Toward a Centralized Hatch-Waxman Venue

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Pharmaceutical litigation often begins when a generic drug company files an application to have its generic drug approved by the FDA. That application is received by the FDA in the District of Maryland. To "submit" it is a statutory act of patent infringement under the Hatch-Waxman Act. Establishing venue in subsequent Hatch-Waxman litigation can be complex because Hatch-Waxman litigation often involves simultaneous and independent lawsuits against many generic applicants. A Hatch-Waxman plaintiff might reasonably attempt to consolidate litigation in a single district court; Hatch-Waxman defendants might reasonably resist consolidation in the plaintiff's preferred venue. Recent Supreme Court and Federal Circuit case law has narrowed venue options for Hatch-Waxman plaintiffs. This Comment argues for an interpretation of Hatch-Waxman's statutory act of patent infringement and the patent venue rules that moves toward a centralized venue for Hatch-Waxman litigation in the District of Maryland.

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INTRODUCTION

The Hatch-Waxman Act[1] strikes a sensitive balance in the pharmaceutical market. "Pioneer" pharmaceutical companies bear the immense cost of developing new drug products approved by the Food and Drug Administration (FDA). As a result, these pioneers typically protect their valuable drug products with numerous patents. Other "generic" pharmaceutical companies can later enter markets created by pioneers, offering competing generic drug products and driving down prices for patients. Hatch-Waxman creates a statutory scheme that enables patent infringement litigation between pioneers and generic drug companies in advance of the market release of a generic drug.[2] Hatch-Waxman's rules for patent infringement litigation create unique procedural hurdles for pioneer plaintiffs attempting to establish proper venue at the start of litigation. To facilitate litigation before the actual sale of a generic drug, Hatch-Waxman requires generic companies to submit an Abbreviated New Drug Application (ANDA)[3] for approval by the FDA[4] and permits pioneer companies to sue them for a "highly artificial act of [patent] infringement"[5] that consists of that submission.[6] Venue in Hatch-

1 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, and 35 U.S.C.).

2 *See* 35 U.S.C. § 271(e)(2)–(4).

3 *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990) ("That is what is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA."). *See generally* 21 U.S.C. § 355(j) (containing many of Hatch-Waxman's substantive provisions governing ANDAs).

4 *See Eli Lilly*, 496 U.S. at 678.

5 *Id.* at 678 (emphasis added); *see also* Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc., 978 F.3d 1374, 1381 (Fed. Cir. 2020) (collecting cases).

6 35 U.S.C. § 271(e)(2).

Waxman litigation, in turn, can be established where a generic ANDA applicant's "acts of infringement" occur[7]—i.e. where the generic applicant has submitted their ANDA.[8]

But in 2017, the Supreme Court's decision in *TC Heartland LLC v. Kraft Foods Group Brands LLC*[9] brought about substantial changes to patent venue law.[10] Then, in *Valeant Pharmaceuticals North America LLC v. Mylan Pharmaceuticals Inc.*[11] the Federal Circuit specifically addressed the question of venue in Hatch-Waxman patent infringement cases, holding that an ANDA submission occurs "for venue purposes only in districts where actions related to the submission of an [ANDA] occur."[12] The Federal Circuit, however, expressly did "not define what all relevant acts involved in the preparation and submission of an ANDA might be, leaving those questions for other cases where the precise contours are presented and briefed."[13] By doing so, the Federal Circuit retained the ability to narrow or broaden the patent venue rules for Hatch-Waxman litigants in response to new arguments or venue trends post-*Valeant*.

The Federal Circuit intriguingly suggested, however, that the ANDA submission always occurs in the District of Maryland—the site where the FDA receives ANDAs.[14] By this reasoning, a generic ANDA applicant, through the act of submitting an ANDA to the FDA in Maryland, would always commit an act of infringement in the District of Maryland. Thus, the District of Maryland would always satisfy the acts of infringement requirement of the patent venue statute for purposes of establishing venue. This interpretation of the patent venue rules would make it meaningfully easier for *all* Hatch-Waxman plaintiffs to establish venue in Maryland and would move toward a centralized venue for Hatch-Waxman litigation.

Because Hatch-Waxman litigation is often extremely complex, the "precise contours"[15] of the patent venue rules can have

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7 28 U.S.C. § 1400(b).

8 35 U.S.C. § 271(e)(2).

9 137 S. Ct. 1514 (2017).

10 *See Valeant*, 978 F.3d at 1375 ("In [*TC Heartland*], the Supreme Court dramatically changed the venue landscape in patent cases."). *See generally, e.g.*, *TC Heartland*, 137 S. Ct. 1514.

11 978 F.3d 1374 (Fed. Cir. 2020).

12 *Id.* at 1375.

13 *Id.* at 1384 n.8.

14 *See id.* ("While it may well be that the District of Maryland satisfies the test for venue that we have laid out here, we do not resolve that question.").

15 *Id.*

significant financial, organizational, and efficiency-related consequences for Hatch-Waxman litigants. Pioneers frequently confront a situation "in which there are multiple ANDA filers but they do not all reside in the same district."[16] In *Valeant*, for instance, the plaintiff Valeant filed separate and essentially simultaneous lawsuits against no fewer than twenty-five generic ANDA applicants in the District of New Jersey[17]—with accompanying protective suits in at least three other district courts[18] as well, including against Mylan, the defendant on appeal, in the Northern District of West Virginia.[19]

If the patent venue rules do not allow a Hatch-Waxman plaintiff to consolidate multiple lawsuits in a centralized venue, the pioneer "will be required to file and maintain largely identical suits in multiple districts," thus increasing "the time and expense that is required to resolve these cases on the merits" and potentially resulting "in inconsistent judgments."[20] Yet, allowing a Hatch-Waxman plaintiff to hale all defendants into *any* district court could violate a central tenet of venue policy: litigation should ideally be limited to districts "that are fair and reasonably convenient" to the defendant.[21]

This Comment argues for an interpretation of the patent venue rules that establishes a single centralized venue for Hatch-Waxman litigation in the District of Maryland. A centralized Hatch-Waxman venue is a legally sound result that would facilitate more efficient resolution of Hatch-Waxman litigation. This Comment proceeds in three parts: First, Part I reviews Hatch-

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16 Bristol-Myers Squibb Co. v. Mylan Pharms. Inc., C.A. No. CV 17-379-LPS, 2017 WL 3980155, at *12 n.17 (D. Del. Sept. 11, 2017).

17 *Cf. Valeant*, 978 F.3d at 1377 n.3 (summarizing Valeant's Hatch-Waxman filings in the District of New Jersey). *See generally, e.g.*, Order Consolidating Cases for All Purposes, Valeant Pharms. N. Am. LLC v. Strides Pharma Inc., No. 3:19-cv-00133 (D.N.J. Jan. 4, 2019), ECF No. 10 (listing the different cases ultimately consolidated in the District of New Jersey).

18 *See Valeant*, 978 F.3d at 1377 (describing a protective suit against Mylan filed in the Northern District of West Virginia); Complaint for Patent Infringement, *Valeant Pharms. N. Am. LLC v. KVK-Tech, Inc.*, No. 2:18-cv-04195-PD at 2 (E.D. Pa. Sep. 27, 2018), ECF No. 1 (initiating a protective suit against KVK-Tech, Inc. in the Eastern District of Pennsylvania); Complaint for Patent Infringement, *Valeant Pharms. N. Am. LLC v. Par Pharms., Inc.*, No. 1:18-cv-08221-LLS at 2 (S.D.N.Y Sep. 10, 2018), ECF No. 1 (initiating a protective suit against Par Pharmaceutical, Inc. in the Southern District of New York).

19 *See Valeant*, 978 F.3d at 1377.

20 *Bristol-Myers Squibb*, 2017 WL 3980155, at *12 n.17.

21 32A AM. JUR. 2D *Federal Courts* § 1082 (2022) (citing *KM Enter., Inc. v. Glob. Traffic Techs., Inc.*, 725 F.3d 718, 724 (7th Cir. 2013)).

Waxman's regulatory scheme and the rules for Hatch-Waxman litigation. Part II evaluates the recent Supreme Court and Federal Circuit case law that has substantially restructured the patent venue rules for Hatch-Waxman litigants. Finally, Part III provides a number of legal and policy arguments supporting a move toward a centralized Hatch-Waxman venue in the District of Maryland.

I. HATCH-WAXMAN ACT LITIGATION

The Hatch-Waxman statutory scheme is unique even in the patent infringement context. Part I.A describes how Hatch-Waxman structures the drug approval process to incentivize generic applicants to initiate premarket patent infringement litigation with pioneers. Part I.B then provides an overview of Hatch-Waxman patent infringement litigation.

A. Regulation of Pioneer and Generic Drug Product Approval

The FDA regulates the marketing and sale of drug products; without FDA approval, a drug company cannot market or sell its products in interstate commerce.[22] To secure FDA approval of a new drug product, pioneers must "submit lengthy preclinical and clinical data demonstrating the drug's safety and efficacy to [the] FDA" in the form of a "New Drug Application" (NDA).[23] Securing FDA approval to market and sell a new drug product is a lengthy and enormously expensive process.[24]

Instead of incurring the significant costs and risks associated with new drug product development, generic applicants enter an existing drug product market created by an FDA-approved pioneer. By definition, a generic drug product is either "the same as a so-called 'pioneer drug' previously approved"[25] or only "differs

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[22] *See* 21 U.S.C. § 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug.").

[23] Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011). More generally, this piece offers an excellent overview of the background and core provisions of the Hatch-Waxman Act.

[24] *Id.* at 422 (stating that development of a new drug takes "some 15 years" and "costs in excess of $1.5 billion" (quoting PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 764 n.16 (3d ed. 2007))).

[25] Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990) (citing 21 U.S.C. § 355(j)(2)(A)).

from the pioneer drug in specified ways."[26] Thus, a generic drug company seeking FDA approval for its generic drug is in a fundamentally different position than the pioneer applicant. When the pioneer files its NDA, there are no safety or efficacy data for the new drug product in question; the point of the NDA is for a pioneer to provide such data to the FDA. In contrast, when the generic drug company files its generic drug product application with the FDA, it may rely on the pioneer's *existing* safety and efficacy data for that drug product. For the generic company, producing and submitting a second NDA would confer no additional benefit beyond the pioneer's NDA; the generic company would expend the same research costs in order to merely duplicate the same safety and efficacy findings.

