Patterson Belknap Webb & Tyler LLP

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For the First Time Since *TC Heartland*, the Federal Circuit Addresses Venue in an ANDA Case – the Holding May Also Impact BPCIA Litigation

On November 5, 2020, in ***Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.***, No. 2019-2402, the Federal Circuit held that venue in Hatch-Waxman cases brought under 35 U.S.C. § 271(e)(2)(A) is proper "only in districts where actions related to the submission of an Abbreviated New Drug Application ('ANDA') occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated." Slip op. at 3. If the ruling stands, it will restrict venue available against domestic generic drug makers in ANDA cases, and may similarly impact venue in litigation under the Biologics Price Competition and Innovation Act ("BPCIA").

In *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017), the Supreme Court "held that the general venue provision in 28 U.S.C. § 1391—which provides that a corporation is deemed to 'reside' in any judicial district in which it is subject to personal jurisdiction—does not modify the term 'resides' in 28 U.S.C. § 1400, the more specific venue statute applicable to patent cases." *Valeant* Slip op. at 2. As a result, "a [domestic] corporation may be sued for patent infringement [only] in . . . the state in which it is incorporated and . . . [the state(s) in which] it has a regular and established place of business and an act of infringement has occurred." *Id.*

Valeant is the Federal Circuit's first decision addressing the impact of *TC Heartland* on venue in ANDA proceedings. Under the patent venue statute, 28 U.S.C. § 1400(b), to determine "whether venue is proper in a district other than one in a state in which a defendant is incorporated, a court must determine . . . 'where the defendant has committed acts of infringement.'" *Id.* at 8 (quoting 28 U.S.C. § 1400(b)). ANDA cases are unique among patent litigations because the act of infringement is the submission of an application to the FDA to market a generic drug in the future, rather than making, using, offering to sell, selling, or importing a patented product. *See* 35 U.S.C. § 271(e)(2). The question before the Federal Circuit in *Valeant* was whether the act of infringement identified in the patent venue statute "occurs only when and where an ANDA-filer submits its ANDA to the FDA or occurs wherever future distribution of the generic is contemplated." Slip op. at 9.

The Federal Circuit held that "venue in Hatch-Waxman cases must be predicated on past acts of infringement," namely "actions related to the ANDA submission." *Id.* at 13. The Federal Circuit rejected the position that venue is proper in a judicial district where future infringement would occur if and when the ANDA was approved. *See id.* at 15-16. For this reason, venue was not proper in New Jersey for the two domestic defendants because they did not reside, and had not performed any acts related to the preparation or submission of the ANDA application, in New Jersey. (Notably, the Federal Circuit declined to decide whether the judicial district in which all ANDAs are received—the District of Maryland, where the FDA is located—would be a proper venue in Hatch-Waxman cases. *Id.* at 19 n.8.)

The Federal Circuit acknowledged several policy concerns raised by *Valeant*, including the risk that "a generic company may 'game' the system to avoid venue in certain jurisdictions" and that "brand name drug companies may 'be required to file and maintain largely identical suits in multiple districts' causing an increase in time and expense to resolve the cases and 'result[ing] in inconsistent judgments.'" *Id*. at 17. The court concluded, however, that "these policy arguments cannot trump the plain language of § 271(e)(2) and the requirements of § 1400(b)." *Id.* at 18.[1]

[1] Shortly following the Federal Circuit's *Valeant* decision, on November 16, 2020, Mylan merged with Pfizer Inc.'s spun-off Upjohn unit to form a new company called Viatris.

Notably, if the decision stands, the holding of *Valeant* may apply to BPCIA cases, in which the act of infringement, as in ANDA cases, is based on the filing of an application seeking marketing approval from the FDA. Specifically, 35 U.S.C. § 271(e)(2)(C) makes the submission of an abbreviated Biologics License Application ("aBLA") an act of patent infringement "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2)(C). For this reason, venue in BPCIA cases brought against domestic biosimilar manufacturers may be more restrictive if *Valeant* applies, because future commercial activities pursuant to an aBLA may not constitute acts of infringement for purposes of establishing proper venue under 28 U.S.C. § 1400(b).

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