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Where Can Hatch-Waxman and BPCIA Cases Stick After *TC Heartland LLC v. Kraft Foods Group Brands LLC*?

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Hatch-Waxman[1] litigators are accustomed to cases with multiple generic drug company defendants. Brand drug company plaintiffs often sue multiple defendants in the same district court, even when those defendants are not incorporated in the district and have no facilities there. Until now, as long as the court had personal jurisdiction over a defendant, there was little that defendant could do to get out of that court.[2] With the Supreme Court's decision in *TC Heartland LLC v. Kraft Foods Group Brands LLC*,[3] a defendant may now be able to dismiss a case for improper venue, even from a court that has personal jurisdiction over that defendant.

So where can Hatch-Waxman and BPCIA[4] plaintiffs file cases now that venue is no longer coextensive with personal jurisdiction? The Supreme Court provided one answer: A domestic company can be sued in its state of incorporation. But questions remain about where else a defendant can be sued and whether plaintiffs will be forced to litigate cases with common issues in different district courts. Here, we examine some of those possibilities, and we analyze how *TC Heartland* might change ANDA[5] and aBLA[6] litigation.

Background

Since the Federal Circuit ruled, in *VE Holding Corp. v. Johnson Gas Appliance Co*.,[7] that venue in patent cases was proper in any court having personal jurisdiction over the defendant, venue has been coextensive with personal jurisdiction. When the Supreme Court narrowed general personal jurisdiction in *Daimler AG v. Bauman*,[8] some practitioners thought it would limit the courts in which an ANDA filer could be sued because most courts would lack personal jurisdiction over the defendant.[9] Historically, courts relied on the generic defendant's large sales revenues in a forum as justification for asserting *general* personal jurisdiction. After *Daimler*, however, large sales revenues in the jurisdiction were no longer

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[1] "Hatch-Waxman" is the common name for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[2] One of the more popular options was a motion for change of venue under 28 U.S.C. § 1404, which is different from venue in patent infringement cases under 28 U.S.C. § 1400(b) that is discussed in this article.

[3] TC Heartland LLC v. Kraft Foods Group Brands LLC, No. 16-341, slip op. (U.S. May 22, 2017), https://www.supremecourt.gov/opinions/16pdf/16-341_8n59.pdf.

[4] Biologics Price Competition and Innovation Act of 2009, 42 U.S.C. § 262 (2009).

[5] Abbreviated New Drug Application.

[6] Abbreviated Biologics License Application, which includes applications for follow-on biologics that are biosimilar to or interchangeable with a reference biologic product approved under a Biologics License Application.

[7] VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574 (Fed. Cir. 1990).

[8] Daimler AG v. Bauman, 134 S. Ct. 746 (2014).

[9] *See, e.g.,* Brian O'Reilly, *High Court Changed Hatch-Waxman Cases—Nobody Noticed*, LAW360 (Mar. 26, 2014, 10:55 PM), https://www.law360.com/articles/520995/high-court-changed-hatch-waxman-cases-nobody-noticed.

enough to confer general personal jurisdiction. In addition, most courts have not relied on *specific* personal jurisdiction in ANDA cases because it required a relationship between the in-state activity and the lawsuit, and a generic company's activities in a jurisdiction were usually unrelated to the patent infringement action.

Daimler has had limited effect on ANDA and aBLA cases because of the Federal Circuit's recent decision in *Acorda Therapeutics, Inc. v. Mylan Pharm., Inc.*[10] There, the generic drug manufacturers argued against specific personal jurisdiction. They noted that filing an ANDA with a paragraph IV certification was a technical act of infringement,[11] but it was not aimed at any particular forum. Moreover, ANDA cases typically arrive before the generic product has been approved, let alone sold into a jurisdiction, and therefore typically before any in-forum infringement.[12] In *Acorda*, the Federal Circuit looked past this and held that the "link" between an ANDA filing and the filer's subsequent entry into the market[13] subjected the filer to *specific* personal jurisdiction in any district court where it intends to sell the generic product in the future, i.e., nearly any district court.[14] Thus, despite *Daimler*, personal jurisdiction remained a weak or nonexistent defense.