Importantly, a generic drug product often cuts heavily into the market formerly monopolized by the patent-holding pioneer.[27] This competition is clearly bad for the pioneer's profit margins but good for patients and consumers who can obtain FDA-approved drug products at significantly lower costs. Congress consequently created an expedited process for generic drug product approval within Hatch-Waxman "to speed the introduction of low-cost generic drugs to market."[28]

Hatch-Waxman allows generic applicants to "piggyback" on the clinical data supplied by pioneers[29] by submitting "an abbreviated new drug application, or ANDA."[30] The only scientific data required in an ANDA is a showing "that the generic drug is 'bioequivalent' to the [pioneer] drug."[31] Usually, bioequivalence

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[26] *Id*. (citing 21 U.S.C. § 355(j)(2)(C)).

[27] *See* Matthew Avery, *Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments*, 60 HASTINGS L.J. 171, 172 (2008) ("Generic drugs can capture 80–90% of the market, often within months of entering the marketplace."); Michael A. Carrier, Mark A. Lemley & Shawn Miller, *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 HASTINGS L.J. 307, 313 (2020) ("Once a generic enters the market, the brand product on average loses 90% of its market share within the first year.").

[28] Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 405 (2012) (citing *Eli Lilly*, 496 U.S. at 676).

[29] FTC v. Actavis, Inc., 570 U.S. 136, 142 (2013).

[30] Celgene Corp. v. Mylan Pharms. Inc., 17 F.4th 1111, 1117 (Fed. Cir. 2021) ("With an ANDA, a generic-drug sponsor need not repeat a brand drug's safety-and-efficacy trials at great (and scientifically redundant) expense.").

[31] Kelly, *supra* note 23, at 423 (citing 21 U.S.C. § 355(j)(2)(A)(iv)) ("[I]nstead of having to supply FDA with clinical data demonstrating the safety and effectiveness of the drug, the only scientific study that generic manufacturers need to submit to FDA is one demonstrating that the generic drug is 'bioequivalent' to the [pioneer] drug."). Bioequivalence is measured by "the rate and extent of absorption of the drug," which might be

studies are cheaper and faster for the generic ANDA applicant than the original safety-and-efficacy studies were for the pioneer NDA applicant.[32] Therefore, were bioequivalence studies the only part of an ANDA application, generic ANDA applicants could enter drug markets at far lower costs and much more quickly than the pioneer NDA applicant.

B. Pharmaceutical Patent Infringement Litigation

In addition to scientific bioequivalence data, however, an ANDA must also, by statute, address the pioneer's patents that cover its drug. A generic ANDA applicant's strategic decision to piggyback on a pioneer's safety and efficacy data can, because of Hatch-Waxman's statutory scheme, create the risk of patent infringement litigation.

Despite the significant expense of drug development, new drug products often generate substantial revenues for pioneers because of monopoly profits secured by patents.[33] Indeed, the "pharmaceutical industry is one of the few industries that requires patent protection to ensure the profitability of its innovative products."[34] As a result, pioneers almost uniformly have patents protecting their FDA-approved drug products. In fact, the FDA is required by statute to maintain a public list of FDA-approved new drug products and related patents in the so-called "Orange Book."[35]

Regardless of any patents, under Hatch-Waxman, a generic ANDA applicant may *use* the patented drug if the use is "reasonably related to the development and submission of" an ANDA.[36]

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affected by, for example, different pill formulations or methods of administration for a generic drug product. 21 U.S.C. § 355(j)(8)(B); *see also* Kelly, *supra* note 23, at 423 & n.66.

[32] *See Celgene*, 17 F.4th at 1117 ("With an ANDA, a generic-drug sponsor need not repeat a brand drug's safety-and-efficacy trials at great (and scientifically redundant) expense.").

[33] *See* Carrier et al., *supra* note 27, at 318, 321 (reporting, for thirty-six firms studied, that branded pharmaceutical sales increased from $35.2 billion in 1992 to $292.2 billion in 2016, and that "brand sales remain about 80% of all sales").

[34] Avery, *supra* note 27, at 171.

[35] *See* 21 U.S.C. § 355(j)(7)(A); Kelly, *supra* note 23, at 422.

[36] 35 U.S.C. § 271(e)(1). Before Hatch-Waxman, under the Federal Circuit's holding in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), the use of FDA-approved drug products that related to the preparation and submission of an ANDA constituted patent infringement under 35 U.S.C. § 271(a). *See id.* at 861–64. Because of *Roche*, "generic manufacturers were forced to wait until the pioneer's patent term expired before they could begin the development and approval processes for their generic drugs," and "[t]his gave pioneers a de facto extension of their patent terms during the period the generic manufacturers spent testing and seeking FDA review." Avery, *supra*

Performing bioequivalence studies for an ANDA, for instance, is *not* actionable patent infringement. After bioequivalence studies are completed, however, Hatch-Waxman requires a generic ANDA applicant to make a strategic decision about how to confront a pioneer's patents.

A generic ANDA applicant may opt to wait to sell or market its generic drug product until after a pioneer's patents expire.[37] Alternatively, if a generic applicant considers a pioneer's patents invalid or believes that its sale or marketing of a generic drug product would not infringe on a pioneer's patents, it may attempt to accelerate market entry by challenging that pioneer's existing patent monopoly. The generic applicant may do so through a statutory mechanism contained in 21 U.S.C. § 355(j)(2)(A)(vii) called a Paragraph IV certification, which permits an ANDA applicant to challenge existing Orange Book patents of a pioneer's FDA-approved drug product.[38] A Paragraph IV certification declares that, in the ANDA applicant's opinion, an Orange Book–listed patent for a pioneer drug product is either "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted."[39]

A Paragraph IV certification submitted in an ANDA often provokes litigation.[40] But such litigation is not conventional pa-

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note 27, at 175. The Hatch-Waxman Act, via 35 U.S.C. § 271(e)(1), corrected this de facto term extension.

37 *See* 21 U.S.C. § 355(j)(2)(A)(vii). If a generic ANDA applicant decides not to directly challenge a pioneer's active patents, instead filing a Paragraph I, II, or III certification, there is usually no patent infringement litigation. This is because the generic applicant certifies either that there are no Orange Book–listed patents to infringe (Paragraph I), that any Orange Book–listed patent has already expired (Paragraph II), or, if the generic applicant evaluates the pioneer's listed patents as unassailable, that the generic drug will not be marketed until after any Orange Book–listed patents expire (Paragraph III). *See* 21 U.S.C. § 355(j)(2)(A)(vii).

38 To incentivize ANDA applicants to challenge weak patents or innovate around existing patents, Hatch-Waxman provides the first ANDA applicant to file under Paragraph IV with a 180-day period of market exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). During this 180-day period, the FDA will not approve any later-filing generic applicant's ANDA application; the first-filing Paragraph IV generic applicant is essentially allowed the exclusive right to compete with the pioneer. Hatch-Waxman's generic exclusivity prize is potentially worth millions of dollars. *See Actavis*, 570 U.S. at 144.

39 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

40 Hatch-Waxman incentivizes pioneers to initiate immediate litigation against Paragraph IV ANDA applicants. If a pioneer initiates litigation within a forty-five-day window of receiving notice of the generic drug company's ANDA application, approval of the generic drug product is stayed for thirty months, temporarily maintaining the pioneer's monopoly. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

tent infringement litigation because ANDA-related use of a pioneer's patented drug is exempted from patent infringement under 35 U.S.C. § 271(e)(1). Instead, Hatch-Waxman contains a subsequent provision, 35 U.S.C. § 271(e)(2), that allows pioneers and generic applicants to resolve any "infringement dispute . . . before the generic drug hits the market."[41] Strikingly, this Hatch-Waxman provision states that it is "an act of infringement to *submit*"[42] a Paragraph IV ANDA.[43] In other words, Hatch-Waxman creates an unusual cause of action for patent infringement that derives solely from a filing with a federal regulatory agency. Accordingly, the Supreme Court has called the Hatch-Waxman patent infringement scheme "a highly artificial act of infringement that consists of submitting an ANDA."[44]

Hatch-Waxman litigation can be quite complex for two related reasons. First, Hatch-Waxman litigation regularly proceeds in parallel against many defendants. Because marketing a generic alternative can be immensely profitable,[45] pioneers frequently face multiple ambitious ANDA filers.[46] Pioneers must engage in litigation with each of those generic applicants to protect their patent monopolies.[47]

Second, Hatch-Waxman litigation regularly proceeds in multiple locations because the multiple ANDA applicants "do not all reside in the same district."[48] Ideally—for efficiency's sake and to ensure consistent judicial rulings on similar invalidity or noninfringement arguments—a Hatch-Waxman plaintiff would prefer to consolidate litigation before a single judge in a single district

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41 *Cf.* Kelly, *supra* note 23, at 424. If a generic drug product enters and quickly captures a large portion of the pioneer's market but is later found to infringe on the pioneer's valid, enforceable patent(s) and is enjoined from sales, the upheaval in the pharmaceutical market from removing a significantly cheaper alternative generic drug could be severe and painful. The Hatch-Waxman statutory scheme attempts to prevent such disruptions.

42 35 U.S.C. § 271(e)(2) (emphasis added).

43 *See* Kelly, *supra* note 23, at 424. ("The Hatch-Waxman Act added this artificial infringement provision to protect NDA patent holders, so that the infringement dispute could be resolved before the generic drug hits the market.").

44 *Eli Lilly*, 496 U.S. at 678; *see also Valeant*, 978 F.3d at 1381 (collecting cases).

45 *See supra* notes 27, 38.

46 *See* Bristol-Myers Squibb Co. v. Mylan Pharms. Inc., No. CV 17-379-LPS, 2017 WL 3980155, at *12 n.17 (D. Del. Sept. 11, 2017).

