A District Court Split On Hatch-Waxman Venue Determinations

By **Ron Vogel and Brian Coggio** (August 30, 2019)

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On Aug. 13, the U.S. District Court for the District of New Jersey rejected the premise that an abbreviated new drug application filer's future intended acts should be considered in determining patent venue and, in doing so, furthered an inter- and intra-district split on what constitutes an "act of infringement" in Hatch-Waxman actions.[1]

The recent decision in Valeant Pharmaceutical North America LLC v. Zydus Pharmaceuticals (USA) Inc. is contrary to a line of cases (including an earlier New Jersey district court decision) that followed Bristol-Myers Squibb Co. v. Mylan Pharmaceuticals Inc., in which the U.S. District Court for the District of Delaware held that that an ANDA submission constitutes a nationwide act of infringement (which meant that venue is essentially proper in any district, assuming that a regular and established place of business exists).

The Valeant court's ruling that an act of infringement is committed in the district where an ANDA is submitted — rather than nationwide — creates a split in authority in two of the nation's busiest districts for Hatch-Waxman litigation and poses an important question that is ripe for review by the U.S. Court of Appeals for the Federal Circuit. This article discusses the cases leading to this split.

Venue in Patent Infringement Actions

Venue challenges spiked in the wake of the U.S. Supreme Court's 2017 decision in TC Heartland LLC v. Kraft Food Group Brands LLC,[2] which held that a corporate defendant "resides" only in its state of incorporation for purposes of determining venue in patent infringement actions.

This narrow interpretation of "residence" under the first prong of the patent venue statute, 28 U.S.C. Section 1400(b), accentuated the importance of the second prong of that section, which makes venue proper in a district where the defendant has committed an act of infringement and has a regular and established place of business. Under the second prong, locating an act of infringement is particularly troublesome in Hatch-Waxman actions because the relevant statute, 35 U.S.C. Section 271(e)(2)(A), defines infringement as the submission of an ANDA, but does not state where that infringing act occurs:

> It shall be an act of infringement to submit an application under 505(j) of the Federal Food, Drug and Cosmetic Act [ANDA] or described in section 505(b)(2) of such Act [Section 505(b)(2) NDA] for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under the Act to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.[3]

Although neither the Supreme Court nor the Federal Circuit has opined on where this artificial act of infringement occurs, the Federal Circuit in In re Cray cautioned that "courts should be mindful of [§ 1400(b)'s] history in applying the statute and be careful not to

conflate showings that may be sufficient for other purposes, e.g., personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent infringement cases."[4]

Three of the district courts that have addressed acts of infringement have each considered the Federal Circuit's decision in Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.[5] regarding personal jurisdiction in Hatch-Waxman actions and reached different conclusions as where the infringing act under Section 271(e)(2) occurs. Before discussing these cases, this article will briefly revisit Acorda because personal jurisdiction has been entwined by the courts in deciding venue jurisprudence.

Personal Jurisdiction Case Law Has Influenced Venue in Hatch-Waxman Actions

Acorda Creates Nationwide Personal Jurisdiction in Hatch-Waxman Actions

In Acorda,[6] the Federal Circuit held that personal jurisdiction in Hatch-Waxman actions exists wherever a defendant intends to market its generic product after approval by the U.S. Food and Drug Administration. The ruling, which effectively establishes nationwide personal jurisdiction in Hatch-Waxman actions, was based on "the real-world actions for which approval is sought," meaning the "manufacture, use, or sale of the new drug for which the application is submitted."[7]

Bristol Holds That an ANDA Submission Is a Nationwide "Act of Infringement"

In Bristol,[8] the Delaware district court recognized the "almost impenetrable problem" in the Hatch-Waxman litigation arising from the "complete mismatch" between Section 1400(b), which is written in the past tense, i.e., "where the defendant has committed acts of infringement," and the act, which focuses on the future, i.e., the drug that will be sold after FDA approval.[9]

After Bristol alleged that West Virginia-based Mylan had committed an act of infringement in Delaware, the court denied Mylan's motion to dismiss for improper venue because, with respect to acts of infringement, "the non-speculative future acts of the ANDA filer must be deemed, for purposes of the litigation, to have already occurred."[10]

By considering a defendant's future intended acts when evaluating venue, U.S. District Judge Leonard Stark relied heavily on the Acorda rational for establishing personal jurisdiction and held that an act of infringement had occurred in Delaware (and apparently anywhere) where the generic product would be marketed after FDA approval:

> In the Court's view, the best, most reasonable conclusion after Acorda is that an ANDA filer's future, intended acts must be included as part of the "acts of infringement" analysis for purposes of determining if venue is proper under the patent venue statute. In Acorda, the Federal Circuit plainly held that intended, planned, future acts that will occur in a district in the future (after FDA approval) are acts that must be considered now in determining whether an ANDA filer has sufficient contacts with that district right now to make Hatch–Waxman litigation in such a district appropriate from a jurisdictional perspective. [11]

The court rejected Mylan's position that there is no actual infringement in an ANDA case because this rationale would negate the second prong of Section 1400(b) and thereby limit venue to a generic defendant's state of incorporation — West Virginia in Mylan's case. [12]

Several courts have accepted Bristol without question[13], including the New Jersey district

court.[14] But two courts have now rejected the Bristol reasoning and have found that an infringing act does not extend nationwide.

Galderma and Valeant Limit the Situs of Infringing Acts to the Place of ANDA Submission

In Galderma Laboratories LP v. Teva Pharmaceuticals U.S.A. Inc.,[15] Teva moved to dismiss because, inter alia, it had not committed an act of infringement in Texas, and the district court agreed.[16] The Galderma court held that in determining proper venue in a Hatch-Waxman action, one should look to the forum where the ANDA was prepared and submitted.[17] In response to the plaintiffs' argument that Teva USA's ANDA preparation was irrelevant under the Section 271(e)(1) safe harbor,[18] the court noted that it was not relying on any research or activities other than the preparation and actual submission of the ANDA itself.[19]

The court rejected the Bristol's court's rationale as "inconsistent with the plain language of the [Hatch Waxman] statute, which does not identify any artificial act of infringement other than the ANDA submission."[20] The Galderma court also noted that Bristol disregarded the Supreme Court's admonition that Section 1400(b) "is [not] to be given a 'liberal' construction."[21] Lastly, the Galderma court also noted that Bristol's reliance on Acorda was suspect because Acorda addressed personal jurisdiction — not venue.

Recently, in Valeant, after Mylan Pharmaceuticals Inc. submitted its ANDA seeking approval to sell a generic version of Jubila, the Valeant plaintiffs sued MPI, Mylan Laboratories Ltd. and Mylan Inc. in the New Jersey district court for infringement under the Hatch-Waxman Act and for corresponding declaratory judgments of infringement.[22] None of the Mylan defendants are incorporated in New Jersey; moreover, MPI is incorporated in and has its principal place of business in West Virginia. [23]

The Valeant plaintiffs argued that venue was appropriate under Bristol because MPI had taken steps to engage in future activities that will be purposefully directed at New Jersey. The Mylan defendants countered that the only alleged act of infringement was MPI's electronic submission of the ANDA, which occurred in West Virginia and not in New Jersey.

The court agreed with the Mylan defendants and dismissed the Hatch-Waxman infringement counts for improper venue. After noting that "because MPI electronically submitted the at issue ANDA in West Virginia, MPI committed an act of infringement in West Virginia,"[24] the Valeant court — like the Galderma court — noted that Bristol was counter to the Federal Circuit's guidance that venue is not given a liberal construction as well as the explicit wording of the Hatch-Waxman statute:

> Regarding defendant MPI, the Court is not persuaded that the ANDA filer's future, intended acts are included in the acts of infringement analysis. The Federal Circuit has cautioned against liberally construing the patent venue statute, and on its face, the patent venue statute states "a civil action for patent infringement may be brought where the defendant has committed acts of infringement." See §1400(b) (emphasis added). Bristol-Myers Squibb Co.'s interpretation of that statute does not follow from a plain reading of the statute, which is clear: only where a defendant has committed an act of infringement may a party bring a patent suit. Here, it is undisputed that defendant MPI submitted its ANDA application in West Virginia, or the FDA in Maryland. None of these actions occurred in New Jersey.[25]

The court also declined to extend declaratory judgment jurisdiction and dismissed those

counts, noting that an identical, protective suit had been filed in the U.S. District Court for the Northern District of West Virginia.

The Question of Where an ANDA Act of Infringement Occurs Seems Ripe for Federal Circuit Review

The Valeant decision creates an intra- and inter- district court split and makes the act of infringement question ripe for Federal Circuit review. An appellate panel will have to consider whether the expansion of personal jurisdiction to venue under Bristol in Hatch-Waxman actions is inconsistent with earlier Supreme Court precedent that strictly limited general jurisdiction for all civil actions.[26]

It will likely also consider whether Bristol aligns the Supreme Court's admonition that Section 1400(b) should not be liberally construed. Proponents of Bristol may argue that even with nationwide acts of infringement, the regular and established place of business requirement under the second prong of Section 1400(b) ensures that a defendant is not haled into a remote district having no real relationship to the dispute.

