grounds. In the remand proceedings, the Board should determine whether claim 1 and its dependent claims are unpatentable as anticipated or obvious based on the instituted grounds.

Id. at 1355.

D. *Cochlear Bone Anchored Sols. AB v. Oticon Med.* AB, 958 F.3d 1348 (Fed. Cir. 2020)

The PTAB found that Oticon proved some of the challenged claims unpatentable but not all. The PTAB considered claims 7-10 means-plus-function claims that did not have corresponding structure in the specification. As such, "the Board could not "ascertain the differences between the claimed invention and the asserted prior art" for those claims" and concluded Oticon had not proven claims 7-10 unpatentable.

The Federal Circuit affirmed with respect to all claims but claim 10, for which it vacated and remanded. According the Federal Circuit, relying on Samsung, the PTAB acted properly with respect to claims 7-9:

> If the specification fails to recite a corresponding structure [in a MPF claim], then there is a wholly undefined claim element: the claim has what amounts to an inkblot as a required element of the claim. Such a claim logically cannot be compared to prior art, because an essential claim element has no discernible meaning. Such a claim is indefinite, …, but that is not the inquiry in an inter partes review, in which the Board may not hold a challenged claim of a patent indefinite. …. The crucial point for purposes of an inter partes review of issued claims is that, in the situation just described, if it is impossible to conduct a prior-art analysis because there is a required claim element without meaning. In this situation, the Board should "conclude that it could not reach a decision on the merits with respect to whether petitioner had established the unpatentability of those claims under sections 102 or 103." *Samsung*, 948 F.3d at 1353.

Id. at 1359.

But claim 10 did not contain a required element in means-plus-function form. One of the three alternatives recited in the claim had "a discernible meaning and can be compared to prior art." *Id.* at 1359-60. Since one of the alternatives could have been compared to the prior art, it should have been. "Samsung establishes that indefiniteness of a claim does not always imply inability to conduct a prior-art analysis needed for an inter partes review. The questions are different. Here, even if claim 10 is indefinite, such a conclusion would not imply that it is incapable of being compared to prior art to determine if one of its alternatives is anticipated or would have been obvious on the grounds asserted. We vacate the Boards ruling as to claim 10 and remand." *Id.* at 1360.

E. *Nike v. Adidas*, 955 F.3d 45 (Fed. Cir. 2020)[9]

In *Nike Inc. v. Adidas Inc*, the Federal Circuit held that the Board may introduce independent grounds for unpatentability for claims raised on a motion to amend based on the prior art of record so long as the parties are provided notice and granted an opportunity to respond.

Following Nike I, the Board reconsidered Nike's motion to amend. Citing art that was in the record but otherwise not relied upon to establish unpatentability, the Board issued a final determination finding Nike's proposed substitute claims obvious over the art and denying Nike's request for entry of the substitute claims.

9. Summary is reprint of Finnegan blog, "PTAB Permitted to Raise New Grounds for Unpatentability Following Motion to Amend," Safiya Aguilar, Samhitha Muralidhar Medatia, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/ptab-permitted-to-raise-new-grounds-for-unpatentability-following-motion-to-amend.html, April 14, 2020.

On appeal, Nike argued that the Board's final determination, specifically its failure to notify the parties of the new grounds for unpatentability, violated the APA's notice requirement. The Federal Circuit agreed—although it was proper for the Board to rely on the art of record to develop its own theory of unpatentability, inclusion of the theory in its final determination deprived Nike of its right to notice and an opportunity to address the factual and legal underpinnings of the determination. The Court noted that the Board might have satisfied these requirements by notifying the parties of its intention to rely on the reference and requesting a supplemental brief or hearing directed to the reference's merits.

III. Doctrine of Equivalents

A. *Amgen v. Sandoz*, 923 F.3d 1023 (Fed. Cir. 2019)[10]

The Federal Circuit affirmed the district court's summary judgment of noninfringement of Amgen's biologic products, filgrastim (marketed as Neupogen®) and pegfilgrastim (marketed as Neulasta®) by Sandoz's biosimilars.

Amgen, the reference product sponsor, sued Sandoz under the Biologics Price Competition and Innovation Act (BPCIA) on U.S. Patents 6,162,427 ("the '427 patent") and 8,940,878 ("the '878 patent"). Sandoz submitted an abbreviated Biologics License Applications ("aBLAs") referencing Neupogen® and Neulasta® but had elected not to provide Amgen with its aBLAs or manufacturing information. Sandoz received FDA approval for its filgrastim biosimilar, Zarxio®, but has not yet received approval for its proposed pegfilgrastim biosimilar.

Claim 7 of the '878 patent reads:

1. A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising:
    a. expressing a protein in a non-native limited solubility form in a non-mammalian cell;
    b. lysing a non-mammalian cell;
    c. solubilizing the expressed protein in a solubilization solution comprising one or more of the following:
        i. a denaturant; ii. a reductant; and iii. a surfactant;
    d. forming a refold solution comprising the solubilization solution and a refold buffer, the refold buffer comprising one or more of the following:
        i. a denaturant; ii an aggregation suppressor; iii a protein stabilizer; and (iv) a redox component;
    e. directly applying the refold solution to a separation matrix under conditions suitable for the
    f. protein to associate with the matrix;
    g. washing the separation matrix; and
    h. eluting the protein from the separation matrix, wherein the separation matrix is a non-affinity resin selected from the group consisting of ion exchange, mixed mode, and a hydrophobic interaction resin.

The district court construed limitations (f) and (g) as separate steps that must occur in order:

> performing limitations (e)–(g) of the process of claim 7 requires:
>
> (e) applying the refold solution to a separation matrix . . . ,
>
> (f) applying a solution to remove . . . unwanted components of the refold solution . . . while preserving [protein] binding . . . ; and
>
> (g) applying a solution that reverses the binding of the purified protein . . . .

Id. at *7.

10. Summary is reprint of Finnegan blog, "The Perils of Ordered Patented Processes and Narrow Claim Construction: Recipes for Non-Infringement," M. Paul Barker, Amy Madl, Michael Liu Su, Stacy Lewis, Thomas L. Irving, https://www.finnegan.com/en/insights/blogs/prosecution-first/the-perils-of-ordered-patented-processes-and-narrow-claim-construction-recipes-for-non-infringement.html, May 13, 2019.

Sandoz's process only involves one step—applying the refold solution to the matrix, with no separate washing or eluting steps ((f) and (g) of claim 7). The district court granted summary judgment that neither Zarxio® nor Sandoz's proposed pegfilgrastim biosimilar infringed claim 7 of the '878 patent.

On appeal, Amgen argued that it was an error to require the "washing" and "eluting" to be separate steps in claim 1 of the '878 patent. "Instead, Amgen argues, the claims cover any number of solutions or steps as long as the functions of washing and eluting happen in sequence[.]" *Id.* at *8.

The Federal Circuit affirmed the district court's claim construction of the washing and eluting limitations as separate process steps performed by adding discrete solutions to the separation matrix in sequence. The Federal Circuit characterized Amgen's argument as a proposition that the washing and eluting steps describe functions rather than actual process steps. It rejected this argument:

> First, . . . the claim language logically requires that the process steps, lettered (a) through (g), be per formed in sequence. For example, expressing the protein in a nonmammalian cell (limitation (a)) obvious ly must occur before the step of lysing that cell (limitation (b)). There is no indication on the face of claim 7 that the washing and eluting steps are any different. Second, washing and eluting are consistently de scribed in the specification as separate steps performed by different solutions.

Id. at *9.

Even if it adopted Amgen's proposed construction, the Federal Circuit still found no literal infringement because Sandoz's current process only uses one step and one solution.

The Federal Circuit also rejected Amgen's doctrine of equivalents argument. "Sandoz's one-step, one-solution process does not function in the same way as the claimed" three-step, three-solution process.

In essence, Amgen seeks to cover, one way or another, any method of using a salt concentration gradient in an adsorbent matrix to separate a protein of interest from other solutes. But claim 7 is not that broad.

Id. at *11.

Every case depends on its own facts and circumstances. In this case, Amgen's process claim in the '878 patent was written in a sequential way, which was also how the process was described in the specification. This eliminated the possibility of capturing a competitor who changed the order of the steps or skipped steps.

B. *Amgen Inc. v. Coherus Biosciences Inc.*, 931 F.3d 1154 (Fed. Cir. 2019)[11]

In *Amgen Inc. v. Coherus Biosciences Inc.*, the Federal Circuit affirmed the district court's dismissal of Amgen's infringement claim under the doctrine of equivalents. The asserted patent claimed certain methods of purifying proteins involving the use of any of three particular combinations of salts. Coherus's acknowledged purification method employed a combination of salts but not one of particular three claimed combinations.