47 As an example, in *In re Rosuvastatin Calcium Pat. Litig.*, MDL No. 08-1949, 2008 WL 5046424 (D. Del. Nov. 24, 2008), a Hatch-Waxman plaintiff that had developed the drug product Crestor filed separate actions for patent infringement against at least seven different groups of defendants, all generic ANDA applicants, in three different district courts. *Id.* at *6–7.

48 *Bristol-Myers Squibb*, at *12 n.17.

court. To do so, a Hatch-Waxman plaintiff must establish venue and jurisdiction in the same district court for *all* defendants. But if a pioneer attempts this and fails because the court dismisses the suit against one or more generic applicants for lack of venue or jurisdiction, the pioneer might lose the benefit of the statutory thirty-month stay of generic approval.[49] The stay of generic approval only survives while litigation is ongoing.[50] Therefore, to protect against dismissal and preserve the thirty-month stay, a pioneer will usually file parallel protective suits in multiple different district courts, intending to properly establish venue and jurisdiction against *every* defendant in at least one district.[51]

II. *VALEANT*, *CELGENE*, AND THE FEDERAL CIRCUIT'S HATCH-WAXMAN VENUE JURISPRUDENCE

As a threshold matter, in Hatch-Waxman litigation the plaintiff—a pioneer that wishes to enforce active patents—faces the question of venue. Recent case law has significantly altered the patent venue rules for Hatch-Waxman litigants. This Part overviews those recent changes. Part II.A reviews general changes to patent venue law established by the Supreme Court's 2017 decision in *TC Heartland*. Part II.B details how the general changes to patent venue law from *TC Heartland* have affected venue law for Hatch-Waxman litigation by examining the recent Federal Circuit cases *Valeant* and *Celgene Corp. v. Mylan Pharmaceuticals Inc.*[52]

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[49] *See* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. 69,580, 69,627 (Oct. 6, 2016) (Response 59) ("[T]he 30-month period . . . will be terminated if the court(s) enter(s) an order of dismissal without a finding of infringement in each pending suit for patent infringement brought within 45 days of receipt of the notice of paragraph IV certification sent by the . . . ANDA applicant.")

[50] *See* 35 U.S.C. § 271(e)(2).

[51] *See* Amanda Walton Newton, Note, *Tightening the Gilstrap: How* TC Heartland *Limited the Pharmaceutical Industry When It Reined in the Federal Circuit*, 25 J. INTELL. PROP. L. 255, 279 (2018) (describing why protective suits have become particularly important for preserving a pioneer's thirty-month stay of generic approval in lieu of recent changes to patent venue law—after *TC Heartland*—described *infra* in Part III); *cf.* Abbreviated New Drug Applications and 505(b)(2) Applications, 81 Fed. Reg. at 69,627 (Response 59).

[52] 17 F.4th 1111 (Fed. Cir. 2021).

A. *TC Heartland*'s Recent Changes to the Patent Venue Rules

Venue is substantively and procedurally distinct from jurisdiction. Jurisdiction is about "constitutional authority" and "relates to the power of a federal court to hear and determine a cause or to adjudicate."[53] Venue, in contrast, "is a creature of statute, intended to limit the potential districts where one may be called upon to defend oneself in any given matter to those that are fair and reasonably convenient."[54]

Venue for Hatch-Waxman litigation is dictated by 28 U.S.C. § 1400(b), the patent venue statute.[55] Under that statute, a plaintiff bears "the burden of establishing proper venue"[56] and has two options for doing so. A Hatch-Waxman plaintiff may establish venue either (1) where a generic ANDA applicant "resides"; or (2) where a generic ANDA applicant has both "committed acts of infringement and has a regular and established place of business."[57]

For many years, the Federal Circuit interpreted the word "resides" in the patent venue statute to construe venue as essentially coextensive with personal jurisdiction.[58] Furthermore, the Federal Circuit later determined that "planned future acts were sufficient to justify the exercise of specific personal jurisdiction over a defendant in ANDA cases."[59] Importantly, a generic ANDA applicant's planned future acts included any plans to sell "its generic drugs throughout the United States."[60] Thus, a Hatch-Waxman plaintiff would likely have been able to establish specific personal jurisdiction—and therefore venue—in a suit against a generic ANDA applicant in *any* federal district court.

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53 32A AM. JUR. 2D *Federal Courts* § 1082 (2021).

54 *Id.* (emphasis added) (citing KM Enter., Inc. v. Glob. Traffic Techs., Inc., 725 F.3d 718, 724 (7th Cir. 2013)).

55 The patent venue statute 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." 28 U.S.C. § 1400(b).

56 *Celgene*, 17 F.4th at 1119.

57 28 U.S.C. § 1400(b).

58 *See Valeant*, 978 F.3d at 1379 (citing VE Holding Corp. v. Johnson Gas Appliance Co., 917 F.2d 1574, 1584 (Fed. Cir. 1990), *overruled by TC Heartland*, 137 S. Ct. 1514 (2017)) (noting that *VE Holding Corp.* held that "changes to the general venue statute meant that, in patent cases, corporations reside in every venue where personal jurisdiction is proper").

59 *Id.* (citing Acorda Therapeutics Inc. v. Mylan Pharms. Inc., 817 F.3d 755, 760 (Fed. Cir. 2016)).

60 *See Acorda*, 817 F.3d at 763.

That changed in 2017. The Supreme Court's interpretation of the patent venue statute in *TC Heartland* severely curtailed venue options for Hatch-Waxman plaintiffs. *TC Heartland* directly overruled the Federal Circuit's broad reading of the first prong of the patent venue statute[61] ("where the defendant resides") by limiting the meaning of "resides" under the statute to a defendant's state of incorporation.[62] In the aftermath, the Federal Circuit has adopted a narrow reading of the patent venue statute.[63]

B. *Valeant* and *Celgene*'s Interpretation of the Patent Venue Rules for Hatch-Waxman Litigants

In this shifting legal landscape, Hatch-Waxman plaintiffs have attempted to establish venue under the second prong of the venue statute by filing suit in districts where the defendant has purportedly committed "acts of infringement."[64] But the Hatch-Waxman act of infringement is the "highly artificial"[65] infringing act of "submit[ting]"[66] an ANDA to the FDA. Recently, important cases have addressed the questions of exactly which acts constitute "acts of infringement" under Hatch-Waxman and where, for venue purposes, these acts occur.

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61 Notably, *TC Heartland* did not overrule the Federal Circuit's broad reading of specific personal jurisdiction in Hatch-Waxman litigation based on planned future acts. For Hatch-Waxman litigants, under current Federal Circuit jurisprudence, specific personal jurisdiction likely still *can* be established nationwide; only venue options are more limited for Hatch-Waxman litigants after *TC Heartland*. *See Valeant*, 978 F.3d at 1379:

> Prior to 2017, defendants hoping to transfer Hatch-Waxman cases to a different district generally objected to a plaintiff's chosen venue on personal jurisdiction grounds. We definitively resolved those arguments in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), where we held that planned future acts were sufficient to justify the exercise of specific personal jurisdiction over a defendant in ANDA cases. . . . The practical significance of *Acorda* was markedly contracted when the Supreme Court changed the venue landscape for patent cases in *TC Heartland*.

62 *See TC Heartland*, 137 S. Ct. at 1519–21.

63 *See, e.g.*, *Valeant*, 978 F.3d at 1379 ("When faced with other questions growing out of *TC Heartland*, we have narrowly construed the requirements of venue in patent cases."); *In re* Google LLC, 949 F.3d 1338, 1346 (Fed. Cir. 2020) ("[T]he Supreme Court has cautioned against a broad reading of the venue statute."); *In re* Cray Inc., 871 F.3d 1355, 1361 (Fed. Cir. 2017) ("[T]he requirement of venue is specific and unambiguous; it is not one of those vague principles which, in the interests of some overriding policy, is to be given a liberal construction." (quoting Schnell v. Peter Eckrich & Sons, Inc., 365 U.S. 260, 264 (1961))).

64 28 U.S.C. § 1400(b).

65 Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

66 35 U.S.C. § 271(e)(2).

The first of those cases, *Valeant*, involved a Hatch-Waxman patent infringement lawsuit filed by Valeant against Mylan, a generic ANDA applicant, related to Valeant's drug Jublia for treating fungal toenail infections.[67] Although Mylan is a West Virginia corporation with its principal place of business in West Virginia, Valeant attempted to file suit in the District of New Jersey,[68] which is a common location for Hatch-Waxman litigation.[69] In parallel litigation, Valeant filed lawsuits against no fewer than twenty-four other generic ANDA applicants in the District of New Jersey.[70] Valeant also filed parallel protective suits, including against Mylan in the Northern District of West Virginia.[71]

Mylan challenged venue in the District of New Jersey, arguing that "the only alleged act of infringement—submission of the ANDA—did not occur in New Jersey" but had instead occurred in West Virginia.[72] The district court largely agreed, holding that "the two places where an act of infringement might have occurred before the filing of the action were West Virginia and Maryland [where the FDA received the ANDA], not New Jersey."[73] Thus, the district court dismissed the patent infringement claims for improper venue.[74]

In the lower court and on appeal to the Federal Circuit, Valeant asserted that venue in New Jersey was proper. Valeant's main argument was that, for venue purposes, "planned future conduct," including the planned nationwide sale of a generic drug product, constituted an "act of infringement" under 28 U.S.C. § 1400(b).[75] The Federal Circuit disagreed.[76] Based on its reading

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67 *Valeant*, 978 F.3d at 1376.

68 *Id.*

69 *See* Shawn P. Miller, *Venue One Year After* TC Heartland*: An Early Empirical Assessment of the Major Changes in Patent Filing*, 52 AKRON L. REV. 763, 803–04 (2018).

70 *See* Order Consolidating Cases for All Purposes, *Valeant Pharmaceuticals North America LLC v. Strides Pharma Inc.*, No. 3:19-cv-00133 (D.N.J. Jan. 4, 2019), ECF No. 10 (listing cases to be consolidated in caption).

71 *See Valeant*, 978 F.3d at 1377.

