Precedential Patent Case Decisions During February 2019

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I. Introduction

This paper abstracts what I believe to be the significant new points of law from the precedential decisions in patent cases this month. Cases captions relating to the PTAB are in **red** text. Case captions of extraordinary importance are in **blue** text.

II. Abstracts and New Points of Law

University of Florida Research Foundation, Inc. v. General Electric Company, 2018-1284 (Fed. Cir. 2/26/2019).

This is a decision on an appeal from the S.D. Fla. case 1:17-cv-00171-MW-GRJ. The district court granted General Electric (GE)'s FRCP 12b(6) motion to dismiss on the ground that the patent claimed ineligible subject matter. Florida appealed. The Federal Circuit affirmed.

Legal issue: Eleventh Amendment of the constitution, sovereign immunity, whether a subject matter eligibility challenge is defense to a claim of infringement, thereby constituting waiver of sovereign immunity.

The Federal Circuit concluded subject matter eligibility challenge is defense to a claim of infringement, thereby constituting waiver of sovereign immunity.

> The Eleventh Amendment provides that: "The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State . . . ." U.S. Const. amend. XI. " [A] state waives its Eleventh Amendment immunity when it consents to federal court jurisdiction by voluntarily appearing in federal court," as UFRF has here. *Regents of the Univ. of N.M. v . Knight*, 321 F.3d 1111, 1124 (Fed. Cir. 2003) (citing *Clark v. Bernard*, 108 U.S. 436, 447 (1883)); *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1564–65 (Fed. Cir. 1997) ("[T]he Eleventh Amendment applies to suits 'against' a state, not suits by a state."). That waiver extends "not only to the cause of action but also to any relevant defenses and counterclaims." *Vas-Cath, Inc. v. Curators of Univ. of Mo.*, 473 F.3d 1376, 1381 (Fed. Cir. 2007). The parties agree that here there are no counter-claims. At issue, then, is whether GE's § 101 eligibility challenge is a defense to UFRF's claim of infringement. We hold that it is. [University of Florida Research Foundation, Inc. v. General Electric Company, 2018-1284 (Fed. Cir. 2/26/2019).]

> Even if § 282 did not extend to a § 101 eligibility challenge, such a challenge would still be a defense to a claim of infringement. [1] We and the Supreme Court have long treated § 101 eligibility as a "condition[] of patentability" alongside §§ 102 and 103. *See, e.g., Graham v. John Deere Co.*,

383 U.S. 1, 12 (1966) ("The Act sets out the conditions of patentability in three sections . . . novelty and utility as articulated and defined in § 101 and § 102, and nonobviousness . . . as set out in § 103."); *Versata Dev. Gr., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1330 (Fed. Cir. 2015) ("It would require a hyper-technical adherence to form rather than an understanding of substance to arrive at a conclusion that § 101 is not a ground available to test patents."); *Aristocrat Techs. Austl. PTY Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir. 2008) ("It has long been understood that the Patent Act sets out the conditions for patentability in three sections: sections 101, 102, and 103."). And we and he Supreme Court have entertained § 101 eligibility challenges brought to defend against claims of infringement. *See, e.g., Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75-76 (2012); *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1368 (Fed. Cir. 2011); *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 862 (Fed. Cir. 2010). We see no reason to depart from this practice now. [University of Florida Research Foundation, Inc. v. General Electric Company, 2018-1284 (Fed. Cir. 2/26/2019).]

In sum, we hold that a § 101 eligibility challenge is a defense to a claim of infringement. By bringing its claim of infringement, UFRF waived its sovereign immunity "not only [as] to the cause of action but also [as] to any relevant defenses," *Vas-Cath*,473 F.3d at 1381. Because GE's § 101 eligibility challenge is a defense to UFRF's claim, UFRF has waived sovereign immunity as to GE's § 101 eligibility challenge. The district court had subject matter jurisdiction to hear that challenge. [University of Florida Research Foundation, Inc. v. General Electric Company, 2018-1284 (Fed. Cir. 2/26/2019).]

CODA Development S.R.O. v. Goodyear Tire & Rubber Company, 2018-1028 (Fed. Cir. 2/22/2019).

This is a decision on an appeal from the N.D. Ohio district court case 5:15-cv-01572-SL. CODA sued Goodyear for patent inventorship correction. The district court dismissed the complaint for failure to state a claim. CODA appealed. The Federal Circuit vacated and remanded.

Legal issue: FRCP 12(b)(6), sufficiency of the complaint, plausibility requirement.

This opinion indicates that district court committed multiple procedural errors, including the consideration of material outside the pleadings and taking judicial notice of contested facts, leading to its incorrect result.

Accepting the complaint's well pleaded factual allegations as true and drawing all reasonable inferences in Plaintiffs' favor, we conclude that Plaintiffs' claims for correction of inventorship are plausible. *** The "plausibility standard is not akin to a 'probability requirement.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 556). Rather, Plaintiffs need only "nudge[] their claims across the line from conceivable to plausible." *See Twombly*, 550 U.S. at 570.

Under these circumstances, we conclude that Plaintiffs have done so as to their correction of inventorship claims. [CODA Development S.R.O. v. Goodyear Tire & Rubber Company, 2018-1028 (Fed. Cir. 2/22/2019).]

The district court's contrary conclusion rested largely on a procedural error—namely, the consideration of material outside the pleadings. The principle is familiar: ["] Assessment of the facial sufficiency of the complaint must ordinarily be undertaken without resort to matters outside the pleadings. If a court does consider material outside the pleadings, the motion to dismiss must be treated as a motion for summary judgment under Rule 56 and all parties must be given a reasonable opportunity to present all material pertinent to the motion. ["] *Gavitt v. Born*, 835 F.3d 623, 640 (6th Cir. 2016) (citation omitted); see Fed. R. Civ. P. 12(d) (stating similarly); 5C Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1366 (3d ed. 2018) ("Once the district court decides to accept matters outside of the pleadings, the presence of the word 'must' [in Rule 12(d)] indicates that the judge must convert the motion to dismiss into one for summary judgment . . . . [T]hat is what has been done in a vast array of cases, especially when the district court actually considers the contents of this material in deciding the motion."). [CODA Development S.R.O. v. Goodyear Tire & Rubber Company, 2018-1028 (Fed. Cir. 2/22/2019).]