The Federal Circuit held that prosecution history estoppel barred Amgen from succeeding on its infringement claim under the doctrine of equivalents because, during prosecution, Amgen "clearly and unmistakably surrendered" salt combinations other than the three particular combinations recited in the claims. The file history showed that, in response to an obviousness rejection, Amgen had argued that the cited reference failed to disclose the particular salt combinations recited in Amgen's claims. The argument was not the only one Amgen raised, nor was it included in the remarks that ultimately led to allowance. Nevertheless, the Court reasoned that each argument in support of patentability can create a separate estoppel, including assertions that were not actually required to secure allowance.

C. *Eagle Pharms. Inc. v. Slayback Pharma Inc.*, 958 F.3d 1171 (Fed. Cir. 2020)[12]

Eagle sued Slayback alleging infringement under the doctrine of equivalents ("DOE") of four patents: U.S. Patent Nos. 9,265,831 ("the '831 patent"), 9,572,796 ("the '796 patent"), 9,572,797 ("the '797 patent"), and

11. Summary is excerpt of Finnegan blog, "Prosecution History Estoppel Leads to Dismissal of DOE Claim," Brandon T. Andersen, Samhitha Muralidhar Medatia, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/prosecution-history-estoppel-leads-to-dismissal-of-doe-claim.html, Aug. 15, 2019.

10,010,533 ("the '533 patent"). Slayback submitted New Drug Applications ("NDAs") to the FDA to manufacture and sell a bendamustine drug bioequivalent to BALRAPZO® prior to the expiration of Eagle's patents.

All four patents possess the same written description and similar claim limitations. Claim 1 of the '796 patent is representative and reads:

> A non-aqueous liquid composition comprising:
>
> a. bendamustine, or a pharmaceutically acceptable salt thereof;
>
> b. a pharmaceutically acceptable fluid comprising a mixture of polyethylene glycol and propylene glycol, wherein the ratio of polyethylene glycol to propylene glycol in the pharmaceutically acceptable fluid is from about 95:5 to about 50:50; and
>
> c. a stabilizing amount of an antioxidant;
>
> d. wherein the composition has less than about 5% total impurities after 15 months of storage at about 5° C

In Slayback's proposed bendamustine drug, the "pharmaceutically acceptable fluid" contains the same polyethylene glycol recited in claim 1 but utilizes ethanol as an alternative to the recited propylene glycol. Slayback argued that Eagle is barred from asserting infringement under the doctrine of equivalents in view of the disclosure-dedication doctrine because the written description discloses, but does not claim, ethanol as an alternative to polyethylene glycol:

> In other aspects of the invention, the bendamustine-containing compositions include a) a pharmaceutically acceptable fluid which contains one or more of propylene glycol, ethanol, polyethylene glycol, benzyl alcohol and glycofurol . . .

'796 patent specification at 1:60-64.

Eagle argued that "a POSITA would understand from the written description of the asserted patents that ethanol can only be an alternative to propylene glycol in embodiments that include a stabilizing amount of a chloride salt and not embodiments that require, as the claims do, a stabilizing amount of an antioxidant." The court rejected this argument, explaining that the disclosure-dedication doctrine applies to unclaimed subject matter identified by the patentee as an alternative to a claim limitation, and not to the exact formulation of an alternative embodiment.

The court noted that Eagle's argument ignored the Federal Circuit's en banc decision on the disclosure-dedication doctrine found in *Johnson & Johnston Assocs., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002), wherein the Federal Circuit overruled previous caselaw purporting to limit the disclosure-dedication doctrine to unclaimed alternative embodiments distinct from the invention. *Id.* at 1052. The district court in Eagle understood Johnson & Johnston to hold that "the disclosure-dedication doctrine is not restricted to disclosures of embodiments," rather it "applies to claim limitations." Applying the doctrine, the district court found it would have been clear to a POSITA that the asserted patents disclosed ethanol as an alternative to propylene glycol:

Consequently, Eagle was barred by the disclosure-dedication doctrine from alleging that Slayback's bendamustine drug product infringed its asserted claims under the doctrine of equivalents.

The Federal Circuit affirmed, also relying on *Johnson & Johnston*: "[W]hen a patent drafter discloses but declines to claim subject matter, . . . this action dedicates the unclaimed subject matter to the public." Eagle, 958 F.3d at 1175. "To determine whether the disclosure-dedication doctrine applies in a given case, we ask whether the specification discloses unclaimed subject matter with 'such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.'" *Id.*

D. Rebutting *Festo* Presumption

12. Summary is excerpt of Finnegan blog, "When Will They Ever Learn? Subject Matter Disclosed in the Patent Specification But Never Claimed is Dedicated to the Public," Michele C. Bosch, Sara A. Leiman, Ph.D., Clinton Greub, Stacy Lewis, Thomas L. Irving, https://www.finnegan.com/en/insights/blogs/prosecution-first/when-will-they-ever-learn-subject-matter-disclosed-in-the-patent-specification-but-never-claimed-is-dedicated-to-the-public.html , May 24, 2019.

1. *Ajinomoto Co. v. ITC*, 932 F.3d 1342 (Fed. Cir. 2019) (tangential)[13]

In Ajinomoto, the Federal Circuit applied the tangential relation exception to the doctrine of prosecution history estoppel in its doctrine of equivalents analysis. The claims at issue recite alternative descriptions of the claimed protein: "(A) comprising the amino acid sequence shown in SEQ ID NO:2, or (B) comprising an amino acid sequence encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEQ ID NO:1 under stringent conditions." The Commission found that the protein encoded by a codon-randomized gene of the respondent's strain was an equivalent of SEQ ID NO:2.

Initially, the Federal Circuit noted that the originally filed claim 1 recited a different (B) alternative, i.e., an amino acid sequence including deletion, substitution, insertion, or addition of one or several amino acids in SEQ ID NO:2. During prosecution, to overcome an anticipation rejection over an unrelated prior-art E. coli YfiK protein technically covered by the original (B) alternative, applicants amended (B) to recite an amino acid sequence encoded by a nucleotide sequence that hybridizes with the nucleotide sequence of SEQ ID NO:1 under stringent conditions. The court concluded that the objective rationale for the amendment was to limit the scope of (B) so that it no longer covered the unrelated YfiK prior-art protein and had nothing to do with choosing among several DNA sequences in the redundant genetic code corresponding to the protein at issue in the case (i.e., application of codon-randomization). Accordingly, the court affirmed the Commission's finding of infringement under DOE.

2. *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320 (Fed. Cir. 2019) (tangential)[14]

In *Eli Lilly & Company v. Hospira*, the Federal Circuit affirmed the district court's application of the doctrine of equivalents and clarified that the tangential exception of prosecution history estoppel should not be viewed too rigidly.

The dispute centered on whether Lilly's claims at issue, which recited particular methods of treatment by administering pemetrexed disodium, covered administration of a different pemetrexed salt, pemetrexed ditromethamine, under DOE. During patent prosecution, Lilly submitted a claim amendment changing "an antifolate" to "pemetrexed disodium."

The Federal Circuit held that the amendment did not bar the application of DOE because narrowing "antifolate" to "pemetrexed disodium" could not possibly distinguish art referencing pemetrexed disodium in then-pending obviousness rejections. The court emphasized that when determining whether prosecution history estoppel applies to DOE, courts should analyze the context surrounding an amendment. In this case, the court concluded that the reason for the amendment was not to cede other, functionally identical, pemetrexed salts, and that it was unlikely that competitors would be justified in believing that equivalent pemetrexed salts would not infringe. The court refused to adopt a bright-line rule that the tangential exception does not apply where the reason for the amendment and the equivalent in question both related to the same claim element. Considering the prosecution history as a whole and the patent-at-issue itself, the court concluded that it was implausible that the reason for Lilly's amendment was to surrender other pemetrexed salts.

3. *Bio-Rad Labs. v. 10X Genomics*, 967 F.3d 1353 (Fed. Cir. 2020) (tangential)[15]

In *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, the Federal Circuit rejected 10X's prosecution history estoppel and claim vitiation defenses and upheld the jury's finding of willful infringement under the doctrine of equivalents.

