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How District Courts Split Over 'Infringing Acts'

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Following the U.S. Supreme Court's May 22, 2017, decision in TC Heartland LLC v. Kraft Foods Grp. Brands LLC, 137 S. Ct. 1514 (2017), one open question was how to interpret the patent venue's statutory language regarding "has committed acts of infringement" in the Hatch-Waxman Act (hereinafter, ANDA) context.[1]

Currently, only two courts have addressed this issue and have interpreted the statutory language differently. The District of Delaware has held that "planned, future acts that the ANDA filer will take ... must be considered now in determining whether venue is proper."[2] In contrast, the Northern District of Texas rejected that interpretation and instead limited the defendant's acts of infringement to "where the ANDA submission itself was prepared and submitted."[3]

Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.

On Sept. 11, 2017, Chief Judge Leonard Stark of the District of Delaware held that when determining whether a defendant "has committed acts of infringement" in a particular district, a court should not only look at the applicant's ANDA submission, but also "all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market."[4]

In its holding, the court recognized a "temporal mismatch" between prospective ANDA litigation and the statutory language of Section 1400(b) referring to "where the defendant *has committed* acts of infringement."[5] To reconcile this anomaly, the court relied on (1) Congress's creation of ANDA litigation, which established a framework for "artificial" infringement before a generic product is launched, and (2) the Federal Circuit's decision on personal jurisdiction in Acorda Therapeutics Inc. v. Mylan Pharm. Inc., 817 F.3d 755, 760 (Fed. Cir. 2016).[6]

In particular, the court relied on the Federal Circuit's explanation in Acorda that intended, planned and future acts that will occur in a district must be considered in determining proper jurisdiction.[7] Accordingly, the court held "that the same approach must apply in the context of a venue analysis: planned, future acts that the ANDA filer will take in this District must be considered now in determining whether venue is proper

here."[8]

The court also rejected Mylan Pharmaceuticals' arguments that (1) no act of infringement had been committed yet, and (2) venue is proper where the submission is made; where the submission is made from; or where the work associated with the preparation and submission of the ANDA took place.[9] As to the first argument, the court stated "this interpretation would have the consequence of rendering the second prong of § 1400(b) effectively a nullity in Hatch-Waxman cases, violating norms of statutory construction."[10]

As to the second, the court found that Mylan Pharmaceuticals offered "no persuasive reason for why the Court should expand the scope of the 'acts of infringement' inquiry to include preparatory activities that are explicitly not infringing acts under § 271(e)(1)'s safe harbor."[11] Moreover, the court found that Mylan Pharmaceuticals offered "no persuasive reason for why, if the 'acts of infringement' are something more than just the submission of an ANDA, the pertinent 'acts of infringement' should not be understood as something broader than what [Mylan Pharmaceuticals] seems to have arbitrarily selected."[12]

The court concluded that "an applicant's submission of an ANDA, in conjunction with other acts the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District, must all be considered for venue purposes, and can be sufficient to demonstrate that the ANDA-filing Defendant 'has committed' 'acts of infringement.'"[13]

Galderma Lab. LP v. Actavis Lab. UT Inc.

On Nov. 17, 2017, Chief Judge Barbara Lynn of the Northern District of Texas interpreted the statutory language "has committed acts of infringement" more narrowly than Chief Judge Stark, noting "[w]hile the Delaware court's opinion is very thorough, there are several issues with the decision that counsel this Court away from adopting the holding that an act of infringement occurs in any district where the ANDA filer intends to market the ANDA product after it receives FDA approval."[14] Instead, the court held that when "determining proper venue in a Hatch-Waxman Act case, it is appropriate to look to the forum where the ANDA submission itself was prepared and submitted."[15]

First, the court noted that "the Delaware court's approach to venue in ANDA cases is a liberal interpretation of the venue statute" that fails to comport with the Federal Circuit's guidance in In re Cray.[16] As the court noted, the patent venue statute states that venue is proper "where the defendant *has committed* acts of infringement."[17] Therefore, the Delaware court's holding that the "acts of infringement" must include acts constituting ordinary patent infringement when the generic drug product, upon FDA approval, is launched "is inconsistent with the plain language of the statute."[18]

