Precedential Patent Case Decisions During April 2018

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I. Introduction

This article presents a summary of precedential issues from patent cases for this month. Cases captions relating to the PTAB are in **red** text. Cases captions relating to district courts are in black. Case captions of extraordinary importance are in **blue** text.

II. Abstracts of New Points of Law

<u>01 Communique Laboratory, Inc. v. Citrix Systems, Inc.</u>, 2017-1869 (Fed. Cir. 4/26/2018).

This is an appeal from the N.D. Oh. district court case 1:06-cv-00253-SL. The district court denied 01's motion for a new trial. 01 appealed. The Federal Circuit affirmed.

Although marked precedential, I see no novel point of law in this case. The Federal Circuit however reaffirmed that a defendant can present evidence to the jury, that if a claim term is broadly construed resulting in infringement, then it also reads on the prior art making the claim invalid.

Communique asserts that it is entitled to a new trial on the issues of infringement and damages because Citrix resorted to "a well-known defendant's trick," known as the "practicing the prior art defense." It contends that the jury verdict of non-infringement must be set aside because the trial court improperly permitted Citrix to bypass the required comparison between the asserted claims and the accused product and instead to focus on the similarities between Citrix's current GoToMyPC product and its prior art BuddyHelp product. *** Citrix's infringement defense was firmly rooted in a limitation by limitation comparison between the asserted claims and the GoToMvPC product. But Citrix also presented an alternative invalidity defense that focused on its prior art BuddyHelp product. It argued that under the trial court's claim construction claims 24 and 45 were valid, but not infringed, J.A. 1489–90, 2509, but that if Communique attempted to expand the scope of its claims to include systems in which a location facility merely "directs" other components, such as the end point computers, to create the communication channel, J.A. 1901; see also J.A. 1477–81, then the claims would be invalid in light of the prior art, J.A. 2509–15; see also J.A. 1518–19, 2462, 3501–02. There was nothing improper about this argument. [01 Communique Laboratory, Inc. v. Citrix Systems, Inc., 2017-1869 (Fed. Cir. 4/26/2018).]

We next address whether the Board properly affirmed the examiner's rejection of the claims under 35 U.S.C. § 102(f) given its joint inventorship determination. *** This case presents the "rare situation," or at least an

uncommon one, where the '201 application and VerHoef's affidavit make clear that he did not himself solely invent the subject matter sought to be patented, as those materials establish that Lamb was a joint inventor improperly omitted from the application. We therefore conclude that the Board properly sustained the examiner's rejection of the claims under § 102(f). [In re VerHoef, 2017-1976 (Fed. Cir. 5/3/2018).]

<u>Gilead Sciences, Inc. v. Merck & Co., Inc.</u>, 2016-2302, 2016-2615 (Fed. Cir. 4/25/2018).

This is decision on appeals from the N.D. Cal. district court case 5:13-cv-04057-BLF. The district court found Merck's patents unenforceable against Gilead under the doctrine of unclean hands due to pre and post litigation misconduct, and also awarded Gilead attorney's fees. Merck appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 282(b)(1), unenforceability, misconduct, unclean hands.

Here, the Federal Circuit concluded that the findings of the district court were not clearly erroneous. These findings included: that Merck represented to Gilead that Merck's patent attorney designated to receive confidential disclosures from Gilead as part of due diligence for an anticipated business deal between Gilead and Merck, was fire-walled within Merck for work relating to the deal; that the patent attorney was in fact not fire-walled within Merck and used the disclosed information to expedite prosecution and issuance of Merck's asserted patent by (presenting narrowed claims during prosecution of Merck's patent application that covered the compound that Gilead had disclosed); and that the same patent attorney's related testimony during the litigation on these activities including "intentional testimonial falsehoods."

The Federal Circuit summarized the legal standard for unclean hands.

The Supreme Court has articulated the governing legal standard. In Keystone Driller Co. v. General Excavator Co., the Court explained that a determination of unclean hands may be reached when "misconduct" of a party seeking relief "has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation," i.e., "for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court." 290 U.S. 240, 245 (1933). In Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., the Court stated that the doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant," and requires that claimants "have acted fairly and without fraud or deceit as to the controversy in issue." 324 U.S. 806, 814-15 (1945). The Court added that the doctrine "necessarily gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant." Id. at 815; see also Northbay Wellness Grp., Inc. v. Beyries, 789 F.3d 956, 960 (9th Cir. 2015) (explaining need for equitable balancing). [Gilead Sciences, Inc. v. Merck & Co., Inc., 2016-2302, 2016-2615] (Fed. Cir. 4/25/2018).]

The Federal Circuit then summarized the facts supporting the unclean hand determination.

The district court found, with adequate evidentiary support, two related forms of pre-litigation business misconduct attributable to Merck. First, Dr. Durette learned of Pharmasset's PSI-6130 structure by participating, at Merck's behest, in a conference call with Pharmasset representatives, violating a clear "firewall" understanding between Pharmasset and Merck that call participants not be involved in related Merck patent prosecutions. Second, Merck continued to use Dr. Durette in the related patent prosecutions even after the call. The district court also found, with adequate evidentiary support, a direct connection to the ultimate patent litigation involving sofosbuvir. Thus, Dr. Durette's knowledge of PSI-6130, acquired improperly, influenced Merck's filing of narrowed claims, a filing that held the potential for expediting patent issuance and for lowering certain invalidity risks. Those findings establish serious misconduct, violating clear standards of probity in the circumstances, that led to the acquisition of the less risky '499 patent and, thus, was immediately and necessarily related to the equity of giving Merck the relief of patent enforcement it seeks in this litigation. [Gilead Sciences, Inc. v. Merck & Co., Inc., 2016-2302, 2016-2615 (Fed. Cir. 4/25/2018).]

The district court also found, with adequate evidentiary support, essentially two forms of litigation misconduct involving Dr. Durette as a witness and attributable to Merck. First, in his deposition, where he appeared partly as Merck's corporate witness on issues to which the March 2004 call was relevant, Dr. Durette gave testimony that he did not participate in the March 2004 call testimony that was later conceded to be false and that the court found to be intentionally so. Second, both in the deposition and then at trial, Dr. Durette, in support of Merck's validity positions, gave testimony about the role the January 2005 Clark Application played in Dr. Durette's filing of the February 2005 amendment that the court found so incredible as to be intentionally false. The intentional testimonial falsehoods qualify as the kind of misconduct that can, in these circumstances, support a determination of unclean hands. The court also found, with adequate evidentiary support, that the false testimony, in both respects, bore on the origin story of the February 2005 amendment, which was relevant to the invalidity issues in the litigation and hence immediately and necessarily related to the equity of the patentenforcement relief Merck seeks in this case. [Gilead Sciences, Inc. v. Merck & Co., Inc., 2016-2302, 2016-2615 (Fed. Cir. 4/25/2018).]

Merck argues that even where there is misconduct related to one patent, "that does not defeat claims under another patent simply because they were 'brought . . . in the same lawsuit.'" Merck Br. 69. We agree; but the assertion does not undermine the district court's ruling here. The Supreme Court's

decisions in *Keystone* and *Precision Instruments*, dealing with findings of unclean hands when multiple patents were at issue in the litigation and the alleged misconduct related to a subset of the patents, are instructive. In both cases, the Supreme Court applied the finding of unclean hands to all of the patents. *Keystone*, 290 U.S. at 246–47; *Precision Instruments*, 324 U.S. at 819. The district court in the present case had sufficient reason to find that both patents were tainted by the patentee's misconduct, especially the litigation misconduct. Thus, we see no abuse of discretion with respect to either the '499 patent or the '712 patent. [Gilead Sciences, Inc. v. Merck & Co., Inc., 2016-2302, 2016-2615 (Fed. Cir. 4/25/2018).]

SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).

This is a decision reviewing the decision in Federal Circuit cases 2015-1346, 2015-1347 holding that the PTAB "did not need to address in its final written decision claims it did not institute." SAS appealed. The Supreme Court majority reversed, and in fact went further to hold that the PTO did not have the "partial institution" authority. The PTO must either fully institute or not institute review based upon a PTAB AIA petition. While unstated, *SAS* makes it clear that the PTAB must institute on the grounds and claims, not just the claims, specified in a petition. While this holding mentions only IPRs, it obviously extends to PGRs and CBMs.

The majority consisted of Chief Justice Roberts, and Justices Gorsuch, Kennedy, Thomas, Alito. Justices Breyer dissented. Justices Ginsburg, and Sotomayor joined in the dissent. Justice Kagan joined in the dissent, except for Part III-A which stated that *Chevron* is a rule of thumb, instead of a black-letter rule of law.

Note on impact: While not constitutional in nature, the impact of *SAS* on patent law and practice is massive. *SAS* reset the scope of PTAB AIA proceedings, requiring an all or nothing institution decision, which required the PTAB to immediately reset all ongoing proceedings based upon partial institution decisions to full institutions and reconsider how to exercise its discretion whether to institute. SAS also required the Federal Circuit to consider standing issues in pending appeals from PTAB cases involving partial institutions. SAS also indirectly impacts district court patent infringement civil actions because of the interplay of district court stay decisions with the scope of overlap between claims challenged in the PTAB and asserted in corresponding civil actions, and the corresponding dramatic impact *SAS* has on 315(e) estoppel resulting PTAB final decisions on full institutions.

Legal issue: 35 USC 314(a), discretion of the Director institution decisions.

The Court majority held that the Director has no authority to partially institute an IPR proceeding.

We find that the plain text of §318(a) supplies a ready answer. It directs that "[i]f an inter partes review is instituted and not dismissed under this chapter, the [Board] *shall issue* a final written decision with respect to the patentability of *any patent claim challenged by the petitioner* "§318(a) (emphasis added). This directive is both mandatory and comprehensive. The word "shall" generally imposes a nondiscretionary duty. *See Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U. S. 26, 35 (1998). And the word "any" naturally carries

"an expansive meaning." *United States v. Gonzales*, 520 U. S. 1, 5 (1997). When used (as here) with a "singular noun in affirmative contexts," the word "any" ordinarily "refer[s] to a member of a particular group or class without distinction or limitation" and in this way "impl[ies] every member of the class or group." Oxford English Dictionary (3d ed.,Mar. 2016), www.oed.com/view/Entry/8973 (OED) (emphasis added) (all Internet materials as last visited Apr. 20, 2018). So when §318(a) says the Board's final written decision "shall" resolve the patentability of "any patent claim challenged by the petitioner," it means the Board *must* address *every* claim the petitioner has challenged. [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

Start where the statute does. In its very first provision, the statute says that a party may seek inter partes review by filing "a petition to institute an inter partes review." §311(a). This language doesn't authorize the Director to start proceedings on his own initiative. Nor does it contemplate a petition that asks the Director to initiate whatever kind of inter partes review he might choose. Instead, the statute envisions that a petitioner will seek an inter partes review of a particular kind—one guided by a petition describing "each claim challenged" and "the grounds on which the challenge to each claim is based." §312(a)(3). From the outset, we see that Congress chose to structure a process in which it's the petitioner, not the Director, who gets to define the contours of the proceeding. And "[j]ust as Congress' choice of words is presumed to be deliberate" and deserving of judicial respect, "so too are its structural choices." *University of Tex. Southwestern Medical Center v. Nassar*, 570 U. S. 338, 353 (2013). [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

The rest of the statute confirms, too, that the petitioner's petition, not the Director's discretion, is supposed to guide the life of the litigation. For example, §316(a)(8) tells the Director to adopt regulations ensuring that, "after an inter partes review has been instituted," the patent owner will file "a response to the petition." Surely it would have made little sense for Congress to insist on a response to the petition if, in truth, the Director enjoyed the discretion to limit the claims under review. What's the point, after all, of answering claims that aren't in the proceeding? If Congress had meant to afford the Director the power he asserts, we would have expected it to instruct him to adopt regulations requiring the patent owner to file a response to the Director's institution notice or to the claims on which the Director instituted review. Yet we have nothing like that here. And then and again there is §318(a). At the end of the proceeding, §318(a) categorically commands the Board to address in its final written decision "any patent claim challenged by the petitioner." In all these ways, the statute tells us that the petitioner's contentions, not the Director's discretion, define the scope of the litigation all the way from institution through to conclusion. [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

More confirmation comes as we move to the point of institution. Here the statute says the Director must decide "whether to institute an inter partes review . . . pursuant to a petition." §314(b). The Director, we see, is given only the choice "whether" to institute an inter partes review. That language indicates a binary choice—either institute review or don't. And by using the term "pursuant to," Congress told the Director what he must say yes or no to: an inter partes review that proceeds "[i]n accordance with" or "in conformance to" the petition. OED, www.oed.com/view/Entry/155073. Nothing suggests the Director enjoys a license to depart from the petition and institute a different inter partes review of his own design. [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

To this the Director replies by pointing to another part of §314. Section 314(a) provides that the Director may not authorize an inter partes review unless he determines there is a reasonable likelihood the petitioner will prevail on at least 1 of the claims challenged in the petition. The Director argues that this language requires him to evaluate claims individually and so must allow him to institute review on a claim-by-claim basis as well. Brief for Federal Respondent 28. But this language, if anything, suggests just the opposite. Section 314(a) does not require the Director to evaluate every claim individually. Instead, it simply requires him to decide whether the petitioner is likely to succeed on at least 1 claim. Once that single claim threshold is satisfied, it doesn't matter whether the petitioner is likely to prevail on any additional claims; the Director need not even consider any other claim before instituting review. Rather than contemplate claim-by-claim institution, then, the language anticipates a regime where a reasonable prospect of success on a single claim justifies review of all. [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

Faced with this difficulty, the Director tries another tack. He points to the fact that §314(a) doesn't require him to institute an inter partes review even after he finds the "reasonable likelihood" threshold met with respect to one claim. Whether to institute proceedings upon such a finding, he says, remains a matter left to his discretion. *See Cuozzo*, 579 U. S., at ____ (slip op., at 9). But while §314(a) invests the Director with discretion on the question whether to institute review, it doesn't follow that the statute affords him discretion regarding what claims that review will encompass. The text says only that the Director can decide "whether" to institute the requested review—not "whether and to what extent" review should proceed. §314(b). [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