Bio-Rad sued 10X for infringement of three patents covering microscopic droplets of fluids for biochemical reactions, often called "labs-on-a-chip." Bio-Rad amended the patents' claim language during prosecution to claim "a non-fluorinated microchannel," and further argued that, unlike the prior art, the claims require the microchannel be "chemically similar to the carrier fluid and chemically different from the channel walls." 10X

13. ummary is reprint of Finnegan blog, "Claim Amendment to Avoid Unrelated Prior Art Protein Is Unrelated to Codon-Randomized Versions of Protein-at-Issue and Do Not Trigger Prosecution History Estoppel Under the Tangential Exception, Yieyie Yang, Ph.D., Samhitha Muralidhar Medatia, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/claim-amendment-to-avoid-unrelated-prior-art-protein-is-unrelated-to-codon-randomized-versions-of-protein-at-issue-and-do-not-trigger-prosecution-history-estoppel-under-the-tangential-exception.html, Aug. 28, 2019.
14. Summary is reprint of Finnegan blog, "The Tangential Exception to Prosecution History Estoppel Should Not Be Viewed Rigidly," Yieyie Yang, Ph.D., Samhitha Muralidhar Medatia, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/the-tangential-exception-to-prosecution-history-estoppel-should-not-be-viewed-rigidly.html, Aug. 23, 2019.

argued that its product, which includes 0.02% of a fluorine-containing resin in its microchannels, did not infringe.

The Court rejected 10X's prosecution history estoppel argument because the non-fluorine claim element was only tangentially related to the accused equivalents. Bio-Rad amended the claim language to distinguish its invention from a prior art product in which a chemical reaction occurs between the fluorine-containing microchannel and the carrier fluid. 10X's product contained such a small amount of fluorine that it would not chemically react with the carrier fluid; therefore, prosecution history estoppel did not bar Bio-Rad from asserting that microchannels containing a negligible amount of fluorine are equivalent. 10X's claim vitiation argument similarly failed because the element is not "effectively eliminated" by Bio-Rad's theory as a fluorine-containing microchannel that reacts with the carrier fluid would not infringe.

4. *Pharma Tech Sols. Inc. v. LifeScan Inc.*, 942 F.3d 1372 (Fed. Cir. 2019) (not tangential)[16]

In *Pharma Tech Solutions Inc. v. Lifescan Inc.*, the Federal Circuit affirmed the district court's grant of Lifescan's motion for summary judgment based on its finding that prosecution history estoppel barred Pharma Tech's doctrine of equivalents infringement claim. The technology at issue involved blood glucose monitoring systems that required a user to insert a sample into a device that measured an electric current running through the sample and then converted the measurement into blood glucose level data.

Pharma Tech's patents covered a device that measured multiple electric currents from each sample, then converted each current reading into an analyte concentration measurement before comparing the different measurements to ensure accuracy and reliability. In contrast, the accused Lifescan device reported measurements as current over a given time rather than concentration and did not compare multiple readings of concentration levels to ensure accuracy.

Pharma Tech argued that the Lifescan device infringed under the doctrine of equivalents. During prosecution of the asserted patents, in response to anticipation and obviousness rejections, the applicant amended its claims to require both a conversion of current readings to analyte concentration and subsequent comparisons of those concentrations. As a result, the district court held that the claim amendments barred Pharma Tech's claims of infringement under the doctrine of equivalents and granted Lifescan's motion for summary judgment.

The Federal Circuit rejected Pharma Tech's argument that its amendment bore no more than a "tangential relation" to the equivalent in question. The court held that Pharma Tech's asserted equivalent was within the territory that its own inventors had surrendered during prosecution. Additionally, the court held that the " objectively apparent reason" for the claim amendments was to "distinguish the invention over prior art systems," and thus were necessary for the application to achieve patentability. The court noted that even if Pharma Tech may have conceded more claim scope than was necessary, such concessions were irrelevant to the current argument at issue.

The Federal Circuit also rejected Pharma Tech's argument for certain exceptions where amendment-based prosecution history estoppel does not apply when the amendment does not emphasize or rely on the added claim language. Instead, the court held that "the comparison of analyte concentration measurements was integral to the inventors' . . . amendment." Furthermore, the court held that the rationale for the amendments—avoiding prior art which did not convert current readings to analyte concentrations or compare the concentrations to

15. Summary is reprint of Finnegan blog, "Prosecution History Estoppel and Claim Vitiation Not Enough to Avoid Willful Infringement," Tyler B. Latcham, Caitlin E. O'Connell, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/prosecution-history-estoppel-and-claim-vitiation-not-enough-to-avoid-willful-infringement.html, Aug. 12, 2020.
16. Summary is reprint of Finnegan blog, "Federal Circuit Upholds Finding that Amendments Directly Related to Accused Equivalent Bars Doctrine of Equivalents Infringement, Y. Leon Lin, Samhitha Muralidhar Medatia, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/federal-circuit-upholds-finding-that-amendments-directly-related-to-accused-equivalent-bars-doctrine-of-equivalents-infringement.html, Dec. 16, 2019.
17. Summary is reprint of Finnegan blog, "A Belated Lesson in How to Avoid a Finding of Obviousness Based Upon Inherent Disclosure," Adriana L. Burgy, Michele C. Bosch, Daniele M. San Román, Stacy Lewis, Thomas L. Irving, https://www.finnegan.com/en/insights/blogs/prosecution-first/a-belated-lesson-in-how-to-avoid-a-finding-of-obviousness-based-upon-inherent-disclosure.html, Jan. 13, 2020. See also,"Federal Circuit Reaffirms Inherency May Supply Missing Claim Limitation in Obviousness Analysis from a Combination of Prior Art Elements," Y. Leon Lin, by Caitlin E. O'Connell, Elizabeth D. Ferrill, https://www.finnegan.com/en/insights/blogs/federal-circuit-ip/federal-circuit-reaffirms-inherency-may-supply-missing-claim-limitation-in-obviousness-analysis-from-a-combination-of-prior-art-elements.html.

each other—directly related to the accused equivalent. Rejecting all of Pharma Tech's remaining arguments, the court upheld the district court's findings and affirmed Lifescan's motion for summary judgment.

IV. 35 U.S.C. §103

A. *Persion Pharms. LLC v. Alvogen Malta Operations LTD.*, 945 F.3d 1184 (Fed. Cir. 2019)[17]

The District Court of Delaware held Persion's claims invalid for obviousness and lack of written description. The Federal Circuit affirmed the obviousness determination, recognizing the proper application of inherent disclosure in an obviousness determination, and did not reach the written description issue.

Persion owns U.S. Patent Nos. 9,265,760 ("the '760 patent") and 9,339,499 ("the '499 patent) directed to treating pain associated with renal or hepatic impairment using hydrocodone-only formulations. The patents cover the commercial product Zohydro ER and share a common written description and priority date. When the FDA evaluated Zohydro ER, it required a clinical study that is described in Example 8. The results of this study led researchers to file patent applications that eventually issued as the '760 and '499 patents. The claims, however, are not limited to the use of the Zohydro ER formulation, rather they cover any extended release formulation with hydrocodone bitartrate as the only active ingredient. Claims 1 and 12 of the '760 patent are representative:

> '760 patent claim 1. A method of treating pain in a patient having mild or moderate hepatic impairment, the method comprising:
>
> > administering to the patient having mild or moderate hepatic impairment a starting dose of an oral dosage unit having hydrocodone bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of hydrocodone bitartrate, and wherein the starting dose is not adjusted relative to a patient without hepatic impairment.
>
> '760 patent claim 12. A method of treating pain in a patient having mild or moderate hepatic impairment, the method comprising:
>
> > administering to the patient having mild or moderate hepatic impairment an oral dosage unit having hydrocodone bitartrate as the only active ingredient, wherein the dosage unit comprises an extended release formulation of hydrocodone bitartrate,
> >
> > wherein the dosage unit provides a release profile of hydrocodone that:
> >
> > (1) does not increase average hydrocodone AUC0–inf in subjects suffering from mild hepatic impairment relative to subjects not suffering from renal or hepatic impairment in an amount of more than 14%;
> >
> > (2) does not increase average hydrocodone AUC0–inf in subjects suffering from moderate hepatic impairment relative to subjects not suffering from renal or hepatic impairment in an amount of more than 30%;
> >
> > (3) does not increase average hydrocodone Cmax in subjects suffering from mild hepatic impairment relative to subjects not suffering from renal or hepatic impairment in an amount of more than 9%; and
> >
> > (4) does not increase average hydrocodone Cmax in subjects suffering from moderate hepatic impairment relative to subjects not suffering from renal or hepatic impairment in an amount of more than 14%.

