JULY/AUGUST 2021
VOLUME 27 NUMBER 4

IP Litigator®

DEVOTED TO INTELLECTUAL PROPERTY LITIGATION & ENFORCEMENT

Edited by Gregory J. Battersby and Charles W. Grimes

Wolters Kluwer

Standing to Appeal Post-Grant Proceedings: A Brief Review of Recent Federal Circuit Opinions

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On April 7, 2021, the Federal Circuit decided *Apple Inc. v. Qualcomm Inc.*, where it held that Apple lacked standing to appeal the final written decisions in two inter partes review (IPR) proceedings before the U.S. Patent Trial and Appeal Board (PTAB). Shortly before that, on March 22, 2021, almost one year after the Federal Circuit issued an earlier standing opinion in *Argentum Pharm. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374 (Fed. Cir. 2020), the Supreme Court denied a petition for a writ of *certiorari* by Argentum. The Federal Circuit's recent decision in *Apple* and the Supreme Court's recent denial of *certiorari* in *Argentum* necessitate a careful review of the prerequisites a party must satisfy in order to gain access to the federal courts on appeal from IPR and other post-grant proceedings.[1]

Article III of the United States Constitution limits the jurisdiction of federal courts to "Cases" and "Controversies."[2] This limitation gave rise to the doctrine of standing, which requires that a party satisfy three elements in order to invoke the jurisdiction of the federal courts.[3] In particular, standing requires that a party (1) suffer an injury in fact, (2) that is fairly traceable to the challenged action, and (3) that is likely to be redressed by a favorable judicial decision.[4] "This holds true 'even if there is no such requirement in order to appear before the administrative agency being reviewed."[5] The party seeking to invoke the jurisdiction of the federal courts bears the burden of establishing that it has standing on appeal, and risks dismissal if it cannot satisfy its burden.[6]

In this article, we provide a brief analysis of six recent Federal Circuit cases laying out the ongoing jurisprudence on standing in appeals of IPR and other post-grant proceedings.

Apple v. Qualcomm: Payment Obligations under License Agreements Insufficient to Establish Standing Where No Allegation That Validity of the Licensed Patents Affects Obligations

In *Apple Inc. v. Qualcomm Inc.*, the Federal Circuit elaborated on the prerequisites for standing to appeal an adverse decision in post-grant proceedings. After Qualcomm sued Apple alleging infringement of U.S. Patent Nos. 7,844,037 (the "'037 patent") and 8,683,362 (the "'362 patent"), Apple petitioned for IPR.[7] The PTAB ultimately held that Apple had failed to prove the invalidity of the challenged claims.[8] Before Apple appealed the final written decisions of the PTAB, Apple and Qualcomm settled all worldwide litigation between the parties, thus resulting in the dismissal of the parties' district court proceedings.[9] Pursuant to the settlement agreement, Apple obtained a six-year license to the '037 patent and '362 patent, which carried with it the possibility of a two-year extension.[10] Nevertheless, Apple still sought to appeal the PTAB's final written decisions in the IPR proceedings it had initiated.

At the outset, Qualcomm argued that Apple waived any argument in support of its standing "by failing to address, or submit evidence supporting, standing in its opening brief."[11] Although the Court recognized 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," it nevertheless held that "waiver is a matter of discretion," and exercised its discretion to reach the merits of the standing issue.[12] Apple argued that it had standing based upon: (1) its ongoing payment obligations under the license agreement; (2) the threat of being sued upon the expiration of the license; and (3) the estoppel effects of 35 U.S.C. § 315(e) on future validity challenges to the '037 patent and '362 patent.[13] The Court rejected each argument in turn.

With respect to Apple's first argument—that it possessed standing based on its payment obligations under the license—the Court held that "Apple ha[d] not alleged that the validity of the patents at issue [would] affect . . . its ongoing royalty obligations," and "[t]his failure [was] fatal . . . ."[14] The Court next held that the possibility that Qualcomm might sue Apple for infringement of the '037 patent and the '362 patent after the license agreement expired was "too speculative to confer standing," and that Apple's "sparsest of declarations" were insufficient to establish an injury in fact.[15] The Court further declined to take judicial notice of the fact that "Apple sells and will continue to sell" its allegedly infringing products after the expiration of the license, noting that judges "are not fortune-tellers."[16] Turning finally to Apple's estoppel-based argument, the Court held, as it has on many occasions before, that estoppel is not an independently sufficient basis to establish standing.[17] The Court thus dismissed Apple's appeal.