72 *Id.*

73 *Id.* at 1378.

74 *See Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, No. 18-cv-13635, 2019 WL 4179832, at *2 (D.N.J. Aug. 14, 2019), *aff'd in part, rev'd in part, and remanded sub nom.*, *Valeant*, 978 F.3d 1374.

75 *Valeant*, 978 F.3d at 1377.

76 The Federal Circuit in *Valeant* was resolving a district court split. *Compare* Bristol-Myers Squibb Co. v. Mylan Pharms. Inc., No. CV 17-379-LPS, 2017 WL 3980155, at *8 (D. Del. Sept. 11, 2017) ("[T]he Court concludes that in the context of Hatch-Waxman litigation, the 'acts of infringement' an ANDA filer 'has committed' includes all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is launched into the market."), *and* Celgene Corp. v. Hetero Labs Ltd.,

of 35 U.S.C. § 271(e)(2)(A), the Federal Circuit held that "infringement occurs for venue purposes only in districts where actions related to the submission of an [ANDA] occur."[77] The Federal Circuit, however, declined to "define what all relevant acts involved in the preparation and submission of an ANDA might be, leaving those questions for other cases where the precise contours are presented and briefed."[78]

Celgene involved a similar fact pattern. Celgene initiated Hatch-Waxman litigation against "many drug companies," including Mylan, based on the ANDAs filed by those companies related to Celgene's cancer drug Pomalyst.[79] Celgene filed suit in the District of New Jersey; Mylan moved to dismiss for improper venue.[80] The district court agreed to dismiss the claims against Mylan.

Celgene argued that New Jersey satisfied the statutory venue requirements based on the finer details of Hatch-Waxman's notice provisions. Specifically, the FDA's regulations require ANDA applicants to provide notice to the pioneer that they have filed a Paragraph IV ANDA and to then amend the ANDA to include proof that notice was in fact delivered.[81] Celgene argued that receipt of the notice letter at its headquarters in New Jersey was part of the ANDA submission for venue purposes.[82]

The Federal Circuit disagreed. *Celgene* first reaffirmed the holding from *Valeant* that "it is the [ANDA] *submission* that infringes."[83] *Celgene* also reiterated that "acts involved in [the

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No. 17-3387, 2018 WL 1135334, at *3 (D.N.J. Mar. 2, 2018) (relying on the reasoning in *Bristol-Myers Squibb* for determining venue), *with* Galderma Lab'ys, L.P. v. Teva Pharms. USA, Inc., 290 F. Supp. 3d 599, 608 (N.D. Tex. 2017) ("This Court declines to find that an act of infringement occurs wherever an ANDA filer intends to market the accused product."). In *Valeant*, the Federal Circuit did reiterate that its specific personal jurisdiction jurisprudence allowed a showing of "minimum contacts" in any district court based on an ANDA submission, thereby leaving *Acorda*'s holding undisturbed, 817 F.3d 755. *Valeant* specifically stated that its narrow reading of venue was distinct from, and justified on different grounds than, its specific personal jurisdiction jurisprudence for Hatch-Waxman litigants. *See Valeant*, 978 F.3d at 1384 ("[W]e would be remiss to treat venue and personal jurisdiction as the same inquiry.").

77 *Valeant*, 978 F.3d at 1375.

78 *Id.* at 1384 n.8.

79 *See Celgene*, 17 F.4th at 1116–17.

80 *See id.* at 1117, 1119.

81 *See* Applications for FDA Approval to Market a New Drug, 21 C.F.R. § 314.95(a), (e).

82 *See Celgene*, 17 F.4th at 1121.

83 *Id.* (emphasis in original).

ANDA submission's] 'preparation'" may still constitute acts of infringement for the purposes of the patent venue statute if those preparatory acts "at a minimum, [are] fairly . . . *part of* the submission—not merely 'related to' it in some broader sense."[84] Decisively, however, the Federal Circuit noted that "although the ANDA applicant must later send a notice letter and inform the FDA of the letter's receipt, that all happens *after* the infringing submission."[85] Therefore, as in *Valeant*, no acts of infringement occurred in New Jersey, and venue was correctly held improper in that district.[86]

After *Valeant* and *Celgene*, litigants know that they *cannot* establish venue in Hatch-Waxman litigation in any district nationwide by default. Litigants also know that they *can* establish venue in Hatch-Waxman litigation under the patent venue rules, in part, where a generic applicant's relevant acts of infringement—those that are part of an ANDA submission—occur. Nonetheless, *Valeant* and *Celgene* left the "precise contours" of the patent venue rules undefined.[87] The Federal Circuit left it to future litigation to resolve what acts are legally relevant, for venue purposes, in ANDA submissions. Perhaps most significantly, *Valeant* and *Celgene* left Hatch-Waxman litigants without flexible venue rules that allow for the consolidation, in a single district and ideally before a single judge, of the numerous "largely identical suits" that often arise during Hatch-Waxman litigation.[88]

III. CENTRALIZING HATCH-WAXMAN VENUE IN THE DISTRICT OF MARYLAND

The "precise contours"[89] of the patent venue rules can have significant consequences in terms of litigation costs and judicial efficiency and organization. Recall that a plaintiff may establish venue in a patent infringement suit "where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." [90] Given the limitations on the "resides" prong of the patent venue statute imposed by *TC Heartland*, a pioneer might try to use the second acts

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84 *Id.* (emphasis in original).
85 *Id.* at 1122 (emphasis in original).
86 *See id.*
87 *Valeant*, 978 F.3d at 1384 n.8.
88 *Contra Bristol-Myers Squibb*, 2017 WL 3980155, at *12 n.17.
89 *Valeant*, 978 F.3d at 1384 n.8.
90 28 U.S.C. § 1400(b).

of infringement prong of 28 U.S.C. § 1400(b) to find a convenient, centralized venue to pursue all related Hatch-Waxman litigation stemming from a single drug product. However, as explained, if the patent venue rules do not allow for any centralized Hatch-Waxman venue, the pioneer may "be required to file and maintain largely identical suits in multiple districts."[91]

Inflexible patent venue rules thus increase the "time and expense" that is required "to resolve the cases."[92] In essence, spreading Hatch-Waxman litigation over multiple courts wastes judicial resources as multiple judges must hear and decide the same fundamental noninfringement or invalidity arguments. Moreover, such duplicative litigation could result "in inconsistent judgments"[93] at the district court level, where one generic's noninfringement or invalidity arguments succeed but another generic's identical arguments, made before a different judge, fail. Such inconsistency could create undesirable uncertainty and instability in the generic drug market. Indeed, the entire point of the Hatch-Waxman statutory scheme is to resolve any "infringement dispute . . . before the generic drug hits the market,"[94] and inconsistent judgments at the district court level could strongly impede that objective. Some courts have already indicated that multidistrict litigation cannot completely solve this efficiency problem.[95]

The Federal Circuit, in *Valeant*, ultimately felt legally compelled by the "plain language of the two statutes at issue"[96] to reach a conclusion that disfavored flexible options for a nationalized or centralized Hatch-Waxman venue. The court, however, was "sympathetic"[97] to the policy concerns favoring a centralized venue and found them "intuitively persuasive."[98] The Federal Circuit was especially concerned that its holding would result in

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91 *Valeant*, 978 F.3d at 1383 (quoting *Bristol-Myers Squibb*, 2017 WL 3980155, at *12 n.17).

92 *Id.*

93 *Id.* (quoting *Bristol-Myers Squibb*, 2017 WL 3980155, at *12 n.17).

94 Kelly, *supra* note 23, at 424.

95 *See Bristol-Myers Squibb*, 2017 WL 3980155, at *12 n.17 (emphasis added):

> While the Joint Panel on Multidistrict Litigation might, in these circumstances, be expected to create more Hatch-Waxman multidistrict litigations ('MDLs'), the process of creating an MDL often involves litigation (adding time and expense) and, even once created, cases are transferred to an MDL only for *pretrial* purposes. They must be transferred back to the transferor districts for trial, unless a party waives its right to be transferred back.

96 *Valeant*, 978 F.3d at 1385.

97 *Id.*

98 *Id.* at 1383.

"lost judicial efficiencies in the handling of these mostly multi-defendant cases."[99]

Perhaps motivated by these concerns, the Federal Circuit raised the possibility that the District of Maryland might *always* satisfy the acts of infringement prong of 28 U.S.C. § 1400(b).[100] Under this theory, proper receipt by the FDA in Maryland serves as the final act that operationalizes an ANDA submission under 35 U.S.C. § 271(e)(2) and initiates Hatch-Waxman litigation. As such, receipt of an ANDA submission by the FDA is "fairly [ ] part of" the ANDA submission, not "merely 'related to' it in some broader sense."[101] Overall, this would mean that each ANDA submission necessarily includes an act of infringement—the receipt of the ANDA by the FDA—in the District of Maryland. A Hatch-Waxman litigant, consequently, would always be able to satisfy the acts of infringement prong of 28 U.S.C. § 1400(b) in the District of Maryland.

By holding that an ANDA submitter always commits an act of infringement in the District of Maryland, a court would not, de facto, create a centralized Hatch-Waxman venue. In addition to committing an act of infringement, under 28 U.S.C. § 1400(b), a defendant would need to have "a regular and established place of business" in Maryland for venue to be proper.[102] After *TC Heartland*, the Federal Circuit has also articulated limitations on the "place of business" prong of the patent venue statute.[103] However, it remains unclear whether the Federal Circuit's rulings on the place of business prong set a particularly stringent standard. For example, one district court recently ruled that Amazon lockers constitute a regular and established place of business of Amazon for venue purposes.[104] Another Federal Circuit judge has suggested the possibility that "Google is indeed doing business at

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99 *Id.* at 1385.

100 *See id.* at 1384 n.8 ("While it may well be that the District of Maryland satisfies the test for venue that we have laid out here, we do not resolve that question.").

101 *Celgene*, 17 F.4th at 1121 (emphasis and quotation marks omitted).

102 *See* 28 U.S.C. § 1400(b).