Although a district court may consider judicially noticeable matters outside the pleadings without converting a Rule 12(b)(6) motion into one for summary judgment, *see Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999), overruled on other grounds by *Swierkiewicz v. Sorema N. A.*, 534 U.S. 506 (2002), judicially noticeable facts must "not [be] subject to reasonable dispute," see Fed. R. Evid. 201(b). Here, the district court used the Hrabal article to "determine whether it was a 2008 public disclosure of something Coda now claims was secret when disclosed to Goodyear in 2009." Dismissal Opinion, 2016 WL 5463058, at *2; see J.A. 24–25 (concluding that the article publicly disclosed each element of the alleged trade secrets). But whether the Hrabal article actually disclosed those alleged novel trade secrets was a reasonably (indeed, hotly) disputed factual issue—one outside any judicial notice exception to the general rule requiring conversion, and one that should not have been resolved adversely to Plaintiffs on a motion to dismiss. The district court erred in considering the Hrabal article for this purpose without converting Defendants' motion to dismiss into one for summary judgment and giving Plaintiffs a reasonable opportunity to present all pertinent material. [CODA Development S.R.O. v. Goodyear Tire & Rubber Company, 2018-1028 (Fed. Cir. 2/22/2019).]

Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).

This is a decision on appeals from PTAB cases IPR2016-00297; IPR2016-01386; and

IPR2016-01409; the N.D.W. Va. district court case 1:15-cv-00109-IMK; and the D.N.J. district court cases 2:15-cv-08180-SRC-CLW; 2:15-cv-08353-SRC-CLW; 2:16-cv-00035-SRC-CLW, 2:16-cv-00889-SRC-CLW; and 2:17-cv-06714-SRC-CLW.

Legal issue: Model Rule of Professional Conduct 1.7(a), concurrent conflict of interest; conflicts defined by engagement contracts and interrelated corporate entities.

The Federal Circuit concluded that the law firm, Katten Muchin Rosenman LLP, was in violation of the rule after applying the "total context" test. The "total context" included Katten's general engagement agreement with Bausch & Lomb, and entity affiliated with the movant entities. That agreement precluded Katten from representations against affiliates, parents, and subsidiaries, of Bausch & Lomb.

The Federal Circuit identified the parent, subsidiary and affiliate relationships of the movants.

> The parties relevant to the motions to disqualify include, Valeant-CA1, Valeant Pharmaceuticals International ("Valeant-DE"), Salix, and Bausch & Lomb. Valeant-CA, a Canadian corporation and the movant in Valeant II and Dr. Falk II, is the ultimate parent of these entities. Specifically, Salix—a movant in all three appeals—is a wholly-owned subsidiary of Salix Pharmaceuticals, Limited, which is a wholly-owned subsidiary of Valeant-DE, which is an indirect, wholly-owned subsidiary of Valeant-CA. Bausch & Lomb is also an indirect subsidiary of Valeant-CA and an affiliate of the above-listed entities. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit identified the scope of Katten's representation of Bausch and Lomb.

> Valeant-CA contends that it has been a longstanding client of Katten, both directly and through its subsidiaries. Specifically, movants allege that a concurrent conflict arises in all three appeals from Katten's ongoing representation of Bausch & Lomb in a trademark matter regarding the mark MOISTURE EYES. [2] A partner in Katten's Chicago office has been representing Bausch & Lomb since 2001. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit summarized the relevant terms of the engagement agreement between Katten and Valeant-CA that Katten signed in the course of representing Bausch & Lomb.

> In the course of representing Bausch & Lomb, Katten signed a general engagement letter "governing the overall relationship between [Katten] and Valeant Pharmaceuticals International, Inc."—i.e., Valeant-CA. Gorman Decl. Ex. A, at 1. This engagement letter incorporates by reference Valeant's Outside Counsel Guidelines ("OC Guide-lines" or "Annex 1"). Section 1.1 of the OC Guidelines states that "[t]hese guidelines will govern the relationship between

Valeant Pharmaceuticals International[, i.e. Valeant-DE], its subsidiaries and affiliates. . . and outside counsel." Gorman Decl. Ex. A, at § 1.1. The terms of the OC Guidelines also require that Katten complete a conflict check "before representation of [Valeant-DE and its subsidiaries and affiliates] commences." Gorman Decl. Ex. A, at § 1.2. The terms further state that "[a]ny conflict of interest that is discovered in such a check or that develops during an ongoing representation can only be approved, waived or otherwise cleared by the written agreement of the Valeant General Counsel." Gorman Decl. Ex. A, at § 1.2. The OC Guidelines do not define "conflict of interest," but state that "Valeant expects its firms to adhere to local rules and ethics rules relating to conflict of interest and client representation." Gorman Decl. Ex. A, at § 1.2. *** Salix and Valeant-CA contend, and Mylan does not dispute, that the engagement letter, including the OC Guidelines, remains active under this provision. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit identified the applicable law.

We apply regional circuit law to disqualification matters. *Celgard, LLC v. LG Chem, Ltd.*, 594 F. App'x 669, 671 (Fed. Cir. 2014); *accord Atasi Corp. v. Seagate Tech.*, 847 F.2d 826, 829 (Fed. Cir. 1988). The relevant regional circuits in all three appeals apply the Model Rules of Professional Conduct. [3] Thus, all three motions allege violations of the same rule—Rule 1.7(a) of the Model Rules of Professional Conduct—which states: a lawyer shall not represent a client if the representation involves a concurrent conflict of interest. A concurrent conflict of interest exists if:(1) the representation of one client will be directly adverse to another client . . . . [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit identified their test for violation of model rule 1.7(a):

When applying this rule, we look to "the total context, and not whether a party is named in a lawsuit," to assess "whether the adversity is sufficient to warrant disqualification." *Celgard*, 594 F. App'x at 672*; see also Freedom Wireless, Inc. v. Bos. Commc'ns Grp., Inc.*, No. 2006-1020, 2006 WL 8071423, at *2 (Fed. Cir. Mar. 20, 2006) ("The parties debate whether Freedom Wireless and Nextel are 'directly adverse' in these circumstances, where Nextel was not a named party to the initial lawsuit. We conclude, on the facts of the case, that the parties are directly adverse for purposes of analyzing a conflict of interest and determining the need for disqualification."). *** Circumstances in which an affiliate is considered a client of a lawyer can arise by express agreement or when affiliates are so interrelated that representation of one constitutes representation of

all. *GSI Commerce Sols., Inc. v. BabyCenter, LLC*, 618 F.3d 204, 210–12 (2d Cir. 2010) (finding that client and client's corporate affiliate were so interrelated such that "representation adverse to a client's corporate affiliate implicate[d] the duty of loyalty owed to the client"). [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit concluded that Katten was in violation of model rule 1.7(a), and explained its reasoning.