The prior art disclosed (1) the Zohydro ER formulation itself and an in vivo study of the formulation for treating pain ("Devane"), (2) that pharmacokinetic parameters for hydrocodone did not vary much between normal subjects and subjects with mild and moderate hepatic impairment ("Jain"), and (3) safety and use instructions from drug labels that do not mention restrictions for patients with mild or moderate hepatic impairment.

Persion sued Alvogen after Alvogen filed an ANDA seeking to market a generic version of Zohydro ER. The district court held that Alvogen would indirectly infringe the asserted claims because its product label would

induce doctors and patients to administer Alvogen's product in an infringing manner. The district court also concluded that the asserted claims were not invalid as anticipated but were invalid for obviousness. A POSITA would have been motivated to administer the extended-release hydrocodone bitartrate formulation disclosed in Devane to patients with mild or moderate hepatic impairment at an unadjusted dose and would have had a reasonable expectation of success in so doing. Furthermore, the district court found that the "pharmacokinetic limitations in the pharmacokinetic claims are 'inherent in any obviousness combination that contains the Devane formulation' because the recited pharmacokinetic parameters were 'necessarily present' in the Zohydro ER formulation described in both Devane and the asserted patents." The district court also held the claims invalid for lack of written description support because the claims are broader than the only formulation disclosed, that in Example 8.

The Federal Circuit, in a decision authored by Judge Reyna, affirmed the obviousness holding but did not reach the written description issue.

Although a high bar exists for its use in obviousness cases, the Court found that inherency was properly applied and supplied "'a missing claim limitation in an obviousness analysis' where the limitation at issue is 'the natural result of the combination of prior art elements.'" *Id.* at *12–13 (emphasis in original). According to the Federal Circuit, there was "no dispute that the Devane formulation, which was identical to the Zohydro ER formulation described in the patents in suit, necessarily exhibited the claimed parameters" and that a POSITA "would have been motivated, with reasonable expectation of success, to administer an unadjusted dose of the Devane formulation to hepatically impaired patients." *Id.* at 13.

Persion also argued the district court improperly relied upon the submission of safety data relating to an immediate-release combination product to the FDA that the FDA found insufficient. But the district court dismissed this argument by noting that the patentability standard of motivation to combine is far below that of safety and efficacy to the FDA. Objective evidence of patentability was also found insufficient. The Federal Circuit agreed.

Persion additionally argued that the district court's obviousness decision was inconsistent with its finding of a lack of written description support. The Federal Circuit rejected this position, noting that the district court's finding that there was no guidance as to "which of the broadly claimed formulations would work and which would not, with the exception of the single embodiment described in Example 8" was not inconsistent with the finding that the "embodiment described in Example 8 of the common written description of the '760 and '499 patents is the Devane formulation, which formed the basis for the district court's obviousness findings." *Id.* at *19. "[T]he district court found that the prior art provided adequate guidance with respect to the sole formulation described in Example 8: the Devane formulation." *Id.* at *19–20.

B. *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322 (Fed. Cir. 2020)[18]

The Northern District Court of Illinois found that claim 6 of U.S. Pat. 8,648,106 (the '106) patent would have been obvious based on a finding that the prior art inherently contained a certain property.

The claims at issue in *Hospira v. Fresenius* recite a product made from dexmedetomidine (dex) that Hospira sells as Precedex Premix. Precedex Premix is a ready-to-use diluted version of Hospira's Precedix Concentrate, on the market since 1999. Fresenius, filing an an ANDA with the FDA to sell its own proposed dex products, challenged the '106 patent.

After the district court's claim construction order and prior to trial, Hospira dropped all but claim 6 of the '106 patent. Fresenius stipulated that its proposed product would infringe claim 6 but asserted invalidity of claim 6, which depended from claim 1 and both are repeated herein:

> Claim 6. The ready to use liquid pharmaceutical composition of claim 1, wherein the dexmedetomidine or pharmaceutically acceptable salt thereof is at a concentration of about 4 ug/mL.
>
> Claim 1. A ready to use liquid pharmaceutical composition for parenteral administration to a subject, comprising dexmedetomidine or a pharmaceutically acceptable salt thereof disposed

18. Summary is excerpt of Finnegan blog, "Inherency and Obviousness, Adriana L. Burgy; Stacy Lewis, Thomas L. Irving, https://www.finnegan.com/en/insights/blogs/prosecution-first/inherency-and-obviousness.html, Dec. 27, 2018.

within a sealed glass container, wherein the liquid pharmaceutical composition when stored in the glass container for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine.

The obviousness issue, centering on the claim limitation of "no more than about 2% decrease" in the concentration of dex, was articulated as follows:

> whether 4 μg/mL dexmedetomidine HCl—when stored at room temperature in a Type I glass vial, sealed with a coated rubber stopper—will always "exhibit[ ] no more than about 2% decrease in the concentration of dexmedetomidine" at five months.

According to Hospira, the answer was "no" - a 4 μg/mL formulation stored under these conditions will not always meet that claim limitation.

Fresenius, however, proffered expert testimony that none of the data Hospira submitted with its NDA showed a loss of concentration of more than 2% at five months. Another Fresenius expert testified that "the stability data he analyzed for Precedex Concentrate (100 μg/mL and 200 μg/mL formulations) showed that dex experienced no more than two percent loss at five months."

While the district court found that all of the limitations of claim 6 were present in the prior art except for the "about 2%" limitation, the court found that one of ordinary skill in the art would have been motivated to modify the prior art to obtain a ready-to-use product and would have had a reasonable expectation of success in obtaining a product that met the "about 2%" limitation.

Here, the "about 2%" limitation was found inherent in a 4 μg/mL dexmedetomidine HCl formulation stored in a Type I glass vial sealed with a coated rubber stopper, and stored at room temperature for five months, in view of stability data of record and expert testimony. Specifically, expert testimony showed that every sample tested lost no more than 2% concentration at five months. Furthermore, from a chemical properties' perspective, expert testimony showed that dex was expected to be "rock stable" over "any long period of time."

The Federal Circuit affirmed, holding that the district court's finding that 2% limitation was "necessarily present" in the prior art was supported by substantial evidence. "Extrinsic evidence can be used to demonstrate what is 'necessarily present' in a prior art embodiment even if the extrinsic evidence is not itself prior art." Hospira, 946 F.3d at 1329.

V. 35 U.S.C. §112

A. *Quake v. Lo*, 928 F.3d 1365 (Fed. Cir. 2019)

In an interference proceeding between Quake's '018 patent and '833 application and Lo's application, the Board granted Lo's motion that Quake's claims lacked written description support.

The Federal Circuit affirmed; although two elements of the claimed method were expressly disclosed, the method as a whole was not. Only two paragraphs of the Quake specification relate to the claimed method using massively parallel sequencing (MPS) technology: "the two are (at most) faint 'blaze marks' for determining fetal aneuploidy by random MPS, while the rest of the specification marks a clear trail to targeted MPS." *Id.* at 1376.

The problem seems to have arisen from Quake trying to trigger the interference:

[T]he first time Quake tried to cover random MPS with this specification was after the publication of Lo's patent application directed to random MPS: Quake then canceled all his pending claims and replaced them with claims covering random MPS, creating a mismatch between the claims and the originally filed specification.

Id. at 1373.

B. *Idenix Pharms. v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019)

The district court held Idenix's claim 1 invalid for lack of enablement. Claim 1 read: A method for the treatment of a hepatitis C virus infection, comprising administering an effective amount of a purine or pyrimidine ß-D-2'-methyl-ribofuranosyl nucleoside or a phosphate thereof, or a pharmaceutically acceptable salt or ester thereof.

The Federal Circuit affirmed after analyzing the Wands factors. The Court noted that gaps in the specification leaving novel aspects of the invention lacking enablement cannot be supplied by knowledge of the POSITA. "It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)." *Id.* at 1159. The Federal Circuit also concluded the claims lacked written description support because subject matter fell within the boundaries of the claim that was not described by the formulas or examples in the specification.

C. *Purdue Pharma L.P. v. Iancu*, 767 Fed. Appx. 918 (Fed. Cir. April 17, 2019)

Purdue's patent claims using two gelling agents, polyethylene oxide (PEO) and hydroxypropylmethylcellulose (HPMC) in an oxycodone formulation. The PTAB held the claims were not entitled to the priority date of provisional application and were therefore knocked out by the asserted reference. The provisional and the draft application merely include laundry list disclosures of possible gelling agents, in which "[HPMC] [PEO] and mixtures thereof" are among a large number of other possible gelling agents. There was no specific[] named or mentioned the combination in any manner.

