No. 19-2402

In the United States Court of Appeals for the Federal Circuit

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., AND KAKEN PHARMACEUTICAL CO., LTD.,
PLAINTIFFS-APPELLANTS

v.

MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES LTD., AND MYLAN INC.,
DEFENDANTS-APPELLEES

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY, NO. 3:18-CV-14305, HON. PETER G. SHERIDAN, PRESIDING

DEFENDANT-APPELLEES' BRIEF IN OPPOSTION TO VALEANT'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Appellees certifies the following:

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1): Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd., and Mylan Inc.

2. Real Party in Interest. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2): none.

3. Parent Corporations and Stockholders. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3): Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc. Mylan Laboratories Ltd. is a subsidiary of Mylan Inc. Mylan Inc. is wholly owned by Viatris Inc., a publicly held company. No publicly held company owns 10% or more of Viatris Inc.'s stock.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47(a)(4):

- Wilson Sonsini Goodrich & Rosati, P.C.:

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- Saiber LLC:

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). *See also* Fed. Cir. R. 47.5(b):

- *In re Jublia,* C.A. No. 18-13635-BRM-LHG (Consolidated) (D.N.J.)
- *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.,* C.A. Nos. 18-00184-IMK and 19-cv-00037-IMK (N.D.W. Va.)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6): None/Not applicable.

Dated: January 5, 2021

/s/ Steffen N. Johnson
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ANDA	Abbreviated new drug application
MLL	Mylan Laboratories Limited
MPI	Mylan Pharmaceuticals Inc.

INTRODUCTION

Valeant has not begun to show that the panel's unanimous decision gives rise to "exceptional" circumstances warranting en banc review. Cir. R. 35(b)(2). Valeant prefers the regime it enjoyed for "36 years" (Pet. 4)—invoking 28 U.S.C. § 1391 and suing generics wherever there is personal jurisdiction. But *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017), which Valeant never cites, ended that regime. None of the cases cited in support of Valeant's "conflict" claims even involved venue, let alone evidence a genuine conflict. And as all four judges to hear this case have agreed, black-letter rules of statutory interpretation compel the result, which serves venue law's purpose—safeguarding defendants' convenience.

The second prong of the patent venue statute allows patentees to file suit only where the defendant "has committed acts of infringement." 28 U.S.C. § 1400(b). All agree that "the plain language" of the statute "requires a past act of infringement"; it "must have already occurred." Op. 13. And as the panel explained, "Congress's choice of … the present tense" elsewhere in § 1400(b) confirms that its choice to require "infringement in the past was intentional." Op. 13.

The only "past act of infringement" alleged here is MPI's submission of an ANDA prepared in West Virginia and sent to FDA. Nothing happened in New Jersey. As Valeant admits, the only allegations supporting venue there involve possible "future acts"—"acts of making, using, and selling" MPI's product. Pet. 5, 6. Indeed,

Valeant openly demands that the Court treat "future" acts "as having happened in the past," "even though they have not yet occurred." *Id*. But the future is not the past.

Valeant notes that in defining the ANDA submission as an "act of infringement," Congress added: "if the purpose of such submission is to obtain approval" of the "commercial manufacture, use, or sale" of the related ANDA product. 35 U.S.C. § 271(e)(2)(C)(ii); Pet. 6. Yet Congress required only the purpose to obtain FDA approval, not to sell in any particular market—let alone "nationwide." Pet. 2. Further, a "purpose" is a mental state; it has no place. Section 1400(b) keys off the location of the "act of infringement," which remains "submission" of the ANDA. And as the panel noted, the Supreme Court and this Court "[c]onsistently … have warned" that "the requirement of venue is specific and unambiguous," "not one of those vague principles which, in the interests of some overriding policy, is to be given a liberal construction." Op. 10 (citations omitted). Valeant never mentions these precedents.

Enforcing § 1400(b)'s terms is not unfair to brands. Had the shoe been on the other foot, MPI could not have sought a declaratory judgment anywhere nationwide, or even where Valeant "resides"—only "where [it] has its principal place of business or a regular and established place of business." 21 U.S.C. § 355(j)(5)(C)(i)(II). Both § 1400(b) and § 355(j) serve "the convenience of litigants," venue's traditional

concern, by limiting where parties may be sued. *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 167-68 (1939). And Valeant has a reasonable forum: It separately sued MPI in West Virginia, and the case advanced past fact discovery during this appeal.

