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FEATURE

Standing to Appeal IPR Decisions of the PTAB: Article III and the Federal Circuit

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Standing in inter partes review (IPR) appeals has become a hotly contested issue. As the Patent Trial and Appeal Board (PTAB or Board) is an administrative tribunal, there is no issue of Article III standing in IPRs. Any person (other than the patent owner) may file an IPR petition.[1] But in the Federal Circuit, as in any other Article III court, the appellant has the burden, if challenged, to establish its constitutional standing.[2] Generally, this boils down to showing sufficient injury in fact. Recently, the Federal Circuit has decided a substantial body of cases illuminating how and when appellants may establish, or fail to establish, injury in fact.

Consumer Watchdog

The Federal Circuit first addressed the issue of Article III standing in appeals from U.S. Patent and Trademark Office administrative proceedings in *Consumer Watchdog v. Wisconsin Alumni Research Foundation*, a case involving the now superseded inter partes reexamination procedure.[3] Consumer Watchdog, a not-for-profit public charity, challenged a patent concerning human embryonic stem cell cultures before the PTAB. The Board confirmed the patentability of the challenged claims of U.S. Patent No. 7,029,913, and Consumer Watchdog appealed.[4]

On appeal, the patent holder challenged Consumer Watchdog's standing. The Federal Circuit began its analysis by explaining that the requirement of Article III standing has three prongs. The appellant must demonstrate that (1) it suffered an "injury in fact"; (2) the injury is "fairly traceable

to the challenged action"; and (3) it is likely that "a favorable judicial decision will redress the injury."[5] Where Congress has provided a right to appeal, as was the case for inter partes reexaminations (and is true today for IPRs), the "traceability" and "redressability" requirements "may be relaxed."[6] But "injury in fact" remains as the "hard floor of Article III jurisdiction."[7] In other words, "the party invoking federal jurisdiction must have 'a personal stake in the outcome.'"[8]

Applying these principles, the court found that Consumer Watchdog did not allege any injury aside from the denial of cancellation of the at-issue claims, and that such denial was insufficient for Article III standing.[9] While Congress may create rights, the invasion of which would confer standing, the only rights created with respect to inter partes reexamination were to request reexamination, and if reexamination were granted, to participate in the process.[10] Consumer Watchdog was not denied either of those rights. Rather, it was dissatisfied with the outcome of the process. "The statute did not guarantee a particular outcome," and "the Board's denial of Consumer Watchdog's request did not invade any legal right conferred upon Consumer Watchdog."[11]

Consumer Watchdog attempted to argue that the statutory estoppel arising from inter partes reexamination was sufficient to confer standing upon it. The Federal Circuit rejected this argument, holding that, at least as to Consumer Watchdog, the estoppel provisions "do not constitute an injury in fact for Article III purposes."[12] Consumer Watchdog did not claim to be involved in any activity that could lead to a possible infringement suit, nor did it claim that it intended to file another request to cancel the patent claims at issue. As such, the estoppel could work no concrete injury upon Consumer Watchdog.[13]

In sum, Consumer Watchdog "only alleged a general grievance concerning the '913 patent" and failed to "identif[y] a particularized, concrete interest in the patentability of the '913 patent, or any injury in fact flowing from the Board's decision."[14] The Federal Circuit dismissed the appeal.

Phigenix

Three years after *Consumer Watchdog*, the Federal Circuit had its first occasion to grapple with the issue of appellate standing in the context of the current IPR procedure in *Phigenix, Inc. v. ImmunoGen, Inc.*[15] Phigenix, a "for-profit discovery stage biotechnology, pharmaceutical, and biomedical research company," requested an IPR of ImmunoGen's U.S. Patent No. 8,337,856.[16] The patent related to methods of using specific antibodies to treat certain cancers. Phigenix sought review, not because it faced any risk of infringement litigation, but rather because the existence of

the '856 patent purportedly "encumbered" Phigenix's efforts to license its own patent portfolio, while "ImmunoGen receives millions of dollars in license revenue."[17] The Board found the subject claims nonobvious.[18] Phigenix filed an appeal.