> Katten's representation of Mylan adverse to Valeant-CA and Salix in Valeant II and its ongoing representation of Bausch & Lomb, an affiliate of movants, presents a concurrent conflict of interest in violation of Rule 1.7. This is true even though movants are affiliates of Bausch & Lomb because the terms of the engagement letter and movants' demonstration of interrelatedness between the various Valeant affiliates presents circumstances such that movants should also be considered a client of Katten. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit found a concurrent conflict as a result of the engagement agreement extending to the movants.

> Because the engagement letter creates an ongoing attorney-client relationship between the law firm, Katten, and its organizational clients, Valeant-CA and Salix, Katten's representation of Mylan adverse to movants in *Valeant II* gives rise to a concurrent conflict of interest under Rule 1.7. The express terms of the engagement letter and accompanying OC Guidelines indicate that Katten formed such a relationship with the movants when it signed the engagement letter for the Bausch & Lomb trademark litigation. Specifically, the engagement letter states that it "represents the general terms of engagement governing the overall relationship between [Katten] and Valeant Pharmaceuticals International, Inc.," i.e. Valeant-CA. Gorman Decl. Ex. A, at 1. This sentence, on its face, demonstrates that Katten's relationship extends beyond just Bausch & Lomb to at least Valeant-CA. The OC Guidelines, which are expressly incorporated into the engagement letter, further extend the relationship to include any Valeant entity. Section 1.1 of the OC Guide-lines states that the guidelines "will govern the relation-ship between Valeant[-DE], its subsidiaries and affiliates, . . . and outside counsel." Gorman Decl. Ex. A, at § 1.1. And section 1.2 of the OC Guidelines requires that Katten complete a conflict check "before representation of [Valeant-DE and its subsidiaries and affiliates] commences." Gorman Decl. Ex. A, at § 1.2. While these sections reference Valeant-DE and not Valeant-CA, the phrase "its subsidiaries and affiliates" encompasses Valeant-CA

because Valeant-CA is the parent company, i.e. affiliate, of Valeant-DE. That same phrase also encompasses another movant in *Valeant II*, Salix, because Salix is a subsidiary of Valeant-DE. For these reasons, the engagement letter creates an ongoing relationship between Katten and both Valeant-CA and Salix. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

The Federal Circuit also found a concurrent conflict as a result of sufficient inter-relationship of the movants and the engaged party to give rise to a corporate affiliate conflict, relying upon second circuit law.

> The relevant regional circuits have not previously set out factors governing corporate interrelatedness in this context. In *GSI Commerce Solutions, Inc. v. BabyCenter, L.L.C.*, 618 F.3d 204, 211–12 (2d Cir. 2010), the Second Circuit considered the circumstances in which "representation adverse to a client's corporate affiliate implicates the duty of loyalty owed to the client." *Id.* at 210. It found that the factors relevant to this inquiry include "(I) the degree of operational commonality between affiliated entities, and (ii) the extent to which one depends financially on the other." *Id.* Regarding the first factor, it noted that "courts have considered the extent to which entities rely on a common infrastructure," focusing "on shared or dependent control over legal and management issues," which "reflects the view that neither management nor in-house legal counsel should, without their consent, have to place their trust in outside counsel in one matter while opposing the same counsel in another." *Id*. Regarding the second factor, it noted that, "several courts have considered the extent to which an adverse outcome in the matter at issue would result in substantial and measurable loss to the client or its affiliate." *Id*. at 211. The Second Circuit applied these factors to find that a parent and its subsidiary were sufficiently interrelated to give rise to a corporate affiliate conflict. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]
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> In the absence of evidence to the contrary, we conclude that the relevant regional circuits would likely find the Second Circuit's reasoning persuasive and would therefore adopt its factors here. In particular, we find that they would agree that shared or dependent control over operational and legal matters between the affiliates is significant to the inquiry. Accordingly, we apply the Second Circuit's interrelatedness test to the facts in this case, and find that Valeant-CA, Salix, and Bausch & Lomb all share a high degree of operational commonality and are financially interdependent. [Dr. Falk Pharma GMBH v. Generico, LLC, 2017-2312; 2017-2636; 2018-1320; and 2018-2097 (Fed. Cir. 2/8/2019; published 2/20/2019).]

Centrak, Inc. v. Sonitor Technologies, Inc., 2017-2510 (Fed. Cir. 2/14/2019).

This is a decision on an appeal from the D. Del. district court case 1:14-cv-00183-RGA. The district court granted Sonitor's SJ motion that some claims were invalid for lack of written description and others were not infringed. Sonitor appealed. The Federal Circuit reversed and remanded.

Legal issue: Genuine issue of material fact regarding written description; whether it adequately conveyed to a skilled artisan that the inventors possessed the invention.

The specification discussed an ultrasonic alternative to infrared, in two sentences. The Federal Circuit relied upon the written description test, that the specification should identify the claimed invention in a definite way, to conclude that the specification satisfied the ultrasonic embodiment defined by the claims.

> Regarding written description, Sonitor argued that the two sentences in the specification dedicated to ultrasound, quoted above, did not show that the inventors had possession of an ultrasound-based RTL system. *** In this case, genuine issues of material fact remain as to whether disclosure of the implementation details that the district court identified is necessary to satisfy the written description requirement. The considerations relied on by the district court and Sonitor do not compel summary judgment for lack of written description. As an initial matter, the district court leaned heavily on the fact that the specification devoted relatively less attention to the ultra-sonic embodiment compared to the infrared embodiment. But in *ScriptPro LLC v. Innovation Associates, Inc.*, 833 F.3d 1336, 1341 (Fed. Cir. 2016), we explained that "a specification's focus on one particular embodiment or purpose cannot limit the described invention where that specification expressly contemplates other embodiments or purposes." [Centrak, Inc. v. Sonitor Technologies, Inc., 2017-2510 (Fed. Cir. 2/14/2019).]