The rest of the statute confirms, too, that the petitioner's petition, not the Director's discretion, is supposed to guide the life of the litigation. For example, §316(a)(8) tells the Director to adopt regulations ensuring that, "after an inter partes review has been instituted," the patent owner will file "a response to the petition." Surely it would have made little sense for Congress to insist on a

response to the petition if, in truth, the Director enjoyed the discretion to limit the claims under review. What's the point, after all, of answering claims that aren't in the proceeding? If Congress had meant to afford the Director the power he asserts, we would have expected it to instruct him to adopt regulations requiring the patent owner to file a response to the Director's institution notice or to the claims on which the Director instituted review. Yet we have nothing like that here. And then and again there is §318(a). At the end of the proceeding, §318(a) categorically commands the Board to address in its final written decision "any patent claim challenged by the petitioner." In all these ways, the statute tells us that the petitioner's contentions, not the Director's discretion, define the scope of the litigation all the way from institution through to conclusion. [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

The Director says we can find at least some hint of the discretion he seeks by comparing §314(a) and §318(a). *** We just don't see it. Whatever differences they might display, §314(a) and §318(a) both focus on the petitioner's contentions and, given that, it's difficult to see how they might be read to give the Director power to decide what claims are at issue. Particularly when there's a much simpler and sounder explanation for the statute's wording. As we've seen, a patent owner may move to "[c]ancel any challenged patent claim" during the course of an inter partes review, effectively conceding one part of a petitioner's challenge. §316(d)(1)(A). Naturally, then, the claims challenged "in the petition" will not always survive to the end of the case; some may drop out thanks to the patent owner's actions. And in that light it is plain enough why Congress provided that only claims still challenged "by the petitioner" at the litigation's end must be addressed in the Board's final written decision. The statute's own winnowing mechanism fully explains why Congress adopted slightly different language in §314(a) and §318(a). We need not and will not invent an atextual explanation for Congress's drafting choices when the statute's own terms supply an answer. See United States v. Ron Pair Enterprises, Inc., 489 U. S. 235, 240–241 (1989) ("[A]s long as the statutory scheme is coherent and consistent, there generally is no need for a court to inquire beyond the plain language of the statute"). [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

At this point, only one final question remains to resolve. Even if the statute forbids his partial institution practice, the Director suggests we lack the power to say so. By way of support, he points to §314(d) and our decision in *Cuozzo*, 579 U. S. ____. Section 314(d) says that the "determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." *In Cuozzo*, we held that this provision prevented courts from entertaining an argument that the Director erred in instituting an inter partes review of certain patent claims. *Id.*, at _____ (slip op., at 7–12). The Director reads these authorities as foreclosing judicial review of any legal question bearing on the institution of inter partes re-view—including whether the statute permits

his "partial institution" practice. But this reading overreads both the statute and our precedent. *** In fact, *Cuozzo* proceeded to emphasize that §314(d) does not "enable the agency to act outside its statutory limits." *Id.*, at ____ (slip op., at 11). *** And that, of course, is exactly the sort of question we are called upon to decide today. SAS does not seek to challenge the Director's conclusion that it showed a "reason-able likelihood" of success sufficient to warrant "institut[ing] an inter partes review." 35 U. S. C. §§314(a), (d). No doubt SAS remains very pleased with the Director's judgment on that score. Instead, SAS contends that the Director exceeded his statutory authority by limiting the review to fewer than all of the claims SAS challenged. And nothing in §314(d) or *Cuozzo* withdraws our power to ensure that an inter partes review proceeds in accordance with the law's demands. [SAS Institute Inc. v. Iancu, 16–969 (4/24/2018).]

Oil States Energy Services, LLC, V. Greene's Energy Group, LLC, 16–712 (4/24/2018).

This is a decision of the Supreme Court on an appeal from the Federal Circuit case 2015-1855. The Federal Circuit summarily affirmed a decision of the PTAB canceling claims of Oil States' patent. Oil States sought Supreme Court review. A majority of the Supreme Court affirmed.

This case generated extraordinary interest because it challenged both the aspect of the AIA entitling the Patent Office to entertain court-like proceedings to cancel patents as well as the constitutional power of the executive branch. The Supreme Court was split. Justices Thomas, Kennedy, Ginsburg, Breyer, Alito, Sotomary, and Kagan joined the majority affirmance. Chief Justice Robert and Justice Gorsuch dissented.

Legal issue: Constitutionality of Inter Partes Review petition and proceedings canceling patents (IPRs).

The Supreme Court majority concluded that IPRs were constitutional. While this holding mentions only IPRs, it obviously extends to all other statutes entitling the PTAB to cancel patents.

The Leahy-Smith America Invents Act, 35 U. S. C. §100 et seq., establishes a process called "inter partes review." Under that process, the United States Patent and Trademark Office (PTO) is authorized to reconsider and to cancel an issued patent claim in limited circumstances. In this case, we address whether inter partes review violates Article III or the Seventh Amendment of the Constitution. We hold that it violates neither. [Oil States Energy Services, LLC, V. Greene's Energy Group, LLC, 16–712 (4/24/2018).]

Legal issue: Constitution, Article II, Section 1, scope of "executive Power."

The Court majority concluded that a patent was a public franchise, as a predicate to its conclusion that reconsideration of grant of patents were matters "arising between the government and others, which from their nature do not require judicial determination." And as such was a matter within the constitutional overlap of powers between the executive and judicial branches created by the Court's "public rights" doctrine.

This Court has not "definitively explained" the distinction between public and private rights, Northern Pipeline Constr. Co. v. Marathon Pipe Line Co., 458 U. S. 50, 69 (1982), and its precedents applying the public-rights doctrine have "not been entirely consistent," Stern, 564 U. S., at 488. But this case does not require us to add to the "various formulations" of the public-rights doctrine. *Ibid*. Our precedents have recognized that the doctrine covers matters "which arise between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments." *Crowell v. Benson*, 285 U. S. 22, 50 (1932). In other words, the public-rights doctrine applies to matters "'arising between the government and others, which from their nature do not require judicial determination and yet are susceptible of it.' " *Ibid*. (quoting *Ex parte Bakelite Corp.*, 279 U. S. 438, 451 (1929)). Inter partes review involves one such matter: reconsideration of the Government's decision to grant a public franchise. [Oil States Energy Services, LLC, V. Greene's Energy Group, LLC, 16–712 (4/24/2018).]

Article III vests the judicial power of the United States "in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." §1. Consequently, Congress cannot "confer the Government's 'judicial Power' on entities outside Article III." Stern v. Marshall, 564 U. S. 462, 484 (2011). When determining whether a proceeding involves an exercise of Article III judicial power, this Court's precedents have distinguished between "public rights" and "private rights." Executive Benefits Ins. Agency v. Arkison, 573 U. S. ____, ___ (2014) (slip op., at 6) (internal quotation marks omitted). Those precedents have given Congress significant latitude to assign adjudication of public rights to entities other than Article III courts. See ibid.; Stern, supra, at 488–492. *** Inter partes review falls squarely within the public-rights doctrine. This Court has recognized, and the parties do not dispute, that the decision to grant a patent is a matter involving public rights—specifically, the grant of a public franchise. Inter partes review is simply a reconsideration of that grant, and Congress has permissibly reserved the PTO's authority to conduct that reconsideration. Thus, the PTO can do so without violating Article III. *** Thus, the public-rights doctrine covers the matter resolved in inter partes review. The Constitution does not prohibit the Board from resolving it outside of an Article III court. [Oil States Energy Services, LLC, V. Greene's Energy Group, LLC, 16–712 (4/24/2018).]

Legal issue: Constitution, Seventh Amendment, right to a jury trial on the facts, for suits at common law.