After reviewing the three elements of Article III standing, the Federal Circuit addressed for the first time "the legal standard for demonstrating standing in an appeal from a final agency action."[19] First, the court discussed the "burden of production" (i.e., "[a] party's duty to introduce enough evidence on an issue to have the issue decided by the fact-finder").[20] After reviewing several cases, the court concluded that the appellant's burden is "the same as that of a plaintiff moving for summary judgment in the district court."[21]

Second, the court turned to the evidence that will suffice to meet that burden. If the appellant's standing is not "self-evident" from the administrative record, the court held, the appellant may submit arguments and "affidavits or other evidence."[22]

Third, the court addressed when an appellant should produce its evidence. The court held that "an appellant must identify the relevant evidence demonstrating its standing 'at the first appropriate' time, whether in response to a motion to dismiss or in the opening brief."[23] In other words, if there is no evidence to support standing in the administrative record, the appellant must produce it "at the appellate level at the earliest possible opportunity."[24]

With these procedural issues decided, the court considered Phigenix's appellate standing. As in *Consumer Watchdog*, the critical issue was injury in fact.[25] Phigenix's only purported injury was the supposed barrier that ImmunoGen's '856 patent posed to Phigenix's efforts to license its own patents.[26] In substance, Phigenix contended that if the '856 patent were invalidated, some of the licensing revenue earned by ImmunoGen would inure to Phigenix. Phigenix attempted to support this claim with a declaration stating that "[t]he existence of ImmunoGen's '856 patent has . . . encumber[ed] Phigenix's licensing efforts" and a letter from Phigenix's attorney to ImmunoGen asserting that Phigenix "believes that it has a strong patent portfolio."[27] However, Phigenix presented no evidence that it had licensed its patents to anyone. The Federal Circuit held that such "conclusory statements" did not meet the standard for supporting a motion for summary judgment.[28] Federal Rule of Civil Procedure 56 requires declarations setting out facts, not legal conclusions.[29] Phigenix failed to demonstrate the existence of any facts that would establish a concrete injury.[30]

Phigenix attempted to argue in the alternative that it had an injury in fact based on the statutory estoppel that applies after a party has invoked the IPR process. The Federal Circuit rejected this argument, relying on its decision in *Consumer Watchdog* concerning the analogous estoppel provision under the inter partes reexamination system.[31] The court found (again) that the estoppel did not create an injury in fact where the appellant "is not engaged in any activity that would give rise to a possible infringement suit."[32] The Federal Circuit dismissed Phigenix's appeal.

Altaire Pharmaceuticals

In 2018, the Federal Circuit encountered two cases where it found that the appellants established Article III standing. The first of these was *Altaire Pharmaceuticals, Inc. v. Paragon Bioteck, Inc.*, a bitter dispute between erstwhile partners.[33] Altaire and Paragon had a contractual arrangement to develop and market phenylephrine, a drug used to dilate patients' pupils. Altaire was the manufacturer of the compound, and Paragon had responsibility for preparing and submitting new drug applications to the Food and Drug Administration (FDA). During the course of that relationship, Paragon filed an application for a patent covering phenylephrine and methods of using it—notwithstanding Altaire's objection and assertion that its CEO was the actual inventor of the claimed subject matter. The application issued as U.S. Patent No. 8,859,623.[34]

Subsequently, Altaire filed actions in federal court against Paragon for breach of a nondisclosure provision of their contract and for a declaratory judgment of invalidity of the '623 patent. Altaire also filed a petition with the PTAB for post-grant review of the '623 patent. Paragon responded with claims of its own for breach of the parties' agreement, seeking the right to terminate it.[35]

The Board instituted the post-grant review. But in its final written decision, the Board concluded that Altaire had not proved the claims of the '623 patent obvious.[36] Altaire appealed.

In the appeal, Altaire argued that it had Article III standing because it faced "an imminent risk of suit on the '623 patent."[37] Paragon argued that, due to the agreement between the parties, Altaire was not engaging in infringing activities, and any future plans Altaire might have could not give rise to an imminent risk of suit.[38]

