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TC Heartland May Cause Protective Suits In ANDA Cases

Law360, New York (March 24, 2017, 12:27 PM EDT) -- In TC Heartland, the U.S. Supreme Court will decide where patent suits can be filed under the patent venue statute, 28 U.S.C. § 1400(b). Much has been written about the potential impact of this case in barring most suits from the Eastern District of Texas.[1] Little attention, however, has been paid to the effect that this case could have on the decision of where innovator pharmaceutical companies should file patent infringement actions brought pursuant to the Hatch-Waxman Act. In this article, we explore whether TC Heartland could affect the need to file "protective suits" in such cases and provide guidance regarding best practices to employ both before and after the Supreme Court issues a decision.

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Relevant ANDA Framework and Its Implications

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The Hatch-Waxman Act[2] provides the process for generic manufacturers to submit an abbreviated new drug application for approval of a generic drug by the U.S. Food and Drug Administration. A generic manufacturer submitting an ANDA must make one of four certifications as to each patent listed in the Orange Book as covering the reference listed drug.[3] In the fourth certification, known as the Paragraph IV Certification, the generic manufacturer certifies that the listed patent(s) is/are invalid and/or will not be infringed by the proposed generic product. Upon receipt of a Paragraph IV Certification, a patentee may file an infringement action against the generic manufacturer. If the action is filed within 45 days of receipt of the Paragraph IV Certification, the FDA may not grant final approval of the ANDA for 30 months from the receipt date.[4]

It is unclear whether dismissal of an ANDA action filed within 45 days from receipt of the Paragraph IV Certification could jeopardize the 30-month stay of FDA approval. One practical consequence of this uncertainty is that patentees often file two suits in cases where generic manufacturers are expected to challenge personal jurisdiction: one suit in the forum where they wish to litigate the case and a second, so-called "protective suit," in the forum where jurisdiction over the generic manufacturer is certain. The purpose of the protective suit is to insure that the 30-month stay of FDA approval remains in place even if the first-filed action in the preferred forum is dismissed on jurisdictional grounds.

TC Heartland

In Acorda, the Federal Circuit held that generic manufacturers are subject to specific jurisdiction in any state where they plan to market their proposed generic products.[5] This decision has been widely heralded as preserving the forum options for patentees and creating nationwide personal jurisdiction.[6]

It also led legal commentators to predict that Acorda would reduce or eliminate the need for protective suits in ANDA cases.[7] While concerns with personal jurisdictional challenges may no longer encourage the filing of protective suits, venue considerations may still require the filing of such suits, as reflected by the Supreme Court's recent decision granting certiorari in TC Heartland.[8]

In TC Heartland, the Supreme Court will review the Federal Circuit's interpretation of patent venue statute, 28 U.S.C. § 1400(b). Section 1400(b) provides that patent suits may be filed where the defendant "resides" or "has committed acts of infringement and has a regular and established place of business."[9] In the underlying case, Kraft Foods Group Brands LLC filed suit against TC Heartland in Delaware federal court alleging that Heartland's liquid water enhancer products infringe three of Kraft's patents.[10] In response, Heartland sought unsuccessfully to dismiss the action or transfer venue to the Southern District of Indiana.[11] With respect to venue, the Federal Circuit relied on VE Holding to deny Heartland's motion.[12]

In VE Holding, the Federal Circuit held that the general venue statute, 28 U.S.C. § 1391, redefined the term "resides" in the patent venue statute, 28 U.S.C. § 1400(b).[13] Because Section 1391 provides that a corporate defendants resides in any judicial district in which it is subject to personal jurisdiction,[14] VE Holding allows a patentee to sue for infringement in any district in which the defendant is subject to personal jurisdiction.[15] On the appeal at issue, Heartland asked the Supreme Court to overrule VE Holding and find that the term "resides" in the patent venue statute means the place where the defendant is incorporated.[16]

The Battleground May Shift to Venue in ANDA Cases

If the Supreme Court agrees with Heartland, the broad personal jurisdiction afforded by Acorda in ANDA cases may be limited by the patent venue statute. If this occurs, generic manufacturers may be more likely to file motions to dismiss for improper venue under Section 1400(b) pursuant to Federal Rule of Civil Procedure 12(b)(3).[17] Because it is unclear whether dismissal of an ANDA action for improper venue could jeopardize the 30-month stay of approval, branded pharmaceutical companies should safeguard against this possibility by filing protective suits when appropriate. Below, we provide our recommendations.