> Here, as in *ScriptPro*, the fact that the bulk of the specification discusses a system with infrared components does not necessarily mean that the inventors did not also constructively reduce to practice a system with ultrasonic components. Sonitor attempts to distinguish *ScriptPro* on the basis that the specification at issue disclosed multiple problems and multiple, exemplary solutions, but "the written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice" may be sufficient if it "identifies the claimed invention" and does so "in a definite way." *Ariad*, 598 F.3d at 1352. [Centrak, Inc. v. Sonitor Technologies, Inc., 2017-2510 (Fed. Cir. 2/14/2019).]

Adello Biologics LLC v. Amgen Inc., PGR2019-00001, paper 11 (PTAB 2/142019; designated precedential 2/14/2019).

Legal issue: 35 USC 322(a)(2), PGR petition requirement to identify all real parties in interest, addition of RPI after filing and prior to institution.

The PTAB allowed the petitioner to add an RPI after filing and prior to a decision on

institution, noting that the original RPI allowed the PTAB to effectively check for conflicts, and there was no undue prejudice to Patent Owner.

> With our authorization, Adello Biologics, LLC, Apotex Inc., and Apotex Corp. (collectively "Petitioners") filed a Motion to Amend Mandatory Notices. Paper 9 ("Mot."). In the Motion, Petitioners seek to amend their mandatory notices to add Amneal Pharmaceuticals LLC ("Amneal LLC") as a real party in interest ("RPI") without altering the petition filing date. *Id*.at 1. *** [R]equiring a petition to identify all RPIs serves "to assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012). Here, Petitioners explain, and Patent Owner does not dispute, that Amneal LLC, the missing RPI, is a wholly owned subsidiary of Amneal Inc. Mot. 4. Because the Petition properly identified Amneal Inc. as an RPI, the Board was able to check for conflicts. Requiring a petition to identify all RPIs also protects a patent owner from "harassment via successive petitions by the same or related parties,"and prevents parties from having a "second bite at the apple." Trial Practice Guide, 77 Fed. Reg. at 48,759. Allowing Petitioners to—before an institution decision is made—add Amneal LLC as an RPI serves exactly this "core function." [Adello Biologics LLC v. Amgen Inc., PGR2019-00001, paper 11 (PTAB 2/142019; designated precedential 2/14/2019).]
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> In sum, Petitioners' delay in identifying all RPIs does not result in any undue prejudice against Patent Owner. Allowing Petitioners to update the mandatory notices while maintaining the original filing date promotes the core functions of RPI disclosures and secures a "just, speedy, and inexpensive resolution" of this proceeding.See37 C.F.R. § 42.1. Thus, we exercise our discretion under 37 C.F.R. § 42.5(b) to allow Petitioners to add Amneal LLC as an RPI while maintaining the original filing date. [Adello Biologics LLC v. Amgen Inc., PGR2019-00001, paper 11 (PTAB 2/142019; designated precedential 2/14/2019).]

Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).

This is a decision on an appeal from the D. Az. district court case 2:16-cv-02026-DGC. The parties stipulated to noninfringement based upon the district court's claim construction. The district court entered judgement of noninfringement. Continental appealed. The Federal Circuit vacated and remanded.

Legal Issue: 35 USC 112, claim construction, product-by-process.

The Federal Circuit disagreed with the conclusions the district court that the claimed device required structure "*produced by a repeated desmear process*." That is, a product-by-process limitation. The Federal Circuit disagreed on virtually all of the district court conclusions regarding what implications arose from the specification, prosecution history, and extrinsic evidence.

The Federal Circuit identified a relevant device claim.

> All of the asserted claims include claim limitations regarding the "surface," "removal," or "etching" of "a dielectric material" or "epoxy," which the district court construed together as the "Category 1 Terms," and their construction depends on resolving whether they should be limited to a repeated desmear process. *See Claim Construction Order*, 2017 WL 3478659, at *2; *see also* J.A. 1879–89. [2] Claim 100 of the '582 patent is illustrative of a claim that includes a "surface" claim term and reads as follows: ["] 100. An electrical device including: a conductive layer built up so as to fill undercuttings with respect to a *surface of a dielectric material* so as to form teeth in cavities, a plurality of the undercuttings being obtuse to the surface, wherein the conductive layer is a portion of circuitry of an electrical device, and a plurality of the teeth are within the range of 1 tenth of a mil deep to 1.75 tenths of a mil deep, and wherein at least one of the cavities includes an upgrade slope with respect to the *surface of the dielectric material*, and one of the teeth engages a portion of the dielectric material at the slope.["] [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019); italics in the original.]

The Federal Circuit noted that the claim was not expressly limited to a structure formed by a "repeated desmear process."

> With these principles in mind, we turn to the construction of the Category 1 Terms. Beginning with the claim language, we first note that none of the asserted claims actually recite a "repeated desmear process." *Accord Claim Construction Order*, 2017 WL 3478659, at *2. Thus, at least based on the plain language, the claims are not limited to a repeated desmear process. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

The Federal Circuit conducted a fact based inspection of the specification and concluded the specification did not disavow; did not limit the clams to require structure formed by a "repeated desmear process."

First, the Federal Circuit restated relevant legal principles.

> We continue our analysis by reading the claims "in view of the specification, of which they are a part." *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979). Our case law has recognized that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." *Id.* at 1316. When the patentee acts as its own lexicographer, that definition governs. *See id.* "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (quoting *CCS Fitness, Inc. v.*

Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)). We have also found instances where "the specification may reveal an intentional disclaimer, or disavowal, of claim scope." *Phillip*s, 415 F.3d at 1316. In those situations, it is again the inventor's disavowal that is dispositive of the claim construction. *See id.* "To disavow claim scope, the specification must contain 'expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.'" *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1306 (Fed. Cir. 2011) (quoting *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1335 (Fed. Cir. 2009)). [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

We acknowledge the difficulty in drawing the "fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims." *Id*. at 1305. To avoid improperly importing limitations into the claims, "it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so." *Phillips*, 415 F.3d at 1323.

