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HERE, THERE, & EVERYWHERE: JURISDICTION & VENUE IN PATENT CASES

How, Where, and Who Frames Patent Suits

Venue shopping can exert strong influence on patent suit success, causing litigants, courts, and legislatures to wrestle with boundaries. The Federal Circuit's recent decisions in *Acorda Therapeutics, Inc. v. Mylan Pharms., Inc.*[1] *and In re TC Heartland, LLC*,[2] highlight proposed changes in Senate Bill S.2733, and offer practical IP practice tips.

Broad Ruling of Personal Jurisdiction in *Acorda*

The Federal Circuit's March 2016 ruling in *Acorda* effectively held that *any* federal court may exercise personal jurisdiction over any patent infringement defendant that filed an Abbreviated New Drug Application ("ANDA") with the FDA.

Acorda arose from two District of Delaware cases in which Acorda and Alkermes Pharma Ireland, Ltd., in one, and AstraZeneca AB, in the other, accused Mylan of infringement under the Hatch-Waxman Act. The allegations were based on Mylan's ANDA filings which sought permission to market generic versions of drugs patented and owned by these companies.[3]

Mylan had moved to dismiss for lack of personal jurisdiction in both actions, and the Court denied both motions. The Federal Circuit affirmed, finding Mylan was subject to specific personal jurisdiction[4] and refusing to address general personal jurisdiction.[5]

The Court said Mylan had the necessary minimum contacts with Delaware to support specific personal jurisdiction, which is "based on the connection of the State to the subject matter of the particular case."[6] A court "may exercise specific personal jurisdiction…when the defendant 'has certain minimum contacts with the forum such that…the suit does not offend traditional notions of fair play and substantial justice.'"[7]

Although Mylan is a West Virginia corporation, the Court found jurisdiction proper since (1) Mylan filed ANDAs, and (2) it *intended* to market its drugs in the state of Delaware upon approval by the FDA.[8]

1. Nos. 2015-1456 & 2015-1460, 2016 U.S. App. LEXIS 4942 (Fed. Cir. Mar. 18, 2016).
2. *See In re TC Heartland, LLC*, No. 16-105, Petition for Writ of Mandamus, Dkt. 2 (Fed. Cir. Oct. 23, 2015).
3. *Id.* at *5.
4. *Id.* at *5-6.
5. *Id.* at *6 (describing general personal jurisdiction as that "based on certain facts even where the case involves subject matter not itself sufficiently connected to the State"). It is interesting that the Federal Circuit did not address general personal jurisdiction because (a) the two lower court decisions reached opposite conclusions on the issue for Mylan, and (b) in the past federal courts often relied on general personal jurisdiction for Hatch-Waxman defendants because the alleged acts of infringement had not yet occurred. *See e.g., Eli Lilly & Co. v. Sicor Pharms. Inc., No. 06-cv-238, 2007 U.S. Dist. LEXIS 31657 (S.D. Ind. Apr. 27, 2007).*
6. *Id.* at *5-6.
7. *Id.* at *8 (citing *Int'l Shoe Co. v. Washington,* 326 U.S. 310, 316 (1945)) (internal brackets and quotation marks omitted).
8. *Id*.

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Mylan argued that courts should analyze minimum contacts based on a "past/future divid[e]."[9] The Federal Circuit rejected that notion. Mylan, said the Court, failed to show that "a State [should be] forbidden to exercise its judicial power to prevent a defendant's planned ***future conduct*** in the State, but must wait until the conduct occurs."[10]

The Federal Circuit decided Mylan's proposed rule "would run counter to the legal tradition of injunctive actions"[11] and the Congressional purpose of §271(e)(2).[12] The Court explained that the ANDA filing is an "artificial act of infringement" that "allow[s] the brand-name manufacturer to sue the ANDA filer" for patent infringement *before* actual infringement has occurred.[13]

"Indeed, the Court noted it was undisputed that 'Mylan s[ought] approval to sell its generic drugs throughout the United States, including in Delaware…' and that 'Mylan admits, it develops drugs for the entire U.S. market and does some business in every State, either directly or indirectly.'"