Argentum v. Novartis: Generic Drug Company Lacks Standing Where It Fails to Show Intent to File an ANDA

Not long before *Apple*, the Federal Circuit decided—and the Supreme Court denied certiorari in—*Argentum Pharm. LLC v. Novartis Pharm. Corp.* Novartis owns U.S. Patent No. 9,187,405 (the "'405 patent"), which relates to the Gilenya® drug and "the treatment or prevention of . . . multiple sclerosis."[18] Apotex Inc. and Apotex Corp. petitioned for an IPR of the '405 patent, later joined by Argentum, seeking to challenge the validity of the '405 patent.[19] The PTAB instituted review but ultimately found that the IPR petitioners had failed to demonstrate the unpatentability of the challenged claims.[20] All petitioners appealed to the Federal Circuit and—except for Argentum—settled during the appeals process.[21] Novartis then moved to dismiss Argentum's appeal for lack of standing.[22]

Argentum entered into a joint venture with KVK-Tech, Inc. (KVK) in 2016 "to develop and commercialize generic versions of brand name drugs," including Novartis' Gilenya®.[23] Under the terms of the agreement, Argentum was the "sole party responsible for representing the Joint Venture's interest in any patent-related litigation" arising in connection with their activities, while KVK bore responsibility for manufacturing the generic drug products, as well as seeking regulatory approval.[24] In other words, the agreement gave KVK—not Argentum—the responsibility of filing any Abbreviated New Drug Application (ANDA) with the FDA in order to get approval to market a new generic drug, including a generic version of Gilenya®. Novartis argued that because "any ANDA to be filed for a generic version of Gilenya® '[would] be filed by KVK, Argentum's manufacturing and marketing partner," Argentum could not show an injury in fact necessary to establish that it had standing to appeal the PTAB's decision.[25]

"To establish injury in fact, a[n appellant] must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'"[26] Argentum argued that it had sufficiently shown at least three concrete injuries in fact.[27] *First*, Argentum argued that "without an opportunity to seek [the Federal Circuit's] redress, it face[d] a real and imminent threat of litigation as it jointly pursue[d], along with its partner KVK[], a generic version of Novartis' Gilenya® product . . . ."[28] *Second*, Argentum argued that it would "incur significant economic injury as its investments in developing a generic version of Gilenya® and preparing an ANDA would be at risk with a looming infringement action by Novartis."[29] *Third*, Argentum argued that "absent relief from [the Federal Circuit], Argentum would be estopped under 35 U.S.C. § 315(e) from raising the patentability and validity issues," that it "raised or reasonably could have raised" during the IPR.[30]

The Federal Circuit rejected each of Argentum's arguments in turn, ultimately holding that Argentum failed to show that it suffered an injury in fact.[31] The Court first rejected Argentum's reliance on *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, in support of its standing argument, finding "Argentum's contentions [] unavailing."[32] Unlike the appellant in *Altaire*, discussed in further detail below, Argentum provided no evidence "showing that it would bear the risk of any infringement suit or anything related to its involvement in the ANDA process beyond generic statements."[33] Moreover, the Court found that Argentum failed to provide "sufficient evidence to establish an injury in fact through economic harm."[34] Finally, the Court rejected Argentum's standing argument based upon estoppel, holding that "[it had] already rejected the invocation of the estoppel provision as a sufficient

basis for standing."[35] Accordingly, the Court dismissed Argentum's appeal for lack of standing.[36]

Altaire v. Paragon Bioteck: Generic Drug Company Has Standing Where It Shows Intent to File an ANDA

Prior to *Argentum*, the Federal Circuit held in *Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274 (Fed. Cir. 2018) that a drug company possessed standing to appeal post-grant proceedings where it alleged that it intended to file an ANDA for a generic ophthalmic solution that would infringe an issued patent.[37] There, Altaire had entered into an agreement with Paragon whereby the two would jointly pursue FDA approval for the ophthalmic solution, with Altaire bearing responsibility for chemistry, manufacturing, and controls, and Paragon bearing responsibility for filing a New Drug Application (NDA) for the product.[38] Thereafter, Paragon sought and obtained U.S. Patent No. 8,859,623 (the "'623 patent"), which covered the ophthalmic solution developed by Altaire, resulting in a series of lawsuits based upon the parties' agreement, as well as post-grant proceedings initiated by Altaire challenging the validity of the '623 patent.[39] After the PTAB found in favor of Paragon in the post-grant proceedings, Paragon challenged Altaire's standing to appeal, arguing that Altaire lacked standing because (1) it was not then engaging in infringing activities and any future plans it had to engage in infringing activities were "at most, contingent," (2) Altaire suffered no reputational injury for failing to be named as an inventor of the invention claimed in the '623 patent, and (3) even if it had suffered reputational injury, it could not be remedied by post-grant review of the '623 patent.[40] The Federal Circuit disagreed with Paragon, ultimately concluding that Altaire possessed standing to appeal the post-grant proceedings.