The Federal Circuit affirmed. "Purdue never met its burden to show that the 376 patent is entitled to claim the benefit of the 534 application's filing date." *Id.* at 924. Simply describing a large genus may not satisfy the written description requirement. "Such 'laundry list' disclosures do not provide adequate specificity to constitute written description support for Purdues claim of priority. To be sure, the language 'mixtures thereof' suggests the possibility of combining two or more of the listed gelling agents. Without more, however, that language fails to highlight any preference for how many and which gelling agents to combine." *Id.*

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

The claims at issue are directed to the fusion protein etanercept and methods of making it. According to Sandoz, Immunex's priority application 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 upheld the validity of the claims. The specification indicates the inventors possessed the full-length p75 DNA sequence (description and examples) and "the claimed p75-IgG1 fusion protein." Also, the full-length p75 sequence was known in the prior art. "It is well-established that a patent specification need not re-describe known prior art concepts." *Id.* at 1064.

E. *Verinata Health v. Ariosa Diagnostics*, 809 Fed. Appx. 965 (Fed. Cir. 2020)

A jury found Verinata's patents valid and infringement. Claim 1 read: A method for determining a presence or absence of a fetal aneuploidy in a fetus for each of a plurality of maternal blood samples . . . comprising fetal and maternal cell-free genomic DNA, said method comprising:
(f) . . . determining the presence or absence of a fetal aneuploidy comprising using a number of enumerated sequence reads corresponding to the first chromosome and a number of enumerated sequence reads corresponding to the reference chromosome of (e).

The district court denied JMOL of invalidity and noninfringement.

Ariosa argued that there was no enablement because the patent fails to disclose an algorithm for determining the presence or absence of a fetal aneuploidy in the context of a targeted sequencing approach as claimed in claim 1, step (f).

The Federal Circuit affirmed; it is sufficient that statistical methods are known in the art.

F. *Pacific Coast v CertinTeed Gypsum*, 2020 U.S. App. LEXIS 20421 (Fed. Cir. 2020)

The district court held that Pacific Coast's claim was indefinite because there the claim recited a term that was not well known in the art and did not specifically indicate how to measure it. Pacific Coast's claim read: A laminated, sound-attenuating structure which comprises: a scored flexural strength of the laminated structure is about 22 pounds per 1/2 inch thickness of the structure; the scored flexural strength being the flexural Strength of the laminated structure after the outer, paper-clad surface of one of the first and second gypsum

boards has been scored. (Emphasis added)

The Federal Circuit affirmed:

> there are multiple ways to measure 'scored flexural strength' and that the specifications lack of guidance choosing which measurement to use renders claim 21 indefinite.

Id. at *2. A POSITA would not know the term "scored flexural strength" or how to measure it.

VI. "Error" and 35 U.S.C. §256

A. *Egenera, Inc. v. Cisco Sys.*, 2020 U.S. App. LEXIS 27447 (Fed. Cir. 2020)

Egenera sued Cisco for infringement and separately petitioned the USPTO to remove one of the eleven listed inventors from the patent. Removing the one inventor would facilitate swearing behind art raised in a related IPR.

After claim construction and a trial on inventorship (and after the IPR petition was denied on other grounds), Egenera asked the district court to add the removed inventor back to the patent.

The district court concluded that judicial estoppel prevented Egenera from relisting the inventor and held the patent invalid for failing to name all inventors.

The Federal Circuit vacated and remanded because judicial estoppel does not apply:

> [W]e disagree that a § 256 petition, without more, counts as "persuasion" of a court for judicial-estoppel purposes.

Id. at *27.

With respect to whether Egenera should be allowed to use §256 to correct inventorship, the Federal Circuit held "yes." "Our precedent provides that 'error' in §256 includes 'all varieties of mistakes—honest and dishonest'—rather than only unintentional inaccuracy. Indeed, § 256 is a savings provision, functioning to prevent invalidation when correction is available. It is the inequitable-conduct rules that provide a safety valve in the event of deceit." *Id.* at *19. This was not changed by the AIA removing the phrase "without deceptive intention" from § 256.

"§ 256 does not exclude 'considered acts,' or even 'deceptive intention,' from the meaning of error.' … 'Error' is simply the incorrect listing of inventors." *Id.* at *20-21.

VII. "By Another"

A. *Trans Ova Genetics, LC v. XY, LLC*, No. 2019-2312 (Fed. Cir. Sept. 8, 2020) Rule 36 affirmance of IPR2018-00250

XY's patent claims related to a method of producing a frozen-thawed, sorted artificial insemination sample. The inventors named on the XY patent challenged by Trans Ova were Lu, Cran, Seidel, and Suh. Trans Ova's IPR petition asserted references, including a Lu article. The Patent Owner maintained that Lu was not prior art because it was not "by another."

The Lu article listed authors as Lu, Cran, and Seidel and cited data from Green (unpublished) in a table. Green worked for UK bull stud COGENT. The FWD issued by PTAB in the IPR noted testimony that Green was a "lab technician" for COGENT. The patent specification includes the Green table from the Lu reference (without citation to Green) and incorporates by reference the Lu article.

In the FWD, PTAB concluded 2-1 that Trans Ova did not show the claims were unpatentable. PTAB concluded that the whole case turned on whether the Lu article was prior art. PTAB held that Trans Ova, the petitioner, did not establish that Lu was prior art. Green's contribution to the reference was insufficient for authorship. In considering authorship, PTAB also considered issues of inventorship: "The decision not to name Mr. Green as an inventor strongly suggested to PTAB that Mr. Green did not make an inventive contribution to Lu's Table 3." IPR 2018-00250, Paper 35, at 19. One judge filed a concurring opinion noting her dissent to the Institution Decision. She believed the IPR should not have been instituted because the issue of whether Mr. Green is an unattributed

coauthor of the Lu reference was not raised in the petition.

The Federal Circuit affirmed PTAB's FWD with a Rule 36 judgment. The press reported at the oral hearing that Judge Clevenger suggested to the parties that they did not want to actually find out Green's role in the patented method because if they found out, they "might get the wrong answer" and lose. And sure enough, one party, the petitioner bearing the burden, did lose.

Of interest, there were two independent claims, 1 and 16. It is possible that proving infringement of claim 1 might implicate the "single entity" theory of *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (en banc). Claim 16 may avoid that issue by use of "capable of fertilizing."

VIII. Claim construction

A. Preamble limiting?

1. *Bio-Rad Labs. v. 10X Genomics*, 967 F.3d 1353 (Fed. Cir. 2020)

In Bio-Rad, the claim with the preamble issue read: "[a] method for conducting a reaction in plugs in a microfluidic system, comprising the steps of:" (emphasis added). According to the district court, the preamble was not limiting but rather stated an intended use. This was despite that the term provided an antecedent basis for the terms "microfluidic system" and "reaction.

The Federal Circuit vacated and remanded. Under the correct construction, the claimed methods are limited to on-chip reactions. The district court erred in separating the antecedent basis for claim terms from the rest of the preamble. "Based on the antecedent relationship, it is clear the claim drafters intended to limit the claimed methods to on-chip reactions, using both the preamble and the body of the claim to define the claimed invention." *Id.* at __.

2. *Sanofi Mature IP v. Mylan Labs. Ltd.*, 757 Fed. Appx. 988 (Fed. Cir. Feb. 5, 2019)

This preamble case arose in the context of a motion to amend proposing substitute claims at PTAB. Sanofi's claim at issue read: "31. A method of increasing survival comprising administering to a patient in need thereof" (emphasis added). The PTAB construed the claim as not limited by the preamble. The preamble language only provided "additional description." *Id.* at *990. The PTAB denied Sanofi's motion.

The Federal Circuit vacated and remanded, finding the preamble limiting. The Federal Circuit relied on its case law, *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001) ("[a] method for treatment of sleep apneas") and *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) ("[a] method of treating or preventing macrocytic-megaloblastic anemia"). Further, "there is a direct link between the claim as a whole and the preamble, which provides an antecedent basis for 'in need thereof.'" *Id.* at 993.

B. *"About": Cobalt Boats v. Brunswick Corp.*, 773 Fed. Appx. 611 (Fed. Cir. 2019)[19]

At trial, a jury found that the defendant boat maker infringed one of two claims at issue in the plaintiff's 8,375,880 patent, which claims a retractable swim step "capable of being rotated 180 degrees." Brunswick appealed the 2017 jury verdict, which found that it had literally infringed the patent and awarded $2.7M to Cobalt.

