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Practical Issues for the Pharmaceutical and Biopharmaceutical Industry in the Wake of TC Heartland

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The US Supreme Court this week held that the broad venue provision of 28 U.S.C. § 1391(c) does **not** apply to patent law—at least, when the defendant is a domestic entity. This decision arises after years of judicial interpretation of two seemingly interrelated statutory provisions regarding “residency” in patent cases. In a boon for accused infringers, the Supreme Court has held that “‘reside[nce]’ in § 1400(b) refers **only** to the State of incorporation.” *Slip op.* at 10. The decision has significant consequences for Hatch-Waxman litigants and for litigants under the Biologics Price Competition and Innovation Act (BPCIA).

For the past 27 years, patent owners and accused infringers have operated under a Federal Circuit decision that made venue analysis under 28 U.S.C. § 1400 co-extensive with personal jurisdiction analysis. See *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (1990). The practical impact of *VE Holding Corp.* is that it gave substantial leeway to patentees in forum selection and it left defendants with limited options for challenging that choice. From this flexible interpretation of § 1400, patent-friendly jurisdictions emerged in the most unlikely of locations and patent-assertion entities made their homes in jurisdictions with favorable views on patents and patent damages. *VE Holding* also gave flexibility to pharmaceutical companies to select a single jurisdiction for bringing Hatch-Waxman cases against multiple ANDA filers.

The Federal Circuit extended and exacerbated the forum-selection flexibility given to patentees in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016). In that case, the Federal Circuit held that a patentee could assert personal jurisdiction in any state where an ANDA filer intended to sell its drug product. Because most, if not all, generic drug manufacturers likely intend to sell their products nationwide, this gives patentees significant flexibility to select forums to suit their needs. The Supreme Court's *TC Heartland* decision curtails the patent owner's range of choices, including in Hatch-Waxman cases.

The Supreme Court's ruling means that, for domestic corporations, venue in a patent case is proper only in a defendant's state of incorporation or, alternatively, where “the defendant has

committed acts of infringement and has a regular and established place of business." 28 U.S.C. §1400(b). Because many generic drug manufacturers are incorporated in Delaware, the *TC Heartland* decision means that Delaware will likely retain its favored-venue status for Hatch-Waxman cases. This may also be the case for infringement actions brought under the BPCIA prior to commercial marketing.

The implications for an innovator-brand company are important. The primary focus in selecting a forum must now be on where the defendant resides or has a regular and established place of business. In many cases, this will still be Delaware, New Jersey or New York. Where an innovator-brand company faces the possibility of enforcing against multiple defendants in different jurisdictions, it will need to develop a strategy for coordinating across parallel proceedings. It could also seek to persuade generic manufacturers to consent to a single jurisdiction.

The implications for generic drug and biosimilar manufacturers are also important. Certain defendants who have made a conscious decision not to have a presence in Delaware or New Jersey will no doubt be satisfied to see more cases filed in their home forum. But they may also face increased uncertainties associated with parallel litigations, including inconsistent results between jurisdictions. This could be particularly problematic in situations where there is shared first-filer exclusivity.

The new venue regime may give rise to opportunities for negotiation, in which defendants consent to venue in a jurisdiction in exchange for concessions from the patentee relating to scheduling, number of asserted claims, and the like.

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