103 *See, e.g.*, *In re* Cray Inc., 871 F.3d 1355, 1366 (Fed. Cir. 2017) (finding that work conducted from an employee's home is insufficient to establish a place of business); *In re* Google LLC, 949 F.3d 1338, 1345–47 (Fed. Cir. 2020) (finding that computer servers hosted by a contractor, standing alone, are insufficient to establish a place of business); *Celgene*, 17 F.4th at 1122–27 (finding that employees' homes and a separate subsidiary's office did not establish a place of business).

104 Rensselaer Polytechnic Inst. v. Amazon.com, Inc., 1:18-cv-00549 (BKS/CFH), 2019 WL 3755446, at *14 (N.D.N.Y. Aug. 7, 2019).

the computer of each of its users/customers."[105] Ultimately, the place of business prong in the context of Hatch-Waxman venue is still loosely defined.[106] If the courts define place of business narrowly, pioneers would find it more difficult to consolidate venue. But the Federal Circuit's concern with the policy implications of limiting venue in Hatch-Waxman litigation specifically suggests that a broad reading of the place of business prong, at least in Hatch-Waxman cases, could accompany any developments in the court's reading of the acts of infringement prong.

Importantly, however, holding that the FDA's receipt of the ANDA submission counts as an "act of infringement" in the District of Maryland for venue purposes would make centralizing venue meaningfully easier for Hatch-Waxman litigants. The following sections argue, first, that courts should do so for reasons founded in substantive and procedural law and, second, that they should do so as a matter of sound venue policy.

A. Receipt of the ANDA by the FDA Is Part of the ANDA Submission

In *Valeant*, the Federal Circuit signaled that pressing the button,[107] so to speak, that formally sends a proper ANDA to the FDA is the most clear-cut act of infringement under 35 U.S.C. § 271(e)(2).[108] At least one district court has understood *Valeant* to stand for the proposition that the second prong of 28 U.S.C. § 1400(b) "is met by filing the lawsuit in the state where the [ANDA] was filed." [109] The Federal Circuit itself has also stated

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[105] *Google*, 949 F.3d at 1348 (Wallach, J., concurring).

[106] Although a full analysis of the place of business prong in the Hatch-Waxman context is beyond the scope of this Comment, other commentators have more generally argued that the patent venue statute's place of business prong is ripe for further doctrinal development. *See, e.g.*, Micah Quigley, Comment, *Simplifying Patent Venue*, 87 U. CHI. L. REV. 1893, 1925–33 (2020) (suggesting that courts focus on and develop doctrine around the "place" requirement of the patent venue statute's place of business prong).

[107] The ANDA would almost certainly be submitted online in an electronic format. *See* Galderma Lab'ys, L.P. v. Teva Pharms. USA, Inc., 290 F. Supp. 3d 599, 609 (N.D. Tex. 2017) (citing *Abbreviated New Drug Application (ANDA) Forms and Submission Requirements*, FDA (Mar. 7, 2022), https://perma.cc/8UQ4-HGU5) ("The FDA no longer accepts paper ANDA submissions. All ANDA submissions MUST be in [electronic] format.").

[108] *See Valeant*, 978 F.3d at 1381 ("A plain language reading of this provision directs us to the conclusion that it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context.").

[109] Fresenius Kabi USA, LLC v. CUSTOpharm, Inc., No. 20-cv-03254, 2021 WL 849635, at *2 (D. Colo. Jan. 26, 2021) (citing *Valeant*, 978 F.3d at 1375), *report and recommendation adopted*, No. 20-cv-03254, 2021 WL 651022 (D. Colo. Feb. 19, 2021).

that *Valeant* "means venue is proper 'where an ANDA-filer submits its ANDA to the FDA.'"[110] For example, sending an ANDA to the FDA from New Jersey would mean that an act of infringement had occurred, for venue purposes, in the District of New Jersey.

In contrast, while formally sending a proper ANDA to the FDA is clearly an act of infringement, it is equally clear that actions taken after an ANDA is properly submitted cannot retroactively become part of that earlier submission. The Federal Circuit in *Celgene*, for instance, explicitly stated that acts taken to comply with Hatch-Waxman's Paragraph IV notice requirements do not constitute infringement under 35 U.S.C. § 271(e)(2).[111] Hatch-Waxman's notice provisions relate to acts that happen "*after* the infringing submission."[112] Therefore, the Federal Circuit concluded that "[s]ending a paragraph IV notice letter does not fall within 'submitting' the ANDA."[113] Basically, actions taken to comply with Hatch-Waxman's notice provisions occur too late to be useful in establishing venue under the patent venue statute.

FDA receipt of an ANDA falls directly between these two events. There are a number of legal arguments, however, both substantive and procedural, that strongly support the conclusion that an ANDA submission occurs, at least in part, in the district where the FDA receives it—the District of Maryland. First, Federal Circuit case law directly supports the proposition that an ANDA submission occurs where the FDA receives the ANDA. Second, a number of district court cases hold that an actionable ANDA submission has not occurred *until* the FDA formally receives the ANDA. Third, the Hatch-Waxman Act's text and purpose support a statutory interpretation of the word "submit" that involves receipt of the ANDA submission in Maryland. Fourth, the Supreme Court's guidance on statutory causes of action further supports the argument that an ANDA applicant proximately causes the FDA to receive the ANDA in Maryland. Fifth, comparisons with other areas of law suggest that Hatch-Waxman's cause of action only accrues when the FDA has properly received an ANDA.

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110 *Celgene*, 17 F.4th at 1120 (quoting *Valeant*, 978 F.3d at 1378–79).

111 *See id.* at 1121–22 (disagreeing with the argument that receiving the notice letter is part of the infringing act because the ANDA submission precedes and is separate from the notice). For a brief overview of the Paragraph IV ANDA notice scheme that Hatch-Waxman establishes, see *id.* at 1121.

112 *Id.* at 1122 (emphasis in original).

113 *Id.*

1. An ANDA applicant commits a federal tort in Maryland.

Federal Circuit case law directly supports the idea that receipt of a proper ANDA by the FDA should be considered part of an ANDA submission. In *Zeneca Ltd. v. Mylan Pharmaceuticals Inc.*,[114] the Federal Circuit expressly stated that a generic ANDA applicant, by filing its ANDA, had "purposefully committed a federal tort in Maryland"[115]—the statutory tort of patent infringement under Hatch-Waxman.[116] *Zeneca* further elaborated that "[a] party that commits a federal tort in a state is on notice that it may be haled into court in that state."[117] Moreover, *Zeneca* noted that a Hatch-Waxman plaintiff would have "a legitimate interest in litigating in Maryland because it could *consolidate* cases arising from the filing of two different ANDA's with respect to the same patent, which may result in judicial and litigant economy."[118]

Critically, for venue purposes, 28 U.S.C. § 1400(b) concerns "where the *defendant* has committed acts of infringement."[119] The plain language of the statute shows that actions taken solely by the FDA cannot be used to establish venue, even if these actions are acts of infringement under 35 U.S.C. § 271(e)(2). In Hatch-Waxman cases like *Zeneca*, however, the generic ANDA applicants themselves submitted the applications to the FDA in the District of Maryland. Further, according to *Zeneca*, it is the generic ANDA applicant, not the FDA, who has "purposefully committed a federal tort in Maryland."[120]

Zeneca, to be clear, was a case about personal jurisdiction that predated the Federal Circuit's current broad personal jurisdiction jurisprudence. For constitutional reasons related to an ANDA applicant's right to petition the federal government,

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114 173 F.3d 829 (Fed. Cir. 1999).

115 *Id.* at 833.

116 *See* Peter E. Strand, *Back to Bedrock: Constitutional Underpinnings Set 'New' Standards for Patent Infringement Causation*, 8 B.U. J. SCI. & TECH. L. 375, 379 (2002) ("Suits for patent infringement are actually tort suits."); Amy L. Landers, *Proximate Cause and Patent Law*, 25 B.U. J. SCI. & TECH. L. 329, 331 (2019) ("Patent infringement is considered a form of tort that originates from the Patent Act." (first citing Carbice Corp. of Am. v. Am. Pats. Dev. Corp., 283 U.S. 27, 33 (1931); and then citing Arctic Cat Inc. v. Bombardier Recreational Prod. Inc., 876 F.3d 1350, 1366 (Fed. Cir. 2017))).

117 *Zeneca*, 173 F.3d at 833.

118 *Id.* at 834 (emphasis added).

119 28 U.S.C. § 1400(b) (emphasis added).

120 *Zeneca*, 173 F.3d at 833 (discussing how the government contacts exception, as the question certified on appeal, means that the court must also consider the right to petition the government).

Zeneca eventually held that personal jurisdiction for ANDA applicants was improper in the District of Maryland because of the government contacts exception.[121] Nonetheless, the Federal Circuit's opinion in *Zeneca* carefully argued that its holding, relying on the government contacts exception, required as a premise the conclusion that ANDA applicants directly commit a federal tort in Maryland.[122] So, importantly, *Zeneca*'s statement that an ANDA submission constitutes a federal tort that occurs, in part, in Maryland is not dicta. That position—that ANDA applicants commit an act of infringement in Maryland—has never been explicitly or implicitly overruled.

2. Proper receipt is an essential procedural part of an ANDA submission.

A related line of cases further supports the idea that proper receipt of an ANDA by the FDA is an essential procedural part of an ANDA submission; thus, proper receipt should be sufficient to establish an act of infringement under the patent venue statute. First, in *SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co.*,[123] a district court faced a generic ANDA applicant that had sent Paragraph IV notice to the pioneer without confirmation of receipt from the FDA.[124] The court noted that "[u]nder the statute and regulations, the sending of notice of a Paragraph IV certification [from the generic to the pioneer] is expressly predicated upon

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[121] *See id.* at 834. Judge Arthur Gajarsa would have found sufficient contacts between the ANDA applicant the District of Maryland under traditional personal jurisdiction analysis but for the government contacts exception. *See id.* at 833–34 ("[U]nder traditional personal jurisdiction analysis, there is no way to avoid the fact that Mylan has purposefully committed a federal tort in Maryland. . . . Thus, under traditional personal jurisdiction analysis, I believe the exercise of personal jurisdiction over Mylan in Maryland would be permissible."). Judge Randall Rader's concurrence in *Zeneca*, in contrast, expressed unease with the idea that ANDA applicants had created sufficient contacts with the state of Maryland such that personal jurisdiction would be proper, *see id.* at 834–36 (Rader, J., concurring). Judge Rader would have found a lack of jurisdiction in Maryland under traditional principles of personal jurisdiction analysis. Overall, *Zeneca* was a 2-1 vote with Judge Rich dissenting without an opinion. The Federal Circuit later pointedly distinguished *Zeneca* when revising its personal jurisdiction jurisprudence in *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

[122] *See Zeneca*, 173 F.3d at 833–34.

