TC Heartland’s Restraints On ANDA Litigation Jurisdiction

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The mandamus petition of In Re TC Heartland, which seeks to restrict the Federal Circuit’s interpretation of the venue statutes, may dramatically affect abbreviated new drug application patent infringement litigation.[1] In Acorda Therapeutics Inc. v. Mylan Pharmaceutical Inc.[2] and AstraZeneca AB v. Mylan Pharmaceutical Inc.[3] the Federal Circuit recently held that an ANDA filer is subject to specific jurisdiction wherever that ANDA filer plans to sell its generic drug product. But, if TC Heartland prevails then venue, under 28 U.S.C. § 1400(b), could limit where a branded-drug company can sue an ANDA filer for patent infringement under 35 U.S.C. § 271(e)(2)(A).

TC Heartland’s Writ of Mandamus

Kraft Food Groups Brands LLC filed a complaint for patent infringement against TC Heartland LLC in the District of Delaware.[4] TC Heartland, a limited liability company organized and registered under the laws of Indiana, moved to dismiss for lack of personal jurisdiction or to transfer the case to a different venue.[5] After the district court denied its motion, TC Heartland filed a petition for writ of mandamus with the Federal Circuit seeking an order directing dismissal or transfer of the case to Indiana.[6] In its petition TC Heartland has asked the Federal Circuit to reconsider its interpretation of 28 U.S.C. § 1400(b) so that a complaint for patent infringement could only be filed in district courts where (1) the defendant resides or (2) the defendant has both committed acts of infringement and has a regular and established place of business.[7]

A key issue presented by TC Heartland is whether the broad residency definition of § 1391(c) applies to modify and expand the “resides” language of § 1400(b).[8] Title 28 U.S.C. § 1391 addresses venue generally, and § 1400(b) addresses venue in civil actions for patent infringement. Section 1400(b) states: “Any civil action for patent infringement may be brought in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business.” Section 1391(c)(2) states that “an entity ... shall be deemed to reside, if a defendant, in any judicial district in which such defendant is subject to the court’s personal jurisdiction with respect to the civil action in question.” TC Heartland contends that § 1400(b) is the sole and exclusive provision governing venue in patent actions, and under controlling U.S. Supreme Court precedent, the terms of § 1400(b) are not to be supplemented by § 1391.[9] TC Heartland points out that in Fourco Glass Co. v. Transmirra Products Corp.[10] the Supreme Court held that § 1400(b) is the sole and exclusive provision controlling venue in patent infringement actions, and that it is not to be supplemented by the provisions of § 1391(c).[11]
In 1988, 28 U.S.C. § 1391 was amended to expand the residency definition to the limits of personal jurisdiction and included a statement that its residency definition in § 1391(c) was “for purposes of venue under this chapter.”[12] In 1990, the Federal Circuit in VE Holding Corp v. Johnson Gas Appliance Co.[13] examined § 1400(b) and § 1391 and determined that a defendant is deemed to reside in any judicial district in which it is subject to personal jurisdiction for patent infringement actions. TC Heartland contends, however, that the Federal Courts Jurisdiction and Clarification Act of 2011 repealed the statutory text that was held in VE Holding to have overruled Fourco and prescribed that the term “resides” in § 1400(b) was supplemented by § 1391(c).[14] In the Federal Courts Jurisdiction and Clarification Act of 2011, Congress amended § 1391(c) — repealing the “for purposes of venue under this chapter” — and, as amended, § 1391 now contains the predicate that the entirety of the section applies “except as otherwise provided by law.”[15] In its petition, TC Heartland argues that the holding of VE Holding no longer applies given the change in the language in §§ 1391(a) and (c), and, in the alternative, VE Holding should be re-examined en banc because it conflicts with the Supreme Court holding in Fourco.[16] In support of TC Heartland, over 20 companies have filed amicus briefs seeking to restore balance in patent litigation because the current patent system allows plaintiffs to flock to the Eastern District of Texas, which is known for delivering plaintiff-friendly verdicts.

The Consequential Impact On ANDA Litigation

In 35 U.S.C. § 271(e)(2), Congress declared the filing of an ANDA to be an “artificial act of infringement,” allowing the branded-drug company to sue the ANDA filer to litigate patent validity and infringement.[17] In ANDA cases, like other patent infringement actions, courts have typically applied the broader statute § 1931(c) and permitted venue if the district court has personal jurisdiction over the defendant. The consequence of not importing a broad “residency” definition in the patent venue statute would mean that a branded-drug company could only file an ANDA patent infringement complaint in districts (1) where the ANDA filer resides or (2) where the ANDA filer has both committed acts of infringement and has a regular and established place of business. For purposes of venue, a corporation “resides” in the state where it is incorporated.[18] If the first prong is not met, the burden is on the branded-drug company to establish that the ANDA filer has a “regular and established place of business.”[19]

For an ANDA filer, what is a “regular and established place of business?” Given that VE Holding may no longer be good law, federal cases that predate VE Holding are illustrative of how a court may determine a “regular and established place of business.”

