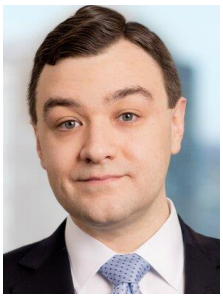
Managing ANDA Venue Issues As Del. And NJ Filings Rise

By **Timothy Cook and Kevin Yurkerwich** (December 1, 2023)



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In 2023, pharmaceutical patent owners filed nearly 250 infringement complaints against generic drug manufacturers. More than 90% of those cases were filed in the Districts of Delaware or New Jersey.

This year's filings reflect a consensus about venue in pharmaceutical patent infringement cases that has emerged since the U.S. Supreme Court reinterpreted the patent venue statute in 2017.

Although many predicted that the Supreme Court's decision would scatter cases like this around the country, cooperation and workarounds have allowed parties to avoid that outcome.

However, this venue scheme presents traps for the unwary. Legislation may still be necessary to ensure fairness and predictability.

TC Heartland changed the venue rules for ANDA cases.

The 2017 TC Heartland v. Kraft Foods Group Brands LLC decision overhauled where infringement suits can be filed.[1] Before TC Heartland, a plaintiff could sue anywhere a defendant sold or planned to sell its product.

Now, a patent holder must sue either where a defendant is incorporated or where it has committed acts of infringement and has a regular and established place of business.[2]

This change created unique challenges for the pharmaceutical industry. The Hatch-Waxman Act governs pharmaceutical patent disputes. Litigation usually starts soon after the generic files an abbreviated new drug application, or ANDA, and before it launches its product.

The complaint triggers a 30- to 42-month stay of the U.S. Food and Drug Administration's approval of the ANDA.[3] Litigants and courts strive to complete Hatch-Waxman cases during the stay to avoid motion practice related to preliminary relief or damages.

Before TC Heartland, most patent holders streamlined ANDA cases against multiple generic challengers by consolidating them in one district. But the decision threatened to splinter these cases into multiple jurisdictions, raising the specter of duplicative litigation, inconsistent findings, and delayed case resolution.

Following TC Heartland, pharmaceutical plaintiffs have tried unsuccessfully to restore the status quo for Hatch-Waxman litigation. The U.S. Court of Appeals for the Federal Circuit has rejected arguments that the general venue statute governs Hatch-Waxman cases,[4] that ANDA filings are nationwide acts of infringement[5] and that mailing a notice of an ANDA filing to the patent holder is an act of infringement in the patent holder's district.[6]

The Federal Circuit has limited the acts of infringement to "acts that occurred before the action alleging infringement was filed, [which] occur only in districts where actions related

to the ANDA submission occur," according to the 2020 Valeant Pharmaceuticals North America v. Mylan Pharmaceuticals Inc. decision.[7]

Courts have also rejected many case-specific attempts to impute venue from a corporate relative to an ANDA filer.[8] This has caused venue to become a "major point of dispute" in Hatch-Waxman cases.[9]

Patent holders still file most ANDA cases in Delaware and New Jersey.

Case-filing data, however, shows that Hatch-Waxman litigation has proceeded as usual. Most generic defendants have not challenged venue, and Hatch-Waxman cases have become even more clustered in Delaware and New Jersey.

Since 2009, there has been a sustained increase in cases filed in Delaware, steady filings in New Jersey, and a drop in cases filed elsewhere.[10] The worst-case scenario of splintered litigation envisioned in TC Heartland's wake has not come to pass.

This trend is likely due to the predictability of Hatch-Waxman litigation in Delaware and New Jersey. Judges in these districts have experience with Hatch-Waxman cases and have local rules or well-established individual practices to manage them.[11]

These courts also have a proven record of promptly trying Hatch-Waxman cases within the stay period. This predictability benefits branded and generic companies.

Changes in the generic industry may be driving the trend. There are often multiple generic companies that file ANDAs on a single drug.

When faced with many defendants, the convenience and predictability of Delaware and New Jersey may outweigh any perceived advantages of a patent holder's home district. The opportunity to share defense costs may incline generics not to challenge venue.

Multidistrict litigation has been an effective but imperfect solution.

Even with this apparent consensus for litigating Hatch-Waxman cases in Delaware and New Jersey, some generics have challenged venue there.[12] Multidistrict litigation has emerged as an effective — but imperfect — tool to manage these cases.