Suing a Generic Company Defendant After TC Heartland

The Supreme Court's decision in *TC Heartland*[15] uncoupled venue from personal jurisdiction by overturning the *VE Holding Corp.* decision and holding that 28 U.S.C. § 1400(b)[16] is the sole provision governing venue in patent infringement cases. Under § 1400(b), there are two prongs for determining where a plaintiff can bring a patent infringement action against a domestic corporation: (1) "where the defendant resides," or (2) "where the defendant has committed acts of infringement *and* has a regular and established place of business."[17]

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[10] Acorda Therapeutics, Inc. v. Mylan Pharm., Inc., 817 F.3d 755, 761–62 (Fed. Cir. 2016).

[11] ANDAs are filed with the Food and Drug Administration ("FDA") in Maryland, which may make the District of Maryland seem like a proper forum for an ANDA litigation. The Federal Circuit, however, has decided that an ANDA filing does not make the District of Maryland an appropriate forum for ANDA litigation. *See* Zeneca Ltd. v. Mylan Pharm., Inc., 173 F.3d 829, 835–36 (Fed. Cir. 1999) (Rader, J., concurring) (concurring opinions finding that the "highly artificial act of infringement" by filing an ANDA is "Constitutionally deficient" to exercise personal jurisdiction).

[12] *Id.* at 836; *see also* Mylan's Opening Brief in Support of Motion to Dismiss (Redacted) at 13–14, Acorda Therapeutics, Inc. v. Mylan Pharm., Inc., No. 14-cv-935 (D. Del. Aug. 27, 2014), ECF No. 13.

[13] *Acorda*, 817 F.3d at 761–62 (Fed. Cir. 2016) ("The magnitude and costs of the work required before the ANDA is filed soundly link the ANDA filing to the filer's entry into the market to compete with the brand-name manufacturer if approval is obtained.").

[14] *See id.* at 762–64*, discussed by* Trevor M. Gates et al., *ANDA Filing May Subject a Pharmaceutical Company to Personal Jurisdiction in Patent Infringement Suits Anywhere in the U.S.*, K&L GATES (Jun. 6, 2016), http://www.klgates.com/anda-filing-may-subject-a-pharmaceutical-company-to-personal-jurisdiction-in-patent-infringement-suits-anywhere-in-the-us-06-06-2016/.

[15] A more detailed discussion of the significance of *TC Heartland* and its implications for patent litigation in general is available at http://www.klgateshub.com/details/?pub=Supreme-Court-Restricts-Where-Plaintiffs-Can-Sue-for-Patent-Infringement-05-25-2017.

[16] § 1400(b) currently states:

> (b) 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*.

28 U.S.C. § 1400(b) (*emphasis added*).

[17] *Id (emphasis added)*.

Where Can Hatch-Waxman and BPCIA Cases Stick After *TC Heartland LLC v. Kraft Foods Group Brands LLC*?

A Brand Plaintiff Can Sue Where the Generic Company Defendant Is Incorporated

Following *TC Heartland*, a brand plaintiff will be able to sue in any district in the state where the generic company defendant is incorporated. In particular, *TC Heartland* reaffirmed the Court's 1957 decision that under the first prong of § 1400(b), a domestic corporation "resides" only in its state of incorporation.[18]

A Brand Plaintiff May Be Able to Sue Elsewhere

If a brand plaintiff wants to sue a generic company defendant in a district outside the defendant's state of incorporation, it must rely on the second prong of § 1400(b): "where the defendant has committed acts of infringement and has a regular and established place of business."[19] Because of the expansive nature of venue under VE Holding Corp. in 1990, this part of § 1400(b) has not been litigated recently, but courts are already beginning to entertain motions regarding this second prong. Both requirements of the second prong raise questions for ANDA and aBLA cases.