The critical facts were provided in a declaration of Altaire's general counsel, who testified that Altaire intended to file an abbreviated new drug application (ANDA) with the FDA and "resume marketing its proprietary formulation" of phenylephrine if the agreement between the parties were terminated early (as requested by Paragon).[39] If the agreement were not terminated early, it

would end by its terms in 2021, and Altaire would proceed with its ANDA at that time.[40] Altaire had a proven ability to produce and market the drug. The general counsel testified that the '623 patent stood as an impediment to the approval of Altaire's expected ANDA. He further testified that "Altaire believes that Paragon will inevitably sue Altaire for patent infringement upon Altaire filing an [ANDA] with the FDA."[41] At oral argument of the appeal, Paragon declined to stipulate that it would not bring an action against Altaire for infringement of the '623 patent.[42]

On this record, the Federal Circuit held that Altaire had established an injury in fact. The court relied on the testimony that the '623 patent was an obstacle to the approval of its anticipated ANDA.[43] It also bears noting (though the court did not explain this) that under the Hatch-Waxman Act, Altaire's filing of an ANDA would constitute an act of infringement entitling Paragon to sue and invoke an automatic 30-month stay of approval of Altaire's application.[44] Based on the testimony, the court held that Altaire's injury was "concrete and particularized."[45]

The court also found that the injury was imminent. On this issue, the court distinguished between a mere "fear of future harm," which is not sufficient to support an injury in fact, and a "threat of future injury," which "may be sufficient to establish injury in fact."[46] Because (1) the parties were actively litigating, with Paragon seeking the right to terminate their agreement; (2) the agreement would terminate by 2021 in any event; (3) Altaire's general counsel testified that the company intended to file an ANDA and market its version of the drug; and (4) Paragon refused to stipulate that it would not sue Altaire for patent infringement, the court found that Altaire faced an imminent—indeed "inevitable"—threat of litigation.[47]

Intriguingly, the court also found that "Altaire's injury is compounded by the likelihood that it would be estopped from arguing that the '623 patent would have been obvious."[48] Acknowledging that it had previously rejected such arguments, the court held that in this case Altaire faced an imminent threat of suit rather than a mere general grievance. Under such circumstances, the risk of estoppel supported the finding of an injury in fact. The court was careful to state, "we do not decide whether this potential estoppel effect is sufficient independently to establish standing."[49]

For all these reasons, the Federal Circuit denied Paragon's motion to dismiss the appeal. And on the merits, the court ruled in favor of Altaire.[50]

This was, however, a split decision. The dissenting judge, Judge Schall, reasoned that with the expiration of the parties' agreement potentially three years away and the outcome of the parties' contract litigation uncertain, "we do not know what will happen."[51]

DuPont

E.I. DuPont de Nemours & Co. v. Synvina C.V. was the second recent case in which the Federal Circuit found that an appellant successfully demonstrated standing.[52] Synvina owned U.S. Patent No. 8,865,921, relating to a method of synthesizing a certain chemical compound used as a "building block" for "high-value bio-based chemicals or materials."[53] DuPont, a competitor of Synvina, sought an IPR of the '921 patent. The PTAB held the patent claims not unpatentable, and DuPont appealed.

Synvina argued that DuPont did not have standing to appeal. Because no action for infringement had been filed against DuPont, Synvina argued that any injury was speculative.[54]

DuPont countered that a "specific threat" of suit was not required for standing, and a "significant risk of infringement liability" sufficed.[55] DuPont contended that it faced a significant risk because (1) it had built a plant to produce the relevant compound; (2) the plant was capable of operating according to the specific conditions of the manufacturing method claimed in the '921 patent; (3) DuPont and Synvina were competitors; and (4) Synvina refused to grant DuPont a covenant not to sue.[56]

The Federal Circuit agreed with DuPont. An appellant/petitioner "need not face 'a specific threat of infringement litigation by the patentee'" but rather "must generally show a controversy 'of sufficient immediacy and reality' to warrant the requested judicial relief."[57] Article III standing existed in this case because DuPont had constructed and was operating "a plant capable of infringing the '921 patent."[58] DuPont provided declarations of three scientists showing that the "plant uses the same reactants to generate the same products using the same solvent and same catalysts as the '921 patent," under the same temperature and pressure conditions.[59] Further, the Federal Circuit found that "Synvina's allegations of copying before the Board and its refusal to grant DuPont a covenant not to sue further confirm that DuPont's risk of liability is not 'conjectural' or 'hypothetical.'"[60] The court concluded that DuPont had standing because it had "concrete plans" that create "a substantial risk of future infringement" or would "likely cause the patentee to assert a claim of infringement."[61]

JTEKT

In a third 2018 case, *JTEKT Corp. v. GKN Automotive Ltd.*, the Federal Circuit again found that injury in fact (and hence Article III standing) was lacking.[62] JTEKT, a manufacturer of car parts,

sought an IPR of GKN's U.S. Patent No. 8,215,440, which concerned a drivetrain for four-wheel drive vehicles. GKN disclaimed some of the claims, and the PTAB found some of the claims obvious. But the Board also held that JTEKT had not shown claims 2 and 3 to be obvious.[63] JTEKT appealed.