[123] 552 F. Supp. 2d 500 (E.D. Pa. 2008), *appeal dismissed by*, 318 F. App'x 897 (Fed. Cir. 2008).

[124] *SB Pharmco*, 552 F. Supp. 2d at 503–04. *See* 21 C.F.R. § 314.101(b)(1) (2016) (describing receipt procedures); 21 C.F.R. § 314.95(b) (2016) (describing Paragraph IV notice procedures).

the ANDA applicant receiving its own notice and acknowledgment from the FDA that the submitted ANDA has been received."[125] Since the ANDA had "not been accepted as received when the notice was sent," the district court held that "the litigation process was prematurely sparked at a time when the danger existed that the ANDA was in fact incomplete."[126] *SB Pharmco* thus supports the proposition that unless and until the FDA formally receives the generic applicant's ANDA, litigation based on an ANDA *submission* cannot properly begin.

Second, and perhaps more strikingly, in *Allergan, Inc. v. Actavis, Inc.*,[127] the FDA refused to receive an ANDA that it viewed as incomplete.[128] The generic ANDA applicant nonetheless sent a Paragraph IV notice letter to the pioneer.[129] The court, relying on *SB Pharmco*, concluded that "the mere transmission of documents purporting to be an 'ANDA' is insufficient to trigger infringement under 35 U.S.C. § 271(e)(2)."[130] In other words, without proper receipt by the FDA confirming that a generic applicant's filing is truly a substantially complete ANDA, a generic applicant has not committed actionable patent infringement.

In sum, *SB Pharmco* and *Allergan* strongly suggest that without proper receipt of an ANDA by the FDA and subsequent notice of that proper receipt, an applicant has not formally submitted an actionable ANDA submission. This interpretation preserves Hatch-Waxman's careful statutory ordering of the events that initiate litigation. Further, reading Hatch-Waxman's cause of action under 35 U.S.C. § 271(e)(2) as requiring proper receipt of the ANDA preserves judicial resources by preventing premature or sham litigation.

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125 *SB Pharmco*, 552 F. Supp. 2d at 507.

126 *Id.* at 508.

127 Case No. 14-CV-638, 2014 WL 7336692 (E.D. Tex. Dec. 23, 2014).

128 *See id.* at *9.

129 *Id.*

130 *Id.* at *10–13. Both *SB Pharmco* and *Allergan* thus foresaw the problem of potential sham litigation if merely filing a purported ANDA was sufficient to initiate litigation. *See SB Pharmco*, 552 F. Supp. 2d at 508 (concluding that "in accepting an ANDA for review, so that it is *received* and not merely *delivered*," receipt by the FDA "acts as a safeguard to prevent a potentially incomplete ANDA from triggering the litigation process" (emphasis in original)); *Allergan*, 2014 WL 7336692, at *11 ("To hold otherwise would invite generic manufacturers to submit incomplete or otherwise deficient applications, in order to secure their position as the first-filed generic."); *see also* Amarin Pharma, Inc. v. Apotex, Inc., No. 14-2550 (MLC), 2016 WL 287082, at *2–3 (D.N.J. Jan. 22, 2016) (following *SB Pharmco* and *Allergan* on similar facts).

3. The statutory text fairly suggests that a valid ANDA submission includes receipt.

Beyond case law, the text of the Hatch-Waxman statute itself supports the statutory construction that submission of an ANDA necessarily involves receipt of that ANDA by the FDA. The patent venue statute allows venue, in part, wherever a defendant commits "acts of infringement,"[131] and Hatch-Waxman makes it an act of patent infringement "to submit" an ANDA.[132] The statute could be clearer—"submit" is not defined.[133] Moreover, Hatch-Waxman neither expressly specifies that its cause of action includes "receipt" of the ANDA nor states that merely "sending" or "mailing" the ANDA to the FDA is actionable.

Nevertheless, principles of statutory construction indicate that an ANDA is only submitted when properly received, and therefore receipt of the ANDA at the FDA is part of the Hatch-Waxman cause of action. First, courts increasingly look to dictionaries to understand the meaning of undefined words.[134] To "submit" means "to present or propose *to another* for review, consideration, or decision" or "to *deliver* formally."[135] Submitting something, in short, is defined by reference to the party receiving that thing. If a dictionary definition is a proxy for ordinary meaning even in the specialized, technical context of patent disputes,[136] Hatch-Waxman's use of the word "submit" seems to suggest that receipt is implicit in the cause of action of submitting an ANDA.

Similarly, more purposivist tools of statutory construction also indicate that submission of an ANDA includes receipt by the FDA. Given that at least one judge has "found no help in dictionary definitions" of the word "submit,"[137] purposivist approaches

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131 28 U.S.C. § 1400(b).

132 35 U.S.C. § 271(e)(2).

133 *See In re* Rosuvastatin Calcium Pat. Litig., MDL No. 08-1949, 2008 WL 5046424, at *10 (D. Del. Nov. 24, 2008) ("The Hatch-Waxman Act does not provide a definition of 'submit.'").

134 *See* Joseph Scott Miller & James A. Hilsenteger, *The Proven Key: Roles and Rules for Dictionaries at the Patent Office and the Courts*, 54 AM. U. L. REV. 829, 832 (2005) ("Over the past twenty years, the Supreme Court has increasingly relied on dictionaries to explain its constructions of legal text.").

135 *Submit Definition and Meaning*, MERRIAM-WEBSTER (Jan. 31, 2022) (emphasis added), https://perma.cc/MV9U-6TRG.

136 *See* Miller & Hilsenteger, *supra* note 134, at 843–51 (arguing that the Federal Circuit, guided by the Supreme Court's increasingly dictionary-based approach to statutory interpretation, has frequently used dictionary definitions to understand ordinary meaning when interpreting patent claims).

137 *Rosuvastatin*, 2008 WL 5046424, at *10 (Stark, Mag. J.).

are particularly warranted when interpreting Hatch-Waxman. Indeed, Justice Antonin Scalia observed that because 35 U.S.C. § 271(e) is not an "elegant piece of statutory draftsmanship," it can be reasonable to construe Hatch-Waxman's language (and the language of FDA's derivative regulations) based on "substantive intent."[138] Doing so fits within the Supreme Court's broader approach to the "holistic endeavor" of statutory interpretation.[139] As the Court has pointed out:

> A provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme—because the same terminology is used elsewhere in a context that makes its meaning clear, or because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.[140]

Under both lines of reasoning, interpreting the word "submit" to include proper receipt of the ANDA by the FDA is the superior statutory construction.

First, at least one court has noted that the word "submit," as used in other parts of Hatch-Waxman, is used to imply "action on the part of the party to whom the submission has been made."[141] For an ANDA submission, "the time of submission can be understood to refer to the time when that party is actually in a position to take the relevant action, which is at the moment of actual receipt."[142] A Hatch-Waxman submission, in sum, necessarily implies receipt because a proper submission requires action by the receiving party—in this case, the FDA.

Second, interpreting the word "submit" to include receipt by the FDA preserves the highly intentional ordering of events in Hatch-Waxman litigation.[143] If a cause of action is created simply because a generic applicant mails documents to the FDA—documents that have "not been accepted as received" when litigation begins—"the litigation process [could be] prematurely

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138 *See* Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 679 (1990).

139 United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd., 484 U.S. 365, 371 (1988).

140 *Id.* (citation omitted) (collecting cases).

141 TorPharm, Inc. v. Thompson, 260 F. Supp. 2d 69, 81 (D.D.C. 2003), *aff'd sub nom.*, Purepac Pharm. Co. v. Thompson, 354 F.3d 877 (D.C. Cir. 2004) (interpreting the word "submits," as used in the related Hatch-Waxman provision 21 U.S.C. § 355(j)(2)(B)(ii) governing notice of amendments).

142 *Id.*

143 *See supra* note 130.

sparked at a time when the danger existed that the ANDA was in fact incomplete."[144] The purpose of Hatch-Waxman's careful statutory scheme is to resolve any "infringement dispute . . . before the generic drug hits the market."[145] But statutory constructions that allow premature and potentially sham litigation do nothing to further that substantive goal of initiating and resolving patent infringement litigation. In other words, interpreting "submit" to include receipt by the FDA is a "permissible meaning[ ]" that best "produces a substantive effect that is compatible with the rest of the law."[146]

The FDA's own regulations do present an important counterargument. Although receipt may be important for the Hatch-Waxman litigation scheme to proceed in an orderly manner, the FDA's regulations suggest that submission and receipt of an ANDA are distinguishable acts. *SB Pharmco* and *Allergan* explicitly state that an ANDA is only *submitted*—and therefore legally actionable—when it is properly *received*.[147] But the FDA's regulations specify that "[a]n ANDA will be evaluated *after* it is submitted to determine whether the ANDA may be received."[148] In this sense, the FDA's regulations make receipt by the FDA sound more similar to the receipt of the Paragraph IV notice letter as analyzed in *Celgene*: a separate act that occurs after and apart from the legally actionable submission of the ANDA.

This counterargument based solely on the FDA's regulatory text is ultimately unpersuasive. First, the FDA's regulations seem more like sloppy draftsmanship than a substantive statutory statement about when an ANDA is submitted. We only know retroactively that a filing is and can be correctly referred to as an ANDA—and not "the mere transmission of documents purporting to be an 'ANDA'"[149]—because the filing was properly received by the FDA. The FDA regulations thus appear to use "ANDA" as an inaccurate shorthand for the set of filed documents that is later

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144 *SB Pharmco*, 552 F. Supp. 2d at 508.