Committing an Act of Infringement for ANDA and aBLA Cases

One question that a brand plaintiff must consider before suing a domestic corporation in a district court outside the defendants' state of incorporation is whether the defendant "has committed acts of infringement" there.[20] In a typical ANDA or aBLA case brought under 35 U.S.C. § 271(e)(2), the only "act of infringement" the defendant "committed" is the act of filing the ANDA or aBLA with the FDA. Based on the current state of the law, it is unclear where that "act of infringement" has occurred.

One possibility is that, for purposes of venue, infringement may be deemed to have been committed in any district where the generic company intends to sell the ANDA product. That possibility extends the analysis of *Acorda*[21] for specific personal jurisdiction into the venue context. If courts follow *Acorda*, venue would be proper in any district court where a defendant has a "regular and established place of business."

Unlike specific personal jurisdiction, however, infringement is expressly required for venue in § 1400(b), which states that "the defendant *has committed* acts of infringement." To the extent *Acorda* relies on the prospect of future infringement as a justification for personal jurisdiction, a court interpreting § 1400(b) literally may not follow it because those future acts of infringement have not yet been "committed." Thus, if courts construe "committed" to require a prior, real-world act of infringement, venue may be restricted to a district court in

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[18] Fourco Glass Co. v. Transmirra Prods. Corp., 353 U.S. 222 (1957). *Fourco Glass* held that 28 U.S.C. § 1391(c) "is a general corporation venue statute, whereas § 1400(b) is a special venue statute" that applies "to all defendants" in patent infringement actions. *Id.* at 228. In 1988, however, Congress amended the language of § 1391(c). In *VE Holding Corp.*, the Federal Circuit relied on that intervening change to disregard *Fourco Glass.* The Federal Circuit held that the change to § 1391(c) applied to § 1400(b) to make venue proper in any court having personal jurisdiction over a corporate defendant. *VE Holding*, 917 F.2d at 1578, 1583. In *TC Heartland*, the Supreme Court overruled the statutory interpretation in *VE Holding Corp*, and reinstated § 1400(b) based on a 2011 revision to § 1391.

[19] *Id.*

[20] Even without the complications of an ANDA or aBLA case , the answer can be unclear. *Compare* W.S. Tyler Co. v. Ludlow-Saylor Wire Co., 236 U.S. 723 (1915) *with* Union Asbestos & Rubber Co. v. Evans Prods. Co., 328 F.2d 949 (7th Cir. 1964).

[21] *See* Trevor M. Gates et al., *ANDA Filing May Subject a Pharmaceutical Company to Personal Jurisdiction in Patent Infringement Suits Anywhere in the U.S.*, K&L GATES (Jun. 6, 2016), http://www.klgates.com/anda-filing-may-subject-a-pharmaceutical-company-to-personal-jurisdiction-in-patent-infringement-suits-anywhere-in-the-us-06-06-2016/.

the domestic generic company defendant's state of incorporation or in a forum in which there is a regular and established place of business and where the courts ultimately deem the technical act of infringement to have occurred.[22]

Regular and Established Place of Business

Another question a brand plaintiff must consider before suing a domestic generic company defendant in a district court outside the defendant's state of incorporation is whether the defendant has a "regular and established place of business" in that district. The statute seems to require a physical "place" of business, and some courts appear to have required a "physical location" in the forum,[23] but what is required to have a "place of business" will likely be a point of contention. The Federal Circuit last addressed the "regular and established place of business" portion of § 1400(b) in 1988 in *In re Cordis Corp*.,[24] and adopted a liberal approach to find that Cordis Corp. had a "regular and established place of business" in Minnesota.