Also, the ANDA filing shows the generic manufacturer's *intent*, upon approval, to "'engage in the commercial manufacture, use, or sale of a drug'…—concrete, non-artificial acts of infringement."[14] Congress, said the Court, meant to remedy "the distinctly non-artificial infringing activities that threaten commercial harm" by allowing suit based on an ANDA filing.[15]

Thus, the Federal Circuit in *Acorda* held "the minimum-contacts standard is satisfied by the particular actions Mylan has already taken—its ANDA filings" because the filings alone "constitute formal acts that reliably indicate plans to engage in [injury-causing and allegedly wrongful] marketing of the proposed generic drugs" in Delaware.[16]

Indeed, the Court noted it was undisputed that "Mylan s[ought] approval to sell its generic drugs throughout the United States, including in Delaware…" and that "Mylan admits, it develops drugs for the entire U.S. market and does some business in every State, either directly or indirectly."[17]

The Federal Circuit also noted that simply having "a network of independent wholesalers and distributors with which [the company] contracts to market the drugs in Delaware….is sufficient for minimum contacts."[18] Therefore, the ANDA filings and the intent to market the generic drugs nationwide subjected Mylan to personal jurisdiction in Delaware, despite its West Virginia corporate residence.

Following *Acorda,* generic drug manufacturers, like Mylan, can be sued in any state upon filing an ANDA and intending to sell nationwide, barring an effective challenge to the minimum contacts requirement. However, this is likely a narrow decision. The Federal Circuit emphasized the unique circumstances of §271 infringement, including artificial infringement as the basis of suit,[19] and specifically noted that an "ANDA filer [i]s distinctive."[20] Thus, this case will likely apply only to ANDA cases and not create a general rule that *future* marketing or acts *intended* but not yet taken serve as a basis for personal jurisdiction in non-ANDA cases.

9. *Id. at *16.*
10. *Id. at *16 (emphasis added).*
11. *Id.*
12. *Id. at *11.*
13. *Id.*
14. *Id.*
15. *Id.*
16. *Id. at *10.*
17. *Id. at *19.*
18. *Id. at *19-20.*
19. *See id. at *11-13.*
20. *Id. at *13.*

"Kraft argued that because the issue was statutory, the legislature, not the Federal Circuit, should address any policy concerns. On April 29, 2016, the Federal Circuit denied TC Heartland's petition and sided with Kraft. The denial effectively allows forum shopping to continue."

Denial to Restrict Venue Under §1400(b)

In a different case, TC Heartland urged the Federal Circuit to restrict venue by overturning *VE Holding Corp. v. Johnson Gas Appliance*[21] which had expanded the notion of where a defendant "resides." Currently, 28 U.S.C. §1400(b) governs venue in patent cases and makes venue appropriate (1) "in the judicial district where the defendant resides," or (2) "where the defendant has committed acts of infringement and has a regular and established place of business…" but leaves the term "resides" undefined.

Before *VE Holding,* a corporation resided only in "the state in which it is incorporated."[22] In *VE Holding,* the Federal Circuit expanded the definition of corporate "residence" in 28 U.S.C. §1391(c), the general civil venue statute by saying it should be read alongside §1400(b). Section 1391(c) defines corporate residence as "any judicial district in which it is subject to personal jurisdiction." Therefore, plaintiffs could sue in *any* district in which personal jurisdiction would be proper.

Kraft Food Group Brands, LLC sued TC Heartland for patent infringement in the District of Delaware in 2014.[23] TC Heartland moved to dismiss for lack of personal jurisdiction and to transfer.[24] The district court denied the motions and TC Heartland filed a petition for a writ of mandamus.[25] Among other arguments, TC Heartland argued the Federal Circuit should re-visit *VE Holding* since it conflicted with the Supreme Court's *Fourco* decision and has resulted in "enormous venue shopping opportunities in patent infringement actions."[26]

Kraft argued that because the issue was statutory, the legislature, not the Federal Circuit, should address any policy concerns. On April 29, 2016, the Federal Circuit denied TC Heartland's petition and sided with Kraft. The denial effectively allows forum shopping to continue.