145 Kelly, *supra* note 23, at 424.

146 *Cf. United Sav. Ass'n*, 484 U.S. at 371.

147 *See SB Pharmco*, 552 F. Supp. 2d at 507–08; *Allergan*, 2014 WL 7336692, at *10–13.

148 21 C.F.R. § 314.101(b)(1) (2016) (emphasis added); *see also* 21 C.F.R. § 314.101(b)(2) (2016) ("If FDA determines, upon evaluation, that an ANDA was substantially complete as of the date it was submitted to FDA, FDA will consider the ANDA to have been received as of the date of submission.").

149 *Allergan*, 2014 WL 7336692, at *13.

confirmed, via receipt, to be a proper ANDA submission in the first instance.

A better response is that, as the Supreme Court noted, it is reasonable to construe Hatch-Waxman's language, and therefore the language of FDA's derivative regulations, based on "substantive intent."[150] To reemphasize, interpreting the word "submit" in 35 U.S.C. § 271(e)(2) to preserve the highly intentional ordering of events in Hatch-Waxman litigation, to conserve judicial resources, and to prevent premature or sham litigation is a stronger statutory construction than an overly literal reading based only on imprecisely drafted FDA regulations. In sum, the text of the statute should be primarily construed in light of the entirety of the Hatch-Waxman Act and its carefully crafted procedures, not in light of imprecise regulatory drafting. Doing so, in this case, requires reading the word "submit" to include receipt.

4. Receipt proximately causes Hatch-Waxman's statutory act of infringement.

The Supreme Court's jurisprudence on statutory causes of action also supports the idea that receipt of the ANDA by the FDA is fairly "*part of*"[151] the Hatch-Waxman Act's statutory cause of action. In *Lexmark International, Inc. v. Static Control Components, Inc.*,[152] the Court applied a proximate-cause-based analysis to determine limitations on liability in a Lanham Act false advertising claim. Although *Lexmark* addressed limitations on liability for *plaintiffs*, the same proximate cause principles logically apply in the Hatch-Waxman context, where the inquiry concerns limitations on liability for *actions*. Indeed, *Celgene*—by querying which acts are fairly "*part of*"[153] and not "merely 'related to'"[154] an ANDA submission—invoked reasoning much like that at play in tort proximate cause analysis. In turn, applying principles of proximate cause for statutory causes of action can help clarify *which* acts are part of Hatch-Waxman's cause of action. Once courts make that determination, they can more easily resolve the venue question of *where* those acts occur.

Lexmark stated that "a statutory cause of action is limited to plaintiffs whose injuries are proximately caused by violations of

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150 *Eli Lilly*, 496 U.S. at 679.

151 *Celgene*, 17 F.4th at 1121 (emphasis in original).

152 572 U.S. 118 (2014).

153 *Celgene*, 17 F.4th at 1121 (emphasis in original).

154 *Id.* (quoting *Valeant*, 978 F.3d at 1384).

the statute."[155]Although *Lexmark* noted that "[t]he proximate-cause inquiry is not easy to define," the Supreme Court considered it unobjectionable that "[p]roximate-cause analysis is controlled by the nature of the statutory cause of action."[156]When determining the limits of liability for statutory causes of action, "[t]he question . . . is whether the harm alleged has a sufficiently close connection to the conduct the statute prohibits."[157]

In Hatch-Waxman litigation, the ANDA submission is the statutory violation that proximately causes the plaintiff's injury.[158] Case law strongly suggests that proper receipt of an ANDA by the FDA is required for the legal harm related to Hatch-Waxman's act of infringement to become actionable.[159] More concretely, receipt by the FDA in Maryland is an event that proximately causes a generic applicant's filing of papers, legally, to become an actionable ANDA *submission*.[160] Importantly, the generic ANDA applicant directly causes the FDA to receive the ANDA by sending it to the agency. There is a direct causal chain linking filing, to receipt, to submission. And if the ANDA is not properly received by the FDA, there is, quite literally, no statutory cause of action and therefore no "unlawful conduct."[161] Receipt of an ANDA by the FDA, in conclusion, is not "'too remote' from the defendant's unlawful conduct" for legal liability to attach.[162]

5. Comparison with other areas of law supports the idea

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155 *Lexmark*, 572 U.S. at 132.

156 *Id.* at 133.

157 *Id.*

158 *Cf.* Pfizer Inc. v. Apotex, Inc., No. 08-cv-00948-LDD, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009) ("That holding suggests that the location of the injury in an infringement action based on an ANDA filing is the location of the preparation and submission of the ANDA." (citing Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1571 (Fed. Cir. 1994))). Though an ANDA submission does not result in a concrete injury at the time of filing, Congress recognized in Hatch-Waxman that a Paragraph IV ANDA filing initiates a causal chain that would lead, directly and almost inevitably, to a future concrete injury. *See Acorda*, 817 F.3d at 762 ("Congress deemed the ANDA filing to have a non-speculative causal connection to the ANDA filer's future infliction of real-world market injury on the patent holder.").

159 *See supra* Part III.A.2.

160 If the ANDA is not formally received by the FDA, there is a real risk that the generic has only sent, in Judge James Gilstrap's words, "the mere transmission of documents purporting to be an 'ANDA.'" *Allergan*, 2014 WL 7336692, at *13.

161 *Lexmark*, 572 U.S. at 133.

162 *Id.*

that receipt is part of the ANDA submission.

Finally, as with the submission of an ANDA, receipt of a document in other areas of law is often necessary to initiate causes of action or comply with statutory requirements.

Under the Fair Debt Collection Practices Act,[163] for example, venue is usually proper "in the plaintiff's home district" so long as "a collection agency had mailed a collection notice to an address in that district or placed a phone call to a number in that district."[164] Even a notice that is sent to one district and forwarded to a completely different and completely unintended district may create venue in the district where final receipt by the plaintiff occurs.[165] On the other hand, "if the notice were lost in the mail, it is unlikely that a violation of the Act would have occurred" in the first place.[166] In other words, the cause of action is created *only* upon receipt, and venue can be properly established in the district where receipt occurs.

Similarly, in the tax context, documents are generally "timely filed only if they were *physically delivered* to the IRS by the applicable deadline."[167] Furthermore, though Congress created a statutory exception to this physical delivery rule for tax documents, even the exception depends on actual physical delivery at some point.[168] "If the document is never delivered at all—say, because it gets lost in the mail—the exception by its terms does not apply."[169] As a final resort "[t]o protect against a failure of delivery, some taxpayers choose to send documents by registered

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163 Pub. L. No. 95-109, 91 Stat. 874 (codified as amended in 15 U.S.C. §§ 1692, 1692a–1692p).

164 Bates v. C & S Adjusters, Inc., 980 F.2d 865, 867–68 (2d Cir. 1992).

165 *See id.* at 868. Of course, venue under the Fair Debt Collection Practices Act is determined by the general venue statute, 28 U.S.C. § 1391, and not the patent venue statute. However, the language interpreted in *Bates*, 980 F.2d at 868, is largely similar to the acts of infringement prong from the patent venue statute. 28 U.S.C. § 1391(b)(2), the general venue statutory provision at play in *Bates*, allows a plaintiff to establish venue where a "substantial part of the events . . . giving rise to the claim occurred." 28 U.S.C. § 1391(b)(2); *see also Bates*, 980 F.2d at 868. This is essentially the same inquiry as the patent venue statute, which asks in part where the defendant "has committed acts of infringement." 28 U.S.C. § 1400(b).

166 *Bates*, 980 F.2d at 868.

167 Baldwin v. United States, 921 F.3d 836, 839–40 (9th Cir. 2019) (emphasis added), *cert. denied*, 140 S. Ct. 690 (2020).

168 *Id.* at 840 ("This exception means that a document will be deemed timely filed so long as two things are true: (1) the document is *actually delivered* to the IRS, even if after the deadline; and (2) the document is postmarked on or before the deadline." (emphasis in original)).

169 *Id.*

mail."[170] But even in that case, the registration acts as "prima facie evidence that the document was *delivered*, and the date of registration will be treated as the postmark date."[171] In other words, delivery of tax documents to the postal service, along with registration through the registered mail service, constitutes legal receipt by the IRS.[172]

These examples parallel what happens when an ANDA applicant submits their ANDA to the FDA. The FDA's historical treatment of mailed ANDAs is, in fact, analogous. Though ANDAs today are generally filed electronically,[173] the FDA has historically used a "date-of-receipt rule" rather than an "alternative mailbox rule" to govern some priority dates, including those for ANDA submissions.[174] This date-of-receipt rule implies that an ANDA submission occurs *no earlier* than the date on which the FDA receives the ANDA. Thus, the FDA's treatment of ANDA documents received in Maryland along with analogies to other fields of law supports the conclusion that receipt of an ANDA is part and parcel of the submission of the ANDA.

B. Centralizing Hatch-Waxman Venue in the District of Maryland is Justified on Policy Grounds

As demonstrated above, numerous legal arguments support reading the patent venue statute's acts of infringement prong to favor a centralized Hatch-Waxman venue in the District of Maryland. In addition, there are unique venue policy arguments that favor the District of Maryland as a centralized Hatch-Waxman venue. Moreover, the Federal Circuit has expressly noted policy considerations favoring a centralized Hatch-Waxman venue.[175] Future Hatch-Waxman litigants, invited by the Federal Circuit to define the "precise contours" of "what all relevant acts involved in the preparation and submission of an

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[170] *Id.*

[171] *Id.*

[172] There are similar provisions for electronic tax filings. *See Baldwin*, 921 F.3d at 841 n.1.

[173] *See supra* note 107.

[174] *See, e.g.*, *Purepac*, 354 F.3d at 889 (upholding the FDA's use of the date-of-receipt rule for physically mailed ANDAs).

[175] *Valeant*, 978 F.3d at 1383 ("Valeant does have strong policy reasons for adopting its reading of the statutes.").