The following analysis is based on federal cases that predate VE Holding. An ANDA filer’s plans to direct sales of its generic drug product in a district is not itself sufficient to confer venue under §1400(b). Something more is required.[20] In In Re Cordis Corp. the Federal Circuit interpreted “regular and established place of business” to mean doing business “through a permanent and continuous presence” in the district, but not necessary a fixed physical presence.[21] An appropriate inquiry would focus on the nature of the ANDA defendant’s presence with the district,[22] which is necessarily a fact-extensive inquiry. The mere presence of sales representatives in the district would not create a regular and establish place of business for venue in patent cases.[23] Maintaining an office space or physical location that does not exclusivity promotes and sell the allegedly infringing generic drug product may not be enough to confer venue.[24] But, in ANDA cases the proposed generic product is yet to be promoted, marketed or sold, and thus many traditional venue inquiries seem impractical. Evidence that an ANDA defendant conducts a substantial part of its ordinary business or has a permanent and continuous presence in the district will more likely establish that venue is proper under § 1400(b).[25] To
that end, patent venue may arguably be established where an ANDA filer: (a) sales generic products in a
district; (b) has an internet website accessible to public in that district; (c) is registered with the State
Board of Pharmacy as a licensed pharmacy wholesale drug distributor; (d) has a network of independent
wholesalers and distributors it contracts to market drugs within the district; (e) has contracts with third-
party payers within the district; and (f) is registered to do business in the state.

On March 11, 2016, the Federal Circuit held oral arguments in In Re TC Heartland. During oral
arguments, Judge Kimberly A. Moore probed TC Heartland about whether the patent venue issue should
be addressed by Congress rather than the court. Congress may eventually do exactly as Judge Moore
suggests. A group of senators has introduced the Venue Equity and Nonuniformity Elimination Act
(VENUE Act) of 2016.[26] If the purposed VENUE Act becomes law, a branded-drug company can sue an
ANDA filer for patent infringement in districts where: (1) the ANDA defendant has its principal place of
business or is incorporated; (2) the ANDA defendant has committed an act of infringement and has a
regular and established physical facility that give rise to infringement; (3) where an inventor named on
the patent-in-suit conducted research or development that led to the application for the patent-in-suit;
or (4) where a party controls a physical facility engaged in the research and development of an invention
claimed in the patent or manufactures a product that allegedly embodies the claimed invention.[27]

In conclusion, TC Heartland’s interpretation of venue places restraints on the expansive jurisdiction rule
for ANDA litigation held in Acorda and AstraZeneca. If the Federal Circuit agrees with TC Heartland,
branded drug companies should expect that more ANDA defendants would file a Fed. R. Civ. P. 12(b)(3)
motion to dismiss for improper venue under §1400(b) and parties will engage in a fact-extensive inquiry
about what is a “regular and established place of business” for the ANDA filer.

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DISCLAIMER: Wanda French-Brown represented TC Heartland LLC from Aug. 3, 2014 to March 10,
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[6] In Re TC Heartland, No. 16-105, ECF. No. 2.

[8] See id.
[9] See id.
[12] See § 1391(c) (1988) (“For purposes of venue under this chapter, a defendant that is a corporation shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction ...”).
[14] In Re TC Heartland, Pet’r’s Br. at 6.
[16] In Re TC Heartland, Pet’r’s Br. at 6-9.
[21] In re Cordis Corp., 769 F.2d at 737.
[24] See MAGICorp., 718 F. Supp. at 338-341 (holding the alleged infringer did not maintain a regular and established place of business in New Jersey, even though the defendant was licensed to do business in New Jersey and leased office space for a salesman who did not exclusively promote and sell the allegedly infringing product).
[25] See id., at 340 (noting that plaintiff could have proven proper venue by “propounding other evidence indicating that defendant conducts a substantial part of its ordinary business” in the district); see also, In re Cordis Corp., 769 F.2d at 737 (holding venue is established where a “corporate defendant does its business in that district through a permanent and continuous presence”).


[27] See id.

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