The Judicial Panel on Multidistrict Litigation may combine cases involving common questions of fact for pretrial proceedings.[13] Between 1988 and 2012, the JPML created Hatch-Waxman MDLs for more than 15 drugs.[14]

MDLs fell into disuse for Hatch-Waxman cases in the early 2010s, but since TC Heartland, they have seen a resurgence as a solution for holdout defendants. The JPML has created seven more Hatch-Waxman MDLs since 2019,[15] transferring holdouts to Delaware each time.

In doing so, the JPML explained that the "complexity of the allegations and regulatory framework" and the "need for swift progress in litigation involving the potential entry of generic drugs," favors MDL by a single judge to "foster the efficient resolution" of the actions.[16]

The JPML appears to have denied only two motions to consolidate Hatch-Waxman cases — once when two single-defendant cases existed for infringement of a single patent,[17] and

once when an MDL already existed for the same drug.[18]

But MDLs suffer two main drawbacks: delays and the potential for inconsistent judgments. Delays are a potential problem for two reasons. First, MDLs can slow the start of litigation because the JPML takes about three months to decide motions to create MDLs.

Second, MDLs can delay judgment in transferred cases because defendants can demand that the JPML return or "remand" the case to its original district for trial. These potential delays make it difficult to complete the litigation before the FDA-approval stay expires, though courts have managed this problem so far.

The Delaware judges overseeing the recent Hatch-Waxman MDLs scheduled trials before the stay expired in all but one case, and none has resulted in a preliminary injunction motion or an at-risk launch.

The potential for inconsistent outcomes, particularly on patent validity, is a more troubling problem. The complexities associated with parallel proceedings in different jurisdictions on overlapping claims was made clear in a recent non-MDL case. In 2019, Biogen sued most of the ANDA filers for Tecfidera in Delaware, where the U.S. District Court for the District of Delaware held a bench trial.[19]

While the case was pending, Biogen also sued Mylan on the same claims in West Virginia. The U.S. District Court for the Northern District of West Virginia held a trial two months after the Delaware court, but the West Virginia court issued its decision first and invalidated the claims.[20]

The Delaware court then held the claims invalid because of collateral estoppel,[21] and the Delaware defendants launched their products in the following weeks[22] — all before the Federal Circuit reviewed the West Virginia decision.[23]

While there may be ways to mitigate the risk of cascading invalidity judgments due to collateral estoppel in some cases, it may be unavoidable in others.

How should patent holders manage venue uncertainty?

TC Heartland had the potential to disrupt the Hatch-Waxman litigation scheme, but so far, it has not done so. Most parties have cooperated to avoid wasteful disputes about venue, so for plaintiffs filing new ANDA cases, the simplest way to address potential venue issues may be the most obvious — just ask for a defendant's consent to proceed in Delaware or New Jersey.

Data show that defendants are likely to give it. Branded companies are also often able to select their preferred forum to file suit because foreign defendants "not resident in the United States may be sued in any judicial district,"[24] and many U.S.-based generic pharmaceutical companies are incorporated in Delaware or New Jersey.

MDLs have emerged as an effective alternative if a defendant does not consent and is otherwise ineligible to be sued in a common forum. Moreover, MDLs can even be ordered over a defendant's opposition, as was the case with Viatris's opposition to an MDL in the ongoing patent litigation over the blockbuster drug Ozempic.

As the MDL panel explained, even where "the patents asserted in each action vary somewhat," centralized proceedings in an MDL can "eliminate duplicative discovery" and

"prevent inconsistent pretrial rulings (particularly with respect to claim construction and issues of patent validity)."[25]

But MDLs can cause significant delays, which may threaten the stability created by the FDA-approval stay and lead to inconsistent judgments. Patent holders must manage these risks by quickly seeking MDLs, allowing time for remands and case delays, and crafting case-management procedures to minimize inconsistent decision making.

What's coming next?

The pharmaceutical industry continues to seek a legislative fix to venue problems.[26] Such a solution may be prudent. One purpose of venue laws is to protect defendants,[27] but six years of data show that few Hatch-Waxman defendants feel such protection is necessary.

Indeed, recent cases have shown that the costs of applying the patent venue statute to Hatch-Waxman cases — including less certainty, the potential for gamesmanship, and the burden on courts that MDLs create — far outweigh the value of any protection it provides defendants.

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[1] TC Heartland v. Kraft Foods Group Brands LLC, 581 U.S. 258 (2017) (interpreting 28 U.S.C. §1400(b)).