Second, the Federal Circuit applied those principles to the specification of the patent.

The Federal Circuit held that the specification described methods of making the sole embodiment, as non-exclusive methods. The non-exclusivity of methods description avoided disclaimer.

Based on our review of the specification, none of the statements relied upon by the district court rises to the level of "a clear and unmistakable disclaimer." *Thorne*r, 669 F.3d at 1367. The specification begins by explaining that the invention is an "electrical device" with teeth. *See* '582 patent col. 1 ll. 13–15, col. 1 l. 50–col. 2 l. 6. The specification then explains that *"[o]ne technique* for forming the teeth," which is "contrary to all known teachings in the prior art" is the double desmear process. *See id.* col. 5 ll. 40–44 (emphasis added). Additionally, the disclosures provide that "the present invention *can be carried out* by a new use" of a dielectric material called Probelec XB 7081. *See id.* col. 6 ll. 41–48 (emphasis added). And within this context, *"[f]or example*, the present invention differs from the common desmear process in that sub-steps in the desmear process are repeated as *a way* of forming the teeth." *Id*. col. 8 ll. 49–52 (emphases added). This, the patent explains, is "[i]n stark contrast with the etch and swell process of the known prior art." *Id.* col. 9 ll. 1–2. The specification also notes that the peel strength produced by the new use of Probelec XB 7081 is greater than that of "the prior art, i.e., a single pass desmear process." *See id.* col. 7 ll. 3–9. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

> Overall, those statements simply describe how to make the claimed invention using the preferred Probelec XB 7081 in a "new" way that is different from the prior art process and are not statements clearly limiting the claimed "electrical device" to require a repeated desmear process. Heeding the warning in *Phillips* to keep in mind that a goal of the specification is to provide a best mode to make and use an invention, phrases such as "one technique," "can be carried out," and "a way" indicate that using Probelec XB 7081 is only one method for making the invention and does not automatically lead to finding a clear disavowal of claim scope. *See Phillips*, 415 F.3d at 1323. We have also "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Id.; see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002))). Therefore, we conclude that disclosing only the Probelec XB 7081 embodiment, without more, does not result in a clear disavowal of claim scope. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

The Federal Circuit held that mere criticism of alternative methods of making the sole embodiment did not limit the claims to requiring fabrication by the preferred method.

> Additionally, distinguishing the double desmear process as "contrary to" or "in stark contrast" with the single desmear process, which again appears within the context of disclosures of the preferred embodiment, are not clear and unmistakable limiting statements. We have held that "[m]ere criticism of a particular embodiment . . . is not sufficient to rise to the level of clear disavowal." *Thorne*r, 669 F.3d at 1366. Thus, comparing and contrasting the present technique to that of the prior art does not "rise to the level of [a] clear disavowal" of claim scope. *Id*. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

The Federal Circuit held that, when the phrase "the present invention," actually referred to the preferred embodiment and not the invention as a whole, that reference did not limit the disclosed invention and therefore did not act to disclaim claim scope.

> Similarly, the descriptions of "the present invention," which also appear within the discussion of the preferred embodiment, are not limiting here. While descriptions "of the 'present invention' as a whole" could limit the scope of the invention, *see Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007), "use of the phrase 'present invention' or 'this invention' is

not always so limiting, such as where the references . . . are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent," *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136–37 (Fed. Cir. 2011). In this case, the statements that "*the present invention* can be carried out by a new use" of a dielectric material called Probelec XB 7081, *see* '582 patent col. 6 ll. 41–48 (emphasis added), and "*the present invention* differs from the common desmear process in that sub-steps in the desmear process are repeated as *a way* of forming the teeth," *id.* col. 8 ll. 49–52 (emphases added), do not characterize the present invention "as a whole," *Verizon*, 503 F.3d at 1308. Instead, they disclose one way to carry out the present invention using Probelec XB 7081, and references to "the present invention" occur within this context. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

Moreover, the use of "the present invention" throughout the specification does not uniformly require use of a repeated desmear process. *See Absolute Software*, 659 F.3d at 1136–37. In certain portions of the specification, such as the summary, the invention is described with respect to its "unique surface structure," '582 patent col. 1 l. 52, without any requirement that the invention must encompass the repeated desmear process. In fact, "desmear" does not appear in the summary of the invention section at all. *See id.* col. 1 l. 48–col. 2 l. 29. In light of this, it is difficult to say that the present invention "as a whole," *Verizo*n, 503 F.3d at 1308, necessarily includes the repeated desmear process. Thus, absent "clear and unmistakable" language suggesting otherwise, we conclude that the aforementioned statements do not meet the "exacting" standard required to limit the scope of the claims to a repeated desmear process. *See Thorner*, 669 F.3d at 1366–67. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

The Federal Circuit also held that an expert declaration submitted during prosecution that referred to "a" technique for forming the device, to show that the claims had written description in the specification, did not limit claims to devices formed by that technique.

Additionally, the district court found that the prosecution history corroborated its construction. The examiner made indefiniteness and written description rejections during the prosecution of the '560 patent of the claim limitation "etching of the epoxy uses nonhomogeneity with the solid content," which is used to bring about formation of the nonuniformly roughened surface of the angular tooth-shaped cavities. See J.A. 2122–23. In response to the office action, Continental submitted an expert declaration explaining that the "etching" process disclosed in the specification uses "this known Probelec XB[ ]7081 resin" and "two separate swell and etch steps" as "a technique which forms the teeth." J.A. 2074; see also J.A. 2068–69. The district court found that the expert declaration "clearly describe[d] the patented method as involving two etching

processes." *Claim Construction Order*, 2017 WL 3478659, at *6. Moreover, the district court observed that extrinsic documents produced by the inventors state the use of a "two pass desmear cycle" and that "we use a double pass desmear to achieve the tooth structure." *Id.* (quoting J.A. 3321, 3324). The court acknowledged that those statements were "not reliable enough to be dispositive," but found they "provide[d] helpful corroboration." Id. *** We do not agree that such a clear disavowal exists in this prosecution history. The expert declaration cited by the district court, which the applicants relied on to respond to both the indefiniteness and the written description rejections, explained that the written description disclosed "a technique which forms the teeth" by "performing two separate swell and etch steps." J.A. 2074 ¶ 7 (citing '582 patent col. 9 ll. 1–9) (emphasis added). The district court found this statement "clearly describe[d] the patented method as involving two etching processes." *See Claim Construction Order*, 2017 WL 3478659, at *6. But clearly describing a particular claim term to overcome an indefiniteness or written description rejection is not the same as clearly disavowing claim scope. Moreover, the statements in the expert declaration merely explain one technique for forming teeth and do not amount to clear statements of disavowal. We therefore conclude that the cited statements in the prosecution history do not clearly and unmistakably disavow any claim scope. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