The Federal Circuit noted that "typically in order to demonstrate the requisite injury in an IPR appeal, the appellant/petitioner must show that it is engaged or will likely engage 'in an[] activity that would give rise to a possible infringement suit.'"[64] However, the court also noted that an appellant/petitioner may have standing if it "has contractual rights that are affected by a determination of patent validity."[65] The court pointed out that U.S. Supreme Court precedent does not require a plaintiff to "bet the farm" "before seeking a declaration of its actively contested legal rights."[66]

In this case, JTEKT did not claim to have any product on the market. That fact did not in itself bar JTEKT from standing. But the Federal Circuit held that in a case where there is no currently infringing activity and only "potential infringement," the appellant "must establish that it has concrete plans for future activity that create[] a substantial risk of future infringement or [will] likely cause the patentee to assert a claim of infringement."[67]

Viewed against this statement of the law, JTEKT's evidence fell short. JTEKT submitted two declarations, but they did not establish a substantial risk of infringement or a likelihood of charges of infringement. While JTEKT and GKN were competitors, GKN had not sued JTEKT for patent infringement. As to future plans, JTEKT's declarants testified that it had a product in development, but not "finalized." One of them stated that "[b]ecause JTEKT has not yet developed a final product, there is nothing that can be analyzed for infringement."[68] Yet the declarants asserted that "the '440 patent posed a risk *to future development* significant enough to warrant filing the IPR."[69] The Federal Circuit acknowledged that "IPR petitioners need not concede infringement to establish standing to appeal."[70] But the court concluded that JTEKT had "not established at this stage of the development that its product creates a concrete and substantial risk of infringement or will likely lead to claims of infringement."[71]

JTEKT, like others before it, attempted to argue that the statutory estoppel constituted an injury in fact. The Federal Circuit again rejected this argument.[72] JTEKT's appeal was dismissed.

AVX

In 2019, the Federal Circuit considered some new issues concerning statutory estoppel, as well as a new argument under the "competitor standing" doctrine, in *AVX Corp. v. Presidio Components, Inc.*[73] Presidio, a manufacturer of ceramic capacitors, owned U.S. Patent No. 6,661,639, which covered ceramic capacitors having a "buried metallization" within a ceramic dielectric layer.[74] AVX, a competitor of Presidio, filed a petition for an IPR of the '639 patent. The PTAB found some of the claims unpatentable and others not unpatentable. AVX appealed as to the claims held to be not unpatentable.

AVX did not claim that it was making, or even contemplated making, any capacitors that might infringe the '639 patent.[75] But it submitted a declaration of its general counsel explaining that AVX had spent substantial sums on research and development of capacitors. It further stated that Presidio had litigated patent infringement matters against AVX repeatedly in the recent past, obtaining damages and an injunction in one case. And finally, the general counsel averred that at least one customer refused to buy one of AVX's products due to a risk that AVX could be enjoined.[76]

With this background, AVX relied on two arguments to support Article III standing. First, AVX claimed that it was injured because the statutory estoppel provision of 35 U.S.C. § 315(e) would preclude it from reasserting its invalidity challenges if Presidio were to sue AVX for patent infringement.[77] Moreover, AVX argued, if its appeal were dismissed, it would suffer the estoppel effect without any Article III court having reviewed its validity challenges. The Federal Circuit again rejected this argument, following its prior decisions in *Consumer Watchdog*, *Phigenix*, and *JTEKT*. (The court also took the occasion to point out that it might not necessarily be true that the § 315(e) estoppel would apply where an IPR petitioner was unable to appeal.[78])