The Court majority concluded that, since withdrawal of patent rights were within the constitutional authority of the executive branch, the seventh amendment was not applicable.

In addition to Article III, Oil States challenges inter partes review under the Seventh Amendment. The Seventh Amendment preserves the "right of trial by jury" in "Suits at common law, where the value in controversy shall exceed twenty dollars." This Court's precedents establish that, when Congress properly assigns a matter to adjudication in a non-Article III tribunal, "the Seventh Amendment poses no independent bar to the adjudication of that action by a nonjury factfinder." *Granfinanciera, S. A. v. Nordberg*, 492 U. S. 33, 53–54 (1989); *accord, Atlas Roofing Co., supra*, at 450–455. No party challenges or attempts to distinguish those precedents. Thus, our rejection of Oil States' Article III challenge also resolves its Seventh Amendment challenge. Because inter partes review is a matter that Congress can properly assign to the PTO, a jury is not necessary in these proceedings. [Oil States Energy Services, LLC, V. Greene's Energy Group, LLC, 16–712 (4/24/2018).]

Legal issues <u>not</u> addressed: Retroactivity and due process constitutionality.

We emphasize the narrowness of our holding. *** Moreover, we address only the precise constitutional challenges that Oil States raised here. Oil States does not challenge the retroactive application of inter partes review, even though that procedure was not in place when its patent issued. Nor has Oil States raised a due process challenge. Finally, our decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause. *See, e.g., Florida Prepaid Postsecondary Ed. Expense Bd. v. College Savings Bank*, 527 U. S. 627, 642 (1999); *James v. Campbell*, 104 U. S. 356, 358 (1882). [Oil States Energy Services, LLC, V. Greene's Energy Group, LLC, 16–712 (4/24/2018).]

Wi-Fi One, LLC v. Broadcom Corporation, 2015-1944 (Fed. Cir. 4/20/2018).

This is a decision on an appeal from PTAB case IPR2013-00601 after the en banc court decided in this case that the PTAB's 315(b) time bar determinations are appealable.

Legal issue: 35 USC 315(b), legal criteria for real party in interest, or privy.

The majority Federal Circuit panel, consisting of Judges Dyk and Bryson, concluded that th IPR was not time barred because the PTAB had applied a legally correct standard for determining that the Petitioner was neither a real party nor a privy to defendant in the prior patent infringement litigation. This is a general affirmance of the PTAB's criteria contained in the Trial Practice Guide.

On the merits of the section 315(b) issue, Wi-Fi first argues that the Board applied the wrong legal standard when it determined that no district court defendant was either a privy of Broadcom or a real party in interest in the inter partes review proceeding. *** Contrary to Wi-Fi's contention, the Board recognized that there are a number of circumstances in which privity might be found, including when the nonparty controlled the district court litigation. *** In its decision on Wi-Fi's motion, the Board first observed that privity depends on "whether the relationship between a party and its alleged privy is 'sufficiently close such that both should be bound by the trial outcome and related estoppels.'"

The Board further noted that "[d]epending on the circumstances, a number of factors may be relevant to the analysis, including whether the non-party 'exercised or could have exercised control over a party's participation in a proceeding,' and whether the non-party is responsible for funding and directing the proceeding." *** The Board thus made clear that it understood that privity and real-party-in-interest status could be established not only by Broadcom's exercise of control over the district court proceedings, but also by the D-Link defendants' exercise of control over the inter partes review proceeding. In sum, a review of the Board's decisions in this case, in the context of the arguments Wi-Fi made at each stage, show that the Board did not apply a legally erroneous standard in deciding the "real party in interest, or privy" issue. [Wi-Fi One, LLC v. Broadcom Corporation, 2015-1944 (Fed. Cir. 4/20/2018).]

Gregory C. James v. J2 Cloud Services, LLC, 2017-1506 (Fed. Cir. 4/20/2017).

This is a decision on an appeal from the C.D. Cal. district court case 2:16-cv-05769-CASPJW. The district court dismissed Gregory's 35 USC 256 claim to correct inventorship pursuant to FRCP 12(b)(1), for lack of subject matter jurisdiction. Gregory appealed. The Federal Circuit reversed and remanded.

Legal issue: Contract construction, patent assignment.

Gregory claimed to be the inventor of the subject patent, and to never have assigned his patent rights to the invention. The dispositive issue on standing was whether Gregory retained an interest such that he had standing. That issue turned on the Software Development Agreement ("SDA"). The Federal Circuit found that the SDA, when construed in the light most favorable to Gregory, did not necessarily show that Gregory retained no rights to the invention. Basically, the SDA assigned copyright and code, was silent regarding invention rights, and Gregory was not personally a party to the contract. Accordingly, the Federal Circuit concluded, when construed in the light most favorable to Gregory, the SDA did not show contracting away of patent rights, and did not show that Gregory was hired to invent.

The district court concluded that "the SDA necessarily precludes plaintiff from retaining ownership of the patent rights." *James*, 2016 WL 9450470, at *5. We disagree. Under the standards appropriate at this stage of the proceedings, which require that "the court construe[] all factual disputes in favor of" Mr. James, id. at *3, we cannot conclude that the SDA precludes Mr. James from retaining ownership rights in patents on his inventions— either as itself an assignment or as a contract to assign. *** The SDA is amenable to the construction that it does not assign, or promise to assign, patent rights that would otherwise accrue to Mr. James as an inventor. The district court relied in its ultimate analysis on the SDA's preamble, which states that the contract set the terms on which GSP "will develop software solutions for the exclusive use of JFAX Communications." J.A. 53; see James, 2016 WL 9450470, at *5 (rejecting Mr. James's position because it "would, for example, enable plaintiff to license the rights in contravention of JFAX's exclusive use"). But that language is not

itself a conveyance of any rights and, in any event, does not clearly go beyond GSP-developed specific software products to encompass also any underlying patentable methods embodied in the specific code. It can be read as indicating that it is only the specific code that will be for JFAX's exclusive use. The key SDA Section 3 is open to the same interpretation. *** On that basis, we conclude that the SDA can, and therefore at the present stage of this case must, be construed in Mr. James's favor. So construed, the SDA does not deprive Mr. James of constitutional standing. [Gregory C. James v. J2 Cloud Services, LLC, 2017-1506 (Fed. Cir. 4/20/2017).]

Moreover, the SDA did not indicate that Gregory was hired to invent, and therefore did not indicate that Gregory necessarily had retained no rights in the invention.

Hired to invent rationale inapplicable to contract between artificial legal entities

This case involves a distinctive fact not present in the authorities j2 and AMT cite in support of their hired-to-invent argument. Specifically, we have been directed to no decision applying the hired-to-invent principle where the underlying agreement for engagement of services was between two artificial legal entities and to which the inventor was not personally a party. Here, it was the partnership GSP, not alleged inventor Mr. James, that was engaged by JFAX through the SDA. As the case is presented to us, although the operative complaint does not carefully attend to the distinction between Mr. James and GSP, it appears from the SDA, on which j2 and AMT rely, that Mr. James was not himself an "employee" of JFAX or personally hired by JFAX. [Gregory C. James v. J2 Cloud Services, LLC, 2017-1506 (Fed. Cir. 4/20/2017).]