The Supreme Court will hear oral arguments regarding TC Heartland on March 27, 2017. This means that a decision is likely to come out by the end of June. During this pendency, we recommend that branded pharmaceutical companies file protective suits in the states where the generic manufacturers are incorporated. This approach would protect against the possibility that the Supreme Court agrees with Heartland and limits the definition of the term "resides" in Section 1400(b) to the place where the defendant is incorporated.

The approach to follow after the Supreme Court issues a decision will depend on whether the Supreme Court overrules VE Holding. If the Supreme Court declines to overrule VE Holding and affirms the Federal Circuit, venue would be proper in any district in which the defendant is subject to personal jurisdiction. As a result, venue considerations would not favor the filing of protective suits.

If the Supreme Court overrules VE Holding, we recommend that branded pharmaceutical companies file protective suits in the states where the generic manufacturers are incorporated. The filing of such suits may be necessary until at least we receive guidance from the Federal Circuit regarding the interpretation of Section 1400(b) in the context of ANDA cases. Such guidance may identify additional venue choices. For example, the court's interpretation of where a generic manufacturer "has committed acts of infringement and has a regular and established place of business"[18] could identify additional venue options besides the generic manufacturer's state of incorporation.

The filing of protective suits may increase the costs of litigating ANDA cases as the branded

pharmaceutical companies would have to file suit in each of the generic manufacturers' state of incorporation. One way to reduce these costs is to request for the Judicial Panel on Multidistrict Litigation to consolidate for pretrial proceedings all related ANDA cases in one federal court. Such approach would conserve resources and promote consistency.

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[1] See, e.g., Matthew Bultman, Supreme Court Agrees to Hear Patent Venue Case, Law360, Dec. 14, 2016, at 1; Matthew Bultman, Justices Urged to Overrule Patent Venue 'Reinterpretation', Law360, Feb. 6, 2017, at 2, Kelly Knaub, Hatch Says Patent Venue Legislation Likely Needed, Law360, Feb. 17, 2017.

[2] Pub. L. No. 98-417 (1984).

[3] 21 U.S.C. § 355(b)(2)(A)(i)-(iv).

[4] 21 U.S.C. § 355(j)(5)(B)(iii).

[5] Acorda Therapeutics Inc. v. Mylan Pharms. Inc., 817 F.3d 755, 760 (Fed. Cir. 2016), cert denied, 137 S.Ct. 625 (2017).

[6] See, e.g., Christine Willgoos & Shannon Hedvat, Federal Circuit Preserves Plaintiff's Choice of Forum in Hatch-Waxman Cases, IP Litigator, May/June 2016, at 2; Dennis Crouch, ANDA Filing Creates Nationwide Personal Jurisdiction, Patentlyo, Mar. 18, 2016, at 1.

[7] See, e.g., Melanie R. Rupert & Nicholas A. Tymoczko, The Expansive Impact of Acorda on Hatch-Waxman Cases, Law360, March 23, 2016, at 3.

[8] TC Heartland LLC v. Kraft Food Brands Group LLC, 137 S.Ct. 614 (2016).

[9] 28 U.S.C. § 1400(b).

[10] In re TC Heartland LLC, 821 F.3d 1338, 1339 (Fed. Cir. 2016).

[11] Id.

[12] Id. at 1341-43.

[13] VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1578-84 (Fed. Cir. 1990).

[14] 28 U.S.C. § 1391.

[15] VE Holding, 917 F.2d at 1578-84.

[16] Brief of Petitioner at 20-21, TC Heartland, LLC v. Kraft Foods Group Brands LLC, 2017 WL 474715

(2017) (No. 16-341).

[17] See, e.g., Wanda D. French Brown, TC Heartland's Restraints on ANDA Litigation Jurisdiction, Law360, March 29, 2016, at 3.

[18] 28 U.S.C. § 1400(b).