Similarly, an appellate court may appreciate the Valeant court's focus on nonprospective conduct and Section 1400(b)'s language that "a civil action for patent infringement may be brought where the defendant has committed acts of infringement." It would seem that the Valeant court's statement that the situs of submission of an ANDA is the situs for the infringing act does not impact the Section 271(e)(1) safe harbor, because submission is explicitly defined as an "act of infringement."

One final issue to consider is the recent shift in the burden of persuasion. In finding in Teva's favor, the Galderma court — unlike the Delaware court in Bristol (or the other courts following Bristol) — put the burden on the plaintiff to establish proper venue. Similarly, the Valeant court put the burden on the plaintiffs to establish venue. This approach was subsequently confirmed in In re ZTE (USA) Inc., where the Federal Circuit clarified that "upon motion by the Defendant challenging venue in a patent case, the Plaintiff bears the burden of establishing proper venue."[27] The impact of the shift in burden may become clearer once courts agree on the situs of an act of infringement.

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[1] Valeant Pharmaceutical North America LLC v. Zydus Pharmaceuticals (USA) Inc., 18-cv-13635, 18-cv-14305 (D. N.J. Aug.13, 2017) [hereinafter "Order"]. The analysis herein is also relevant to venue in biosimilar litigation.

[2] 137 S. Ct. 1514 (2017).

[3] 35 U.S.C. § 271(e)(2)(A) (emphasis added).

[4] 871 F.3d 1355, 1361 (Fed. Cir. 2017).

[5] F. Supp. 3d 572, 596 (D. Del. 2015), aff'd, 817 F.3d 755 (Fed. Cir. 2016).

[6] 817 F.3d. 755 (Fed. Cir. 2016).

[7] Id. at 760. Notably, in her concurrence, Judge O'Malley, citing the Supreme Court's decision in Calder v. Jones, 465 U.S. 783 (1984), opined that specific jurisdiction existed in Delaware because plaintiffs — both Delaware corporations — were injured there by defendant's ANDA filing. In Calder v. Jones, the Supreme Court held that courts could exercise personal jurisdiction over a defendant that intentionally targets a forum state, knowing that its acts that will harm a potential plaintiff residing in that state, without violating due process. Id at 788-90. The Court noted that the defendants "'expressly aimed 'their intentional, and allegedly tortious, actions' at California because they knew the National Enquirer 'ha[d] its largest circulation' in California, and that the article would 'have a potentially devastating impact' there." Id. at 789–90.

[8] 2017 WL 3980155 (D. Del. Sept. 11, 2017).

[9] Id. at *6.

[10] Id. at *12.

[11] Id. at *9 (emphasis in original). In relying on Acorda, the court recognized that venue and personal jurisdiction are two different, although related, constructs. Id. at *8 n.10.

[12] Id. at *10 (citing United Sav. Ass'n of Texas v. Timbers of Inwood Forest Assocs., Ltd., 484 U.S. 365, 375 (1988)) (rejecting interpretation that would result in "a practical nullity" of a statutory provision).

[13] See UCB Inc. v. Mylan Tech., Inc. 2017 U.S. Dist. LEXIS 218883 (D. Del. Dec. 1, 2017); Javelin Pharm. Inc. v. Mylan Labs. Ltd., 2017 WL 5953296 (D. Del. 1, 2017); Mallinckrodt IP v. B. Braun Medical Inc., 2017 WL 6383610 (D. Del. Dec. 14, 2017).

[14] Celgene Corp. v. Hetero Labs. Ltd., 2018 WL 1135334 (D.N.J. Mar. 2, 2018).

[15] 290 F. Supp. 3d 599, 608 (N.D. Tex., 2017).

[16] Teva raised other issues, but they are not pertinent to the present discussion. Id.

[17] Id.

[18] 35 U.S.C. § 271(e)(1) provides that "it shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs."

[19] 290 F. Supp. 3d at 609.

[20] Id.

[21] Id. (citation omitted).

[22] Order at 2-3.

[23] Id. at 2.

[24] Id. at 5.

[25] Id. at 6-7.

[26] In Daimler AG v. Bauman, 134 S. Ct. 746 (2014), decided two years before Acorda, the Supreme Court strictly limited general jurisdiction for all civil actions.

[27] 890 F.3d 1008, 1013 (Fed. Cir. 2018).