Regardless, the SDA does not support a hired-to-invent inference so as to deny standing here. j2 and AMT rely on the terms of the SDA to argue that GSP was engaged, and thus Mr. James was hired, to invent, creating an implied contract to assign resulting inventions. The problem with this argument is essentially the same as the problem we have already identified as defeating the SDA-contract argument for Rule 12(b)(1) dismissal. Based on the provisions and arguments presented to us, the SDA is readily capable of being read not to assign or to promise to assign the patent rights at issue. Because the SDA largely or even wholly defines the terms of JFAX's alleged "hiring" of Mr. James (actually of GSP), there is at least a factual dispute about any implied assignment or promise to assign. And that conclusion, though sufficient on its own case-specific terms, may be further supported by cases recognizing a general legal principle that tightly limits the finding of an implied-in fact contract where an express contract governs the parties' relationship. See Atlas Corp. v. United States, 895 F.2d 745, 754 (Fed. Cir. 1990); Chase Manhattan Bank v. Iridium Afr. Corp., 239 F. Supp. 2d 402, 409 (D. Del. 2002) (citing *Atlas*, 895 F.2d at 754). Accordingly, it was improper to dismiss the case under Rule 12(b)(1) for lack of standing based on the hired-to-invent principle. [Gregory C. James v. J2 Cloud Services, LLC, 2017-1506 (Fed. Cir. 4/20/2017).]

<u>Voter Verified, Inc. v. Election Systems & Software LLC, 2017-1930 (Fed. Cir. 4/20/2018).</u>

This is an appeal from the N.D. Fla. case 1:16-cv-00267-MWGRJ. The N.D. Cal. district court dismissed Voter's patent infringement action under FRCB 12(b)(6), concluding that the patent was directed to 35 USC 101 patent ineligible subject matter. Voter appealed. The Federal Circuit affirmed.

Legal issue: Issue preclusion, 35 USC 101, Alice.

In dicta, the Federal Circuit concluded that *Alice* was not a change in the law within the meaning of the requirements for issue preclusion.

Before we reach the merits of the § 101 issue, we must first determine whether the district court properly concluded that the § 101 judgment from the prior litigation does not have preclusive effect in this case for the reason that *Alice* was an intervening change in the law. See Wright et al., 18 Fed. Prac. & Proc. Juris. § 4425 (3d ed.) ("Preclusion is most readily defeated by specific Supreme Court overruling of precedent relied upon in reaching the first decision."); *see also Dow Chem. Co. v. Nova Chems. Corp.* (Can.), 803 F.3d 620, 628–29 (Fed. Cir. 2015); *Wilson v. Turnage*, 791 F.2d 151, 157 (Fed. Cir. 1986) (determining that issue preclusion was inapplicable when there was an "intervening change in the legal atmosphere"). *** We agree with Voter Verified to the extent that it argues that *Alice* was not an intervening change in the law, so that it does not exempt a potential application of issue preclusion. [Voter Verified, Inc. v. Election Systems & Software LLC, 2017-1930 (Fed. Cir. 4/20/2018).]

Turning to the first condition, we conclude that *Alice*, which was decided after the first litigation ended, did not alter the governing law of § 101. In Alice, the Court applied the same two-step framework it created in Mayo in its § 101 analysis. Alice, 134 S. Ct. at 2355 (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77–79 (2012)). The Court stated, "[f]irst, we determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* (citing *Mayo*, 566 U.S. at 77–78). If so, it stated, one must then determine "what else is there in the claims before us?" Id. (quoting Mayo, 566 U.S. at 78). Just as it did in *Mayo*, the Court characterized the second inquiry "as a search for an inventive concept," id. at 2355 (internal quotation marks and citation omitted), that is "sufficient to transform the claimed abstract idea into a patent-eligible application," id. at 2357 (internal quotation marks and citation omitted). It is thus evident from the Court's reliance on Mayo that it was merely applying the same test as it set out in Mayo, and did not materially change it. See id. at 2355, 2357 (citing Mayo for the rule of law). We therefore hold that Alice did not alter the governing law under § 101. [Voter Verified, Inc. v. Election Systems & Software LLC, 2017-1930 (Fed. Cir. 4/20/2018).]

ETrade Bank v. Iancu, 2016-2504, 2016-2602 (Fed. Cir. 4/19/2018).

This is a decision on appeals from PTAB case IPR2015-00470. The PTAB found all claims of the subject patent obvious.

Legal issue, 35 USC 120 requirement for benefit, specific reference, incorporation by reference.

The question in this case was whether incorporation by reference to an earlier application that had a 35 USC 120 benefit claim chain which was missing in the subject patent, complied with the requirements of 35 USC 120. The Federal Circuit agreed with the PTAB that the subject patent was not entitled to the 35 USC 120 benefit of that claim chain. That is, a patent cannot obtain 35 USC 120 benefit by an incorporation by reference to a patent that has the benefit claim chain

Relevant to this appeal, the statute requires that the patent application "contain a specific reference to the earlier filed application" to which it purports to claim priority. *** The PTO has issued a regulation implementing these statutes—37 C.F.R. § 1.78—which requires that an application contain a specific reference to each prior-filed application to which the application seeks to claim priority. *** The regulation thus requires that the specific reference include each prior-filed application's: (1) application number; and (2) familial relationship. *** Consistent with 35 U.S.C. § 120 and 37 C.F.R. § 1.78, the MPEP provides detailed guidance on how to claim priority from multiple prior-filed applications. *** The Board correctly applied § 120 in finding that the '115 Patent claims priority only to the '838 Patent. *** [Because the] '115 Patent does not contain a specific reference to either the intervening '745 Patent or the first-filed '917 Provisional. [E*Trade Bank v. Iancu, 2016-2504, 2016-2602 (Fed. Cir. 4/19/2018).]

We conclude that § 120's "specific reference" requirement does not contemplate incorporation by reference. In reaching this conclusion, we note that Droplets' proposed reading of § 120 conflicts with the statute's purpose, which is to provide clear notice to the public of the patentee's claimed priority date. *See Medtronic*, 741 F.3d at 1366. To require the public to search for an unstated priority claim through incorporated materials would create uncertainty and would require the type of guesswork that the statute is meant to avoid. *Id.* Accordingly, Droplets cannot invoke incorporation by reference to rewrite the priority claim statement in the '115 Patent. [E*Trade Bank v. Iancu, 2016-2504, 2016-2602 (Fed. Cir. 4/19/2018).]

Note: Even after issuance, the patentee could have obtained a certificate of correction correcting the patent to make the missing benefit claims.

<u>John Bean Technologies Corporation v. Morris & Associates, Inc.</u>, 2017-1502 (Fed. Cir. 4/19/2018).

This is a decision on an appeal from the E.D. Ark. case 4:14-cv-00368-BRW. The district

court held that John's patent infringement claims were barred by equittable estoppel and laches. John appealed. The Federal Circuit reversed and remanded.

Legal issue: 35 USC 282(b)(2) equittable estoppel, and its applicability to a patent whose claims were narrowed by reexamination.

The Federal Circuit found that equittable estoppel inapplicable because a long (11 year) failure to assert the original patent was not an act that was misleading with respect to the narrowed reexamined patent.

This case presents an unusual situation where the district court has found that equitable estoppel bars an infringement action based on activity prior to the issuance of the asserted reexamination claims. Here, the reexamined claims did not exist in their present form in 2002 at the time Morris sent the Demand Letter to John Bean. These claims first issued in May 2014 following reexamination. We have no precedent that presents this factual scenario and provides a clear solution. Under the circumstances presented here, we find that the district court abused its discretion in extending equitable estoppel to the reexamined claims. [John Bean Technologies Corporation v. Morris & Associates, Inc., 2017-1502 (Fed. Cir. 4/19/2018).]