Indeed, the panel's decision simply treats ANDA submissions like other pre-launch infringement. Other patentees that wish to challenge pre-launch activity as infringing may not, by citing possible "future" nationwide sales, sue wherever they like; venue exists only where the defendant "has committed" such pre-launch infringement. Hatch-Waxman differs only in the details. Aware that generic drugs must be tested for bioequivalence with branded drugs, Congress created a safe harbor—pre-approval product development that otherwise might infringe "shall not be an act of infringement." 35 U.S.C. § 271(e)(1). Yet Congress wished to facilitate pre-launch patent litigation, so "an[other] act of infringement had to be created." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). Congress thus replaced one potential "act of infringement" (pre-approval R&D) with another (submitting an ANDA), while granting brands an automatic 30-month stay of FDA approval while the parties litigate. 21 U.S.C § 355(j)(5)(B)(iii). Valeant calls it "artificial" to treat ANDA submissions as infringing. Pet. 7–8. But as the panel recognized, Hatch-Waxman "never says the act that constitutes infringement is artificial"; "[i]t speaks in real terms—submission of the ANDA *is* the infringing act." Op. 14. In short,

"[t]he patent statute treats such a filing as itself an act of infringement." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012).

Once these points become clear, nothing remains of Valeant's petition. None of Valeant's "conflict" cases involve venue; some involve unusual "extraterritorial infringement" issues (Op. 11 n.7); and some were not cited in Valeant's opening brief. In any event, as the panel held, the "merits" question of whether an ANDA product would infringe does not "turn potential future acts into past infringement" (Op. 15), and the "conceptual dimension" of infringement applicable to some sales and offers does not authorize nationwide venue based on a regulatory submission. Op. 17.

Valeant's policy claims are equally unfounded. By Valeant's lights, the panel decision lets generics "'game' the system to avoid venue in certain jurisdictions." Pet. 4 (citing Op. 17). But the ANDA here was entirely prepared at and submitted from MPI's headquarters of 65 years, not an odd location chosen for alleged strategic advantage. The panel thus declined to "define what all relevant acts involved in the preparation and submission of an ANDA might be, leaving those questions for other cases." Op. 19 n.8. And regardless, "policy arguments cannot trump the plain language of § 271(e)(2)" and "§ 1400(b)." Op. 18.

In sum, the panel's decision is unassailably correct, and Valeant's conflict and policy arguments are unfounded. Review should be denied.

STATEMENT

Valeant filed suit in New Jersey against Mylan Pharmaceuticals Inc. ("MPI"), a West Virginia corporation based in Morgantown, West Virginia; Mylan Inc., a Pennsylvania corporation based in Canonsburg, Pennsylvania; and Mylan Laboratories Ltd. ("MLL"), a foreign corporation based in India. The complaint alleged patent infringement under 35 U.S.C. § 271(e)(2), but no defendant resides in New Jersey, and it is undisputed that the only "act of infringement" that any defendant allegedly "has committed" (28 U.S.C. § 1400(b)) is submitting an ANDA, prepared at MPI's "West Virginia corporate office" and sent from there "to the FDA." Op. 4. MPI's ANDA seeks approval to market efinaconazole, a generic version of the drug Jublia®.

To support venue in New Jersey, Valeant's complaint speculated that Defendants would "[market the] proposed ANDA products in New Jersey upon approval of [the] ANDA." Op. 5; *see* Appx148, 1104. A day later, Valeant filed a second "protective" suit in the Northern District of West Virginia, where venue is undisputed. Op. 5. While this appeal was pending, that suit progressed beyond the *Markman* hearing and fact discovery closed.[1]

[1] On December 30, 2020, the West Virginia litigation settled on terms contingent upon the outcome of this case.

Citing the undisputed fact that no past infringement is alleged in New Jersey, MPI and Mylan Inc. moved to dismiss Valeant's New Jersey complaint on venue grounds.[2] Valeant responded that, "in the Hatch-Waxman context, the language of § 1400(b) must be deemed to contemplate … planned future conduct." Op. 6. The district court disagreed, holding that Valeant's position conflicts with "a plain reading of the statute, which is clear: only where a defendant has committed an act of infringement may a party bring a patent suit." Op. 7.