Second, AVX relied on a line of cases concerning "competitor standing" to argue that the Board's decision confirming certain claims of the '639 patent impaired AVX's ability to compete with Presidio. Reviewing those cases, the Federal Circuit recognized that "competitor standing" has been found to exist where government action altered competitive conditions, for example by providing a benefit to an existing competitor or increasing the number of competitors in a market.[79] But in such cases "the challenged government action nonspeculatively threatened economic injury to the challenger by the ordinary operation of economic forces."[80]

The Federal Circuit reasoned that a government action upholding certain patent claims was "quite different," because such actions "do not address prices or introduce new competitors."[81] Instead, they confer a "feature-specific exclusivity right" that "does not, by the operation of ordinary

economic forces, naturally harm a firm just because it is a competitor in the same market as the beneficiary of the government action (the patentee)."[82]

Returning to the issue that has been at the center of the Federal Circuit's decisions in this area, the court found that AVX had presented no evidence that it was involved in, or planned to be involved in, any activity that would even arguably be covered by the '639 patent. Given that the court had held in *JTEKT* that having a product in development did not create a sufficiently concrete risk of infringement to establish an injury in fact, in a case with no evidence of any product, there could be no injury in fact.[83]

The court contrasted AVX's case with two cases where standing was established, *Altaire* and *DuPont*.[84] In both cases, the appellants faced serious and nonspeculative risks of patent infringement litigation. There being no evidence of such a risk to AVX, its appeal was dismissed.

General Electric

The Federal Circuit's decision in *General Electric Co. v. United Technologies Corp.* followed this growing body of case law.[85] General Electric (GE) petitioned the PTAB to review United Technologies Corp.'s (UTC's) U.S. Patent No. 8,511,605, which generally concerns turbofan engines for use in aircraft.[86] The Board ultimately upheld the claims against GE's obviousness arguments. GE appealed. UTC moved to dismiss the appeal for lack of standing.

In opposition, GE argued that its injuries included competitive harm, economic losses, and statutory estoppel. On the issue of competitive harm, GE submitted declarations providing evidence that "the '605 patent impedes its ability to use" geared turbofan engines.[87] Such engines could implicate the '605 patent. Thus, the patent restricted GE's design choices, and "forced GE to incur additional research and development [R&D] expenses."[88] GE noted, in particular, that it had researched a geared engine design at the request of Boeing, but ultimately did not submit that design to Boeing.[89]

The Federal Circuit rejected the competitive harm theory. It held that GE's claimed injuries were "too speculative," because the evidence failed to show "a concrete and imminent injury to GE related to the '605 patent."[90] The court faulted GE's declarations for not attesting that GE actually lost the Boeing bid, or any other specific bids, because it could not offer a geared-drive engine, but "only that GE expended some unspecified amount of time and money to consider engine designs

that could *potentially* implicate the '605 patent."[91] "Without a real, particularized injury," the court stated, "GE lacks standing to appeal the IPR decision."[92]

The court also declined to credit GE's theory of economic losses. GE had argued that it experienced increased R&D costs due to the need to design engines to avoid the '605 patent. But the Federal Circuit found GE's evidence to be insufficiently detailed, because it failed to produce "an accounting for the additional [R&D] costs expended to design around the '605 patent" and submitted "no evidence that GE actually designed a geared-fan engine."[93] Further, GE introduced "no evidence that [it] is in the process of designing an engine covered by" the '605 patent or that it had "definite plans to use the claimed features of the '605 patent."[94]

Finally, the court dismissed the statutory estoppel argument, pointing out that it had previously ruled out estoppel as a ground for standing: "Where, as here, the appellant does not currently practice the patent claims and the injury is speculative, we have held that the estoppel provision does not amount to an injury in fact."[95]

Notably, Judge Hughes filed an opinion concurring in the judgment. The judge explained that while he was constrained by precedent to accept the majority's conclusion, he believed that the Federal Circuit's "precedent has developed an overly rigid and narrow standard for Article III standing in the context of appeals from [IPR] proceedings."[96] In particular, Judge Hughes wrote that the Federal Circuit had laid down a rule of competitor standing that is unique to patent law and therefore "out of step" with the Supreme Court's disapproval of patent-specific principles and procedural rules.[97]

What This Means

Appellate standing in IPR cases has not been in doubt when there is an underlying infringement case. But in cases, such as those discussed above, where there is no active litigation, attorneys representing unsuccessful IPR petitioners need to prepare strong evidence of injury in fact, while bearing in mind the findings and reasoning in these cases.