In finding the existence of an injury in fact, the Federal Circuit first held that Altaire "sufficiently demonstrated imminent harm."[41] The Court noted that "'[a] threat of future injury' may be sufficient to establish injury in fact if the 'threat [is] real [and] imminent,'"[42] and held that with Paragon actively seeking to end the parties' agreement authorizing Altaire to manufacture the ophthalmic solution, and Altaire's expressed intent to file an ANDA for and resume marketing the ophthalmic solution upon termination of the agreement, Altaire had sufficiently established that the threat of infringement litigation was "real" and "imminent."[43] Moreover, the Court held that Altaire had suffered "a 'concrete' harm and [was] affected 'in a personal and individual way.'"[44] Accordingly, Altaire had established an injury in fact sufficient to establish standing to appeal the PTAB's final written decision in the post-grant proceedings.[45]

AVX v. Presidio Components: No "Competitor Standing" Where No Engagement in or Nonspeculative Plans to Engage in Conduct Covered by Upheld Claims

In *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357 (Fed. Cir. 2019), the Federal Circuit issued yet another opinion addressing standing to appeal IPR proceedings, where it held that AVX lacked standing.[46] AVX had petitioned for an IPR of all claims of U.S. Patent No. 6,661,639 (the "'639 patent"), owned by Presidio, but the PTAB found only some of the challenged claims unpatentable.[47] AVX appealed, submitting a declaration of its general counsel in support of standing, and attesting, among other things, that: (1) AVX had spent approximately $31 million on research, development, and engineering in fiscal year 2017, (2) AVX protects its inventions by applying for patents, (3) AVX and Presidio interact in the marketplace, (4) since 2008, there had been four district court actions between Presidio and AVX involving patent infringement, and (5) counsel believed that the threat of future litigation between AVX and Presidio concerning the '639 patent was substantial, given the parties' prior litigation history.[48]

In attempting to establish that it had standing to appeal, AVX, like Argentum, argued that "the statutory estoppel provision, 35 U.S.C. § 315(e), would prevent it from asserting the same challenges . . . if Presidio asserts those same claims against AVX in the future."[49] As it did in *Apple* and *Argentum*, the Federal Circuit rejected this argument, holding that Section 315(e) "'do[es] not constitute an injury in fact' when, as [there], the appellant 'is not engaged in any activity that would give rise to a possible infringement suit.'"[50] AVX next argued that the PTAB's decision injured AVX because it "reduce[d] AVX's ability to compete with Presidio," relying on the so-called "competitor standing" doctrine.[51] Under this doctrine, the Federal Circuit recognized that "government actions that 'alter competitive conditions' may give rise to injuries that suffice for standing."[52] Nevertheless, "[t]aking all of AVX's allegations as true, [the Court] conclude[d] that AVX [had] not shown that it [was] engaging in, or ha[d] nonspeculative plans to engage in, conduct even arguably covered by the upheld claims of

the '639 patent."[53] Accordingly, AVX's appeal was dismissed for lack of standing.

General Electric v. United Technologies: No Standing Based on Economic Loss without Sufficient Evidence of Economic Loss

Shortly after the Federal Circuit issued its opinion in *Presidio*, the Court once again addressed standing to appeal an IPR decision in *General Electric Co. v. United Techs. Corp.*, 928 F.3d 1349 (Fed. Cir. 2020). There, General Electric Co. (GE) had petitioned for an IPR of U.S. Patent No. 8,511,605 (the "'605 patent"), owned by United Technologies Corp. (UTC), and after the PTAB found in favor of UTC, GE appealed.[54] GE ultimately offered three theories to support standing, based upon competitive harm, economic losses, and estoppel under § 315(e).[55] GE supported its standing arguments with two declarations by its counsel, attesting, among other things, that: (1) the '605 patent limited GE's ability to use its own product designs, thus limiting GE's ability to compete in a highly regulated industry, (2) designing around the '605 patent restricted GE's design choices and forced GE to incur additional expenses, and (3) GE spent time and money researching a product that would allegedly implicate the '605 patent.[56] The Federal Circuit rejected GE's arguments in turn.