Brunswick appealed to the Federal Circuit on the grounds that its swim step cannot rotate 180 degrees and therefore does not infringe Cobalt's patent. The district court during claim construction gave the "180 degrees" term its "[p]lain and ordinary meaning," noting "[n]o further construction is needed." There was no evidence at trial that any Brunswick step rotates 180 degrees or further, and in its briefs to the Federal Circuit, Brunswick repeatedly emphasized that no Brunswick step is capable of rotating 180 degrees. In response, Cobalt argued that a person having ordinary skill in the art would understand that 180 degrees is an "expression of flipping" rather than requirement of a rotation of exactly 180 degrees.

During oral argument on May 3, 2019, Brunswick argued that "capable of being rotated 180 degrees" does not

19. Summary is excerpt of Finnegan blog, "Conjunctively Disjunctive," Adriana L. Burgy, Amanda K. Murphy, Ph.D., Kaitlyn Pehrson, Stacy Lewis, Thomas L. Irving https://www.finnegan.com/en/insights/blogs/prosecution-first/conjunctively-disjunctive.html, May 30, 2019.

mean "about 180 degrees," and that rotating less than 180 degrees "doesn't meet the claim limitation." The Court seemed to be sympathetic to Brunswick's position, asking Cobalt why it was not more specific in the claim construction. "If you wanted 180 degrees to mean about 180 degrees, why didn't you say that?" Judge Dyk queried. In response, Cobalt conceded that it could have worded the claim construction better.

The Federal Circuit ultimately agreed with Brunswick and reversed the district court, explaining its decision as follows:

> Where the claim recites a precise value without a qualifier such as "about," the claim language imposes a strict numerical boundary, unless there is evidence that such a construction would be inconsistent with the intrinsic evidence (i.e., the specification and prosecution history). The Federal Circuit cited the following prior cases that applied this rule:
>
> *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1381 (Fed. Cir. 2000). In this case, the Federal Circuit construed a claim that recited precise ranges for the weight of dental compositions as being limited to exactly those ranges. The Federal Circuit held that [w]ithout broadening words that ordinarily receive some leeway, such as about, the precise weight ranges of claim 1 do not 'avoid a strict numerical boundary to the specified parameter, (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)).
>
> *Elekta Instrument S.A. v. O.U.R. Scientific International, Inc.*, 214 F.3d 1302, 1307–08 (Fed. Cir. 2000). In this case, the Federal Circuit held that a claim term reciting radiation sources and beam channels only within a zone extending between latitudes 30°–45° encompasses only 30°–45°, not anything less than 30 degrees.

The Federal Circuit examined the intrinsic evidence to see if it suggested anything other than a precise value. It found no such suggestion. To the contrary, it found that the 180 degrees limitation was added during prosecution to distinguish prior art swim steps that were only capable of rotating less than 180 degrees. Consequently, Cobalt was barred by prosecution history estoppel from asserting that Brunswick's swim step satisfied the 180 degrees limitation under the doctrine of equivalents. See Cobalt, 773 F.3d Appx. at 619.

C. *Claim reciting steps: Amgen, Inc. v. Sandoz, Inc.*, 923 F.3d 1023 (Fed. Cir. 2019)

See summary at Section III, A.

D. *Specification as guide: E.I. duPont v. Unifrax*, 921 F.3d 1060 (Fed. Cir. 2019)

The claim limitation at issue was "100% by weight." The district court adopted DuPont's proposed construction that "100% by weight" means "[t]here is no carrier material such as resin, adhesive, cloth or paper in addition to the inorganic platelets. There may be some residual dispersant arising from incomplete drying of the platelet dispersion." Under this construction, "100% by weight" permitted some residual dispersant. Unifrax had proposed that "100% by weight" be given its "[p]lain meaning—no construction is necessary."
A jury found that Unifrax's accused product infringed the asserted patent and that Unifrax failed to prove the asserted patent was invalid. The district court denied JMOL.

The Federal Circuit affirmed the claim construction based on the specification of the patent at issue and familial patents.

E. *Consistent use: Techtronic Indus. Co. v. ITC*, 944 F.3d 901 (Fed. Cir. 2019)

Repeatedly describing the subject matter of the invention in a single way may lead to a narrow claim construction. In *Techtronic Indus. Co. v. ITC*, the Federal Circuit construed the claim narrowly based on the specification (including the background and abstract sections):

> because the specification, in each of its sections, discloses as the invention a garage door opener improved by moving the passive infrared detector from the head unit to the wall console. It is axiomatic that, where the specification "describes 'the present invention' as having [a] feature," that representation may disavow contrary embodiments. The '319 patent, by consistently representing the invention as the placement of the detector in the wall console, has thus effected a disavowal of alternative locations.

Id. at 907-908. The Federal Circuit reversed the infringement holding because the ITC erred in its claim construction.

The limitation at issue was "wall console," which the administrative law judge (ALJ) acknowledged would generally mean a "wall-mounted control unit," but in this case found that the patent holder had disavowed wall consoles lacking a passive infrared detector. The ITC did not adopt the ALJ's construction, and instead construed wall console without the restriction to only those with a passive infrared detector.

The Federal Circuit agreed with the ALJ. The specification discloses the invention as a garage door opener improved by moving the passive infrared detector to the wall console. "The 319 patent, by consistently representing the invention as the placement of the detector in the wall console, has thus effected a disavowal of alternative locations." *Id.* at 908. "The entire specification focuses on enabling placement of the passive infrared detector in the wall console, which is both responsive to the prior art deficiency the 319 patent identifies and repeatedly set forth as the objective of the invention. Thus, the 319 patent disavows locating the detector elsewhere, even without an express concession to that effect." *Id.* at 909.

IX. Inequitable conduct/Supplemental Examination

A. *GS CleanTech Corp. v. Adkins Energy LLC*, 951 F.3d 1310 (Fed. Cir. 2020), reh'g denied (2020)[20]

In *GS Cleantech Corp. v. Adkins Energy LLC*, the U.S. Court of Appeals for the Federal Circuit (Judges Reyna, Wallach, and Hughes) affirmed the District Court's ruling that CleanTech's Patents-in-Suit are unenforceable due to inequitable conduct by the inventors and CleanTech's attorneys. CleanTech subsequently filed a petition at the Federal Circuit for rehearing en banc, but the petition was denied.

Starting in 2009 and continuing through 2014, GS CleanTech Corporation and Greenshift Corporation (together, "CleanTech") filed lawsuits against a number of parties, including Adkins Energy, LLC (Adkins), for infringing CleanTech's patents covering an oil recovery system. The disputed patents include U.S. Patent No. 7,601,858, No. 8,008,516, No. 8,008,517, and No. 8,283,484 (together, "Patents-in-Suit") and share a common specification. The Patents-in-Suit are directed to the recovery of oil from a dry mill ethanol plant's byproduct, called thin stillage.

Multitudinous actions were subsequently combined into a multidistrict litigation case. In 2013, both CleanTech and Adkins moved for summary judgement, and in response, the District Court found that the Patents-in-Suit were invalid because of the on-sale bar. Following the summary judgment determinations, the District Court held an inequitable conduct bench trial. Subsequently, the District Court ruled that the Patents-in-Suits were unenforceable due to inequitable conduct of the inventors and CleanTech's attorneys. CleanTech appealed the District Court's decision to the Federal Circuit, and the Federal Circuit affirmed.

During prosecution, CleanTech transferred its prosecution cases to the Cantor Colburn law firm. A relevant factual history during the prosecution of the Patents-in-Suit is as follows:

July 2005: Dorisio provided the Inventors with a draft clearance opinion to allow the inventors to swear behind Prevost, filed on July 15, 2003, based on his understanding that the Inventors had reduced the invention to practice in June 2003.

March 2008: the prosecution case is transferred from Dorisio to the law firm of Cantor Colburn LLP ("Cantor Colburn").

May 2009: A potential investor in CleanTech conducted due diligence and sought information on the company's pending patent application, including pre-filing offers for sale, but the Inventors denied having such information, notwithstanding that an inventor had retained a signed version of the July 2003 proposal in his home files.

March 2010: An inventor provided Cantor Colburn with a signed copy of the July 2003 Proposal.
June 2010: Cantor Colburn submitted an Information Disclosure Statement ("IDS") to the USPTO, attaching the

20. Summary is excerpt of Finnegan blog, "The Defense of Inequitable Conduct Is Alive and Is to Be Avoided, Kyu Yun Kim, Stacy Lewis, Thomas L. Irving, https://www.finnegan.com/en/insights/blogs/prosecution-first/the-defense-of-inequitable-conduct-is-alive-and-is-to-be-avoided.html, July 13, 2020.