To date, the touchstone of injury in fact for the Federal Circuit has been the threat of infringement litigation. Parties have succeeded in establishing injury in fact where they have been able to substantiate a real and concrete threat of litigation, as opposed to a mere generalized fear of litigation. The Federal Circuit has credited the existence of such threats where parties showed: (1) their intention to pursue a potentially infringing course of action, (2) their capability to carry out

that activity, and (3) that their process or product could be accused of infringing. For example, in *Altaire* the patent was directed to a drug product manufactured (and allegedly invented) by Altaire, and the intended filing of an ANDA by Altaire would have constituted a statutory act of infringement.[98] In *DuPont*, the appellant was already making the patented product in a plant capable of operating under the reaction conditions claimed in the patent.[99]

The Federal Circuit has denied standing in cases where the appellant's evidence was more equivocal—or unsupported. For example, Phigenix claimed an impact to its licensing revenue but failed to identify a single license agreement.[100] JTEKT admitted that it had not settled on a "final product" and thus "there is nothing that can be analyzed for infringement."[101] AVX did not claim to have any products that might infringe the challenged patent.[102] And, although GE arguably provided more specific evidence than these other appellants, the Federal Circuit still found that it fell short because it did not provide an accounting of its increased costs or identify specific designs or specific lost sales.[103]

A slightly broader theory of economic losses could be a viable way to show injury in fact. *General Electric* might be read to suggest that if an appellant could produce evidence of the cost of the additional R&D needed to design around the patent in question, it might be able to establish injury in fact. Alternatively, concrete evidence that the appellant actually designed a product that could plausibly be seen as within the scope of the patent's claims (in GE's case, a geared-fan engine), but did not sell such a product due to the existence of the patent, should go a long way to establishing an injury in fact. In any case, appellants should consider supplying documentary evidence, rather than mere conclusory declarations. But of course, appellants may find these approaches unappetizing, as evidence that is persuasive on the issue of standing could well become an admission exploitable by the patent holder in subsequent patent infringement litigation.

While the statutory estoppel argument has enjoyed virtually no traction with the Federal Circuit, there may be exceptions. If an appellant can show (1) the intention to make, use, or sell a product that is likely covered by the patent in question; and (2) a serious threat of being sued for infringement if it does so, it may be able to argue that the estoppel would hurt its chances in the infringement litigation. In such a case, as in *Altaire*, the estoppel issue may be useful as a supporting argument (though still not a likely winner on its own).

Of course, if the statutory estoppel associated with filing and losing an IPR would interfere with the defense of a likely infringement litigation, the better course may be not to file the IPR in the

first place. A potential patent infringement defendant may wish to wait for the expected infringement litigation to commence and then file the IPR. That way, at least there would be no question as to standing on appeal from the PTAB's decision. Certainly the Federal Circuit's treatment of appellate standing suggests that potential litigants should carefully weigh their options before filing preemptive IPRs.

Endnotes

1. 35 U.S.C. § 311(a).

2. Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992).

3. 753 F.3d 1258 (Fed. Cir. 2014).

4. *Id.* at 1260.

5. *Id.* at 1260–61.

6. *Id.* at 1261.

7. *Id.* (quoting Summers v. Earth Island Inst., 555 U.S. 488, 497 (2009)).

8. *Id.* (quoting City of Los Angeles v. Lyons, 461 U.S. 95, 101 (1983)).

9. *Id.*

10. *Id.* at 1262.

11. *Id.*

12. *Id.*

13. *Id.* at 1262–63.

14. *Id.* at 1263.

15. 845 F.3d 1168 (Fed. Cir. 2017).

16. *Id.* at 1170.

17. *Id.* at 1174.

18. *Id.* at 1170.

19. *Id.* at 1172.

20. *Id.* at 1172 & n.3 (quoting *Black's Law Dictionary*).

21. *Id.* at 1172 (quoting Sierra Club v. EPA, 292 F.3d 895, 899 (D.C. Cir. 2002)).

22. *Id.* at 1173 (quoting *Sierra Club*, 292 F.3d at 900).

23. *Id.* (quoting *Sierra Club*, 292 F.3d at 900).