The Federal Circuit first held that "GE's purported competitive injuries [were] too speculative to support constitutional standing," in part, because "GE assert[ed] only speculative harm untethered to the '605 patent."[57] Moreover, relying on its opinion in *Presidio*, the Court held that "[f]or the competitor standing doctrine to apply, the government action must change the competitive landscape by, for example, creating new benefits to competitors," which did not happen there.[58] The Court next rejected GE's argument based on economic losses and future harm, finding that GE had failed to provide sufficient evidence to establish such harm. For example, the Court noted that GE had failed to present (1) an accounting of alleged research and development costs associated with designing products around the '605 patent, (2) evidence showing that any research and development costs were caused by the '605 patent, (3) evidence showing that GE was in the process of developing a product covered by the claims of the '605 patent, or (4) evidence of definite plans to use the claimed features of the '605 patent.[59] Accordingly, GE's arguments based on economic losses and future harm failed. Finally, the Court once more rejected an argument based upon estoppel, reiterating that "[w]here, as here, the appellant does not currently practice the patent claims and the injury is speculative, [it has] held that the estoppel provision does not amount to an injury in fact."[60]

Pfizer v. Chugai: No Standing Where Appellant Fails to Present Evidence of an Injury in Fact at All Stages of the Appeal

Finally, in *Pfizer Inc. v. Chugai Pharm. Co*, 812 Fed. Appx. 979 (Fed. Cir. 2020), the Federal Circuit reiterated that "an actual controversy must be extent at all stages of review," for an appellant to survive a motion to dismiss for lack of standing in an appeal of IPR and other post-grant proceedings.[61] Pfizer petitioned for IPR of most claims of U.S. Patent Nos. 7,332,289 (the "'289 patent") and 7,927,815 (the "'815 patent"), which share a specification and "describe methods for purifying proteins by 'removing contaminant DNA from a sample containing a physiologically active protein.'"[62] In its final written decisions, however, the PTAB rejected Pfizer's arguments, and Pfizer appealed to the Federal Circuit.[63] Pfizer argued that it had suffered an injury in fact because "Pfizer's launch of its product Ruxience®," a biosimilar to a rituximab drug, was likely to cause Chugai to file suit for infringement of the '289 and '815 patents because "Pfizer's biosimilar uses Protein A chromatography, and because the patents 'concern methods of purifying proteins involving the use of protein A chromatography.'"[64] The Federal Circuit rejected Pfizer's arguments, holding that Pfizer failed to establish that "it had suffered a concrete and particularized injury in fact at the beginning of [its] appeal."[65]

The Court found that Pfizer had filed its notice of appeal on January 30, 2019, but "the only evidence of standing that Pfizer [] provided to th[e] court relate[d] to events that occurred much later in 2019."[66] For example, although Pfizer submitted evidence that the FDA approved its proposed biosimilar product, in July 2019, "Pfizer did not [] cite any evidence regarding its activities or plans" before July 2019.[67] Neither did Pfizer "offer[] evidence that would allow [the Court] to evaluate whether it practice[d] or intend[ed] to practice the patented methods in the course of making its biosimilar product."[68] While Pfizer argued that it was "'self-evident to the parties' that there was 'a product at issue' when the appeal began," it was not "self-evident to the court [] that there was standing at the outset of the appeal, or even

later."[69] In particular, the Court rejected Pfizer's suggestion that it was self-evident there was a product at issue based upon its service of process email address for the IPR proceedings—rituximabIPR@winston.com—and Chugai's response, because "Pfizer's service email address and Chugai's response do not tell the court anything useful about Pfizer's plans for its biosimilar, Ruxience®, as of the beginning of 2019, when this appeal began."[70] Accordingly, the Court dismissed Pfizer's appeal.

Conclusion

Apple, Argentum, and the Federal Circuit's additional opinions addressing standing in IPR and other post-grant appeals provide critical insights on the "irreducible constitutional minimum of standing." It is not sufficient to simply state in generalities that one might suffer some remote injury at some later point in time. Rather, a party must establish an injury in fact that is concrete and particularized and actual or imminent, not conjectural or hypothetical. In the case of an appeal where a party cannot satisfy this standard, it will likely be met with dismissal. While estoppel is, on its own, insufficient to establish standing to appeal, a party may establish standing even if it is not currently engaging in infringing activity, if it can establish that it has concrete plans for future activity that creates a substantial risk of future infringement or would likely cause the patentee to assert a claim of infringement. A party *might* also establish standing where it can show that ongoing payments under a license agreement would be affected by the validity of the challenged patent. The evidence offered must establish that the party seeking to invoke the jurisdiction of the federal courts has standing at all stages of the litigation, and parties should not assume that what is self-evident to them is similarly self-evident to the court.

