Precedential Patent Case Decisions During May 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

Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).

This is a decision on appeals from the N.D. Cal. district court cases 3:17-cv-04032-WHA and 3:17-cv-04033-WHA. The district court dismissed under FRCP 12(b)(1). Lone Star appealed. The Federal Circuit vacated and remanded.

Legal issue: Article III standing of licensee to file suit for patent infringement.

The sleeper issue, buried on pages 17-18 in this case, is the panel's recognition that a long line of Federal Circuit cases equating constitutional Article III standing, for patent infringement with the "patentee" defined in 35 USC 281 (the party entitled to a remedy for patent infringement), was inconsistent with Supreme Court law. The Federal Circuit panel recognized that recent Supreme Court clarified that Article III standing merely required the plaintiff to have suffered a legal harm, and did not require the plaintiff to be the one statutorily entitled to a remedy. The Federal Circuit had previously held that only the 35 USC 281 "patentee" had Article III standing to sue. No more, according to this panel! This case opens the standing door to licensees (1) that have less than the entire right, title, and interest in a patent, and (2) that do not meet the Federal Circuit's "effective patentee" test.

In summarizing the proceedings below, the Federal Circuit stated:

> After it concluded that Lone Star could not sue in its own name, the district court dismissed the case. *Id.* And although it acknowledged that Lone Star had asked to join AMD, the district court concluded that doing so would "reward Lone Star for its litigation gimmick and unfairly prejudice defendants." *Id.* In particular, the district court emphasized that if AMD were joined it "would enjoy earlier filing dates for [its] claims than defendants would for any counterclaims for purposes of recovering damages." *Id.* (citing 35 U.S.C. § 286). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

The Federal Circuit agreed with the district court that Lone Star could not sue in its own name:

In sum, we agree with the district court that AMD did not transfer all substantial rights in the asserted patents. Lone Star is therefore not the relevant patentee and cannot assert these patents in its own name under § 281. [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

But the Federal Circuit did not agree that Lone Star lacked constitutional Article III standing, at the pleadings stage, to sue:

Appellees argue that, because Lone Star is not a patentee and never explicitly alleged that it was an exclusive licensee, it lacks standing to bring suit. We disagree. *** We have recognized that those who possess "exclusionary rights" in a patent suffer an injury when their rights are infringed. *See, e.g., WiAV*, 631 F.3d at 1264–65 ("[A] party holding one or more of those exclusionary rights—such as an exclusive licensee—suffers a legally cognizable injury when an unauthorized party encroaches upon those rights and therefore has standing to sue."). As we explained in *Morrow*, "exclusionary rights" involve the ability to exclude others from practicing an invention or to "forgive activities that would normally be prohibited under the patent statutes." 499 F.3d at 1342. Lone Star alleged that it possesses the sort of exclusionary rights that confer Article III standing. *See, e.g.*, J.A. 13082–13084 (alleging that it possesses rights in the asserted patents). The transfer agreement, which is referenced in each complaint, also suggests as much. *See, e.g.*, J.A. 2621 (mentioning AMD's "assign[ment]" of rights to Lone Star); J.A. 2025 (allowing Lone Star to "collect royalties"). These rights distinguish Lone Star from the plaintiff in *Morrow*, who lacked the ability to grant licenses or "forgive" infringement. 499 F.3d at 1338–43. Lone Star also alleged that Appellees infringe its exclusionary rights. See, e.g., J.A. 2623–2655. And it is clear that a court could redress an injury caused by that infringement. This is enough to confer standing at the pleadings stage. *See WiAV*, 631 F.3d at 1266 (noting that licensees "may have standing to sue some parties and not others"). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

Although Lone Star cleared this constitutional threshold, the district court concluded that it lacked standing to proceed without AMD. But treating AMD's absence as implicating Lone Star's standing confuses the requirements of Article III—which establish when a plaintiff may invoke the judicial power—and the requirements of § 281—which establish when a party may obtain relief under the patent laws. The district court's mistake, repeated by the parties on appeal, is understandable. Indeed, we have often treated "statutory standing," i.e. whether a party can sue under a statute such as § 281, as jurisdictional. *See AsymmetRx*, 582 F.3d at 1318 ('The issue of AsymmetRx's standing to bring suit without Harvard joining as a plaintiff was not raised by either party or by the district court.

However, an appellate court must satisfy itself that it has standing and jurisdiction whether or not the parties have raised them."). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

But the Supreme Court has recently clarified that so-called "statutory standing" defects do not implicate a court's subject-matter jurisdiction: *** *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014); *see also Flast v. Cohen*, 392 U.S. 83, 99 (1968) ("The fundamental aspect of standing is that it focuses on the party seeking to get his complaint before a federal court and not on the issues he wishes to have adjudicated."). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

Lexmark is irreconcilable with our earlier authority treating § 281 as a jurisdictional requirement. Indeed, following *Lexmark*, several courts have concluded that motions to dismiss based on "statutory standing" defects are properly brought under Rule 12(b)(6) rather than Rule 12(b)(1) in recognition of the fact that such defects are not jurisdictional. *See, e.g., Minden Pictures, Inc. v. John Wiley & Sons, Inc.*, 795 F.3d 997, 1001 (9th Cir. 2015) (noting that "[defendant's] Rule 12 motion to dismiss [because the plaintiff was not the owner of the copyright at issue] should have been brought under Rule 12(b)(6) . . . rather than under Rule 12(b)(1) . . . for the issue is statutory rather than Article III standing"); *John Wiley & Sons*, 882 F.3d at 402 n.4 (distinguishing between a plaintiff's "right to pursue a cause of action under the Copyright Act" and "Article III standing" in view of *Lexmark*). Where intervening Supreme Court precedent makes clear that our earlier decisions mischaracterized the effects of § 281, we are bound to follow that precedent rather than our own prior panel decisions. *Cf. Troy v. Samson Mfg. Corp.*, 758 F.3d 1322, 1326 (Fed. Cir. 2014) ("It is established that a later panel can recognize that the court's earlier decision has been implicitly overruled as inconsistent with intervening Supreme Court authority."). We therefore firmly bring ourselves into accord with *Lexmark* and our sister circuits by concluding that whether a party possesses all substantial rights in a patent does not implicate standing or subject-matter jurisdiction. [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

Legal issue: FRCP 19, essential party, requirement for joinder.

The Federal Circuit concluded the district court erred by dismissing the civil action without first considering whether the non-joined essential party should have been joined, noting that normally the patentee should be joined.

After explaining that Lone Star cleared the constitutional Article III standing threshold, the Federal Circuit explained that the district court's dismissal was inconsistent with Supreme

Court and Federal Circuit law relating to FRCP 19, which ordinarily requires joinder instead of dismissal.

> Lone Star argues that, because it has standing, even if it lacks all substantial rights in the patents, it should be given an opportunity to join AMD as a necessary party be-fore this case is dismissed. We agree. This result is compelled by Federal Rule of Civil Procedure 19 and our case law. [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

> In *Independent Wireless*, the Supreme Court acknowledged that licensees cannot bring suit in their own name. 269 U.S. at 466–68. But the Court also concluded that an exclusive licensee should be able to join the patent owner, involuntarily if need be, to maintain suit. Id. at 473. Otherwise, the licensee possesses a right without a remedy. *Id*. at 472. Joinder, by contrast, "secur[es] justice to the exclusive licensee." *Id*. It also honors "the obligation the [patent] owner is under to allow the use of his name and title to protect all lawful exclusive licensees and sublicensees against infringers." *Id*. The joinder rule outlined in *Independent Wireless* was incorporated into Federal Rule of Civil Procedure 19. See 7 Charles Alan Wright et al., Federal Practice and Procedure§ 1606 (3d ed. 2018) (noting that "the involuntary-plaintiff procedure" embodied in Rule 19 was "first enunciated by the Supreme Court in *Independent Wireless*" and observing that the rule "has been used extensively to allow the exclusive licensee of a patent or a copyright . . . to prosecute an action by compelling the joinder of the owner" (internal footnotes omitted)); *see also Caprio v. Wilson*, 513 F.2d 837, 839 (9th Cir. 1975) (acknowledging the same). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

> The rule of *Independent Wireless*, as incorporated into Rule 19, provides a clear command. A necessary party who is subject to service of process and whose joinder will not otherwise destroy a court's subject-matter jurisdiction "must be joined." Fed. R. Civ. P. 19(a)(1). The rule extends its command directly to courts. *See* Fed. R. Civ. P. 19(a)(2) ("If a person has not been joined as required, the court must order that the person be made a party." (emphasis added)). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

> Of course, while the rule's command is mandatory, it is not inflexible. If a party whose joinder is otherwise required by part (a) cannot be feasibly joined, part (b) allows a court to consider whether the case should proceed anyway or be dismissed because that party is indispensable. Fed. R. Civ. P. 19(b); *see also A123 Sys.*, 626 F.3d at 1222(concluding that dismissal was appropriate because the

absent patent owner, who could not be joined because it had not waived sovereign immunity, "was not only a necessary party but also an indispensable party"). Put simply, the rule requires courts to engage with this two- step inquiry when a plaintiff asserts claims that also implicate the rights of necessary third parties. [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