Our resolution of this matter lies in the principles undergirding the issuance of reexamination claims. First, claims amended and issued during reexamination cannot be broader than the original claims. 35 U.S.C. § 305; 37 C.F.R. § 1.552(b). *** Second, and correlatively, a patentee cannot assert reexamination claims to obtain damages prior to the issuance date of the reexamination certificate unless the reexamined claims are identical in scope to the original claims. Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1346 (Fed. Cir. 1998). *** In this case, the amendments made during reexamination were both substantial and substantive. *** Lastly, our resolution of this case is supported by our precedent holding that the defense of equitable estoppel does not apply to pending claims during the examination of a patent application, Radio Sys., 709 F.3d at 1131. In *Radio Systems*, we held that equitable estoppel could not apply to pending patent claims even if those claims when issued could claim priority to a parent patent subject to equitable estoppel. *Id*. The reasoning behind this rule is that claims that have not issued cannot be asserted, and therefore no misleading conduct or silence could be present. Id. In other words, for claims that have not issued, there is no case or controversy and therefore "the elements of equitable estoppel are not present." Id. Here, because the asserted claims did not exist at, or were substantively altered since, the time Morris sent John Bean the Demand Letter, John Bean could not have engaged in misleading conduct or silence with respect to those claims. There may be other cases where the reexamined claims contain fewer amendments and narrower added claims such that the reexamined claims do not differ in scope from the original claims. In those instances, the asserted claims may possibly be considered identical for purposes of infringement, and consequently, for purposes of applying equitable estoppel. But

that is not the case here. We therefore find that the district court abused its discretion in applying equitable estoppel to bar John Bean's infringement action asserting the reexamined claims. [John Bean Technologies Corporation v. Morris & Associates, Inc., 2017-1502 (Fed. Cir. 4/19/2018).]

Note: The Federal Circuit gratuitously identified to Morris, other equitable options.

Our resolution of this case does not mean that Morris wholly lacks any recourse in equity for John Bean's twelve-year delay in asserting the '622 patent. Specifically, the affirmative defenses of absolute and equitable intervening rights may serve to prevent John Bean from enforcing the '622 patent against Morris. See 35 U.S.C. §§ 252, 307; *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1362 (Fed. Cir. 2012) (en banc) ("[A]fter a patent emerges from reexamination, [§307(b)] makes available absolute and equitable intervening rights . . . with respect to 'amended or new' claims in the reexamined patent."); *see also Shockley v. Arcan, Inc.*, 248 F.3d 1349, 1359–61 (Fed. Cir. 2001). Although we decline to apply those defenses for the first time on appeal, as Morris asserted these defenses in its answer, the district court is free to entertain them on remand. J.A. 196. [John Bean Technologies Corporation v. Morris & Associates, Inc., 2017-1502 (Fed. Cir. 4/19/2018).]

Note: John Bean would have won, avoiding the equitable defenses, if it had reexamined its patent promptly after becoming aware of the prior art, and then promptly filed its action. This was tactical legal error.

Raniere v. Microsoft Corporation, 2017-1400, 2017-1401 (Fed. Cir. 4/18/2018).

This is a decision on appeals from the N.D. Tex cases 3:15-cv-00540-M and 3:15-cv-02298-M. The district court awarded attorneys fees and costs to Microsoft. Raniere appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 285, "prevailing party" status for a defendant.

The Federal Circuit concluded that a defendant is a 35 USC 285 "prevailing party" when the district court's decision effects or rebuffs a plaintiff's attempt to effect a material alteration in the legal relationship between the parties. Such as, in this case, a dismissal with prejudice for lack of standing.

Raniere first disputes whether Appellees are prevailing parties under § 285. Raniere contends that dismissal with prejudice for lack of standing is not an adjudication on the merits, as he contends is required to find that a defendant is a "prevailing party" under our case law. Raniere also asserts that dismissal with prejudice, without adjudication of a patent infringement claim, should preclude finding that a defendant has prevailed in a litigation. We disagree with these statements, particularly in light of the Supreme Court's recent decision in *CRST Van Expedited, Inc. v. EEOC*, which held that a favorable judgment on the merits is not necessary for a defendant to be deemed a prevailing party for purposes of

statutory fee-shifting. 136 S. Ct. 1642, 1651 (2016). *** Although *CRST* considered the fee-shifting provision of Title VII, the Court explained there that "Congress has included the term 'prevailing party' in various fee-shifting statutes, and it has been the Court's approach to interpret the term in a consistent manner." *Id.* at 1646 (citing *Buckhannon*, 532 U.S. at 602–03); *see Buckhannon*, 532 U.S. at 602 ("Congress . . . has authorized the award of attorney[] fees to the 'prevailing party' in numerous statutes in addition to those at issue here."); *Hensley v. Eckerhart*, 461 U.S. 424, 433 n.7 (1983) (holding that interpretation of "prevailing party" in a case involving the Civil Rights Attorney's Fees Awards Act of 1976, 42 U.S.C. § 1988, is "generally applicable in all cases in which Congress has authorized an award of fees to a 'prevailing party"). [Raniere v. Microsoft Corporation, 2017-1400, 2017-1401 (Fed. Cir. 4/18/2018).]

We reach the same conclusion our sister circuits have reached regarding *CRST*, which clarified the application of *Buckhannon* to defendants seeking prevailing-party status. The relevant inquiry post-*CRST*, then, is not limited to whether a defendant prevailed on the merits, but also considers whether the district court's decision— "a judicially sanctioned change in the legal relationship of the parties"—effects or rebuffs a plaintiff's attempt to effect a "material alteration in the legal relationship between the parties." *CRST*, 136 S. Ct. at 1646, 1651. And the same policy rationales the *CRST* Court emphasized in support of its holding underscore § 285 actions: the statute deters filing of "exceptional" cases—those "that stand[] out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness*, 134 S. Ct. at 1756. [Raniere v. Microsoft Corporation, 2017-1400, 2017-1401 (Fed. Cir. 4/18/2018).]

Apator Miitors APS v. Kamstrup A/S, 2017-1681 (Fed. Cir. 4/17/2018).

This is a decision on an appeal from PTAB case IPR2015-01403. The PTAB found claim 2 and 10 anticipated and obvious, respectively, on prior art including the prior art reference named Nielson. Apator appealed. The Federal Circuit affirmed. The issue on appeal was whether Apator had antedated Nielson.

Legal issue: Evidentiary requirements to corroborate conception and reduction to practice.

The problem with Apator's showings was that provided no evidence corroborating the inventor's testimony. Apator relied upon the purported existence of attachments to emails sent by the inventor to corroborate conception. The Court however, noted that the Board had found that the emails, per se, contained no indicia that any file was attached: The Federal Circuit stated:

Apator has failed to proffer any evidence of Mr. Drachmann's conception that is not supported solely by Mr. Drachmann himself. *** Again, as the Board observed, "the only evidence that a 'UFM++venture' file was attached to these emails . . . is the Drachmann Declaration, " that is, the testimony of Mr.

Drachmann himself. [Apator Miitors APS v. Kamstrup A/S, 2017-1681 (Fed. Cir. 4/17/2018).]