1. *See generally Apple Inc. v. Qualcomm Inc.*, Nos. 2020-1561, 2020-1642, 2021 U.S. App. LEXIS 10026 (Fed. Cir. Apr. 7, 2021); *Argentum Pharm. LLC v. Novartis Pharm. Corp.*, 956 F.3d 1374 (Fed. Cir. 2020), cert. denied, __ S. Ct. __ (2021).
2. U.S. Const. art. III, § 2.
3. *Apple*, 2020 U.S. App. LEXIS 10026, at *2; *see Argentum*, 956 F.3d at 1376.
4. *Apple*, 2020 U.S. App. LEXIS 10026, at *2; *Argentum*, 956 F.3d at 1376.
5. *Argentum*, 956 F.3d at 1376 (quoting *Amerigen Pharm. Ltd. v. UCB Pharma GmBH*, 913 F.3d 1076, 1082 (Fed. Cir. 2019)).
6. *See id.*
7. *See Apple*, 2020 U.S. App. LEXIS 10026, at *1-2.
8. *Id.* at *2.
9. *Id.*
10. *Id.* at *5–6.
11. *Id.* at *3.
12. *Id.* at *3–5 (quoting *Phigenix, Inc. v. Immunogen, Inc.*, 845 F.3d 1168, 1173 (Fed. Cir. 2017)).
13. *Id.* at *6.
14. *Id.* at *8.
15. *Id.* at *9–10.
16. *Id.* at *10–11.
17. *Id.* at *12.
18. U.S. Patent No. 9,187,405 Abstract; *see* Petition for Writ of Certiorari at 3, *Argentum Pharm. LLC v. Novartis Pharm. Corp.*, No. 20-779 (S. Ct. Dec. 4, 2020) (Argentum's Brief).
19. *Argentum*, 956 F.3d at 1375.
20. *Id.*
21. *Id.*
22. *Id.* at 1375–76.
23. Argentum's Brief at 12.
24. *Id.* at 14.
25. *Argentum*, 956 F.3d at 1377.
26. *Id.* at 1376 (quoting *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1548 (2016)).
27. *Id.*
28. *Id.* at 1376–77.
29. *Id.* at 1377 (internal quotations omitted).
30. *Id.* at 1378; *see also* 35 U.S.C. § 315(e).
31. *See* Argentum, 956 F.3d at 1377–78.
32. *Id.* at 1377.
33. *Id.*
34. *Id.* at 1377–78.
35. *Id.* at 1378 (quoting *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357, 1362–63 (Fed. Cir. 2019)).
36. *Id.*
37. *See generally Altaire Pharm., Inc. v. Paragon Bioteck, Inc.*, 889 F.3d 1274 (Fed. Cir. 2018), *remand order modified by stipulation*, 738 Fed. Appx. 1017 (Fed. Cir. 2018).
38. *Id.* at 1278.
39. *See id.* at 1278–79.
40. *Id.* at 1280–81.
41. *Id.* at 1282.
42. *Id.* (quoting *Prasco, LLC v. Medicis Pharm. Corp.*, 536 F.3d 1329, 1339 (Fed. Cir. 2008)).
43. *Id.* at 1282–83.
44. *Id.* at 1283.
45. *Id.* at 1283–84.
46. *See Presidio*, 923 F.3d at 1359.
47. *Id.*
48. *Id.* at 1360–61.
49. *Id.* at 1362.
50. *Id.* at 1362–63.
51. *Id.* at 1363.
52. *Id.* at 1364 (quoting *Clinton v. City of New York*, 524 U.S. 417, 433 (1998)).
53. *Id.* at 1365, 1367.
54. *See General Electric Co. v. United Techs. Corp*, 928 F.3d 1349, 1351 (Fed. Cir. 2019).
55. *Id.* at 1353.
56. *Id.* at 1352–53.
57. *Id.* at 1353–54.
58. *Id.* at 1354.
59. *Id.* at 1354–55.
60. *Id.* at 1355.
61. *Pfizer Inc. v. Chugai Pharm. Co*, 812 Fed. Appx. 979, 980 (Fed. Cir. 2020).
62. *Id.* at 979 (quoting U.S. Patent No. 7,332,289 col. 1, ll. 5–8).
63. *Id.* at 980.
64. *Id.* at 981.
65. *Id.*
66. *Id.*
67. *Id.*
68. *Id.*
69. *Id.*
70. *Id.* at 981–82.