We have interpreted Rule 19 and *Independent Wireless* as directing courts to join patentees along with licensees who otherwise have standing. In *Abbott*, for example, we explained that such joinder is "required" and consistent with "the policies underlying Fed. R. Civ. P. 19." 47 F.3d at 1133. And, while the patentee in *Abbott* sought to voluntarily join the case, Rule 19 applies with equal force regardless of whether joinder is prompted by the patentee or the licensee. In either case, the patentee must be joined, if feasible, when it is a necessary party. Fed. R. Civ. P. 19. *Abbott* is no outlier in this respect. *See, e.g., Intellectual Prop. Dev.*, 248 F.3d at 1347 ("As a general rule, in accordance with *Independent Wireless*, this court adheres to the principle that a patent owner should be joined, either voluntarily or involuntarily, in any patent infringement suit brought by an exclusive licensee having fewer than all substantial patent rights."); *Morrow*, 499 F.3d at 1340 (noting that "[a] patentee who transferred these exclusionary interests is usually joined to satisfy prudential standing concerns" and stating that "[t]his joinder analysis has been incorporated in Federal Rule of Civil Procedure 19"); *AsymmetRx*, 582 F.3d at 1321–22 (concluding that the plaintiff lacked all substantial rights in the asserted patents, but remanding for consideration of whether the patentee should be joined under Rule 19); *Univ. of Utah v. Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V.*, 734 F.3d 1315, 1326 (Fed. Cir. 2013) (noting that our cases "strongly support the conclusion that patent owners are required to be joined if feasible under Rule 19(a)"); *Alps S., LLC v. Ohio Willow Wood Co.*, 787 F.3d 1379, 1385 (Fed. Cir. 2015) (acknowledging "our practice of endorsing joinder of patent owners . . . in order to avoid dismissal for lack of standing"); *see also* 7 Charles Alan Wright et al., Federal Practice and Procedure§ 1611 (3d ed. 2019) ("[T]he non-joinder of someone described in Rule 19(a) does not result in a dismissal if that person can be made a party to the action."). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

Joinder also furthers the purposes of Rule 19. As the Supreme Court recognized in *Independent Wireless*, joining a patentee under Rule 19 helps "secur[e] justice" for licensees so they can vindicate their rights. 269 U.S. 472–73. It makes little sense here to ignore this rule, even if we could, because the licensee brought suit thinking it was the patentee and turned out to be wrong. Joinder also ensures that the resulting judgment affords complete relief between AMD, Lone Star, and Appellees. *See AsymmetRx*, 582 F.3d at 1322 (concluding that "the

purpose of Rule 19 . . . is best served by joinder of [the patentee], which would permit the relationships between [the licensee], [the defendant], and [the patentee] to all be resolved at the same time as well as solve the standing problem"); *Abbott*, 47 F.3d at 1133 (nothing that "[t]he purpose of Rule 19 . . . is thus served by joinder" to "permit [the patentee's] dispute with [the defendant] to be adjudicated along with [the licensee's]"). [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

The district court's dismissal was inconsistent with Rule 19 and our case law. If AMD is the patentee, as the district court correctly concluded, then AMD's joinder would ordinarily be "required." *See Abbott*, 47 F.3d at 1133 (citing Rule 19). And since Lone Star agreed that AMD should be joined, assuming it retained substantial rights in the asserted patents, Lone Star essentially conceded that AMD is a necessary party. The district court therefore should have considered whether AMD's joinder was feasible. If so, then AMD must be joined—involuntarily if need be. If not, then the district court should consider whether AMD is indispensable. Rather than engaging in this analysis, however, the district court declined to join AMD be-cause it thought doing so "would reward Lone Star" for a "litigation gimmick" and prejudice Appellees. *In re Lone Star*, 2018 WL 500258, at *6. But the application of Rule 19 is mandatory, not discretionary. [Lone Star Silicon Innovations LLC v. Nanya Technology Corporation, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019).]

Papst Licensing GMBH & Co. KG v. Samsung Electronics America, Inc., 2018-1777 (Fed. Cir. 5/23/2019).

This is a decision on an appeal from PTAB case IPR2016-01733. The PTAB determined the claims were unpatentable for obviousness. Papst, the patent owner, appealed. The Federal Circuit affirmed.

Legal issue: Issue preclusion resulting from prior agency action; limitations on the conditions under which issue preclusion would apply.

The Federal Circuit rejected Papst substantive argument because the same issue had been previously decided in another PTAB case. First, the Federal Circuit restated relevant law. Second, the Federal Circuit explained why Papst arguments did not show circumstances that were an exception to when issue preclusion applied. Then, the Federal Circuit " readily conclude that the conditions for issue preclusion are met." So the relevant guidance in this decision is the discussion of the limitations on the conditions under which issue preclusion would apply. In particular, the Federal Circuit concluded that by aggressively litigating the prior case, and failing to settle, or request waiver of estoppel in the prior case, the exceptions to collateral estoppel were inapplicable.

The Federal Circuit restated the law of issue preclusion as follow.

The Supreme Court has made clear that, under specified conditions, a tribunal's resolution of an issue that is only one part of an ultimate legal claim can

preclude the loser on that issue from later contesting, or continuing to contest, the same issue in a separate case. Thus: [“] subject to certain well-known exceptions, the general rule is that “[w]hen an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim. [“] *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1303 (2015) (quoting Restatement (Second) of Judgments § 27, then referring to exceptions stated in § 28); *see, e.g., Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013); *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1371 (Fed. Cir. 2013); *Stephen Slesinger, Inc. v. Disney Enters., Inc.*, 702 F.3d 640, 644 (Fed. Cir. 2012). [Papst Licensing GMBH & Co. KG v. Samsung Electronics America, Inc., 2018-1777 (Fed. Cir. 5/23/2019).]

The Supreme Court also has made clear that issue-preclusion principles apply in a court case even when the first “action” was before an agency if the agency proceeding meets certain standards. *B & B Hardware*, 135 S. Ct. at 1303. Following the Supreme Court’s conclusion in *B & B Hardware* that those standards are met by certain adversary proceedings before the Trademark Trial and Appeal Board, we have held that the same is true of an IPR proceeding before the Patent Trial and Appeal Board, so that the issue preclusion doctrine can apply in this court to the Patent Trial and Appeal Board’s decision in an IPR once it becomes final. *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018); see *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1294 (Fed. Cir. 2018); *Nestle USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350, 1351 (Fed. Cir. 2018). [Papst Licensing GMBH & Co. KG v. Samsung Electronics America, Inc., 2018-1777 (Fed. Cir. 5/23/2019).]

The Federal Circuit pointed out that its prior case did not support Papst’s contentions.

Papst has advanced no persuasive reason for an exception to applying the above-quoted conditions for issue preclusion in this case. Papst cites *Worlds Inc. v. Bungie, Inc.*, 903 F.3d 1237 (Fed. Cir. 2018), but all we did there was remand on issue preclusion because the record before the court was too scant for the panel to decide if issue preclusion existed. *Id.* at 1247. Here, as we will discuss, we can decide that issue preclusion exists. Papst also cites *In re Cygnus Telecommunications Technology, LLC*, Patent Litigation, 536 F.3d 1343 (Fed. Cir. 2008), but there we held only that an accepted rule—that issue preclusion does not apply within the confines of the single case formed when multiple cases are formally consolidated—also applies in the context of cases formally consolidated for pre-trial purposes through the multi-district-litigation process. *See id.* at 1349–50. Here, there was no comparable consolidation; these were distinct “cases” separately resolved. [Papst Licensing GMBH & Co. KG v.

Samsung Electronics America, Inc., 2018-1777 (Fed. Cir. 5/23/2019).]

The Federal Circuit, noted that, by aggressively litigating the prior cases, failing to settle, and failing to request waiver of estoppel in the prior case, the exceptions to collateral estoppel were inapplicable.

> The Supreme Court in *B & B Hardware* noted as a general matter that the Restatement standards allow for some exceptions to issue preclusion even when the above-quoted conditions are met. 135 S. Ct. at 1303, 1309-10. The Court specifically recognized that "[i]ssue preclusion may be inapt if 'the amount in controversy in the first action [was] so small in relation to the amount in controversy in the second that preclusion would be plainly unfair." *Id*. at 1309 (quoting Restatement (Second) of Judgments § 28, cmt. j). *** Nor has Papst presented, let alone supported, any allegation of a legally significant disparity in incentives between the present IPR and the two other Aytac-based IPRs at issue. Papst is in no position now to say that the litigation costs in those other two IPRs were not worth incurring. After all, Papst litigated all the way through to final written decisions—rather than, for example, disclaim the challenged patent claims in the '144 patent and the '746 patent IPRs before the Board reached final written decisions. Papst then litigated all the way up to the eve of oral argument in this court. Such pursuit through nearly all of the available process undermines any assertion of relevantly low incentives in the IPRs involving Aytac and the '144 pa-tent and '746 patent. [Papst Licensing GMBH & Co. KG v. Samsung Electronics America, Inc., 2018-1777 (Fed. Cir. 5/23/2019).]
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> More generally, given the heavy burdens that Papst placed on its adversaries, the Board, and this court by waiting so long to abandon defense of the '144 patent and '746 patent claims, Papst's course of action leaves it without a meaningful basis to argue for systemic efficiencies as a possible reason for an exception to issue preclusion. Papst also has no basis to argue that it tried unsuccessfully to secure an agreement, from Samsung or other petitioners (in this IPR or others), for efficiency-enhancing multi-case-management steps: it did not even ask its adversaries to waive reliance on preclusion. In noting these circumstances, we do not address what if any ultimate legal relevance different circumstances might have in justifying an exception to the important policy of issue preclusion. [Papst Licensing GMBH & Co. KG v. Samsung Electronics America, Inc., 2018-1777 (Fed. Cir. 5/23/2019).]

Quest Integrity USA, LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).

This is a decision on an appeal from the D. Del. district court case 1:14-cv-01483-SLR. This district court entered summary judgement that all claims were invalid under 102(b) due to an offer for sale. Quest appealed. The Federal Circuit affirmed on some claims but reversed on

other claims 30 and 40.