ANDA might be," should come armed with policy arguments to support their legal reasoning.[176]

Specialized courts and centralized courts are familiar to patent litigants, as patent law has a variety of patent-specific methods for adjudicating claims.[177] The Federal Circuit itself is perhaps the quintessential example of a specialized patent court; it has limited and nearly exclusive appellate jurisdiction over patent cases.[178] Some district courts, too, can have certain judges specialize in patent cases by "designating" those judges as participants in the Patent Pilot Program.[179] There are also a number of specialized adjudicatory proceedings for patent matters that take place before administrative patent judges at the U.S. Patent and Trademark Office.[180]

Additionally, moving toward a centralized district court venue for Hatch-Waxman litigation could confer known benefits on Hatch-Waxman litigants. Patent litigation is already concentrated among a relatively small number of district courts—in some cases because of plaintiff-favorable local rules and in other cases because of a heavy technology-sector presence such as the computer industry in Northern California or the pharmaceutical industry in Delaware or New Jersey.[181] Patent litigants, in turn, are familiar with the benefits of judicial specialization at the district court level in patent matters. For example, the Eastern District of Virginia exclusively hears appeals from the Patent and Trademark Office and is praised for its "efficient handling of patent cases" and "bench of judges well-versed in the applicable

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176 *See id.* at 1384 n.8. For a discussion of arguments for and against specialized trial courts, see Amy Semet, *Specialized Trial Courts in Patent Litigation: A Review of the Patent Pilot Program's Impact on Appellate Reversal Rates at the Five-Year Mark*, 60 B.C. L. REV. 519, 532–35 (2019).

177 Other areas of federal law have specialized adjudicatory mechanisms, as well, including tax, bankruptcy, and immigration. *See* Melissa F. Wasserman & Jonathan D. Slack, *Can There Be Too Much Specialization? Specialization in Specialized Courts*, 115 NW. UNIV. L. REV. 1405, 1411–15, 1458 (2021).

178 *See id.* at 1414 n.36.

179 *See* Semet, *supra* note 176, at 539–40.

180 *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–305 (codified as amended in scattered sections of 35 U.S.C.) (creating the inter partes review proceeding); Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 138 S. Ct. 1365, 1379 (2018) (holding that "inter partes review does not violate Article III or the Seventh Amendment" of the U.S. Constitution); United States v. Arthrex, Inc., 141 S. Ct. 1970, 1988 (2021) (holding that the administrative patent judges that preside over inter partes reviews are inferior officers and therefore the Director of the Patent and Trademark Office, who is "nominated by the President and confirmed by the Senate" must have "discretion to review decisions rendered by [administrative patent judges]").

181 *See* Miller, *supra* note 69, at 767, 781–82 & tbl.1.

law."[182] The Districts of Delaware and New Jersey handle most Hatch-Waxman cases,[183] and some have suggested that this specialization results in increased judicial efficiency and predictability due to heightened experience among the judges of those courts.[184] And unlike some notoriously pro-plaintiff district courts with patent-heavy dockets, such as the Eastern District of Texas,[185] the District of Maryland may have specific favorable qualities as a neutral forum for pharmaceutical patent litigation, which offers benefits to both plaintiffs and defendants without unduly favoring either.[186] Relatedly, a centralized venue might also help avoid venue gamesmanship when generic applicants "seek[ ] to defend patent cases on their home turf or otherwise seek[ ] a more favorable forum."[187] In sum, moving toward a centralized venue for Hatch-Waxman litigation could have the beneficial result of enabling district court judges to develop special expertise in neutrally applying Hatch-Waxman's complicated rules. And, of course, centralized venue could meaningfully help avoid the Hatch-Waxman problem of duplicative litigation with potentially inconsistent results.[188]

Over two decades ago, in *Zeneca*, the Federal Circuit did state that the purpose of Hatch-Waxman was not "to create a national forum [for Hatch-Waxman litigation] in Maryland," [189] citing a broader "policy against the creation of national supercourts in the District of Columbia."[190] This policy statement is undermined, however, by the existence of the Federal Circuit itself, which had appellate jurisdiction over *Zeneca* only because of its near-exclusive mandate to review patent cases nationwide.[191] Indeed,

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[182] *See* Alexander Poonai, Note, *Hatch-Waxman in the Heartland: Achieving Fair Venue Reform in Pharmaceutical Litigation*, 27 FED. CIR. BAR J. 103, 121 (2017).

[183] Miller, *supra* note 69, at 803–04.

[184] *See, e.g.*, Katherine Rhoades, Comment, *Do Not Pass Go, Do Not Stop for Summary Judgment: The U.S. District Court for the District of Delaware's Seemingly Disjunctive Yet Efficient Procedures in Hatch-Waxman Litigation*, 14 NW. J. TECH. & INTELL. PROP. 81, 98–100 (2016).

[185] *See* Newton, *supra* note 51, at 267–68.

[186] *See* Poonai, *supra* note 182, at 121–22 ("The relative neutrality of the area in the pioneer/generic debate, combined with a plethora of educated, expert witnesses available to each party, should make the forum acceptable to both parties without offering an advantage to either.").

[187] Newton, *supra* note 51, at 260 (quotation marks omitted).

[188] *See supra* notes 89–99 and accompanying text.

[189] *Zeneca*, 173 F.3d at 833.

[190] *Id.* at 831.

[191] *See* Wasserman & Slack, *supra* note 177, at 1414 (noting that the Federal Circuit has "near-exclusive jurisdiction over patent appeals").

the Federal Circuit *is* a national supercourt in the District of Columbia.[192] It is true that the Federal Circuit's jurisdiction is conferred by statute, but the patent venue rules are also statutory. More concretely, the Federal Circuit's personal jurisdiction jurisprudence and venue jurisprudence has shifted dramatically since *Zeneca*. For Hatch-Waxman litigants, specific personal jurisdiction has broadened significantly since *Zeneca*,[193] but venue has proportionately narrowed.[194] The limitations on patent venue established by *TC Heartland* can cause serious efficiency problems for Hatch-Waxman litigation if plaintiffs cannot successfully consolidate litigation in a centralized venue before one district court and one judge. In short, things have changed since *Zeneca*. Perhaps for this reason, when the district court in *Valeant* stated that acts of infringement that were based on the ANDA submission occurred in the District of Maryland,[195] the Federal Circuit seemed prepared to embrace that reading.[196]

A generic ANDA applicant might nonetheless argue that a centralized Hatch-Waxman venue in the District of Maryland is neither fair nor reasonably convenient. Yet a predictable, neutral venue would prove fair and reasonably convenient to both parties because it would avoid the problem of national venue gamesmanship that the patent venue statute was enacted to combat.[197] Further, ANDA applicants would clearly be on notice when submitting filings to the FDA that the submission would constitute an act of infringement in Maryland that could establish venue. Far from facilitating abuse or gamesmanship, a centralized venue in Maryland would provide a single, predictable, and potentially specialized venue option for Hatch-Waxman litigation.

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192 *Cf. id.*

193 *Cf. Acorda*, 817 F.3d at 762–63.

194 *See TC Heartland*, 137 S. Ct. at 1521.

195 *See Valeant*, 978 F.3d at 1378 ("[T]he [district] court concluded that the two places where an act of infringement might have occurred before the filing of the action were West Virginia and Maryland.").

196 *See id.* at 1384 n.8 ("While it may well be that the District of Maryland satisfies the test for venue that we have laid out here, we do not resolve that question.").

197 The Federal Circuit has recognized that "Congress adopted the predecessor to § 1400(b) . . . to eliminate the 'abuses engendered' by previous venue provisions allowing such suits to be brought in *any district* in which the defendant could be served." *In re* Cray Inc., 871 F.3d at 1361 (quoting Schnell v. Peter Eckrich & Sons, Inc., 365 U.S. 260, 262 (1961)) (emphasis added). In this sense, centralizing venue in Maryland is a far cry from the situation repudiated by *TC Heartland*, where patent plaintiffs could establish venue nationwide.

CONCLUSION

Hatch-Waxman litigation presents unique problems for courts and litigants. The Hatch-Waxman act of patent infringement is "highly artificial"[198] and consists of nothing more than submitting a tightly structured application to a federal regulatory body. The patent venue statute, too, ties one prong of the venue inquiry to the act of patent infringement that is being litigated in the first instance. Hatch-Waxman litigants thus face the confusing scenario where the patent infringement cause of action is tied to actions taken before an administrative agency, the procedural rules for venue are tied in part to the act of patent infringement, and the entire course of litigation is designed to resolve patent disputes in advance of actual, commercial sales using a statute crafted specifically for the pharmaceutical industry.

TC Heartland imposed limitations on venue for patent infringement litigants, and those limitations can result in significant judicial inefficiency in the Hatch-Waxman context. In *Valeant*, the Federal Circuit resolved some of the complexity associated with Hatch-Waxman venue but created new questions. In particular, the Federal Circuit concluded that the "plain language of the two statutes at issue" compelled an inflexible reading of the patent venue statute that precluded a centralized venue in Hatch-Waxman litigation.[199] As this Comment has demonstrated, however, the same statutes are fairly and readily interpreted to move toward a centralized Hatch-Waxman venue in the District of Maryland.

Moving toward a centralized Hatch-Waxman venue would make the patent venue rules work in unison with Hatch-Waxman's substantive provisions, furthering the legislative goal of achieving a "fine balance between the interests of generic and pioneer drug companies."[200] Centralizing Hatch-Waxman venue would help courts. With a centralized Hatch-Waxman venue, district court judges would not need to worry about the possibility of inconsistent judgments on essentially identical arguments in different districts. Centralizing Hatch-Waxman venue would also help litigants. Specialization among judges promotes judicial efficiency and predictability; consolidation of duplicative arguments

198 Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

199 *Valeant*, 978 F.3d at 1385.

200 Kelly, *supra* note 23, at 418.

in complex, multi-defendant cases preserves resources; and a centralized venue can clarify the venue inquiry that arises at the start of litigation. Finally, centralizing Hatch-Waxman venue would help achieve Hatch-Waxman's broader goal of efficiently resolving any patent "infringement dispute . . . before the generic drug hits the market."[201]

[201] *Id.* at 424.