Finally, regarding the prosecution history, the Federal Circuit commented that the criterion required to read a process limitation into a product claim, is that "patentee has made clear that the process steps are an essential part of the claimed invention." The Federal Circuit stated that:

> Before we conclude our analysis of the intrinsic evidence, we note that in order to read a process limitation into a product claim, it must meet one more criterion. Generally, "[a] novel product that meets the criteria of patentability is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372–73 (Fed. Cir. 2000). "However, process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007). For the same reasons that the statements relied upon by the district court do not show that the patentee clearly and unmistakably disavowed claim scope, they also do not make clear that the repeated desmear process is "an essential part" of the claimed electrical device having a tooth structure. *Id*. Far from being essential, the statements from the intrinsic evidence merely indicate a preference for using Probelec XB 7081 and include comparisons with the prior art techniques. Because the patentee has not "made clear" that the repeated desmear process is "an essential part of the claimed invention," *id.*, it was improper for the district court to read this process limitation into the product claims for this additional reason.

[Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

Regarding extrinsic evidence, the Federal Circuit concluded that evidence that the inventors used the preferred embodiment, was not probative evidence supporting a conclusion that the inventors disclaimed claim scope beyond the preferred embodiment.

> Here, the district court acknowledged that the extrinsic evidence, which consisted of documents authored by the inventors, was "not reliable enough to be dispositive," but "provide[d] helpful corroboration." *See Claim Construction Order,* 2017 WL 3478659, at * 6. The inventor documents state that the inventors used "two passes through desmear," J.A. 3321, and a "double pass desmear" J.A. 3324, to achieve the tooth structure. However, similar to the intrinsic evidence, those statements reflect use of the preferred embodiment but give the public no indication that they have any limiting effect. Because we have already determined that the intrinsic evidence does not support reading a repeated desmear process into the claims, the "less reliable" extrinsic evidence, *Phillips*, 415 F.3d at 1318, which even the district court acknowledged was "not reliable enough to be dispositive," *see Claim Construction Order*, 2017 WL 3478659, at * 6, does not counsel otherwise. Accordingly, we conclude that the Category 1 Terms should not be limited to requiring a repeated desmear process and should be given their plain and ordinary meaning. [Continental Circuits LLC v. Intel Corporation, 2018-1076 (Fed. Cir. 2/8/2019).]

Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Company, 2017-1694 (Fed. Cir. 2/7/2019).

This is a decision on an appeal from PTAB case IPR2015-01537. Momenta appealed the PTAB's sustaining patentability of patent claims. The Federal Circuit dismissed for lack of standing, and for mootness.

Legal issues: Article III Standing, mootness, and speculation once petitioner ends commercially relevant activity.

Bristol-Myers's patent covered the drug having brand name Orencia®. Momenta's FDA filings indicated that it abandoned its attempt to commercialize an infringing compound at some time prior to the Federal Circuit's decision in this case. However, had been in a development project with Mylan. Momenta asserted to the Court that it still had "an economic interest in ... biosimilar that might be developed by Mylan." The Federal Circuit concluded that the possibility that Mylan might be obliged to pay Momenta royalties in the future, if Mylan subsequently produced an infringing compound, was insufficient to confer Article III standing.

> Momenta argues that since the purpose of the America Invents Act is to provide an alternative to district court litigation, appeal should be available from the PTAB as it would be available from a district court decision. Momenta states that the estoppel provision provides injury-in-fact, and that this suffices to support constitutional standing. However, estoppel of Momenta is irrelevant now that

> Momenta has "exited" its development of the Orencia® product. Estoppel cannot constitute an injury-in-fact when Momenta "is not engaged in any activity that would give rise to a possible infringement suit." *Consumer Watchdog*, 753 F.3d at 1262; *see also Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013) (the party must be in the position of "seek[ing] a remedy for a personal and tangible harm"); *Gill v. Whitford*, 138 S. Ct. 1916, 1929 (2018) ("the requirement of such a personal stake [in the outcome] 'ensures that courts exercise power that is judicial in nature'" (quoting *Lance v. Coffman*, 549 U.S. 437, 441 (2007))). [Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Company, 2017-1694 (Fed. Cir. 2/7/2019).]
>
> Momenta's argument that it might at some future time receive a royalty from Mylan, if Mylan should produce an Orencia® biosimilar, has no support in precedent. *See Clapper*, 568 U.S. at 414 n.5 (To establish Article III standing, "[p]laintiffs cannot rely on speculation about the unfettered choices made by independent actors not before the court." (internal quotation marks and citation omitted)); *United Transp. Union v. ICC*, 891 F.2d 908, 912 (D.C. Cir. 1989) ("[F]or standing purposes, we may reject as overly speculative those links which are predictions of future events (especially future actions to be taken by third parties)."). [Momenta Pharmaceuticals, Inc. v. Bristol-Myers Squibb Company, 2017-1694 (Fed. Cir. 2/7/2019).]

Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).

This is a decision on an appeal the D. Mass district court case 1:15-cv-40075-IT. Judge Lourie wrote the majority opinion, joined by Judge Stool. Judge Newman dissented.

The district court held Athena's claims 6-9 invalid under 35 UCS 101 and dismissed Athena's complaint pursuant to FRCP 12(b)(6). Athena appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 101, Alice step 1, "directed to," natural law test.

The majority concluded that claims that "involve both the discovery of a natural law and certain concrete steps to observe its operation" were invalid when the concrete steps used in making the observation were conventional.

First, the majority restated the relevant law.