Legal issue: FRCP 56, summary Judgment, genuine issue of material fact, sham declaration doctrine.

The Federal Circuit concluded that the sham declaration doctrine was inapplicable for at least two reasons. First, Bondurant's declaration contradicted earlier testimony of another witness, not his own testimony. Second, De Lorenzo later declaration provided a plausible explanation why his earlier deposition testimony was incorrect.

First, the Federal Circuit restated the law for FRCP 56 sham declarations.

> The Third Circuit "review[s] a district court's decision to exclude materials under the sham affidavit doctrine for abuse of discretion." *Daubert v. NRA Grp., LLC*, 861 F.3d 382, 389 (3d Cir. 2017). Under the Third Circuit's sham affidavit doctrine, "a party may not create a material issue of fact to defeat summary judgment by filing an affidavit disputing his or her own sworn testimony without demonstrating a plausible explanation for the conflict." *Baer v. Chase*, 392 F.3d 609, 624 (3d Cir. 2004). The Third Circuit has explained its approach in applying the sham affidavit doctrine as a "flexible" one, "giving due regard to the 'surrounding circumstances'": ["] If, for example, the witness shows she was confused at the earlier deposition or for some other reason misspoke, the subsequent correcting or clarifying affidavit may be sufficient to create a material dispute of fact. Same result if there's independent evidence in the record to bolster an otherwise questionable affidavit. The court may, on the other hand, disregard an affidavit when the affiant was carefully questioned on the issue, had access to the relevant information at that time, and provided no satisfactory explanation for the later contradiction. It may similarly disregard an affidavit entirely unsupported by the record and directly contrary to other relevant testimony, or if it's clear the affidavit was offered solely to defeat summary judgment. ["] *Daubert*, 861 F.3d at 391–92 (citations, alterations, and internal quotation marks omitted); *see Jiminez v. All Am. Rathskeller, Inc.*, 503 F.3d 247, 254 (3d Cir. 2007) ("[W]hen there is independent evidence in the record to bolster an otherwise questionable affidavit, courts generally have refused to disregard the affidavit."); *see also Gemmy Indus. Corp. v. Chrisha Creations Ltd.*, 452 F.3d 1353, 1359 (Fed. Cir. 2006) ("[A]lthough a party cannot simply contradict an earlier sworn statement" to overcome summary judgment, the court should not disregard the later testimony where there is "credible evidence supporting the contradiction."). [Quest Integrity USA, LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).]

> For example, in *Baer*, the district court disregarded an affidavit by Baer at summary judgment because it contradicted his earlier deposition testimony. 392 F.3d at 624–25. The Third Circuit reversed and remanded because "Baer[] [was able] to point to evidence in the record that corroborate[d] his later affidavit[, which] alleviate[d] the concern that he merely filed an erroneous certification out of desperation to avoid summary judgment." *Id*. at 626. [Quest Integrity USA,

LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).]

The Federal Circuit then explained that the sham affidavit doctrine applied only to an affidavit of the same witness that gave the earlier testimony.

> We conclude that the declarations of De Lorenzo and Bondurant cannot be dismissed as sham affidavits. First, Bondurant's declaration did not contradict any earlier testimony that he gave. The general rule is that the sham affidavit doctrine provides for disregarding "an offsetting affidavit that is submitted in opposition to a motion for summary judgment when the affidavit contradicts the affiant's prior deposition testimony," not another witness's prior deposition testimony. [Footnote 10 omitted.] *Id*. at 624 (emphasis added) (internal quotation marks omitted); *see Nelson v. City of Davis*, 571 F.3d 924, 926 (9th Cir. 2009) ("[T]he 'sham affidavit' rule [does not] preclude[] the introduction of testimony from other witnesses that is arguably inconsistent with a plaintiff's deposition testimony."); *see also Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 806 (1998) (describing the sham affidavit doctrine as preventing a party from "creat[ing] a genuine issue of fact sufficient to survive summary judgment simply by contradicting his or her own previous sworn statement (by, say, filing a later affidavit that flatly contradicts that party's earlier sworn deposition) without explaining the contradiction or attempting to resolve the disparity"). The district court erred for this reason in disregarding the Bondurant declaration. Additionally, the district court erred in disregarding Bondurant's declaration for the same reasons it erred in disregarding De Lorenzo's declaration, as we now discuss. [Quest Integrity USA, LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).]

The Federal Circuit then explained how the later testimony of De Lorenzo demonstrated a plausible explanation for the conflict with his earlier testimony.

> Second, De Lorenzo did not simply contradict his earlier testimony. He submitted a detailed declaration in which he explained why his deposition testimony was incorrect. In the declaration, he stated that the source code shows that the composite bend indicator function was still under development as of July 8, 2004, and was not available for use until after the Norco Sale because the source code shows that the most recent comment line for the composite bend indicator function is dated July 8, 2004 (i.e., after the Norco Sale). He further explained that he was only given a portion of the source code during his deposition and was not given the page with the July 8, 2004, date. He stated that had he seen the July 8, 2004, comment during his deposition, he would have known that the source code was not commercially available on August 28, 2002. De Lorenzo thus offered a plausible explanation for why he misspoke at his deposition, and Cokebusters does not dispute that De Lorenzo was not given

access to the full source code during his deposition. Nor does Cokebusters dispute that the source code contains the July 8, 2004, modification date. [Quest Integrity USA, LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).]

In his declaration, De Lorenzo further stated that the absence of any "x"s in the Norco Strip Charts conclusively proves that the composite bend indicator function was not available or used for the Norco Sale. As he explained, the source code with the July 8, 2004, date shows that, when a bend was detected, the code would instruct the software to display an "x" at the detected bend. The Norco Strip Charts have no such "x"s. De Lorenzo testified at his deposition that he manually marked the bends in the Norco Strip Charts himself with black ticks. [Quest Integrity USA, LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).]

De Lorenzo also stated in his declaration that, even if the source code with the July 8, 2004, date was available at the time of the Norco Sale, the composite bend indicator function was "commented out." It is difficult to tell from the record what it means for a function to be "commented out" of the source code, but the parties at least agree that a function "commented out" could not be used by the program. De Lorenzo explained in his declaration that the composite bend indicator function is preceded by a particular symbol in the source code, and that the particular symbol means that the function was commented out and thus could not have been used to generate composite data markers. *** The detailed explanation in De Lorenzo's declaration and corroborating evidence took the declaration out of the sham affidavit doctrine. [Quest Integrity USA, LLC v. Cokebusters USA Inc., 2017-2423 (Fed. Cir. 5/21/2019).]

Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473; 2017-2481; 2017-2484; 2017-2486; 2017-2489; 2017-2491; 2017-2492; 2017-2493 (Fed. Cir. 5/15/2019).

This is a decision on appeals from the D. NJ. district court cases 3:11-cv-02317-MLC-DEA, 3:13-cv-00091-MLC-DEA, and 3:13-cv-04022-MLC-DE. The district court held the asserted claims to be nonobvious under 103, enabled under 112, and adequately described under 112. Dr. Reddy appealed. The Federal circuit reversed (and dismissed a cross-appeal).

Legal issue: 35 USC 112, requirement for written description of "efficacy" limitation.

The Federal Circuit clarified that when a POSITA reading the disclosure would not have understood the invention provided the claimed efficacy, then written description was missing. Here, the patent did not show that the inventor possessed the claimed invention, although it did enable one skilled in the art to make and use the invention. The problem with the disclosure is that the record evidence showed that the efficacy limitation was speculative.

> The district court held that the Generics failed to prove by clear and convincing evidence that the asserted claims of the '907 and '285 patents are invalid for lack of written description. But its analysis does not support its conclusion. The district court, after finding that the specification lacks "information regarding the efficacy of uncoated PPIs," said it was enough that the specification described the immediate release of uncoated PPI and the potential disadvantages of enteric-coated PPI formulations. J.A. 82–83. But that disclosure it pointed to in no way provides support for the claimed efficacy of uncoated PPI. Even if the district court thought that it was enough that the patents taught how to make and use drug formulations containing uncoated PPI, it flatly rejected Nuvo's argument "that the efficacy of uncoated PPIs need not be described because it is 'necessarily inherent' in a formulation." J.A. 83. Nevertheless, because we review the district court's decision for clear error, we will scour the record created below for evidence supporting the district court's written description finding. [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

The Federal Circuit concluded that the claims required a therapeutically effective amount of uncoated PPI.

> In sum, the parties appear to have assumed before the district court that the claims require a therapeutically effective amount of uncoated PPI that can raise the gastric pH to at least 3.5. We see no reason to change course on appeal. Because the parties' assumption at the trial court is a fair reading of the claim language, we will proceed as everyone did before the district court and search the specification for written description support for the efficacy of uncoated PPI. [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

Then, the Federal Circuit explained why the efficacy limitation lacked written description support.