Note: Assuming the veracity of Mr. Drachmann's testimony, there should have been someone on the other end of his emails that could have corroborated the existence of the emails and their attachments. Why was not that evidence adduced?

<u>Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharmaceuticals Limited,</u> 2017-1798, 2017-1799, 2017-1800 (Fed. Cir. 4/16/2018).

This is a decision on appeals from the D. N.J. district court cases 2:15-cv-00280-SRC-CLW; 2:15-cv-00281-SRC-CLW; and 2:15-cv-06401-SRC-CLW. The district court held claim 14 infringed and not invalid. Emcure appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 112(b), claim construction of a claim defining a compound by chemical formula, but in which the formal is graphically presented and shows one enantiomer for the formula.

The claim is shown below:

14. The imide compound of the formula:

or an acid addition salt thereof.

The Federal Circuit noted that it was sufficient to determine if claim 14 covered the (-) enantiomer graphically depicted in claim 14. That was apparently an easy task. The Court noted that:

Both parties agree that the structure shown in the claim is the (–)-enantiomer; *** The specification confirms our understanding of claim 14's plain and ordinary meaning. Instead of suggesting that the (–)-enantiomer should be excluded, the specification describes it as a preferred embodiment. *** Accordingly, the intrinsic record supports including the (–)-enantiomer—the specific enantiomer that is displayed in the claim and described as a preferred embodiment—within claim 14's scope. [Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharmaceuticals Limited, 2017-1798, 2017-1799, 2017-1800 (Fed. Cir. 4/16/2018).]

The graphic appearing in claim 14 is the same as the graphic identifying

compound 101 in the patent's specification. But the Federal Circuit conclude that similarity was not enough to limit the claim to a racemic mixture.

Even if Compound No. 101 is a racemic mixture, the specification neither defines claim 14's structure as Compound No. 101 nor disclaims scope in a way that confines claim 14 to a racemic mixture. See Thorner, 669 F.3d at 1367–68 ("Both [lexicography and disclaimer] require a clear and explicit statement by the patentee."). To act as a lexicographer, the patentee must "clearly set forth a definition of the disputed claim term." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). Here, the '372 patent does not define the structure in claim 14 as a racemate or as coextensive with Compound No. 101. Claim 14 does not refer to Compound No. 101, and nothing in the specification links the two structures together. Compound No. 101 just happens to be the only other place in the patent where claim 14's structure appears. This, of course, is not enough to restrict a claim's scope. See, e.g., Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 992 (Fed. Cir. 1999) ("[M]ere inferences drawn from the description of an embodiment of the invention cannot serve to limit claim terms."). [Sumitomo Dainippon Pharma Co., Ltd. v. Emcure Pharmaceuticals Limited, 2017-1798, 2017-1799, 2017-1800 (Fed. Cir. 4/16/2018).]

Knowles Electronics LLC v. Iancu, 2016-1954 (Fed. Cir. 4/6/2018).

This is a decision on an appeal from PTAB case 95/001,850. The PTAB affirmed the examiner's rejections of certain claims as anticipate and others as obvious. Knowles appealed. The Federal Circuit majority affirmed. Judge Newman dissented. The only real issue in this case is one that was not officially in the case. The issue was whether the USPTO Director could intervene to defend the PTAB's decision when the inter parte reexamination petitioner failed to appear.

Legal issue: 35 USC 143, standing of the USPTO Director to intervene in an appeal from an inter partes reexamination.

The majority consisting of Judges Clevenger and Wallach concluded in a footnote that the USPTO Director could intervene when the reexamination petitioner had dropped out.

...The Director of the USPTO has an unconditional statutory "right to intervene in an appeal from a [PTAB] decision." 35 U.S.C. § 143; see Leahy-Smith America Invents Act, Pub. L. No. 112-29, §7(e), 125 Stat. 284, 315 (2011) (stating that the Director's right to intervene "shall be deemed to extend to interpartes reexaminations that are requested under section 311 of such title before the effective date" of the America Invents Act). [Knowles Electronics LLC v. Iancu, 2016-1954 (Fed. Cir. 4/6/2018).]

In her dissent, Judge Newman disagreed, stating in the most pertinent part, that:

The America Invents Act's grant to the PTO Director, of the right of

intervention, is consistent with the general rule that litigation solely by an intervenor is not permitted unless the intervenor is itself injured by the conduct at issue. "Injury in fact is a constitutional requirement, and '[i]t is settled that Congress cannot erase Article III's standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing." *Spokeo, Inc. v. Robins*[,] 136 S. Ct. 1540, 1547–48 (2016) (alteration in original) (quoting *Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997)). The principle that a plaintiff "must demonstrate standing for each claim he seeks to press and for each form of relief that is sought" also "applies to intervenors of right." *Town of Chester*, 137 S. Ct. at 1650–51 (quoting *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 734 (2008)). [Knowles Electronics LLC v. Iancu, 2016-1954 (Fed. Cir. 4/6/2018); dissent by Judge Newman.]

Note: Judge Newman's dissent is broader than the standing issue in an reexamination because it addresses the Director's standing in AIA proceedings.

<u>Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited</u>, 2016-2707, 2016-2708 (Fed. Cir. 4/3/2018).

This is a decision on appeals from D.Del District Court cases 1:13-cv-01973-GMS; and 1:14-cv-00757-GMS. The district court held that the asserted claims were infringed and not invalid. West-Ward appealed. A Federal Circuit panel majority consisting of Judges Lourie and Hughes affirmed. Judge Prost dissented.

Legal issue: 28 USC 1338(a), standing, ANDA infringement.

The Federal Circuit majority held that 271(e)(2) provides subject matter jurisdiction regardless when the ANDA was filed.

Legal Issue: 35 USC 271(e)(2), subject matter jurisdiction for an amended paragraph IV certification after the civil action was filed.

The Federal Circuit majority held that 271(e)(2) provides subject matter jurisdiction regardless when the paragraph IV certification was amended.

The Federal Circuit majority addresses these related legal issues as follows:

Here, Vanda's complaint alleged that West-Ward infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by filing the ANDA. J.A. 10002. Nothing more was required to establish the district court's subject matter jurisdiction pursuant to 28 U.S.C. § 1338(a). See AstraZeneca II, 669 F.3d at 1377 (explaining that "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims"). West-Ward's arguments relating to whether there was a qualifying act of infringement raise potential merits problems, not jurisdictional issues. We have previously rejected the argument that a court's jurisdiction "hinged on whether [plaintiff] asserted a 'valid' claim under § 271(e)(2)." *Id.* The Supreme Court has similarly explained that "[t]he want of an infringing act [under § 271(e)(2)] is a merits problem, not a jurisdictional one." *Caraco II*, 566 U.S. at

412 n.5. Thus, whether Vanda alleged, and subsequently proved, an infringing act is a merits question, not a jurisdictional one. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

Legal issue: 35 USC 271(e)(2), whether filing an ANDA prior to issuance of a patent and then amending the ANDA Paragraph IV certification after the issuance of the patent to refer to the patent is a 271(e)(2) act of infringement.