[2] See TC Heartland, 581 U.S. at 261 (holding "that a domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute").

[3] See 21 U.S.C. §355(j)(5)(B)(iii) (providing for a 30-month default stay); id. §355(j)(5)(F)(ii) (extending stay up to a year in certain circumstances).

[4] Celgene Corp. v. Mylan Pharms. Inc., 17 F.4th 1111, 1119 n.5 (Fed. Cir. 2021).

[5] Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1381-82 (Fed. Cir. 2020).

[6] Celgene, 17 F.4th at 1120-22.

[7] Valeant, 978 F.3d at 1381.

[8] See Novartis Pharms. Corp. v. Handa Neuroscience LLC, No. CV 21-645-LPS, 2022 WL 610771, at *6 (D. Del. Mar. 1, 2022); Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc., No. CV 17-374-LPS, 2018 WL 5109836, at *5 (D. Del. Oct. 18, 2018); Celgene, 17 F.4th at 1125-27.

[9] Patrick Wingrove, TC Heartland Becoming 'Major Point of Dispute' in ANDA Cases, ManagingIP (Aug. 7, 2020).

[10] In 2009, plaintiffs in 40% of ANDA cases filed in Delaware, 26% in New Jersey, and 34% in all other districts. In 2022, 63% filed in Delaware, 26% in New Jersey, and only 11% in all other districts.

[11] See, e.g., Hon. Leonard P. Stark, Patent Study Group (PSG) (May 13, 2014), https://www.ded.uscourts.gov/sites/ded/files/news/PSG-FBA-CLE-5-13-2014.pdf.

[12] Some commentators suggested that Mylan Pharmaceutical, which is in West Virginia, might be the only generic manufacturer to challenge venue, see Patrick Wingrove, Brands Fear Effects of ANDA Venue Win — But Should They?, ManagingIP (Dec. 10, 2020), but others have as well. See, e.g., Novartis, 2022 WL 610771, at *6.

[13] 28 U.S.C. §1407.

[14] See, e.g., MDL Nos. 774, 1238, 1291, 1384, 1410, 1445, 1620, 1661, 1851, 1866, 1941, 1949, 2118, 2126, 2200, 2241, and 2364.

[15] See MDL Nos. 2884, 2896, 2902, 2912, 2930, 3017, and 3038.

[16] In re Kerydin (Tavaborole) Topical Sol. 5% Patent Litig., 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019) (citing In re Alfuzosin Hydrochloride Patent Litig., 560 F. Supp. 2d 1372, 1372 (J.P.M.L. 2008)).

[17] In re Sumatriptan Succinate Patent Litig., 381 F. Supp. 2d 1378, 1378 (J.P.M.L. 2005).

[18] In re Palbociclib ('730) Patent Litig., 544 F. Supp. 3d 1369, 1370 (J.P.M.L. 2021) (denying a motion to create a new MDL but transferring subject cases to an earlier-created MDL in the District of Delaware).

[19] Biogen Int'l GmbH v. Amneal Pharms. LLC, 487 F. Supp. 3d 254, 257 (D. Del. 2020).

[20] Biogen Int'l GmbH v. Mylan Pharms. Inc., No. 1:17-CV-116, 2020 WL 3317105, at *16 (N.D. W. Va. June 18, 2020).

[21] Biogen, 487 F. Supp. 3d at 269.

[22] Status Report, ECF No. 84 at 5-6 n.1, Biogen Int'l GmbH v. Amneal Pharms. LLC, No. 21-1078 (Fed. Cir. filed Apr. 6, 2022).

[23] Biogen Int'l GmbH v. Mylan Pharms. Inc., 18 F.4th 1333, 1346 (Fed. Cir. Nov. 30, 2021) (affirming West Virginia decision).

[24] 28 U.S.C. § 1391(c)(3); see also In re HTC Corp., 889 F.3d 1349, 1361 (Fed. Cir. 2018) (holding that venue is proper as to a foreign defendant in any district).

[25] In re Ozempic (Semaglutide) Pat. Litig., 621 F. Supp. 3d 1354, 1355 (J.P.M.L. 2022).

[26] See, e.g., Intellectual Property Owners Association, Venue in Hatch-Waxman and BPCIA Patent Infringement Suits (Sept. 23, 2018), https://ipo.org/index.php/venue-in-hatch-waxman-and-bpcia-patent-infringement-suits/.

[27] Leroy v. Great W. United Corp., 443 U.S. 173, 183-84 (1979).