> The Generics argue that the parts of the specification Dr. Williams identified are not enough to satisfy the written description requirement. They argue that the specification provides only typical dosage amounts of uncoated PPI and the use of uncoated PPI in a drug formulation, but it never discusses or explains its efficacy. We agree with the Generics that Dr. Williams's testimony does not identify parts of the specification sufficient to satisfy the written description requirement. The statements he points to recite the claim limitation by simply calling generally for effective amounts of uncoated PPI, but our precedent clearly establishes that is not enough. [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

Nevertheless, as the Generics point out and Nuvo cannot reasonably dispute, the record evidence demonstrates that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective. And there is nothing in the specification of the patents-in-suit showing "that the inventor actually invented the invention claimed." *Centocor*, 636 F.3d at 1348 (emphasis added); *accord Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). There must be some description, such as a constructive reduction to practice, establishing that the inventor "was in possession of the . . . claimed invention, including all of the elements and limitations." *Univ. of Rochester*, 358 F.3d at 926 (quoting *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998)). Patents are not rewarded for mere searches, but are intended to compensate their successful completion. *Ariad*, 598 F.3d at 1353. That is why the written description requirement incentivizes "actual invention," *id*., and thus "[a] 'mere wish or plan' for obtaining the claimed invention is not adequate written description," *Centocor*, 636 F.3d at 1348(quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997)). [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

In light of the fact that the specification provides nothing more than the mere claim that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work, the specification is fatally flawed. It does not demonstrate that the inventor possessed more than a mere wish or hope that uncoated PPI would work, and thus it does not demonstrate that he actually invented what he claimed: an amount of uncoated PPI that is effective to raise the gastric pH to at least 3.5. That conclusion is confirmed by the inventor's, Dr. Plachetka's, own testimony at trial during which he admitted that he only had a "general concept of coordinated delivery with acid inhibition" using uncoated PPI at the time he filed his first patent application. J.A. 9942, 10000–01. Although Dr. Plachetka said he thought he "put a rationale in [the specification] as to why [uncoated PPI] would work," he did not identify any particular part of the specification supporting that understanding. J.A. 9997. And his only support in the specification for "a rationale explaining why [he] thought the uncoated PPI would be effective for treating gastric related injury" was that, in its "entire context," he explained "why the coordinated delivery system would be of benefit for patients." *Id*. Although inventor testimony cannot establish written description support where none exists in the four corners of the specification, it illuminates the absence of critical description in this case. [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

Teaching how to make and use an invention does not necessarily satisfy the written description requirement. We have recognized that the enablement

requirement, which requires the specification to teach those skilled in the art how to make and use the claimed invention without undue experimentation, is separate and distinct from the written description requirement. *Ariad*, 598 F.3d at 1343–51. And the fact that an invention may be enabled does not mean it is adequately described, and vice versa. *Univ. of Rochester*, 358 F.3d at 921–22. That is because "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]." Id. at 920. The focus of the written description requirement is instead on whether the specification notifies the public about the boundaries and scope of the claimed invention and shows that the inventor possessed all the aspects of the claimed invention. *Id*. at 926. [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

Our case law has recognized that, under a narrow set of circumstances, the written description requirement may be satisfied without an explicit disclosure if the claimed features are necessarily inherent in what is expressly described. *See, e.g., Allergan*, 796 F.3d at 1309 ("A claim that recites a property that is necessarily inherent in a formulation that is adequately described is not invalid as lacking written description merely because the property itself is not explicitly described."); *Yeda Research & Dev. Co. v. Abbott GmbH & Co. KG*, 837 F.3d 1341, 1345 (Fed. Cir. 2016) ("Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention's inherent properties."); cf. Manual of Patent Examining Procedure § 2163 (9th ed. Rev. 3, Jan. 2018) (recognizing that inherency may satisfy the written description requirement). *** The Generics contend that, like *Alcon*, *Allergan* is also factually distinguishable. We agree. *** Here, unlike in *Allergan*, whether uncoated PPI is inherently effective in raising the gastric pH to at least 3.5 is disputed. And there is no written disclosure that in any way relates to the efficacy of immediately released PPI. Neither party has identified any evidence in the record that uncoated PPI necessarily is effective in a certain amount, consistent with the specification, to raise the gastric pH to 3.5 or higher. Nor can we find any evidence in the record demonstrating the inherency of the claimed feature. That failure of proof thus dooms Nuvo's inherency argument. [Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories Inc., 2017-2473 and others (Fed. Cir. 5/15/2019).]

BTG International Limited v. Amneal Pharmaceuticals LLC, 2019-1147, 2019-1148, 2019-1323, 2019-1324, and 2019-1325 (Fed. Cir. 5/14/2019).

This is a decision on appeals from the D. NJ district court cases: 2:15-cv-05909-KM-JBC; 2:16-cv-02449-KM-JBC; 2:17-cv-06435-KM-JBC; and 2:16-cv-02449-KM-JBC; and PTAB cases: IPR2016- 00286; IPR2016-01317; PR2016- 01332;

IPR2017-00853; and IPR2016-01582. BTG sued Amneal et al. in district court. The defendants filed the IPRs. The PTAB held the asserted claims obvious. The district court also held that the asserted claims were obvious over the same prior art. Amneal appealed. The Federal Circuit affirmed the PTAB decision, rending the court decision moot. I see no precedential legal issue in the decision. At best, this case stands for the unremarkable proposition that a court can decide only one dispositive issue, to resolve related cases.

Bradium Technologies LLC v. Iancu, 2017-2579, 2017-2580 (Fed. Cir. 5/13/2019).

This is a decision on appeals from PTAB cases IPR2016-00448, IPR2016-00449. The PTAB held the claims unpatentable for obviousness. Bradium appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 112, claim construction. Lexicography for claim terms. Reciting a claim term similar to but not exactly the same as a term defined in the specification.

The Federal Circuit concluded that disclosure distinguishing a low-bandwidth channel from a high-bandwidth channel did not in this case distinguish a claim to a "limited-bandwidth" channel from a high-bandwidth channel.

> We disagree with Bradium. The statement from the shared written description on which Bradium relies distinguishes low-bandwidth channels from high-bandwidth ones; it does not state that a limited bandwidth communications channel cannot be a high-bandwidth channel. *See id.* In fact, this statement supports the Board's construction because it makes clear that limited bandwidth may result from either "the direct technological constraints" on a channel or "indirect constraints" such as "high concurrent user loads." *Id.* [Bradium Technologies LLC v. Iancu, 2017-2579, 2017-2580 (Fed. Cir. 5/13/2019).]
>
> This single statement in the written description does not serve as clear indication that the patentee meant to redefine the term "limited bandwidth communications channel" to include a specific cause for the bandwidth limitation (e.g., that the channel's bandwidth must be limited by direct technological constraints). We have previously explained that "[t]o 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)). "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Id*. (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008)). The single statement describing two causes for limited bandwidth is not a clear and unambiguous definition limiting the term to only one cause, contrary to its plain and ordinary meaning. The written description makes clear that the problem the patentee was attempting to solve existed with both types of bandwidth limitations. *See, e.g.*, '343 patent col. 3 ll. 40–43. We discern no

> error in the Board's refusal to limit the plain meaning of the term to channels limited by "direct technological constraints," such as wireless technology. [Bradium Technologies LLC v. Iancu, 2017-2579, 2017-2580 (Fed. Cir. 5/13/2019).]

Note: Words in claims matter. If the patentee had included claims reciting a "low-bandwidth communications channel" instead of or in addition to the claim reciting "limited bandwidth communications channel," at least this issue could have been mooted. If the patentee had included claims reciting "limited bandwidth communications channel," in which the limitation was a result of "direct technological constraints," such as wireless technology, this issue could also have been mooted.

Novartis Pharmaceuticals Corporation v. West-Ward Pharmaceuticals International Limited, 2018-1434 (Fed. Cir. 5/13/2019).

This is a decision on an appeal from the D. Del. district court case 1:15-cv-00474-RGA. The district court held claims not obvious over prior art. West-Ward appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 103 obviousness, motivation to combine, distinguishing method of use case law from lead compound case law.

The Federal Circuit, disagreeing with the district court's analysis of motivation to combine. However, the Federal Circuit found no clear error in the district court's finding of lack of a reasonable expectation of success, and therefore affirmed.

First, the Federal Circuit noted that the district court's finding of motivation should have been conclusive on that issue:

> After reviewing the prior art, the district court found that a person of ordinary skill "would have been motivated to pursue everolimus as one of several potential treatment options for advanced solid tumors, including advanced RCC." *Decision*, 287 F. Supp. 3d at 516. This finding should have affirmatively answered whether there would have been a motivation to combine. Yet, the district court continued its analysis and found that West-Ward "failed to prove by clear and convincing evidence that a POSA would have been motivated to select everolimus." *Id.* The district court erred in applying this heightened standard. "[O]ur case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004); *see also Bayer Healthcare Pharm., Inc. v. Watson Pharm., Inc.*, 713 F.3d 1369, 1376 (Fed. Cir. 2013). It is thus improper to require West-Ward to prove that a person of ordinary skill would have selected everolimus over other prior art treatment methods. [Novartis Pharmaceuticals Corporation v. West-Ward Pharmaceuticals International Limited, 2018-1434 (Fed. Cir. 5/13/2019).]

The Federal Circuit explained that the district court erred by requiring a showing of motivation to

specifically select everolimus from other treatment options, as in a lead compound analysis.

> The ’131 patent claims methods of using everolimus to inhibit growth of solid tumors, including in patients having advanced RCC. ’131 patent col. 17 l. 42–col. 18 l. 29. It does not claim the everolimus compound itself, but rather methods of using the compound. This case therefore does not require lead compound analysis or analysis of whether a particular dose in a range of prior art doses would have been obvious. The district court, however, appeared to apply or conflate the standard for these types of cases by requiring clear and convincing evidence that a person of ordinary skill “would have been motivated to select everolimus.” *Decision*, 287 F. Supp. 3d at 516 (emphasis added). To the extent the district court required a showing that a person of ordinary skill would have selected everolimus over other prior art compounds, it erred. The proper inquiry is whether a person of ordinary skill would have been motivated to modify the prior art disclosing use of temsirolimus to treat advanced RCC with the prior art disclosing everolimus. This question was answered affirmatively when the district court found that a person of ordinary skill “would have been motivated to pursue everolimus as one of several potential treatment options for advanced solid tumors, including advanced RCC.” *Id*. [Novartis Pharmaceuticals Corporation v. West-Ward Pharmaceuticals International Limited, 2018-1434 (Fed. Cir. 5/13/2019).]