The Federal Circuit majority held that amending the ANDA Paragraph IV certification after the issuance of the patent to refer to the patent is a 271(e)(2) act of infringement. The majority stated that:

Here, it is undisputed that West-Ward amended the ANDA by submitting a Paragraph IV certification regarding the '610 patent after that patent issued. J.A. 19696; J.A. 6414–15; Appellant Br. 10; Appellee Br. 59. Such an act is a qualifying act of infringement under § 271(e)(2)(A).6 A filer of an ANDA is therefore subject to a § 271(e)(2)(A) infringement claim on a patent that issues after the filing of the ANDA, but before FDA approval. The resolution of infringement claims under § 271(e)(2)(A) for patents that issue after an ANDA is submitted, but before it is approved, "facilitates the early resolution of patent disputes between generic and pioneering drug companies" in accordance with the purpose of § 271(e)(2)(A). *Caraco I*, 527 F.3d at 1283. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

Legal Issue: 35 USC 271(e)(2), predicate direct infringement for showing 35 USC 271(b) inducing infringement.

The Federal Circuit majority held that a marketing the proposed ANDA product would infringe the patent the predicate direct infringement for showing inducing infringement under 271(b).

We agree with Vanda that a patentee does not need to prove an actual past instance of direct infringement by a physician to establish infringement under 35 U.S.C. § 271(e)(2)(A). As we have explained, "section 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug were put on the market, it would infringe the relevant patent." *Bristol-Myers Squibb*, 69 F.3d at 1135 (emphases in original). A § 271(e)(2)(A) infringement suit differs from typical infringement suits in that the infringement inquiries "are hypothetical because the allegedly infringing product has not yet been marketed." *Warner-Lambert*, 316 F.3d at 1365 (emphasis added); *see also Glaxo*, 110 F.3d at 1570 ("The relevant inquiry is whether patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product.").
*** Accordingly, Vanda can satisfy its burden to prove the predicate direct infringement by showing that if the proposed ANDA product were marketed, it

would infringe the '610 patent. The district court made factual findings that the proposed label "recommends" that physicians perform the claimed steps, *see Opinion*, 203 F. Supp. 3d at 432–33, and its analysis of the proposed label to assess potential direct infringement by physicians was proper under our precedent. *See, e.g., Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) ("The infringement determination is thus based on consideration of all the relevant evidence, and because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, the ANDA itself dominates the analysis." (internal quotation marks and alterations omitted)); *AstraZeneca I*, 633 F.3d at 1060 (explaining that the district court "correctly determined" that language in the ANDA label "would inevitably lead some consumers to practice the claimed method"). [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

Legal issue: 35 USC 101, subject matter eligibility, method of treatment claim

The claim defined dependin g dosage upon assay of the patient's genotype. And the specification identified that the genotype correlated to drug metabolism and deleterious QTc prolongation.

The Federal Circuit majority found that the claim defined patent eligible subject matter in *Alice/Mayo* Step 1, and also did not preempt. A major difference from *Alice/Mayo* fact patterns was the existence in this claim of a step depending specifically upon the results of an individual's genotype assay. The step was administration of different dosages, depending upon the individual's genotype as determined by the assay. The utility disclosed in the specification was the reduced adverse side effect, reduced QTc prolongation, afforded by the lower dosage.

The Federal Circuit majority noted that the claim was directed to a method of treatment because it included an actual treatment step depending upon the assay, not a diagnostic method.

Consistent with Supreme Court precedent, we agree with Vanda that the asserted claims are not directed to patent-ineligible subject matter. [Footnote 9] omitted.] Claim 1 recites "[a] method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia." '610 patent col. 17 ll. 2–3. Claim 1 requires specific steps: (1) determining the patient's CYP2D6 metabolizer genotype by (a) obtaining a biological sample and (b) performing a genotyping assay; and (2) administering specific dose ranges of iloperidone depending on the patient's CYP2D6 genotype. Id. col. 17 ll. 2–25. West-Ward contends that the Supreme Court held that similar claims were patent ineligible in Mayo and Myriad. *** This case, however, is not Mayo. First, the claims in Mayo were not directed to a novel method of treating a disease. Instead, the claims were directed to a diagnostic method based on the "relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Id.* This "relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that

relation sets forth a natural law." *Id.* *** To further underscore the distinction between method of treatment claims and those in *Mayo*, the Supreme Court noted that "[u]nlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws." *Id.* at 87. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

In this case, the '610 patent claims are directed to a method of using iloperidone to treat schizophrenia. The inventors recognized the relationships between iloperidone, CYP2D6 metabolism, and QTc prolongation, but that is not what they claimed. They claimed an application of that relationship. Unlike the claim at issue in *Mayo*, the claims here require a treating doctor to administer iloperidone in the amount of either (1) 12 mg/day or less or (2) between 12 mg/day to 24 mg/day, depending on the result of a genotyping assay. The specification further highlights the significance of the specific dosages by explaining how certain ranges of administered iloperidone correlate with the risk of QTc prolongation. *See, e.g.*, '610 patent at col. 4 ll. 1–15. Thus, the '610 patent claims are "a new way of using an existing drug" that is safer for patients because it reduces the risk of QTc prolongation. *Mayo*, 566 U.S. at 87. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

The Federal Circuit majority indicated that the fact that the claim did not cover all subsequent treatment decisions by the physician, indicated it did not preempt.

Moreover, unlike the claim in Mayo, to the extent that preemption is a concern, the '610 patent claims do not "tie up the doctor's subsequent treatment decision." *Id.* at 86. The claim in *Mayo* did not go beyond recognizing (i.e., "indicates") a need to increase or decrease a dose. *Id.* at 75. In *Mayo*, "a doctor... . could violate the patent even if he did not actually alter his treatment decision in the light of the test." Id. The claim was not a treatment claim. It was "not limited to instances in which the doctor actually decreases (or increases) the dosage level where the test results suggest that such an adjustment is advisable." *Id.* at 76. Thus, the claim in *Mayo* did not involve doctors using the natural relationship between the metabolite level and lessening "the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." *Id.* at 77. The claims in Mayo therefore "tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations " Id. at 86–87. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

The Federal Circuit majority distinguished the claim over *Mayo* by noting the claim defined a treatment step depending upon genotype.

Here, the '610 patent claims recite the steps of carrying out a dosage regimen based on the results of genetic testing. The claims require doctors to "internally administer[] iloperidone to the patient in an amount of 12 mg/day or less" if the patient has a CYP2D6 poor metabolizer genotype; and "internally administer[] iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day" if the patient does not have a CYP2D6 poor metabolizer genotype. '610 patent col. 17 ll. 13–20. These are treatment steps. In contrast, as shown above, the claim in *Mayo* stated that the metabolite level in blood simply "indicates" a need to increase or decrease dosage, without prescribing a specific dosage regimen or other added steps to take as a result of that indication. *Mayo*, 566 U.S. at 75. Here, the claims do not broadly "tie up the doctor's subsequent treatment decision." *Id.* at 86. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

The Federal Circuit majority noted that the claim fell within the exclusion identified in *Myriad*, of new applications of knowledge about particular genes.

Nor does *Myriad* compel a different outcome. The Supreme Court in *Myriad* held "that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring." *Myriad*, 569 U.S. at 580. The Court was careful to note that "method claims" and "patents on new applications of knowledge about [particular] genes" were "not implicated by [its] decision." *Id*. 595–96 (emphasis in original). The '610 patent does not claim naturally occurring DNA segments. Rather, the asserted claims fall squarely within categories of claims that the Court stated were not implicated by its decision. [Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Limited, 2016-2707, 2016-2708, (Fed. Cir. 4/13/2018).]

Judge Prost, in dissent, argued that the majority "conflate[d] the inquiry at step one with the search for an inventive concept at step two."