In *Cordis*, defendant Cordis Corp. was a Florida corporation with a principal place of business in Miami and was sued for patent infringement in the District of Minnesota. Among other things, Cordis Corp. had two full-time sales staff who worked out of their homes in Minnesota and sold allegedly infringing products out of their homes. Cordis Corp. argued that venue was improper because it did not have a regular and established place of business in Minnesota. The Federal Circuit disagreed, holding that:

> in determining whether a corporate defendant has a regular and established place of business in a district, the appropriate inquiry is whether the corporate defendant does its business in that district through a permanent and continuous presence there and not . . . whether it has a fixed physical presence in the sense of a formal office or store.[25]

According to the Federal Circuit, the actions of Cordis Corp. and its employees created a sufficient permanent and continuous presence in the forum.[26] It is currently unclear what level of physical presence is required in a forum for a "regular and established place of business," and this issue will likely be extensively litigated over the next few years.

Practical Effects

Over the long term, there are at least three scenarios for the practical impact of *TC Heartland* for ANDA and aBLA cases involving domestic generic companies. Each depends on how

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[22] *See supra* n.11.

[23] *See, e.g.*, Mastantuono v. Jacobsen Mfg. Co., 184 F. Supp. 178, 180 (S.D.N.Y. 1960).

[24] *In re* Cordis Corp., 769 F.2d 733 (Fed. Cir. 1985).

[25] *Id.* at 736.

[26] In *Cordis*, the court distinguished Cordis Corp.'s practices from those in *University of Illinois Foundation v. Channel Master,* 382 F.2d 514 (7th Cir. 1967). In *Channel Master*, the defendant employed an individual salesperson worked from his home in Illinois, promoting products and offering services such as training. However, all Channel Master orders were accepted and fulfilled by Channel Master's New York office. The Seventh Circuit had held that Channel Master did not have a "regular and established place of business" in Illinois based on that one salesperson. A key difference between *Cordis* and *Channel Master* was that the Cordis Corp.'s sales staff maintained a stock of the allegedly infringing devices in their home offices and made direct sales that they fulfilled with that stock, while the *Channel Master* salesperson neither accepted nor fulfilled orders. In addition, in *Cordis*, the salespeople maintained a local secretarial service that received and mailed corporate literature, provided typing services, answered a local telephone number as "Cordis Corporation," and took messages for the salespeople.

courts interpret the second prong of § 1400(b): "where the defendant has committed acts of infringement *and* has a regular and established place of business."

First, if the phrase "where the defendant has committed acts of infringement" requires a prior act of real-world patent infringement, then venue will likely only be proper in the generic defendant's state of incorporation.[27] The result may be that more cases will be brought in the most common venues for incorporation, e.g., California, Delaware, or Florida, instead of traditional pharmaceutical patent litigation venues like the District of New Jersey. This may still permit brand companies to sue multiple defendants in a single district court, so long as all are incorporated there. If not, the brand company might consider filing a motion with the Judicial Panel on Multidistrict Litigation to have the cases consolidated for pretrial proceedings in a single jurisdiction.[28] Under this interpretation, *TC Heartland* may significantly impact the cost, litigation mechanics, and factors affecting settlement of ANDA and aBLA litigation particularly to the extent the cases do not settle and must be remanded back to the district from which it was transferred for trial.[29]

Second, if courts consider an ANDA filer to have "committed infringement"[30] in any district where its products will be sold, perhaps by adopting similar rationale to the Federal Circuit's ruling in *Acorda*, venue would be proper in any district court where a defendant has a "regular and established place of business." Under this interpretation, it will be important to see what level of presence courts require to find a "regular and established place of business" in the forum. If courts decide to adopt an expansive reading of "regular and established place of business," such that it begins to approach the limits of personal jurisdiction, then *TC Heartland* will have a negligible impact on ANDA and aBLA cases.

Third, if courts consider an ANDA filer to have "committed infringement" in any district where its products will be sold, and interpret "regular and established place of business" to require a physical place of business (or its equivalent, as in *Cordis*), then *TC Heartland* could likely have a substantial impact. As with the first scenario discussed above, *TC Heartland* would

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[27] Possible exceptions may exist including where the defendant has a major research and/or corporate footprint.