> The step one "directed to" inquiry focuses on the claim as a whole. *E.g., Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016). To determine whether a claim is directed to an ineligible concept, we have frequently considered whether the claimed advance improves upon a technological process or merely an ineligible concept, based on both the written description and the claims. *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047–49 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015); *see also McRO, Inc. v. Bandai Namco*

Games Am. Inc., 837 F.3d 1299, 1314–15 (Fed. Cir. 2016); *Elec. Power Grp.*, 830 F.3dat 1354. [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).]

Second, the majority construed the claim, identified the natural law, and held that addition of admittedly conventional techniques to obtain a result relating to the natural law, was "directed to" the natural law. That is, not patentable subject matter.

> The claims at issue here involve both the discovery of a natural law and certain concrete steps to observe its operation. Claim 9, the most specific claim at issue, recites the following method to detect MuSK autoantibodies: (1) mixing MuSK or an epitope thereof having a 125I label with bodily fluid; (2) immunoprecipitating any resulting anti-body/MuSK complex; and (3) monitoring for the label on the complex. '820 patent col. 12 l. 62–col. 13 l. 9. The claim then concludes in the wherein clause with a statement of the natural law, i.e., the discovery that MuSK autoantibodies naturally present in a patient sample, detected with the 125I label bound to the MuSK/antibody complex, indicate that the patient is suffering from a MuSK-related neurological disorder. *Id*. col. 13 ll. 2–5. [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).]
>
> As in *Cleveland Clinic* and *Ariosa*, we conclude that claims 7–9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law. The specification of the '820 patent highlights the discovery of the natural law, explaining that "[t]he present inventors surprisingly found that many of the 20% of MG patients [who] do not exhibit any autoantibodies to [the acetylcholine receptor], instead have . . . antibodies directed against the extracellular [amino]-terminal domains of MuSK." *Id*. col. 1 ll. 54–57. Further, the specification describes the claimed concrete steps for observing the natural law as conventional. It teaches that "[t]he actual steps of detecting auto-antibodies in a sample of bodily fluids may be performed in accordance with immunological assay techniques known per se in the art," including radioimmunoassays and ELISA. *Id*. col. 3 ll. 33–37. Likewise, the specification identifies "[i]odination and immunoprecipitation" as "standard techniques in the art." Id. col. 4 ll. 10–12. The '820 patent thus describes the claimed invention principally as a discovery of a natural law, not as an improvement in the underlying immunoassay technology. Consistent with the specification, the claims are directed to that law. [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).]

Legal issue: 35 USC 101, Alice step 2, "inventive concept" test.
The majority also held that the claims did not define an inventive concept, under *Alice*

step 2, for a variety of reasons.

> Athena also argues that the claimed steps were unconventional because they had not been applied to detect MuSK autoantibodies prior to Athena's discovery of the correlation between MuSK autoantibodies and MG. Even accepting that fact, we cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept. This is because "[t]he inventive concept necessary at step two . . . cannot be furnished by the unpatentable law of nature . . . itself." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016); *see Mayo*, 566 U.S. at 73 (considering whether the "claimed processes (apart from the natural laws themselves)" were routine and conventional). Rather, to supply an inventive concept the sequence of claimed steps must do more than adapt a conventional assay to a newly discovered natural law; it must represent an inventive application beyond the discovery of the natural law itself. Because claims 7–9 fail to recite such an application, they do not provide an inventive concept. [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).]

> Similar to its step one argument, Athena further argues that the claims recite an inventive concept because they use a man-made molecule, i.e., labeled MuSK. Athena analogizes its methods involving labeled MuSK to the com-position claims involving cDNA held eligible in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594–95 (2013). However, the method claims at issue here are unlike the claims held eligible in *Myriad*, which recited a new composition of matter that was not a natural product. *Id.* For the same reasons that we have concluded that attaching a label to MuSK did not make the claims directed to an eligible concept at step one, we conclude that appending labeling techniques to a natural law does not provide an inventive concept where, as here, the specification describes 125I labeling as a standard practice in a well-known assay. [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).]

Legal issue: FRCP12(b)(6), evidence submitted in opposition

The majority concluded that the District Court was not required to consider Athena's expert declaration submitted with its opposition to the 12(b)(6) motion, first, because of applicable first circuit law, and second, because the declaration asserted facts not consistent with the complaint nor defined by the claims.

> Even assuming this general principle applies in the First Circuit—an assumption that Athena meagerly supports—the district court did not need to consider the allegations in the expert declaration because they were not consistent with the complaint read in light of the '820 patent. These technical allegations

include: (1) that detecting MuSK autoantibodies required the "creative step" of breaking up MuSK into smaller fragments, J.A. 623, 625; (2) that identifying a specific site on MuSK to label would not have been routine because many factors contribute to whether a binding site for a label is adequate, J.A. 626–28;and (3) that immunoprecipitation is generally uncertain and not routine, J.A. 630. None of these details are recited in the claims of the '820 patent: no claim requires breaking MuSK into fragments as opposed to using the entire MuSK protein; no claim is limited to a particular MuSK binding site; and no claim recites any detail with respect to immunoprecipitation. Those omissions are consistent with the specification's description of iodination, immunoprecipitation, and the overall radioimmunoassay as standard techniques. Because Athena's expert declaration made allegations inconsistent with the '820 patent, the district court was not obliged to accept them as true. For these reasons, the district court did not err in dismissing Athena's complaint under Rule 12(b)(6). [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019).]

Note: A big problem here was with Athena's patent's disclosure. Why did the patent not disclose"breaking up MuSK into smaller fragments"; claim the "factors [that] contribute" to adequacy of the binding site; and information showing uncertainty in "immunoprecipitation"? Why did the patent instead characterize all procedures as conventional? It seems that this case was lost at the patent drafting stage.

Judge Newman, dissenting, began:

> Until discovery of the diagnostic method described in U.S. Patent No. 7,267,820 ("the '820 patent"), some 20% of patients suffering from the neurological disorder Myasthenia Gravis were not capable of being diagnosed. My colleagues rule that this new diagnostic method is not patent-eligible, although new and unobvious. However, "[t]his new and improved technique, for producing a tangible and useful result, falls squarely outside those categories of inventions that are 'directed to' patent-ineligible concepts." *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016). The court again departs from the cautious restraints in the Supreme Court's *Mayo/Alice* application of laws of nature and abstract ideas. [Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC, 2017-2508 (Fed. Cir. 2/6/2019)(Judge Newman, dissenting).]