Proposed Senate Bill 2733 to Amend §1400(b)

In re TC Heartland is not the final word on forum shopping. Recently, Arizona Senator Jeff Flake introduced proposed Senate Bill 2733 - *Venue Equity and Non-Uniformity Elimination Act of 2016* "to ensure that venue in patents [sic] cases is fair and proper."[27]

The bill would amend §1400(b) to restrict venue in patent infringement cases to forums where the parties are incorporated or where they have physical facilities related to the development of the technology at issue or the alleged infringement. If changed, §1400(b) would read, in part:

> Notwithstanding subsections (b) and (c) of section 1391, any civil action for patent infringement or any action for declaratory judgment that a patent is invalid or not infringed may be brought only in a judicial district –
>
> (1) where the defendant has its principal place of business or is incorporated;
>
> (2) where the defendant has committed an act of infringement of a patent-in-suit and has a regular and established physical facility that gives rise to the act of infringement;

21. 917 F.2d 1574 (Fed. Cir. 1990).
22. *In re Cordis Corp.*, 769 F.2d 733, 735 (Fed. Cir. 1985); *see also Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222, 226 (1957).
23. *Kraft Food Group Brands LLC v. TC Heartland LLC*, No. 14-28 (D. Del. Jan. 14, 2014).
24. *Id.* at Dkt. 7 (Jun. 23, 2014).
25. *In re TC Heartland, LLC*, No. 16-105 at Dkt. 2.
26. *Id.* at 16.
27. S. 2733.

(3) where the defendant has agreed or consented to be sued in the instant action;

(4) where an inventor named on the patent-in-suit conducted research or development that led to the application for the patent-in-suit;

(5) where a party has a regular and established physical facility that such party controls and operates, not primarily for the purpose of creating venue, and has

a. engaged in management of significant research and development of an invention claimed in a patent suit prior to the effective filing date of the patent;

b. manufactured a tangible product that is alleged to embody an invention claimed in a patent-in-suit; or

c. implemented a manufacturing process for a tangible good in which the process is alleged to embody an invention claimed in a patent-in-suit; or....

Such legislation would address many of the concerns raised by TC Heartland and could limit the venue options available to patent trolls.

"Remember, '[e]ven if a defendant has minimum suit-related contacts with a State, the defendant may defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable.'"

PRACTICE TIPS

Personal Jurisdiction

While brand-name drug manufacturers may have won an important battle on the minimum contacts front, the war for jurisdiction does not end there. Remember, "[e]ven if a defendant has minimum suit-related contacts with a State, the defendant may defeat specific personal jurisdiction by sufficiently demonstrating that other considerations render jurisdiction unreasonable."[28]

On the one hand, brand-name drug manufacturers should capitalize on *Acorda* to optimize forum selection in their Hatch-Waxman litigation strategy.

Generic drug manufacturers engaged in Hatch-Waxman litigation, on the other hand, should:

- Consider exercising the "special right" of an ANDA filer to seek declaratory judgment; [29] and
- Challenge jurisdiction by making arguments including: (a) the burden to litigate in the forum is too great, (b) the forum state has minimal interest in the case, (c) it is unnecessary for the plaintiff to be in that particular court to receive "convenient and effective relief," and (d) the interstate judicial system's interest in an "efficient resolution" is better served elsewhere.[30] All defendants should also bear these general challenges in mind in the face of *In re TC Heartland*.

Venue

Practitioners, companies, and interested individuals can take action now on venue issues by advising their elected Representatives of support, comments, or concerns relating to pending Senate Bill 2733.

28. *Id.*
29. The "ANDA filer alone [has] a special right to seek a declaratory judgment regarding patent scope and validity if the NDA holder or patent owner does not file suit first." *Id. (citing 35 U.S.C. §271(e)(5).*
30. *Id.* at *20.