July 2003 Proposal, alleging that July 2003 Proposal was irrelevant because the patented method was "never disclosed, carried out, or performed" more than one year before the filing date.

June 2010: An inventor, made an "unannounced" trip to Agri-Energy and offered to provide them with a royalty-free license for CleanTech's ethanol oil recovery system, which Agri-Energy refused. An employee at Agri-Energy testified that he felt that the royalty offer was a quid pro quo to get Agri-Energy to admit the patent was valid.

July 2010: Cantor Colburn sent Agri-Energy a letter, asking Agri-Energy to confirm certain facts, including that the diagrams for the proposed system in 2003 was for testing purposes. Agri-Energy refused to confirm because it believed most of the facts to be "untrue."

November 2010: Cantor Colburn filed its First Declaration to the USPTO, attaching a copy of the July 2003 Proposal. The declaration explained that an applicant had hand delivered the July 2003 Proposal to Agri-Energy on August 18, 2003 and thus, the July 2003 Proposal did not violate the on-sale bar, as it occurred less than a year before the application filing date.

July 2012: Cantor Colburn filed its Second Declaration to the USPTO, stating that an inventor had "forgotten about sending the August 2003 Email," but failing to provide any retractions of the false information set forth in the First Declaration or any explanations of the significance of the August 2003 Email as it related to a pre-critical date offer for sale.

The District Court determined that "[the inventors] took affirmative steps to hide [the July/August 2003 offers] from their lawyers, then later from the USPTO when they learned that it would prevent them from profiting from the Patents-in-Suit." *Id.*

The District Court additionally concluded that Cantor Colburn either purposefully evaded disclosing to the USPTO or failed to seek out relevant information to disclose to the USPTO and so participated in the inequitable conduct, "choosing advocacy over candor." *Id.* The District Court explained that Cantor Colburn never asked the inventors key questions, and Cantor Colburn's focus on "pre-critical date documents" was purposefully and improperly narrow, thereby ignoring "the red flags waving before them." *Id.*

The Federal Circuit explained five reasons that the District Court's determination that CleanTech and Cantor Colburn committed inequitable conduct was correct.

- The record supported the District Court's conclusion that CleanTech knew the July 2003 Proposal to Agri-Energy threatened its chances of patenting its ethanol oil recovery method. *Id.* at 1329 (emphasis added). The Federal Circuit noted that in February 2001, the inventors sought information from the USPTO website about the on-sale bar and days later, Dorisio, the inventors' initial patent attorney, informed the inventors about the on-sale bar. *Id.*
- The record showed that the inventors and the attorneys at Cantor Colburn withheld evidence of successful testing in 2003 and made false representations by implying that the invention was not reduced to practice until 2004. *Id.* The Federal Circuit explained that Cantor Colburn possessed the Ethanol Oil Recovery System Diagram and the test reports themselves, but Cantor Colburn did not provide them to the USPTO during the prosecution and referenced them only to assert that the claimed invention predates Prevost, a cited prior art document. *Id.*
- Sufficient evidence supported the District Court's determination that CleanTech and Cantor Colburn threatened Agri-Energy "to coerce its support regarding the critical date for the Patents-in-Suit, after the July 2003 Proposal surfaced and during the pendency of the '516 and '517 patents." *Id.* at 1330. Specifically, the Federal Circuit noted that an inventor traveled to Agri-Energy and "offered Agri-Energy a royalty-free license in exchange for Agri-Energy's willingness to admit that the pending patents were valid." *Id.* Also, Cantor Colburn sent Agri-Energy an email, "requesting a statement 'confirming and clarifying' certain facts relating to the offer." *Id.*
- The record supported the finding that the inventors and Cantor Colburn made a "patently false" statement in the First Declaration filed in November 2010, by claiming the July 2003 Proposal was delivered to Agri-Energy after the critical date. *Id.* The attorneys at Cantor Colburn testified that they themselves were skeptical of the claim but still filed the First Declaration. *Id.* The Federal Circuit also noted that Cantor Colburn possessed the June and July 2003 Tests and Report and the Ethanol Oil Recovery System Diagram since September 2008. *Id.*

- It was not an abuse of its discretion for the District Court to find that Cantor Colburn's failure to correct the false First Declaration was "strong evidence of intentional deceit." *Id.* at 1331. In a September 2011 deposition, Cantor Colburn "kn[e]w for certain" that the First Declaration was false, but it made no correction at the USPTO. *Id.* Moreover, the Second Declaration provided the USPTO with "the false impression" that the unsigned letter had less significance than the signed one and failed to distinctly point out and/or explain the false information previously provided to the examiner. *Id.*; see also, e.g., *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983).

Based on these reasons, the Federal Circuit concluded that the District Court did not abuse its discretion in concluding that the inventors and Cantor Colburn intended to deceive the USPTO. *Id.*

After the Federal Court issued the decision on March 2, 2020, CleanTech filed a petition for en banc rehearing on April 15, 2020, in which it argued that the panel wrongly determined the Patents-in-Suits unenforceable due to inequitable conduct at the USPTO during prosecution by the inventors and their attorneys. On June 30, 2020, in a nonprecedential order, the Federal Circuit per curiam denied the petition rehearing en banc.

B. Supplemental Examination[21]

The America Invents Act ("AIA") created a new route to access ex parte reexamination. It is called supplemental examination ("SE") and is meant to offer patent owners a possible means of purging a potential inequitable conduct problem discovered after issuance (but before litigation). Before AIA, purging the taint of inequitable conduct in the procurement of the original patent grant was tightly circumscribed by the requirements set forth in *Rohm & Haas Co. v. Crystal Chemical Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983).

SE may provide an alternative tool to purge inequitable conduct.[22] The exact outlines of SE have not yet been tested in court.

In an SE request, a patent owner may request SE of a patent in the USPTO to consider, reconsider, or correct information believed to be "relevant" to the patent.[23] According to the rules, there is a limit of 12 items per SE, but no limit on the number of SE requests that can be filed and no limit on the number of items of information that may be submitted in a subsequent reexamination, if ordered.[24]

The incentive to the patentee to use SE is that the patentee is insulated in subsequent litigation from inequitable conduct allegations for claims that are patentable after the USPTO considers and/or reconsiders the submitted information and/or corrected information:

> §257(c) EFFECT. —
>
> (1) IN GENERAL.—A patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent. The making of a request under subsection (a), or the absence thereof, shall not be relevant to enforceability of the patent under section 282.[25]

SE apparently provides a means for the patentee to clear up possible problems prior to litigation. According to the statute, the information that can be placed before the USPTO in an SE is not constrained by any materiality standard; it does not even require an averment that the information is relevant to patentability. All that is

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21. For articles on and related to supplemental examination, see AIA Supplemental Examination Nuts and Bolts: Get it in your toolbox and don't leave home without it!" https://www.finnegan.com/en/insights/blogs/america-invents-act/aia-supplemental-examination-nuts-and-bolts-get-it-in-your-toolbox-and-dont-leave-home-without-it.html ; "A Tale of Two Supplemental Examinations: Part 1: Unraveling Confusion," https://www.finnegan.com/en/insights/blogs/america-invents-act/a-tale-of-two-supplemental-examinations-part-1-unraveling-confusion.html ; "A Tale of Two Supplemental Examinations, Part II: Surprising Events When Citing Art That, but for a Clerical Error, Would Have Been Cited During Original Prosecution," https://www.finnegan.com/en/insights/blogs/america-invents-act/a-tale-of-two-supplemental-examinations-part-ii-surprising-events-when-citing-art-that-but-for-a-clerical-error-would-have-been-cited-during-original-prosecution.html ; "Supplemental Examinations and Alice: The Bare Essentials of When Not to Poke the Bear," https://www.finnegan.com/en/insights/blogs/america-invents-act/supplemental-examinations-and-alice-the-bare-essentials-of-when-not-to-poke-the-bear.html; "In Supplemental Examination, Discretion Is the Better Part of Valor," https://www.finnegan.com/en/insights/blogs/america-invents-act/in-supplemental-examination-discretion-is-the-better-part-of-valor.html; "The Defense of Inequitable Conduct Is Alive and Is to Be Avoided," https://www.finnegan.com/en/insights/blogs/prosecution-first/the-defense-of-inequitable-conduct-is-alive-and-is-to-be-avoided.html

required is that the information coming before the USPTO is believed to be relevant, which presumably is a subjective standard based on the patent owner's belief.

