

TC Heartland And Hatch-Waxman: Square Peg In A Round Hole

By Jane Love, Robert Trenchard and Paul Torchia (January 30, 2018, 11:55 AM EST)

As has been widely reported, in TC Heartland the U.S. Supreme Court narrowed venue choices in patent cases under the patent venue statute, 28 U.S.C. § 1400.[1] Venue under Section 1400 is now no longer coextensive with the general venue statute, 28 U.S.C. § 1391, which allows lawsuits against companies in any district with personal jurisdiction over the defendant. More is needed under Section 1400, including an analysis of where the defendant has committed “acts of infringement.”[2]

In regular patent cases, identifying where an infringing acts happen — where the invention is made, used or sold — should usually be straightforward. Not so in Hatch-Waxman cases. As codified in 35 U.S.C. § 271(e)(2), the Hatch-Waxman Act permits a branded drug company to sue a generic drug company before any traditional infringing acts have occurred, when the generic merely seeks U.S. Food and Drug Administration approval to sell a copy of the patented drug. The act further excludes any experimental uses prior to FDA approval from suit. For these reasons, the Supreme Court and Federal Circuit have repeatedly characterized 271(e)(2) actions as “artificial” rather than actual infringement actions.[3]

District courts accordingly have struggled to apply Section 1400 in Hatch-Waxman cases. Two recent dueling decisions from Judges Barbara Lynn of the Northern District of Texas and Leonard Stark of the District of Delaware illustrate the problem.[4] Judge Stark observed that “there appears to be a complete mismatch between the backward-looking nature of the patent venue statute and the forward-looking nature of Hatch-Waxman litigation”; Section 1400 thus “creates an almost impenetrable problem in the particular context of Hatch-Waxman patent litigation.”[5] Judge Lynn acknowledged the problem too.[6] In trying to solve the dilemma, each judge came to a different view of where venue should lie, with Judge Stark reading Section 1400 broadly and Judge Lynn providing a narrower construction. The resulting uncertainty in where to sue is serious cause for concern.[7]

An issue no reported decision has yet questioned, however, is whether Section 1400 should apply in Hatch-Waxman cases at all. Before TC Heartland, there was no need — venue under Sections 1400 and 1391 was coextensive. But now the issue is ripe, and there are serious



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arguments in favor of excluding Hatch-Waxman cases from Section 1400's venue provisions. If Section 1391 controls, then these lawsuits could be brought in any district with personal jurisdiction over the defendant. Under the Federal Circuit's *Acorda* decision, that would be anywhere the generic company plans to sell allegedly infringing drugs.[8]

To begin with, Section 1400 by its terms applies only in "a civil action for patent infringement." A Hatch-Waxman case is not simply a "civil action for patent infringement." A normal patent infringement action is a purely private claim for damages and/or injunctive relief by the patent holder against the alleged infringer. In contrast, the Hatch-Waxman Act has procedural and substantive elements that are qualitatively different than routine civil litigation. Among other things, FDA approval of the proposed generic drug can depend on the outcome of the Hatch-Waxman case.[9] If the patent owner prevails, then the FDA is statutorily prohibited from approving the generic drug until the patent expires. In other words, the Hatch-Waxman Act is a hybrid statute with both regulatory and patent elements. It is not a simple "civil action for patent infringement."

It is already well-settled that not all cases that depend on an underlying question of patent infringement qualify as "civil actions for patent infringement" under Section 1400. As Judge Stark observed,[10] declaratory judgment actions by an accused infringer against the patent holder are not covered by Section 1400, even though such actions necessarily rest on the exact same issues as a patent infringement case — the validity of the patent and whether the accused infringer runs afoul of the patent's terms. Like declaratory judgment actions, a Hatch-Waxman case can be viewed as an action that depends on underlying patent validity and infringement questions, but which is not itself a mere "civil action for patent infringement."

Indeed, some courts have held that branded companies may bring declaratory judgment actions against generic drug companies as an adjunct to, or in lieu of, Hatch-Waxman claims under 271(e)(2).[11] No principled reason exists to treat those two sorts of claims differently for venue purposes. Moreover, as commentators have observed, Section 1400 by its terms cannot apply to foreign defendants that have no place of business in the U.S.;[12] the Supreme Court in *TC Heartland* declined to reverse its decision in *Brunette Machine Works v. Kockum Industries* subjecting foreign patent defendants to venue under Section 1391.[13] Many generic drug makers are located abroad. It would be extremely odd for foreign and domestic generic drug company defendants to be subject to different venue rules.

This reading of the statute is buttressed by the very language that bedeviled the Delaware and Texas courts — the ability to bring suit where "acts of infringement" have occurred. Section 1400 was drafted long before Hatch-Waxman,[14] and thus pegs venue to traditional acts of infringement — making, using, or selling an invention. Hatch-Waxman's "artificial" infringement simply does not fit within these categories. Rather than trying to fit a square peg into a round hole, the better solution is to hold that these cases are not within Section 1400's ambit.