The Federal Circuit restated its lead compound case law:

> In lead compound cases, the court first determines whether a person of ordinary skill in the art “would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts.” *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1291–92 (Fed. Cir. 2012). This requires the patent challenger to show by clear and convincing evidence that a person of ordinary skill “would have had a reason to select a proposed lead compound or compounds over other compounds in the prior art.” *Daiichi Sankyo Co.v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010) (emphasis added). The court then determines “whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success.” *Otsuka*, 678 F.3d at 1292. [Novartis Pharmaceuticals Corporation v. West-Ward Pharmaceuticals International Limited, 2018-1434 (Fed. Cir. 5/13/2019).]
>
> We have applied a similar test in obviousness cases where the prior art discloses a range and a claim limitation falls within that range, focusing on “whether there would have been a motivation to select the claimed composition from the prior art ranges.” *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015); *see also Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731,

737–38 (Fed. Cir. 2013) ("The relevant dispute in this case is thus not over whether the prior art discloses all of the claim elements or over the motivation to combine the prior art references. Rather, the dispute is whether there was motivation to select the claimed 0.3% adapalene composition in the disclosed range."). [Novartis Pharmaceuticals Corporation v. West-Ward Pharmaceuticals International Limited, 2018-1434 (Fed. Cir. 5/13/2019).]

AVX Corporation v. Presidio Components, Inc., 2018-1106 (Fed. Cir. 5/13/2019).

This is decision on appeal from PTAB case IPR2016-00636. The PTAB held that AVX had failed to establish unpatentability of some claims ("upheld claims"). AVX appealed. The Federal Circuit concluded that AVX lacked standing, and dismissed.

Legal issue: 35 USC 315(e), statutory estoppel, applicability to a party lacking standing to appeal from a PTAB decision.

The Federal Circuit's review of the facts pertaining to lack of standing covers no new ground. However, the Federal Circuit addressed, AVX's second argument for standing as a result of the harm caused by IPR estoppel, noting that it was not yet decided whether 315(e) estoppel applied to a party lacking standing to appeal an adverse PTAB decision.

> Second, this court has not decided whether the estoppel provision would have the effect that AVX posits—specifically, whether § 315(e) would have estoppel effect even where the IPR petitioner lacked Article III standing to appeal the Board's decision to this court. For this court to so hold, we would have to consider whether that reading of § 315(e) is tied to § 319's right of appeal for any "party dissatisfied with the final written decision" of the Board. Relatedly, we would also have to consider whether § 315(e) should be read to incorporate a traditional preclusion principle—that neither claim nor issue preclusion applies when appellate review of the decision with a potentially preclusive effect is unavailable. *See Penda Corp. v. United States*, 44 F.3d 967, 973 (Fed. Cir. 1994) ("It is axiomatic that a judgment is without preclusive effect against a party which lacks a right to appeal that judgment."); *see Kircher v. Putnam Funds Tr.*, 547 U.S. 633, 647 (2006); *SkyHawke Techs., LLC v. Deca Int'l Corp.*, 828 F.3d 1373, 1376 (Fed. Cir. 2016). We have not addressed those and other considerations bearing on the proper application of § 315(e). [AVX Corporation v. Presidio Components, Inc., 2018-1106 (Fed. Cir. 5/13/2019).]
>
> We decline to do so here. The parties have not briefed the issue; indeed, we have no adversarial presentations on the issue, because AVX assumes estoppel as a predicate for its standing argument and Presidio has evidently decided not to give up a possible future estoppel argument. If, in the future, a live controversy over the upheld claims arises between Presidio and AVX, and if either an infringement action or declaratory judgment action involving those claims is filed in district court, AVX can, in such an action, test whether § 315(e) bars it from raising the obviousness challenges that the Board reviewed and rejected. At that

point, the parties presumably would be adverse on the issue. [AVX Corporation v. Presidio Components, Inc., 2018-1106 (Fed. Cir. 5/13/2019).]

Note1: It appears that a party lacking standing to appeal from a PTAB issue would nevertheless have to appeal in order to preserve the argument that 315(e) did not preclude them from prior art defenses, in case they were subsequently sued for patent infringement.
Note2: This case was decided prior to *Lone Star Silicon Innovations LLC v. Nanya Technology Corporation*, 2018-1581, 2018-1582 (Fed. Cir. 5/30/2019). *Lone Star* may affect how the Federal Circuit characterizes issues it previously referred to as standing issues.

Swagway, LLC v. ITC, 2018-1672 (Fed. Cir. 5/9/2019).

This is a decision on an appeal from ITC investigations 337-TA-1007, 337-TA-1021. The ITC held that Swagway violated 19 USC 1337 ("Section 337"). Swagway appealed. The Federal Circuit affirmed.

Legal issue: Whether an ITC decision has preclusive effect.

The Federal Circuit held that, like in patent issues, in TM issues, and ITC decision does not have preclusive effect.

> We have previously determined that "Congress did not intend decisions of the ITC on patent issues to have preclusive effect." *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1569 (Fed. Cir. 1996); *see Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1019 (Fed. Cir. 1987) ("[O]ur appellate treatment of decisions of the Commission does not estop fresh consideration by other tribunals."). We see no reason to differentiate between the effect of the Commission's patent-based decisions and the Commission's decisions regarding trademarks. Because we hold that the Commission's trademark decisions, like its patent decisions, do not have preclusive effect, we need not reach Swagway's procedural arguments regarding its consent order motion. [Swagway, LLC v. ITC, 2018-1672 (Fed. Cir. 5/9/2019).]

Amgen Inc. v. Sandoz Inc., 2018-1551, 2018-1552 (Fed. Cir. 5/8/2019).

This is a decision on N.D. Cal. district court cases 3:14-cv-04741-RS and 3:16-cv-02581-RS. The district court entered summary judgement of noninfringement of the claim. Amgen appealed. The Federal Circuit affirmed.

Legal issue: 35 USC 112, claim construction, method claims, whether separate functional effects require separate steps, given the facts of the case.

> Amgen contends that the district court misconstrued the "washing" and "eluting" claim limitations in both its claim construction and summary judgment decisions as requiring distinct solutions added to the matrix at different times. Instead, Amgen argues, the claims cover any number of solutions or steps as long as the functions of washing and eluting happen in sequence, and it cites as support the specification's teaching that a wide variety of solutions will work to perform

the washing and eluting steps. [Amgen Inc. v. Sandoz Inc., 2018-1551, 2018-1552 (Fed. Cir. 5/8/2019).]

We agree with Sandoz that the washing and eluting steps of claim 7 require discrete solutions. Amgen's argument to the contrary is, at its core, that the "washing" and "eluting" limitations describe functions, rather than actual process steps. See Reply Br. 14 ("[T]he claims and specification . . . define washing and eluting as functional steps."). We reject this argument for two reasons. First, as in *Mformation*, the claim language logically requires that the process steps, lettered (a) through (g), be performed in sequence. *** Second, washing and eluting are consistently described in the specification as separate steps performed by different solutions. [Amgen Inc. v. Sandoz Inc., 2018-1551, 2018-1552 (Fed. Cir. 5/8/2019).]

Legal issue: 35 USC 271 infringement, doctrine of equivalents (DOE), functions of method steps versus method steps.

The Federal Circuit held that the one step process of Sandoz accomplishing the same functions as the three step claimed process, did not infringe under the DOE.

Amgen next argues that the district court erred by rejecting its argument that Sandoz's process infringes claim 7 through the doctrine of equivalents. *** We agree with Sandoz and conclude that the district court correctly held that Sandoz's one-step, one-solution process does not function in the same way as the claimed process. In essence, Amgen seeks to cover, one way or an-other, any method of using a salt concentration gradient in an adsorbent matrix to separate a protein of interest from other solutes. But claim 7 is not that broad. As the district court held, the claim recites a sequence of steps requiring application of "refolding," "washing," and "eluting" solutions, and our precedent prohibits us from overriding the natural language of claim 7 to extend these limitations to cover nearly any type of adsorbent chromatographic separation. The doctrine of equivalents applies only in exceptional cases and is not "simply the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims." *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991); *see also Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1362 (Fed. Cir. 2019) ("[T]he doctrine of equivalents cannot be used to effectively read out a claim limitation . . . because the public has a right to rely on the language of patent claims." (citing *Primos, Inc. v. Hunter's Specialties, Inc.*, 451 F.3d 841, 850 (Fed. Cir. 2006))). Accordingly, the district court was correct to grant summary judgment that Sandoz does not infringe claim 7 under the doctrine of equivalents because its one-step, one-solution purification process works in a substantially different way from the claimed three-step, three-solution process. [Amgen Inc. v. Sandoz Inc., 2018-1551, 2018-1552 (Fed. Cir. 5/8/2019).]

Valve Corporation v. Electronic Scripting Products, Inc., IPR2019-00062; IPR2019-00063; and IPR2019-00084, paper 11 (4/2/2019, designated precedential 5/7/2019).

This is a decision by the PTAB on three IPR petitions filed by Valve against the same patent. The PTAB denied institution.

Legal issue: 35 USC 314(a), exercise of discretion to deny institution of IPR petitions, "same petitioner" criteria.