In fact, §257(c) decrees that making or not making such a request shall not be relevant to enforceability of the patent. And, as the standard for submission is relevance, the submission should in no way be characterized as an admission of materiality to patentability.[26]

The SE procedure is available for any patent issued before, on, or after September 16, 2012. Once a request for supplemental examination is made, the USPTO has three months to determine whether or not the request raises a substantial new question of patentability (SNQ).[27] If there is no SNQ, the patent owner obtains all the benefit of §257(c) on the items of information submitted and does not need to undergo reexamination. One would think that the patent owner now has extra protection of its claims. See, e.g., 96,000,312.

If an SNQ if found, the Director orders an ex parte reexamination. Any claim surviving reexam, whether in original, new, or amended form, should obtain the protection of §257(c). Interestingly, there is no requirement in §257 to limit the information submitted to patents or printed publications. Hence, new §257 apparently broadens the scope of reexamination beyond what is allowed under traditional ex parte reexamination practice. The rules take this into account in 37 C.F.R. §1.625(d). While no amendment is allowed in the SE proceeding (37 C.F.R. § 1.620(f)), if a reexamination is instituted, at least narrowing amendments may be submitted. See 37 C.F.R. §1.625(d) referring to 37 C.F.R. §§1.530 to 1.570.

There are limitations. For example, the protection afforded to information disclosed in an SE request does not apply against allegations already raised in district court or in an ANDA paragraph IV notice prior to the filing of the request for SE.[28] There will also be no protection against any defenses raised in ITC litigation/district court litigation unless the SE request and any ex parte reexamination ordered there from is finished before the date on which the action is brought.[29]

That second limitation (35 U.S.C. §257(c)(2)(B)) requires a patent owner to think carefully about the timing of any effort at SE if there is a desire to enforce the patent in the foreseeable future. If there is no reexamination ordered then there is a statutory deadline of three months for the termination of the proceeding. However, a re-examination may necessitate taking an appeal to the Federal Circuit to get the patent out of reexamination with claims that can be enforced. Thus, it may mean delaying any effort to enforce the patent for one or more years, which could be problematical for certain patentees.

Further, even if the reexamination is successful, §257(f) cheerfully provides:

> §257(f): Nothing in this section shall be construed—
> to preclude the imposition of sanctions based upon criminal or antitrust laws (including section 1001(a) of title 18, the first section of the Clayton Act, and section 5 of the Federal Trade Commission Act to the extent that section relates to unfair methods of competition);
>
> to limit the authority of the Director to investigate issues of possible misconduct and impose sanctions for misconduct in connection with matters or proceedings before the Office; or
>
> to limit the authority of the Director to promulgate regulations under chapter 3 relating to sanctions for misconduct by representatives practicing before the Office.

And Congress also included new §257(e):

> (e) FRAUD.—If the Director becomes aware, during the course of a supplemental examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have

22. AIA SEC. 12, 125 STAT. 325.
23. 35 U.S.C. §257.
24. 37 C.F.R. § 1.605(a): "Each request for supplemental examination may include no more than twelve items of information believed to be relevant to the patent. More than one request for supplemental examination of the same patent may be filed at any time during the period of enforceability of the patent."
25. 125 STAT. 326.
26. 125 STAT. 326.
27. 35 U.S.C. §257(a) and 37 C.F.R. §1.620.
28. 35 U.S.C. §257(c)(2)(A).
29. 35 U.S.C. §257(c)(2)(B).

> been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate.[30]

It is not clear what is "fraud" and what investigation is needed. So far, there has not been any action under or elucidation of §257(e) or (f).

SE has steep fees. As of Oct. 2, 2020, a request costs $4620 and if a reexamination is ordered, there is an additional fee of an additional $12,700.[31]

The grant rate 72% (167/231) for Fy2014-FY2019 so far on finding a substantial new question of patentability and ordering a reexamination. In other words, 72% is the overall rate at which the USPTO is finding a SNQ in requests for SE supplemental examination. is.[32]

Based on the USPTO Annual Reports, the annual average for Supplemental Exam requests filed is 43 (FY2014-FY2019). Of these, half are labeled by the USPTO as "electrical" (128/258), 22% "mechanical" (56/258), 27% "chemical" (70/258), and 1% design (4/258).[33]

Looking at what types of information patent owners are submitting, over 2/3 of the information is U.S. and foreign patents and patent applications. About 15% is made up of webpages, posters, videos, brochures, manuals, drawings, and presentations. 2% is made up of district court and PTAB litigation documents and 1% is case law and statutes.[34] This last category is basically related to a spate of SE requests patent owners filed trying to get their claims "blessed" by the Patent Office under 35 U.S.C. §101 post-Alice.

When a SNQ is found and reexam ordered and a reexam certificate issued, 69% of the time the claims are changed (new or amended). This is similar to the outcome in conventional ex parte reexams (67%). In 12% of reexams ordered subsequent to SE requests, all claims are confirmed and in 15% all claims are canceled. In the final 4%, there is at least one confirmed claim and at least one canceled claim but no new or amended claims.[35]

SE may be a valuable tool for patent owners who discover possible issues when assessing the enforceability of their patents. It is also a consideration in a due diligence investigation when reviewing the portfolio of a target. In such an investigation, Is there an issue? Is SE an option?

As discussed, SE may be of particular interest to those holding Orange Book listed patents. Owners of Orange Book listed patent may be able to make reasonably accurate predictions of when they will receive patent validity challenges and therefore may be well-suited to submit a SE request before the patents become involved in a litigation.

It is important to remember that although the items of information submitted with a SE request cannot be the basis for an inequitable conduct allegation later, SE is a proceeding before the Patent Office and as such, Rule 56 applies. Therefore, conduct during a SE request (and subsequent reexamination if ordered) may be the basis for a later allegation of inequitable conduct.

XI. Single Entity Requirement Under 35 U.S.C. § 271(a-b) Does Not apply to 35 U.S.C. § 271 (g)

A. *Syngenta Crop Prot., LLC v. Willowood, LLC*, 944 F.3d 1344 (Fed. Cir. 2019), pet. for cert. filed, Mar. 17, 2020

35 U.S.C. §271(g) prohibits importation into the U.S. of a product made by a process patented in the U.S. Willowood China purchased the fungicide azoxystrobin from its Chinese supplier, Yang-cheng Tai He Chemicals Corp. ("Tai He"), and sold it (f.o.b. China) to Willowood USA, which then imported the azoxystrobin into the United States.

30. See 37 C.F.R. §1.620(g).
31. 85 Fed. Reg. 46,932 (Aug. 3, 2020).
32. Source: USPTO Annual Reports, Table 13B.
33. Source: USPTO Annual Reports, Table 13B.
34. Source: USPTO Annual Reports, Table 13B.
35. Source: Finnegan research using USPTO PAIR on 294 supplemental exam requests as of Sept. 2, 2020.

The azoxystrobin was manufactured in China by performing both steps of the claimed process.

The district court held that neither Willowood USA nor Willowood China infringed Syngenta's patent under § 271(g) because § 271(g) requires every step of a claimed process to be performed by or attributable to a single entity. This comes from the "single entity" theory of *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 797 F.3d 1020 (Fed. Cir. 2015) (en banc)

The Federal Circuit reversed for Willowood USA and affirmed for Willowood China; holding that § 271(g) does not require a single entity to perform all of the steps of a patented process for infringement liability to arise.

In contrast to § 271(a), infringement liability under § 271(g) is all about importation and is not predicated on practicing a patented process abroad:

[T]he focus [of 271(g)] is only on acts with respect to products resulting from the patented process. Thus, because the statutory language as a whole is clear that practicing a patented process abroad cannot create liability under § 271(g), whether that process is practiced by a single entity is immaterial to the infringement analysis under that section.

Id. at __.

Willowood USA imported into the United States an azoxystrobin compound that was manufactured abroad using the patented process. Willowood China (f.o.b. China) did not import into the United States or sell or offer for sale in the United States the azoxystrobin compound at issue.

Of interest in this case is that the patent owner claimed copyright violation by the alleged infringer's label. The district court dismissed the claim, but the Federal Circuit said the merits of the claim must be considered.

In this case, the label was not on a pharmaceutical product but on a fungicide. A "me-too" pesticide producer must be making a product similar to a registered product, but the label is not required to be identical. This is in contrast to pharmaceutical products, where the generic manufacturer is generally required by law to use the same labeling as the approved product. *Id.* at __. "On remand, the district court should first discern whether the Copyright Act, as interpreted under existing copyright doctrines, would prohibit Willowood's use of any portion of Syngenta's label." *Id.* at __.