While the legislative history of the Hatch-Waxman Act is notoriously sparse,[15] the act's structure suggests Congress intended that Hatch-Waxman lawsuits should be brought wherever personal jurisdiction over the defendant exists, i.e., wherever allegedly infringing drugs will be sold. The FDA license permitted by Hatch-Waxman is national in scope. Generic drug companies thus generally sell nationwide. Moreover, often more than one generic drug company will seek approval to copy the same branded drug. It makes sense that generic drug companies that intend to compete with each other nationwide should be subject to nation-wide venue.

In contrast, trying these cases in different districts would create a risk of inconsistent results for the

same patent. The FDA would then be in a position the Hatch-Waxman Act does not envision — having to decide how to license a generic drug product when different courts have issued different rulings about the same patent covering the product. That could lead to the absurd result that one generic drug is allowed to market, while another identical generic drug is excluded from the market. Nothing in the Hatch-Waxman Act contemplates that result.

Other commentators have suggested that inconsistent results could be avoided through the multidistrict litigation process of 28 U.S.C. § 1407.[16] The MDL statute allows the Judicial Panel on Multidistrict Litigation to consolidate related cases in a single district for pretrial purposes.[17] While helpful, this mechanism would not solve the uniformity problem. The MDL panel often will not consolidate cases when only a few are pending in different districts.[18] Yet it takes only two cases in different districts to create a risk of inconsistent results. More importantly, MDL consolidation is for pretrial purposes only. Consolidated cases are remanded to their original district for trial.[19] As a result, the MDL statute cannot eliminate the risk that different trial judges will come to different views on the same patent.

In short, the relevant statutes and their policy objectives all point toward using Section 1391 to determine venue in Hatch-Waxman cases. The same is likely true for cases under the Biologics Price Competition and Innovation Act, though that question is beyond the full scope of this article.[20] If Section 1391 applies, then in most cases all matters related to a single patent will be able to be resolved in a single jurisdiction, streamlining litigation and ensuring the FDA receives clear guidance on the licensing decisions that can follow from a Hatch-Waxman litigation.

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[1] *C Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514, 1521 (2017); see Mathew Bultman, *High Court Limits Where Patent Suits Can Be Filed*, Law360 (May 22, 2017, 10:28 AM), <https://www.law360.com/articles/909852/high-court-limits-where-patent-suits-can-be-filed>.

[2] Section 1400(b) reads “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.”

[3] See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990); *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1666 (2017); *Takeda Pharm. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 629 (Fed. Cir. 2015).

[4] See *Bristol-Myers Squibb Company v. Mylan Pharmaceuticals Inc.*, 2017 WL 3980155 (D. Del. Sept. 11, 2017); *Galderma Labs., L.P., v. Teva Pharmaceuticals USA, Inc.*, 2017 WL 6505793 (N.D. Tex. Nov. 17, 2017).

[5] See *Bristol-Myers Squibb*, 2017 WL 3980155 at *10–11.

[6] Galderma Labs., 2017 WL 6505793 at *5.

[7] Michael Abernathy et al., How District Courts Split Over ‘Infringing Acts’, Law360 (December 13, 2017, 3:48 PM), https://www.law360.com/ip/articles/993432/how-district-courts-split-over-infringing-acts-?nl_pk=5ccf77c7-f62b-495d-a761-6fe98f521c93&utm_source=newsletter&utm_medium=email%20&%20utm_campaign=ip

[8] Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc., 817 F.3d 755, 762–63 (Fed. Cir. 2016).

[9] See, e.g., 35 U.S.C. § 271(e).

[10] See Bristol-Myers Squibb, 2017 WL 3980155 at *6 n8.

[11] See, e.g., Cephalon, Inc. v. Watson Pharm., Inc., 629 F. Supp. 2d 338, 351 (D. Del. 2009); Bayer Healthcare LLC v. Norbrook Labs., Ltd., No. 08-C-0953, 2009 WL 6337911, at *13–14 (E.D. Wis. Sept. 24, 2009).

[12] Joseph Re et al., TC Heartland Complicates Venue For Foreign Defendants, Law360 (June 29, 2017, 12:34 PM), <https://www.law360.com/articles/935949/tc-heartland-complicates-venue-for-foreign-defendants>.

[13] TC Heartland, 137 S. Ct. at 1520 n2.

[14] Congress enacted Section 1400 in its current form in 1948. Act of June 25, 1948, 62 Stat. 936. Congress enacted Hatch-Waxman in 1984. Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (1984).

[15] Schering Corp. v. Food & Drug Admin., 51 F.3d 390, 398 (3d Cir. 1995) (describing the “sparse legislative history of the Act”); Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1072 (D.C. Cir. 1998) (referring to legislative history of Paragraph IV as “limited”).

[16] See Nicole DeAbrantes, How Will TC Heartland Impact BPCIA and Hatch-Waxman Litigation?, Rothwell Figg, <http://www.biosimilarsip.com/2017/07/06/will-tc-heartland-impact-bpcia-hatch-waxman-litigation/>.

[17] 28 U.S.C. § 1407(a).

[18] In re Drowning Incident at Quality Inn Ne., Washington, D. C., on May 3, 1974, 405 F. Supp. 1304, 1306 (J.P.M.L. 1976) (finding two actions was “too few” to warrant MDL).

[19] 28 U.S.C. § 1407(a) (“Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated.”)

[20] See Sasha Rao et al., Will TC Heartland Control Venue in BPCIA Litigation?, 94 PTCJ 1036, (2017).