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In Hatch-Waxman litigation, Federal Circuit restricts venue under the TC Heartland to districts relating to ANDA filings

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On November 5, 2020, the United States Court of Appeals for the Federal Circuit, in Valeant Pharmaceuticals N. Am. LLC v. Mylan Pharmaceuticals Inc., No. 19-2402, resolved a split among district courts over what constitutes "acts of infringement" sufficient to support venue in the context of a Hatch-Waxman litigation. The second prong of the patent venue statute, 28 U.S.C. § 1400(b), provides that venue is proper in districts where past "acts of infringement" have occurred. The Federal Circuit clarified that for Hatch Waxman cases, venue only includes districts in which acts related to the submission of an Abbreviated New Drug Application ("ANDA") occurred and not other districts where future distribution of the generic product(s) specified in the ANDA may be contemplated.

After Mylan Pharmaceuticals Inc. ("MPI") submitted an ANDA seeking approval to market a generic version of the drug Julia®, Valeant Pharmaceuticals, Dow Pharmaceutical Sciences, and Kaken Pharmaceutical Co. (collectively "Valeant") filed suit against MPI, Mylan Inc., and Mylan Laboratories Ltd. ("MLL") (collectively "Mylan") in the District of New Jersey. None of the defendant entities were incorporated in New Jersey: MPI is a West Virginia corporation with a principal place of business in West Virginia, Mylan Inc. is a Pennsylvania corporation with a principal place of business in Pennsylvania, and MLL is an Indian corporation.

Arguing that venue was improper because MPI and Mylan Inc. didn't reside in, nor have a regular and established place of business in, New Jersey, Mylan moved to dismiss Valeant's complaint under Federal Rule of Civil Procedure 12(b)(3). Mylan claimed that the only alleged act of infringement – submission of the ANDA – did not occur in New Jersey, but rather in West Virginia where MPI is based. The district court granted Mylan's motion, finding that the venue statute did not contemplate future infringing acts. The district court also dismissed MLL despite MLL being a foreign entity. Valeant timely appealed to the Federal Circuit.

The Federal Circuit affirmed the district court's dismissal of the cases against the domestic Mylan entities, but reversed and remanded with respect to the foreign entity, MLL. This is the first reported opinion in which the Federal Circuit applied the patent venue statute, 28 U.S.C. § 1400(b), to a patent infringement case under the Hatch-Waxman Act. Where one avenue for proper venue under § 1400(b) requires a court to determine where "acts of infringement" have occurred, the Federal Circuit deemed the act of submitting an ANDA to be the "act" of patent infringement under the Hatch Waxman Act, where the purpose of the ANDA submission is to obtain approval to engage in the commercial manufacture, use, or sale of a drug prior to the expiration of an Orange Book listed patent.

Prior to the present appeal, district courts were split as to what "acts of infringement" encompassed. (See our prior coverage of the issue in the district courts, here and here.) The District of Delaware, in Bristol-Myers Squibb v. Mylan Pharmaceuticals Inc., No. 17-cv-379 (Sept. 11, 2017), concluded that because the temporal focus of the infringing acts in Hatch-Waxman suits are in the future, those future acts must be relevant to the venue analysis. The District of New Jersey adopted the District of Delaware's reasoning in Celgene Corp. v. Hetero Labs Ltd., No. 17-cv-3387 (Mar. 2, 2018). However, a district court in the Northern District of Texas disagreed, holding that the only past act of infringement identified by the Hatch-Waxman Act is the ANDA submission. Galderma Labs., L.P. v. Teva Pharms. USA, Inc., 290 F. Supp. 3d 599, 606-09 (N.D. Tex. 2017).

Both Valeant and Mylan agreed that § 1400(b) requires a past act of infringement. The Federal Circuit reasoned that this past act requirement was well supported by the language of the statute, noting the contrasting present perfect tense used for the "has committed acts of infringement" requirement as opposed to the present tense used for the "where the defendant resides" and the "where the defendant . . . has a regular and established place of business" requirements.

Thus, the key issue on appeal was the nature and scope of the acts of infringement defined by 35 U.S.C. § 271(e)(2)(A), which provides that "[i]t shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent." The Federal Circuit rejected Valeant's argument that "acts of infringement" should encompass future planned acts of infringement for the purposes of venue. Valeant argued that because the act of infringement is statutorily created, the act of an ANDA submission is "artificial" infringement. The Federal Circuit disagreed, reasoning that simply because the Hatch-Waxman Act delineates which acts may or may not give rise to a cause of action, does not mean that such acts of infringement are artificial.

Valeant also argued that the nature of Hatch-Waxman litigation requires that the act of infringement encompass more than the submission of the ANDA. To that point, the Federal Circuit noted that that while the judicial inquiry on the merits considers the ANDA defendant's potential future conduct, the result of almost all Hatch-Waxman litigation is that no post-submission infringement actually occurs. Valeant further argued that the submission of an ANDA should be viewed as a nationwide act based on a "conceptual" aspect beyond the literal act of submission, analogizing to situations involving sales and offers for sale of a patented invention. The Federal Circuit rejected this argument too, finding no textual basis in the statute to support such a broad interpretation, and reasoning that there was no common law basis to extend this "conceptual" aspect as with sales and offers for sale. Finally, the Federal Circuit found that Valeant's reliance on Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., 817 F.3d 755 (Fed. Cir. 2016) to be misplaced, because Acorda did not address the question of venue, but rather personal jurisdiction.

The Federal Circuit also noted that strong policy grounds supported Valeant's reading of the statute.

But the avowed risks that a generic company might deliberately choose a specific location from which to submit its ANDA to avoid venue in certain jurisdictions, the possibility that brand name drug companies may be required to engage in identical lawsuits in multiple districts leading to added time and expense to resolve such cases, and the potential for inconsistent judgments did not overcome the plain language of both the Hatch-Waxman Act and the patent venue statute.

Notably, the Federal Circuit declined to resolve the question of whether venue would be proper in the District of Maryland, where the FDA received the ANDA. The Federal Circuit also declined to determine which specific acts involved in the ANDA submission would be relevant to the question of venue. However, the court did assert that acts protected by the safe harbor provisions of § 271(e) were non-infringing for all purposes, including venue.

Finally, the Federal Circuit concluded that the district court's dismissal of MLL, the foreign entity, was in error. As a foreign entity, MLL is subject to venue in any judicial district, including the present district. The Federal Circuit concluded that the district court could find that Valeant's complaint sufficiently alleged MLL's involvement in the submission of the ANDA, and reversed and remanded the district court's venue-based dismissal of MLL.

The Federal Circuit's application of TC Heartland LLC v. Kraft Foods Corp. Brands LLC, 137 S. Ct. 1514 (2017), may narrow the number of judicial districts in which owners of Orange Book listed patents may bring suit under the Hatch-Waxman Act. However, this decision also raises many questions regarding which activities (e.g. formulation development, labeling) may be considered part of the ANDA submission for venue purposes, and may also be inconsistent with the safe harbor provisions under § 271(e)(1). Although clinical trials are non-infringing under § 271(e)(1), such clinical trial data are often essential to showing bioequivalence, and thus essential to the submission of the ANDA. Under the Federal Circuit's current reasoning, a clinical trial would not be sufficient to establish venue in the particular district(s) that the trial took place.

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