The PTAB denied institution of the current IPR petitions because the current petitions and petitioner were closely related to the prior petitions and prior petitioner. The PTAB applied the *General Plastic* factor 1 same petitioner criteria to the closely related petitioners, to conclude the petition should be denied for prudential reasons.

Significantly, while the prior petitions were not filed by the same entity, they were filed by Valve's licensee with whom Valve cooperated in developing the accused product and Valve was initially named as a co-defendant. From those facts, the PTAB found that the *General Plastic* factor 1 "same patentee" criteria weighed against institution on these facts. That is, despite the petitioners in fact being different entities, they were closely enough related by relationship to alleged infringement of the challenged claims to weigh against institution as if they were the same patentee.

The PTAB also found the other *General Plastic* factors (factor 2, imputed knowledge of relevant prior art when first petition was filed; factor 3, access to the POPR in prior petition; factors 4 and 5, delay relative to earlier petitions and excuse for delay; factors 6 and 7, finite PTAB resources and one year deadline to issue a final decision).

I list below the facts supporting the PTAB's conclusion, grouped by relevance to various *General Plastic* factors.

The three new petitions challenged the same claims of the challenged patent as the prior petitions.

Relationship of Valve to HTC: Valve had HTC had been named as co-defendants for infringement by the same device, of the challenged patent. Valve had licensed technology incorporated into the accused infringing device, to HTC. Valve had provided HTC technical assistance during development of the accused infringing device. However, Valve had been voluntarily dismissed from the infringement action response to Valve's motion challenging venue.

Relationship of current petitions by Valve to prior petitions filed by HTC: The following facts related to availability of the evidence relied upon in the current Valve petitions. The current Valve petitions were based upon four different combinations of evidence of prior art: (1) Maeda; (2) Anderson; (3) Welch-HiBall; and (4) Maeda I and Maeda II. Welch-HiBall was one of two references relied upon in one of the prior petitions by HTC. A person named Welch was an author of prior art references cited in one of the prior petitions. Maeda cited two articles by the same person named Welch. Valve filed its IPR petitions less than two months after beginning to prepare those petitions.

Valve's use of information gleaned from HTC's prior petitions: Valve was aware of the existence of the HTC's prior petitions, and of the decision denying institution of those prior petitions. Valve submitted a declaration by the same expert that gave an expert declaration in support of HTC's prior petitions. The expert's declaration submitted with Valve's petitions noted

that the PTAB had disagreed with certain opinions the expert provided in the declaration submitted with HTC's prior petitions, and purported to address those issues.

Time delay between HTC's prior petitions and Valve's current petitions: There was a five month delay between when HTC filed its IPR petitions and when Valve filed its IPR petitions.

I quote the PTAB's *General Plastic* factor conclusion paragraphs, for application of each *General Plastic* factor to the facts.

> Factor 1
>
> We determine that the first *General Plastic* factor weighs against institution. As discussed above, the petitions in these cases challenge the same claims of the '934 patent as the previous petition in the 1031 IPR. As also discussed above, Valve and HTC were co-defendants in the District Court litigation and were accused of infringing the '934 patent based on HTC's VIVE devices that incorporate technology licensed from Valve. Thus, there is a significant relationship between Valve and HTC with respect to Patent Owner's assertion of the '934 patent. The complete overlap in the challenged claims and the significant relationship between Valve and HTC favor denying institution. [Valve Corporation v. Electronic Scripting Products, Inc., IPR2019-00062, et al, paper 11 (4/2/2019, designated precedential 5/7/2019).]
>
> Factor 2
>
> We determine that the second *General Plastic* factor weighs against institution. With respect to IPR2019-00063, Valve knew or should have known of the Welch-HiBall reference around the time HTC filed its petition in the 1031 IPR because it was one of the two references relied upon by HTC. Ex. 1060, 5. With respect to IPR2019-00062 and IPR2019-00084, as indicated above, the petitions in those cases rely on references attributable to Maeda and Anderson. Although Valve may not have known of the Maeda and Anderson references at the time HTC filed its petition in the 1031 IPR, the timing of Valve's petitions suggests that it could have found the Maeda and Anderson references through the exercise of reasonable diligence around the time of HTC's petition. Specifically, by its own admission, Valve began preparing its petitions on or after August 16, 2018, and filed them less than two months later, which indicates that Valve found the Maeda and Anderson references quickly. *See* Reply 2. Valve's knowledge of the Welch-HiBall reference and its ability to quickly locate the Maeda and Anderson references favor denying institution. [Valve Corporation v. Electronic Scripting Products, Inc., IPR2019-00062, et al, paper 11 (4/2/2019, designated precedential 5/7/2019).]
>
> Factor 3

We determine that the third *General Plastic* factor weighs against institution. In the 1031 IPR, the Board construed the term "wearable article" in the preamble of claims 1 and 7 as limiting and including a "controller." IPR2018-01031, Paper 6, 11. The Board determined that HTC failed to show that the asserted prior art teaches a wearable article including the claimed controller. *Id.* at 15. Valve had access to the Board's institution decision in the 1031 IPR before filing the Petition and used the institution decision as guide to addressing the deficiencies in the 1031 IPR. *See* Pet. 27 ("The Board has construed the preamble of claims 1 and 7 to be limiting."). For example, Valve submitted a declaration from the same expert that HTC used in the 1031 IPR, Dr. Welch. Ex. 1003 ¶ 9. In this case, Dr. Welch acknowledges that the Board "disagreed with certain of [his] prior opinions regarding the '934 Patent" in the 1031 IPR, and he "address[es] those issues" in his declaration. *Id.; see also id*. ¶¶ 100, 122, 149, 208, 261, 262, 275, 287, 288, 291. Valve's use of the Board's institution decision in the 1031 IPR as a roadmap for the Petition in this case implicates the fairness concerns discussed in *General Plastic* and favors denying institution. [Valve Corporation v. Electronic Scripting Products, Inc., IPR2019-00062, et al, paper 11 (4/2/2019, designated precedential 5/7/2019).]

Factors 4 and 5

We determine that the fourth and fifth *General Plastic* factors weigh against institution. The *Click-to-Call* decision may have prompted Valve to file the Petition before the deadline under § 315(b), but it does not excuse the five-month delay between the filing of HTC's petition and Valve's Petition. As discussed above, Valve could have found the prior art asserted in its Petition through the exercise of reasonable diligence at or around the time of HTC's petition. As also discussed above, Valve was a co-defendant with HTC in the District Court litigation and provides HTC with technology used in the accused VIVE devices. As a licensor of technology incorporated in the accused products, Valve's interests are aligned closely with HTC's interests, and Valve could have filed its Petition at or around the same time as HTC. The fact that Valve waited five months after HTC's petition to file the Petition in this case favors denying institution. If *Click-to-Call* had been decided differently, and Valve had waited even longer to file these petitions, Valve's delay still would favor denying institution. [Valve Corporation v. Electronic Scripting Products, Inc., IPR2019-00062, et al, paper 11 (4/2/2019, designated precedential 5/7/2019).]

Factors 6 and 7

We determine that the sixth and seventh *General Plastic* factors weigh against institution. In general, having multiple petitions challenging the same patent, especially when not filed at or around the same time as in this case, is

> inefficient and tends to waste resources. Here, Valve waited until after the institution decision in the 1031 IPR, and then filed not one but three additional petitions. These serial and repetitive attacks implicate the efficiency concerns underpinning *General Plastic*, and, thus, favor denying institution. [Valve Corporation v. Electronic Scripting Products, Inc., IPR2019-00062, et al, paper 11 (4/2/2019, designated precedential 5/7/2019).]

NHK Spring Co., Ltd. v. Intri-plex Technologies, Inc., IPR2018-00752, paper 8 (PTAB 9/12/2018; designated precedential 5/7/2019).

This is a decision in PTAB case IPR2018-00752. NHK filed and IPR petition. The PTAB denied institution.

Legal issue: 35 USC 314(a), exercise of discretion to deny institution, inefficient use of resources, timing of parallel district court adjudication of the same prior art issues.

The PTAB concluded that institution should be denied based upon solely upon 325(d).

However, the PTAB also concluded that instituting would not be consistent with the objective of the AIA of providing an efficient and effective alternative to district court litigation because the PTAB decision would be too late to achieve that objective, which suggested denying institution under 314(a).

The PTAB noted facts indicating the likelihood that the district court would have adjudicated the same validity issues raised in the IPR petition long prior to when the PTAB would reach a final written decision. The PTAB noted the timing issues were not consistent with the AIA objective of providing an effective and efficient alternative to district court litigation.

The PTAB referred to this situation as an "additional factor that weighs in favor of denying the Petition under § 314(a)." The relevant facts identified by the PTAB were that in the district court litigation: the same prior art relied upon in the petition was presented; expert discovery closed in two and one half months; the trial date was in six months, and that the PTAB would not reach a final written decision until about 6 months after the district court trial.

> ...Second, Patent Owner argues that instituting an inter partes review "ultimately would be inefficient," given the status of the district court proceeding between the parties. *** We agree. First, we note that there is no "intent to limit discretion under § 314(a), such that it is . . . encompassed by § 325(d)." *Gen. Plastic*, Paper 19, 18–19. Thus, simply because we exercise our discretion to deny the Petition under § 325(d) does not mean that we cannot consider and weigh additional factors that favor denying institution under § 314(a). [Footnote 4 omitted.] Second, Patent Owner argues persuasively that instituting a trial under the facts and circumstances here would be an inefficient use of Board resources. The district court proceeding, in which Petitioner asserts the same prior art and arguments, is nearing its final stages, with expert discovery ending on November 1, 2018, and a 5-day jury trial set to begin on March 25, 2019. Ex. 2004, 1. A trial before us on the same asserted prior art will not conclude until September 2019. Institution of an inter partes review under these circumstances would not be consistent with "an objective of the AIA . . . to provide an effective and efficient

alternative to district court litigation." *Gen. Plastic*, Paper 19, 16–17. Accordingly, we find that the advanced state of the district court proceeding is an additional factor that weighs in favor of denying the Petition under § 314(a). [NHK Spring Co., Ltd. v. Intri-plex Technologies, Inc., IPR2018-00752, paper 8 (PTAB 9/12/2018; designated precedential 5/7/2019).]