Second, the court addressed the Delaware court's reliance on Acorda, noting that Acorda addressed personal jurisdiction, not venue.[19] According to the court, the Federal Circuit's decision in Cray provided "a clear admonition to courts to avoid importing personal jurisdiction standards into a venue analysis."[20]

Finally, the court rejected the plaintiffs' argument that the defendant had committed an act of infringement in the Northern District of Texas when it submitted the ANDA with the paragraph IV challenge to the plaintiffs' patents, as the plaintiffs are residents of that district.[21] The court noted

that the plaintiffs cited no authority that the patent holder's location is relevant to the patent venue analysis.[22] Moreover, the court ruled that the patent venue statute does not provide for such an interpretation, as it states venue is appropriate where (1) the defendant resides or (2) the defendant has committed acts of infringement and has a regular and established place of business.[23]

Differences Between Bristol-Meyers-Squibb and Galderma Decisions

As discussed above, the courts differed in (1) interpreting the language "has committed" in the Section 1400(b) infringement analysis and (2) applying Acorda to the venue analysis. Both courts also applied different burdens to the venue analysis, and the decisions were issued at different stages of venue-related discovery.

In Bristol-Myers Squibb, the court viewed the issue of venue as procedural and followed Third Circuit law, "which places the burden on Defendant to prove improper venue."[24] In Galderma, the court held that the "plaintiff bears the burden of sustaining venue in the district in which the suit was brought."[25]

Finally, the District of Delaware permitted the case to proceed while the parties conducted expedited venue-related discovery on whether Mylan Pharmaceuticals had a "regular and established place of business," leaving open a final opinion on proper venue.[26] The Northern District of Texas issued its opinion after allowing limited venue-related discovery.[27]

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[1] See 35 U.S.C. § 1400(b).

[2] Bristol-Myers Squibb Co. v. Mylan Pharm. Inc., 2017 WL 3980155, at *9 (D. Del. Sep. 11, 2017).

[3] Galderma Lab. LP v. Teva Pharm. USA Inc., Case No. 17-cv-01076, Slip Op. at 11 (N.D. Tex. Nov. 17, 2017). Actavis Lab. UT Inc. was formerly a named party in this case; however, plaintiffs dismissed their claim against Actavis on Nov. 2, 2017. Therefore, the court's holding applied to Teva USA only. Slip Op. a 4, n1.

[4] Bristol-Myers Squibb Co., 2017 WL 3980155, at *8.

[5] Id. at *6-7.

[6] Id. at *7-8.

[7] Id. at *9.

[8] Id. (emphasis in original).

[9] Id. at *11.

[10] Id.

[11] Id.

[12] Id.

[13] Id. at *13.

[14] Galderma Lab., LP v. Actavis Lab. UT, Inc., Case No. 17-cv-01076, Slip Op. at 9 (N.D. Tex. Nov. 17, 2017).

[15] Id. at 11

[16] Id. at 10. The Federal Circuit issued its decision in Cray on Sept. 21, 2017—ten days after the opinion in Bristol-Myers Squibb. 871 F.3d 1355 (Fed. Cir. 2017). In Cray, the Federal Circuit "struck down a patent venue test crafted by a district court because the test was 'not sufficiently tethered' to the statutory language." Galderma, Slip Op. at 10 (citing In re Cray, 871 F.3d at 1362).

[17] Id. at 9 (emphasis in original).

[18] Id. at 9-10.

[19] Id. at 10.

[20] Id. at 10-11.

[21] Id. at 12.

[22] Id.

[23] Id. (citing Section 1400(b)).

[24] 2017 WL 3980155, at *5.

[25] Case No. 17-cv-01076, Slip Op. at 5.

[26] Bristol-Meyers-Squibb, 2017 WL 3980155, at *1.

[27] Case No. 17-cv-01076, Slip Op. at 4.