[28] *See* 28 U.S.C. § 1407(a), (c)(ii).

[29] *See* 28 U.S.C. § 1407(a).

[30] Courts may additionally find acts of infringement to have taken place during one or more of the various steps of the ANDA or aBLA preparation, filing, and required notice processes. Based on examples from personal jurisdiction cases, those might include:

- The venue *from* which the ANDA or aBLA filer submits the application to the FDA (assuming it is from a place of business that is not in the state of incorporation) *see AstraZeneca AB v. Mylan Pharm., Inc.*, 596 F.Supp.3d 551, 558-60 (D. Del. 2014);
- The District of Maryland, where the FDA receives ANDA and aBLA applications; however, the District of Maryland was previously disfavored in an ANDA case in *Zeneca Ltd. v. Mylan Pharm., Inc.*, with Judge Gajarsa citing a "government contacts exception" for contact with the FDA, Judge Rader concurring by opining that the contact was with the FDA and not with Maryland, and Judge Rich dissenting without a written opinion; 173 F.3d 829, 831–34, 835–36 (Fed. Cir. 1999); and
- In the locations of the preparation, testing, and development in connection with an ANDA or aBLA may a basis for venue in the forum in which they occur, but those activities are nearly always covered under the 35 U.S.C. § 271(e)(1) "safe harbor" provision as being "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 or veterinary biological products," and are not infringement, *see Classen Immunotherapies, Inc. v. Elan Pharma., Inc.,* 786 F.3d 892 (Fed. Cir. 2015) (holding that submissions to the FDA are protected under the 271(e)(1) safe harbor in a citizen petition or a supplemental new drug application (sNDA) context).

It remains an open question whether a paragraph IV notice letter constitutes an artificial act of infringement in an ANDA or aBLA since 35 U.S.C. § 271(e)(2), which provides the statutory grounds for the artificial act of infringement in ANDA and aBLA cases, addresses only the submission of "an application" to the FDA and not the sending of a notice of such an application to a patent holder. There may also be other bases for venue that courts wind up addressing as well.

allow domestic generic companies to control where they can be sued and may significantly impact the cost, litigation mechanics, and factors affecting settlement.

In the short term, to test any of the possible scenarios above, brand company plaintiffs will likely file protective suits where the generic company is incorporated, and prepare to litigate the venue issue in a second suit in another district court.[31] The result is likely to be that, until the law is settled, litigating in two or more forums will be the norm, which will increase costs for both brand and generic companies.

Foreign generic companies were not addressed in *TC Heartland*, and venue for their cases continues to be governed by § 1391(c), with venue proper in any court having personal jurisdiction. Some plaintiffs may try to sidestep *TC Heartland* by only suing foreign companies and not naming their U.S. subsidiary as a defendant. In response, companies may want to strategically move FDA-related functions to a domestic subsidiary.

Looking Forward

TC Heartland uncoupled venue from personal jurisdiction for domestic pharmaceutical company defendants in patent litigation. While the Supreme Court established that venue is proper in a district court in the defendant's state of incorporation, it left open the question of what other venue may be proper. There are several issues that courts must resolve before a proper venue beyond the state of incorporation can be predictably determined.

K&L Gates will continue to monitor this case and provide updates regarding developments. Please also see K&L Gates's analysis on the broader impacts of *TC Heartland* at Supreme Court Restricts Where Plaintiffs Can Sue for Patent Infringement.

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[31] To ensure that the statutory 30-month stay preventing approval of an ANDA is in effect, patent holders litigating cases under the Hatch-Waxman Act often file in forums that can withstand jurisdictional challenges to ensure that the case is not dismissed. In cases where this jurisdiction is not the preferred jurisdiction, patent holders often file there complaints anyway as a "protective suit" and concomitantly file in their more preferred jurisdiction.

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