Note: The PTAB did not expressly indicate that it would have denied institution in this case based solely upon the 314(a) factors. However, this decision puts parties on notice that the PTAB may do so in the future. This case is very significant because it places a time constraint relative to district court discover and trial dates, on when a petition on comparable prior art evidence presented in the district court should be filed.

ENDO Pharmaceuticals Inc. v. Actavis LLC, 2018-1054 (Fed. Cir. 5/3/2019).

This is a decision on an appeal from the D. Del. district court case 1:14-cv-01381-RGA. The district court held that Endo failed to prove the asserted claims were invalid for obviousness or anticipation. Endo appealed. The Federal Circuit majority consisting of Judges Wallach and Clevenger affirmed. Judge Stoll dissented.

Legal issue: Pre-AIA 35 USC 102(f), availability of communications.

After noting that the subject patent was subject to pre-AIA prior art law, in footnote 9, the Federal Circuit majority explained why the district court, by concluding that the FDA communications were not prior art, erred. The Federal Circuit majority explained why the FDA communications were available under 102(f)/103; a conclusion also relied upon by the dissent. I reproduce footnote 9, below:

> The FDA communications mandated that opioid manufacturers reduce ABUK impurities in oxycodone and oxymorphone to below 0.001%. J.A. 2895; see J.A. 2904. Although the District Court concluded that the FDA communications are not prior art, *see Endo*, 2017 WL 3731001, at *6–7, we disagree. The District Court determined that (1) "the documents [were not] generally available as required for them to be § 102(b) prior art," *id*. at *6 (internal quotation marks and citation omitted); see 35 U.S.C. § 102(b) (stating a patent may be invalid if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States"); and (2) "declar[ing] a desire to have a product that has a particular characteristic, but . . . [not] provid[ing] any teachings on how to achieve that goal," is not enough to make a reference prior art un-der, inter alia, § 102(f), *Endo*, 2017 WL 3731001, at *6 n.4; see 35 U.S.C. § 102(f) (prohibiting the grant of a patent to one who "did not himself invent the subject matter sought to be patented"). However, we have stated that § 102(f) "does not pertain only to public knowledge, but also applies to private communications between the inventor and another which may never become public." *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401–02 (Fed. Cir. 1997). Moreover, we have also provided that,

"[u]nder an obviousness analysis, a reference need not work to qualify as prior art; it qualifies as prior art, regardless, for what-ever is disclosed therein." *Geo. M. Martin Co. v. All. Mach. Sys. Int'l LLC*, 618 F.3d 1294, 1302 (Fed. Cir. 2010) (internal quotation marks and citation omitted). Thus, confidentiality and the absence of any teachings of how to accomplish a stated goal do not bar the FDA communications from being considered prior art here. *See id.; OddzOn*, 122 F.3d at 1401–02. As discussed below, the District Court considered the FDA communications in its reasonable expectation of success analysis and properly determined that they were insufficient. [ENDO Pharmaceuticals Inc. v. Actavis LLC, 2018-1054 (Fed. Cir. 5/3/2019).]

Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).

This is a decision on both an appeal and a petition for Writ of Mandamus from ITC case 337-TA-3247. The ITC determined not to institute an investigation and dismissed Amarin's complaint. The ITC reasoned that the Food, Drug, and Cosmetic Act ("FDCA") did not give private parties a right of enforcement. Amarin appealed and petitioned for mandamus. The Federal Circuit majority consisting of Chief Judge Prost and Judge Hughs affirmed. Judge Wallach dissented.

In dissent, Judge Wallach wrote:

Although I agree with the majority's conclusion that the ITC did not err in declining to institute an investigation into the complaint under § 1337 brought by Appellants-Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (together, "Amarin"), *see* J.A. 4–114 (Complaint), I disagree with the majority's approach, for it fails to give due respect to Congress's choice to limit our appellate jurisdiction. As the ITC's decision not to institute was made pursuant to § 1337(b), I believe that we lack appellate jurisdiction; however, I would instead exercise mandamus jurisdiction and conclude that Amarin has not demonstrated that the "extraordinary remedy" of issuing a writ of mandamus is appropriate. *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988). Because I would dismiss Amarin's appeal and deny its petition for a writ of mandamus, I respectfully dissent. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019)(Wallach, dissenting).]

Legal issue: Jurisdiction to review a Commission's decision dismissing a complaint.

The Federal Circuit majority concluded that it had jurisdiction to review the dismissal because the dismissal was "intrinsically a final determination that effectively denies Amarin's request for relief under § 337(d) and (f)."

The Intervenors and the Commission argue that the only "final determinations" subject to appellate review are those listed in § 1337(c). Intervenors' Br. 18–19; Commission's Br. 52–56. And these decisions, according to the Intervenors, can only be made "as a result of an investigation." Intervenors'

Br. 19. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

The question as to our jurisdiction in this case is resolved by our decision in *Amgen Inc. v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990). In *Amgen*, the complainant alleged that a company violated § 337 by importing articles made by a patented process. See 19 U.S.C. § 1337(a)(1)(B)(ii). The Commission instituted an investigation. *Amgen*, 902 F.2dat 1534. Ultimately, however, the Commission dismissed the complaint because the patent at issue did not contain a process claim, which the Commission considered to be a jurisdictional prerequisite for an investigation under § 1337(a)(1)(B)(ii). *Id*. at 1535. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

On appeal in *Amgen*, we first addressed our jurisdiction under 28 U.S.C. § 1295(a)(6). Interpreting 19 U.S.C. § 1337(c), we recognized that § 1337(c) "has been interpreted as requiring a 'final determination decision on the merits, excluding or refusing to exclude articles from entry' under section 1337(d), (e), (f) or (g)." *Id*. (quoting *Block v. ITC*, 777 F.2d 1568, 1571 (Fed. Cir. 1985)). But instead of adopting the rigid approach Intervenors argue for in this case, we concluded that the Commission's decision was "intrinsically a final determination, i.e., a determination on the merits," thus making it appealable under § 1295(a)(6). *Id*. (emphasis in original). [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

In reaching that conclusion, we carefully explained the difference between our holding there and our earlier holding in *Block*, a case in which we held that a Commission order was not a final determination. In *Block*, the Commission initiated an investigation on its own motion. The Commission later terminated that investigation after the patent at issue was amended during reexamination. *See id.* As we explained in *Amgen*, "nothing in the termination Order [in *Block*] prejudiced the Commission or any private party in a future proceeding." *Id.* Unlike in *Block*, however, the Commission order in *Amgen* "clearly reach[ed] the merits of [the] complaint and determinatively decide[d] [the complainant's] right to proceed in a section 1337 action." *Id*. We further explained that "any future action brought by [the complainant] would necessarily raise the same issue, and would presumably be dismissed for the same reason." *Id.* at 1536. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

As in *Amgen*, the Commission's decision not to institute in this case is "intrinsically a final determination, i.e., a determination on the merits." *See id.* at 1535 (emphasis in original). Here, the Commission declined to institute an investigation because the claims were precluded by the FDCA and, therefore, the complaint failed to state a cognizable claim under § 337. See J.A 1–3. As in *Amgen*, this decision "clearly reach[ed] the merits of [the] complaint and

determinatively decide[d] [Amarin's] right to proceed in a section 1337 action." *See id.*; *see also Import Motors, Ltd., Inc. v. ITC*, 530 F.2d 940, 946–47 (CCPA 1976) (analyzing the right to appeal a Commission order by asking whether the order "has the operative effect of a 'final determination under subsection (d) or (e)'" and noting that "[s]ubstance, not form, must control"). Any future complaint brought by Amarin alleging these same facts "would necessarily raise the same issue" and "would presumably be dismissed for the same reason"—i.e., for lack of a private right of action to enforce the FDCA. *See Amgen*, 902 F.2dat 1536.1 In other words, as discussed below, as long as Amarin's complaint is based on proving violations of the FDCA (at least where the FDA has not provided guidance as to whether the articles violate the FDCA), Amarin's claims will be precluded. The Commission's decision is therefore intrinsically a final determination that effectively denies Amarin's request for relief under § 337(d) and (f). [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

We are unpersuaded by the Intervenors' and the Commission's argument that a final determination can be made only after institution. See Intervenors' Br. 3; Commission's Br. 52. Although the decision in *Amgen* occurred after institution, the court's reasoning in that case was not based on that procedural detail. *See Amgen*, 902 F.2dat 1535. Instead, the court's analysis focused on the operative effect of the Commission decision. *See id.; Import Motors*, 530 F.2d at 946–47 ("Substance, not form, must control."). [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

Legal issue: Whether the Commission has a mandatory, non-discretionary duty to institute an investigation when presented with a complaint under oath.

The Federal Circuit majority concluded that the ITC need not institute and investigation when the complaint failed to state a cognizable claim under section 337.