In re Google, 2018-152 (Fed. Cir. 2/5/2019).

Legal issue: 35 USC 1400(b), venue, what constitutes a regular and established place of business in e-commerce.

Google petitioned for rehearing en banc of its petition for a writ of mandamus to the E.D. Tex. judge in case 2:17-cv-00442-JRG, to grant Google's 1400(b) venue motion. The en banc Federal Circuit denied rehearing. The dissent to the denial of rehearing en banc, quoted below, identified the issue as one of substantial and widespread importance.

> The court elects not to decide en banc the question of whether servers or similar equipment in third-party facilities are a regular and established place of business, such that venue is proper under 35 U.S.C § 1400(b). The court bases its decision on grounds that the issue it presents does not rise to a level that warrants mandamus review. I dissent because the court's decision causes two adverse results. First, the court sidesteps the precise purpose of mandamus relief, thereby weakening our Writ of Mandamus jurisprudence. Second, we leave unanswered a critical issue that increasingly affects venue in legal actions involving e-commerce. [In re Google, 2018-152 (Fed. Cir. 2/5/2019)(Judge Reyna dissenting, joined in dissent by Judges Newman and Lourie, from en banc denial of rehearing).]
>
> The question poised [sic] before the court is whether Google's servers (shown below in the black box), which have no physical interaction with Google employees or customers and are installed by third-parties in the facilities of third-party internet service providers ("ISPs") located in the Eastern District of Texas, constitute a regular and established place of business under 35 U.S.C. § 1400(b) and this Court's decision in *Cray*. *In re Gray Inc*., 871 F .3d 1355 (Fed. Cir. 2017). *** As we saw in *Cray*, there is again growing uncertainty among district courts and litigants as to the requirements of § 1400(b) when conducting business virtually through servers and similar equipment in the district. *** The same legal issues are relevant to every technology company that, like Google, conducts business over the internet. [In re Google, 2018-152 (Fed. Cir. 2/5/2019)(Judge Reyna dissenting, joined in dissent by Judges Newman and Lourie).]

Mylan Pharmaceuticals Inc. v. Research Corporation Technologies, Inc., 2017-2088, 2017-2089, 2017-2091 (Fed. Cir. 2/1/2019).

This is a decision on appeals from PTAB cases IPR2016-00204, IPR2016-01101, IPR2016-01242, IPR2016-01245. The interesting issues relate to standing and waiver, not to the merits of the case.

Legal Issue: Article III Standing, 35 USC 315(b) time-bar, and zone of interests test.

The Federal Circuit concluded that Congress authorized appeal in section 319, and the timing of the petition more than one year after having been sued for infringement did not annul section 319's right to an appeal.

> As a threshold matter, we first address whether Appellants have standing to make this appeal. RCT does not assert that Appellants lack Article III standing. Appellee's Br. 20. However, RCT submits that each Appellant lacks standing because it does not fall within the zone of interests of 35 U.S.C. § 319. According to RCT, Appellants fall outside that zone because RCT brought an infringement action against each Appellant more than a year before it filed its IPR petition, and each Appellant's petition was therefore time-barred. *** We presume that a

statutory cause of action extends only to litigants that "fall within the zone of interests protected by the law invoked." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014) (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)). The zone of interests limitation "always applies and is never negated." *Id*. To determine whether an appellant falls within the zone of interests, we apply traditional principles of statutory interpretation, asking not "whether in our judgment Congress should have authorized [the appeal], but whether Congress in fact did so." *Id*. at 128. *** RCT argues that allowing Appellants' appeal "would constitute an end-run around the statutory time-limit for instituting IPR proceedings," *id*. at 19, but cites no provision in the text or legislative history supporting its reading. Accordingly, we conclude that Appellants fall within the zone of interests of § 319 and are not barred from appellate review. We therefore proceed to the merits. [Mylan Pharmaceuticals Inc. v. Research Corporation Technologies, Inc., 2017-2088, 2017-2089, 2017-2091 (Fed. Cir. 2/1/2019).]

Legal issue: Waiver of *SAS* relief, timing of the request for relief.

The Federal Circuit held that raising a *SAS* argument only in rebuttal at oral argument was too late, and constituted waiver.

We have held that a party's request for *SAS* relief can be waived. *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1362–63 (Fed. Cir. 2018). In cases where a litigant lodges a prompt request for *SAS*-based relief, however, this court has found waiver inapplicable and remanded to the Board to consider noninstituted grounds. *See, e.g., Adidas AG v. Nike, Inc.*, 894 F.3d 1256, 1258 (Fed. Cir. 2018); *Polaris Indus. Inc. v. Arctic Cat, Inc.*, 724 F. App'x 948, 950 (Fed. Cir. 2018) (per curiam); *South-Tek Sys., LLC v. Engineered Corrosion Sols., LLC*, No. 2017-2297, 2018 WL 4520013, at *5 (Fed. Cir. Sept. 20, 2018); *Baker Hughes Oilfield Operations, LLC v. Smith Int'l, Inc.*, No. 2018- 1754, 2018 WL 4087705, at *2 (Fed. Cir. May 30, 2018). Here, Appellants' request—made over 6 months after the *SAS* decision—was not prompt. To be sure, the Supreme Court's *SAS* decision issued after the briefing was complete in this case. But Appellants had opportunities to raise the *SAS* issue with the court before oral argument (i.e., in a citation of supplemental authority as authorized by Fed. Cir. R. 28(j)) and chose not to do so. Indeed, Appellants could have raised their *SAS* argument even in their opening oral argument. Instead, they chose to raise it in their rebuttal argument—when RCT had no meaningful opportunity to respond. Given the circumstances in this case, we find that Appellants have waived their request for remand. *Cf. Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990) (stating that the court's "sound practice" of finding arguments absent from opening briefs to be waived "may as a matter of discretion not be adhered to where circumstances indicate that it would result in basically unfair procedure"). [Mylan Pharmaceuticals Inc. v. Research Corporation Technologies, Inc., 2017-2088, 2017-2089, 2017-2091 (Fed. Cir. 2/1/2019).]