24. *Id.*

25. *See id.* at 1173–76.

26. *Id.* at 1174.

27. *Id.* (alterations in original).

28. *Id.*

29. *See* Fed. R. Civ. P. 56(c)(4).

30. *Phigenix*, 845 F.3d at 1174–75.

31. *Id.* at 1175–76.

32. *Id.* (quoting Consumer Watchdog v. Wis. Alumni Research Found., 753 F.3d 1258, 1262 (Fed. Cir. 2014)).

33. 889 F.3d 1274 (Fed. Cir.), *remand order modified by stipulation*, 738 F. App'x 1017 (Fed. Cir. 2018).

34. *Id.* at 1278–79.

35. *Id.* at 1279.

36. *Id.* at 1280.

37. *Id.*

38. *Id.* at 1281.

39. *Id.* at 1282.

40. *Id.* at 1282–83.

41. *Id.* at 1282.

42. *Id.* at 1283.

43. *See id.* at 1282–83.

44. 35 U.S.C. § 271(e)(2); 21 U.S.C. § 355(j)(5)(B)(iii).

45. *Altaire*, 889 F.3d at 1283.

46. *Id.* at 1282 (quoting Prasco, LLC v. Medicis Pharm. Corp., 537 F.3d 1329, 1338–39 (Fed. Cir. 2008)).

47. *Id.* at 1282–83.

48. *Id.* at 1283.

49. *Id.*

50. *Id.* at 1284, 1287.

51. *Id.* at 1289 (Schall, J., dissenting).

52. 904 F.3d 996, 1005 (Fed. Cir. 2018).

53. *Id.* at 999.

54. *Id.* at 1003.

55. *Id.*

56. *Id.* at 1003–04.

57. *Id.* at 1004 (quoting ABB Inc. v. Cooper Indus., LLC, 635 F.3d 1345, 1348 (Fed. Cir. 2011)).

58. *Id.*

59. *Id.* at 1004–05.

60. *Id.* at 1005.

61. *Id.* (quoting JTEKT Corp. v. GKN Auto. Ltd., 898 F.3d 1217, 1221 (Fed. Cir. 2018)).

62. 898 F.3d at 1221.

63. *Id.* at 1218–19.

64. *Id.* at 1220 (alteration in original) (quoting Consumer Watchdog v. Wis. Alumni Research Found., 753 F.3d 1258, 1262 (Fed. Cir. 2014)).

65. *Id.*

66. *Id.* (quoting MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 134 (2007)).

67. *Id.* at 1221.

68. *Id.* (alteration in original).

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.*

73. 923 F.3d 1357 (Fed. Cir. 2019).

74. *Id.* at 1359–60.

75. *Id.* at 1365–66.

76. *Id.* at 1360–61.

77. *Id.* at 1362.

78. *Id.* at 1363.

79. *Id.* at 1364.

80. *Id.*

81. *Id.* at 1365.

82. *Id.*

83. *Id.* at 1365–66.

84. *Id.* at 1366–67.

85. 928 F.3d 1349 (Fed. Cir. 2019).

86. *Id.* at 1351–52.

87. *Id.* at 1352.

88. *Id.*

89. *Id.* at 1352–53.

90. *Id.* at 1353.

91. *Id.* at 1353–54.

92. *Id.* at 1354.

93. *Id.*

94. *Id.*

95. *Id.* at 1355.

96. *Id.* (Hughes, J., concurring).

97. *Id.*

98. Altaire Pharm., Inc. v. Paragon Bioteck, Inc., 889 F.3d 1274, 1282–83 (Fed. Cir. 2018).

99. E.I. DuPont de Nemours & Co. v. Synvina C.V., 904 F.3d 996, 1005 (Fed. Cir. 2018).

100. Phigenix, Inc. v. ImmunoGen, Inc., 845 F.3d 1168, 1174 (Fed. Cir. 2017).

101. JTEKT Corp. v. GKN Auto. Ltd., 898 F.3d 1217, 1221 (Fed. Cir. 2018).

102. AVX Corp. v. Presidio Components, Inc., 923 F.3d 1357, 1365–66 (Fed. Cir. 2019).

103. Gen. Elec. Co. v. United Techs. Corp., 928 F.3d 1349, 1354 (Fed. Cir. 2019).

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