Although Amarin appears to raise a broader argument regarding whether the Commission has discretion generally not to institute an investigation, we need not address that question here. Instead, we simply hold, consistent with *Syntex*, that the Commission may decline to institute an investigation where a complaint fails to state a cognizable claim under § 337. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

The facts alleged as the basis for Amarin's complaint demonstrate that Amarin's allegations are based entirely on violations of the FDCA. As we explain below, claims based on such allegations are precluded by the FDCA, at least where the FDA has not yet provided guidance as to whether violations of the FDCA have occurred. Thus, under the facts of this case, where Amarin's complaint fails to state a cognizable claim for relief, the Commission did not err in its decision not to institute. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114

(Fed. Cir. 5/1/2019).]

Legal issue: Whether the Commission correctly determined that Amarin's allegations are precluded by the FDCA.

The Federal Circuit majority held that Amarin's claims were in effect an attempt to enforce the FDCA, which provides no private cause of action. Therefore, the Federal Circuit concluded the ITC correctly determined that Amarin's allegations are precluded by the FDCA.

> We next address the Commission's holding that Amarin's complaint "does not allege an unfair method of competition or unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules." J.A. 1. The Commission explained that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act," and that "the Food and Drug Administration is charged with the administration of the FDCA." J.A. 1. As explained below, we agree. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]
>
> As relevant here, the FDCA authorizes the FDA to regulate drugs and dietary supplements. Introducing a "new drug," 21 U.S.C. § 321(p), into interstate commerce requires FDA approval, *id*. § 355(a). Dietary supplements, however, do not require pre-market approval. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]
>
> The FDCA provides the United States with "nearly exclusive enforcement authority." POM Wonderful LLC v. Coca-Cola Co., 573 U.S. 102, 109 (2014) *** Given the lack of a private right to enforce the FDCA, other circuit courts have grappled with the extent to which private parties' claims under § 43(a) of the Lanham Act are limited by the FDCA. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]
>
> In its complaint, Amarin includes two separate bases for its § 337 claims. *** In sum, Amarin's two § 337 claims are based on the same factual allegations—that respondents' products do not meet the definition of "dietary supplement" in the FDCA, see 21 U.S.C. § 321(ff), and are instead unapproved "new drugs" under the FDCA. E.g.,J.A. 33–34 ¶¶ 60–61; J.A. 47–49 ¶¶ 84–87; J.A. 56 ¶ 106. *** As in *PhotoMede*x (and unlike in *Alpharma*), affirmative FDA approval is not required in the dietary supplement context. Instead, manufacturers self-police. And as in *PhotoMedex* (and unlike in *Alpharma*), the FDA has not provided guidance as to whether the products at issue in this case should be considered "new drugs" that require approval. Given this lack of guidance, we see no need to go further than the court in *PhotoMedex* did. We therefore hold that a complainant fails to state a cognizable claim under § 337 where that claim is based on proving violations of the FDCA and where the FDA has not taken the

position that the articles at issue do, indeed, violate the FDCA. Such claims are precluded by the FDCA. We note that this limited holding is consistent with the Commission's arguments in its briefing, which indicated that Amarin's claims are precluded at least until the FDA has provided guidance as to whether the products at issue are dietary supplements. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

In short, although Amarin presents its claims as violations of the Tariff Act, in reality those claims constitute an attempt to enforce requirements of the FDCA through the remedies provided under the Tariff Act. Because private parties have no such enforcement authority, Amarin's allegations fail to state a cognizable claim for relief. [Amarin Pharma, Inc. v. ITC, 2018-124, 2018-114 (Fed. Cir. 5/1/2019).]

Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).

This is a decision on appeals from the S.D. Cal. district court cases 3:13-cv-00651-JLS-MDD; 3:13-cv-00830-JLS-MDD; and 3:13-cv-01015-JLS-MDD. The district court held all asserted claims invalid. Later, the district court granted of Hi-Tech's and Vital's motions for attorney's fees under 35 USC 285. Thermolife appealed. The Federal Circuit affirmed.

Legal issue: District court discretion to determine a case to be exceptional, within the meaning of 35 USC 285, to support an award of attorney fees.

This case stands out from other Federal Circuit cases reviewing district court 285 exceptionality determinations. This is because the conduct on which the district court based its exceptionality determination were an inadequate pre-filing investigation, not how the patentee litigated the case. Part of the evidence supporting the conclusion of an inadequate pre-filing investigation were a large number of other suits filed by the same patentee, also suggesting an inadequate pre-filing investigation.

ThermoLife and Stanford appeal the district court's award of fees, challenging the determination that these were "exceptional" cases, not the amounts the court awarded after finding the cases exceptional. We recognize that these are unusual cases in that the basis for the fee award had nothing to do with the only issues litigated to reach the judgment on the merits: Infringement had not been adjudicated in reaching the final judgment, and even discovery on infringement had been postponed early in the proceedings so that validity could be litigated first. Nevertheless, we see no abuse of discretion in the district court's determination of exceptionality based on plaintiffs' inadequate pre-suit investigation of infringement in these and related cases. We therefore affirm. [Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).]

On October 12, 2016, Hi-Tech and Vital (but not the GNC entities) moved for attorney's fees under 35 U.S.C. § 285. Rhetoric aside, they made two related arguments for exceptionality that are relevant here.4 Their main argument was that plaintiffs did not conduct an adequate pre-suit investigation into infringement, an investigation that would have revealed that the accused products did not infringe claim 1 of the '459 patent, the only claim Hi-Tech and Vital specifically discussed. One premise of the argument was that the accused products all contained less than one gram of L-arginine (or its hydrochloride salt) per serving. [5] The other premise was that plaintiffs' own validity expert made clear in his 2015 deposition testimony and 2016 trial testimony that studies published before these suits were filed showed that amounts of L-arginine less than one gram were ineffective to enhance nitric oxide production (being too small an increase over the regular human intake of arginine). *See* J.A. 10456, 10461-63. Based on those premises, Hi-Tech and Vital argued that plaintiffs would have discovered that the accused products did not infringe had they read the labels on the accused products and conducted simple tests before suing. In their secondary argument, Hi-Tech and Vital broadened their focus and accused plaintiffs of filing many suits, without adequate investigation, simply to try to extract nuisance-value settlements. [Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).]

Plaintiffs ThermoLife and Stanford jointly responded. They did not deny that the accused products were publicly available, and they neither denied the existence of simple tests to determine the accused products' composition nor asserted that they had conducted any such tests. While noting that Hi-Tech and Vital focused entirely on claim 1 of the '459 patent, to the exclusion of the other patents at issue, plaintiffs did not discuss any other claims to show why they differed as to the adequacy of the pre-suit investigation. Plaintiffs denied the accusation that they sued just to extract settlements and argued that there was insufficient record information to support the speculation that the settlements were for mere nuisance values. [Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).]

On the merits of the attorney's fees requests, the court first found that plaintiffs had conducted an inadequate pre-filing investigation, resulting in objectively unreasonable infringement contentions. *Id*. at *4–7. The court focused entirely on claim 1 of the '459 patent, as the parties had done in their filings. It found that plaintiffs' validity expert testified that less than one gram of arginine would not enhance NO production. *Id*. at *6. The court found that either plaintiffs did not examine the accused products' labels before filing or, if they did, they ignored clear label indications of less than one gram of L-arginine (or its hydrochloride salt) for some of the accused products. *Id*. at *5. The court found that, aside from any (unclear) reliance on labels, plaintiffs relied only on the

defendants' advertising statements, even while disparaging the statements as "bombastic." *Id*. at *6 (quoting J.A. 11060, 11062 (plaintiffs' response)). At least in light of the label information and the tension between such information and defendants' advertising statements, the court concluded, this was a case in which it was unreasonable to dispense with (undisputedly available) testing to identify ingredients and their amounts in the accused products, which were "publicly available." *Id*. at *5-6. And although plaintiffs noted that some accused products contain compounds that are not themselves L-arginine (or its hydrochloride salt), as recited in claim 1 of the '459 patent, but result in L-arginine when dissolved in water pursuant to label instructions, the court found that even those products did not lead to the one gram required for efficacy. *Id*. at *6 (citing, e.g., J.A. 11586). The court thus found "strong evidence that had Plaintiffs conducted any reasonable pre-filing investigation, they would have been on notice that at least some of the products in this litigation could not have infringed." *Id*. at *7. [Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).]

When the court turned to Hi-Tech and Vital's secondary argument, it found that plaintiffs "only list one marketed product, sales of which never amounted to more than 300 units," and "brought suit under three patents that expired several months after ThermoLife agreed to purchase the licenses." *Id*. The court also found that plaintiffs "settled early with many of the defendants in this lawsuit for seemingly small dollar amounts" and "have filed numerous infringement suits." *Id*. The court then built into its finding on this aspect of the matter a notion of irresponsibility in the bringing of the many suits: "[T]he pattern of action here is indeed one that strongly suggests Plaintiffs brought suit against many defendants *without carefully reviewing their claims* as a calculated risk that might yield nuisance-value settlements." *Id*. (emphasis added). [Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).]

We conclude that the district court in this case acted within its discretion in determining, on the limited arguments plaintiffs made in response to the fee motions, that plaintiffs did not conduct an adequate pre-suit investigation into infringement by Hi-Tech and Vital. That determination would suffice to support the exceptional-case determination. And we read the district court's additional discussion of plaintiffs' filing of numerous suits on the patents at issue here as itself ultimately resting on the same lack of adequate pre-suit investigation, not simply on ThermoLife's limited product sales, the expiration dates of three of the four patents, the number of suits filed, or the amounts of the settlements. For those reasons, we affirm the exceptional-case determination. [Thermolife International LLC v. GNC Corporation, 2018-1657, 2018-1666 (Fed. Cir. 5/1/2019).]