Valeant appealed, initially citing *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016), a personal jurisdiction case (Opening Br. 6, 18, 29-33), and arguing that applying the ordinary meaning of § 1400(b) would render its second prong "superfluous" (*id.* at 25-26). On reply, Valeant newly invoked various non-venue, non-§ 271(e)(2) infringement decisions. Reply Br. 16-19.

The panel unanimously affirmed as to MPI and Mylan Inc., holding that "the plain language of the statutes" "requires a past act of infringement." Op. 13. The panel rejected the notion that Hatch-Waxman infringement analysis, which focuses on the ANDA product that will eventually be sold, somehow "turn[s] potential future

[2] MLL sought dismissal under Rule 12(b)(6). Without explicitly stating that Valeant failed to state a claim against MLL, the district court dismissed all defendants. The panel reversed as to MLL, remanding for resolution of "whether Valeant plausibly alleged sufficient involvement" by MLL in the ANDA submission. Op. 20.

acts into past infringement" for venue purposes, stressing that precedent "[c]onsistently … ha[s] warned" that the venue requirement "is specific," "unambiguous," and not amenable to "a liberal construction." Op. 15, 10 (citations omitted).

The panel meticulously considered and rejected Valeant's other arguments. For example, it explained that "[t]he practical significance of *Acorda*," a personal jurisdiction case decided by the same three judges, "was markedly contracted" by *TC Heartland*," and could not be "stretch[ed]" to alter "the venue analysis." Op. 18. Concerning Valeant's infringement precedents, the panel noted that treating an ANDA filing as "a nationwide act" based on "a 'conceptual' aspect" of infringement lacked "any textual hook in the statute" and was "a bridge too far." Op. 17. Finally, the panel concluded that "[Valeant's] policy arguments cannot trump the plain language of § 271(e)(2)" and "§ 1400(b)." Op. 18.

REASONS FOR DENYING THE PETITION

I. The panel correctly applied black-letter rules of statutory interpretation in concluding that venue is proper only where a past act of infringement "has occurred."

The unanimous panel correctly interpreted both 28 U.S.C. § 1400(b) and 35 U.S.C. § 271(e)(2) in accordance with their ordinary meaning and their underlying purposes. That alone warrants denying review.

A. The plain language of the second prong of Section 1400(b), which requires an allegation that the defendant "has committed an act of infringement," compels the outcome here.

In crafting the second prong of the patent venue statute, Congress unambiguously restricted venue to districts where the defendant allegedly "has committed acts of infringement." 28 U.S.C. § 1400(b). And as the unanimous panel recognized, the "plain language" of that provision "requires a past act of infringement." Op. 13. Specifically, Congress used the "present perfect" verb tense, meaning "the acts accused of infringement must have already occurred." *Id*. Further, Congress "included two phrases … in the present tense ('where the defendant resides' and 'where the defendant … has a regular and established place of business')," confirming "that its choice to place the infringement in the past was intentional." *Id*.

This analysis is correct. The "present perfect" tense looks backward to "act[s] that ha[ve] been completed." *Barrett v. United States*, 423 U.S. 212, 216 (1976). And where Congress uses both "present" and "present perfect" tense (*id.* at 217), its choice to limit the "statute's temporal reach" (*Carr v. United States*, 560 U.S. 438, 448 (2010)) cannot be deemed "unintended." *Barrett*, 423 U.S. at 217.

Valeant alleges just one "past act of infringement": MPI's submission of an ANDA prepared in West Virginia and sent to FDA. Appx 370. All agree that nothing has happened in New Jersey. *Id*.; Opening Br. 31. Thus, to show venue there, Valeant alleges speculative "future acts"—"acts of making, using, and selling"

MPI's product. Pet. 5, 6. Valeant readily admits that these acts "have not yet actually occurred." Pet. 5. Nevertheless, it insists on a special rule for Hatch-Waxman cases—treating "future acts of making, using and selling the generic product as having happened in the past." Pet. 6. Not surprisingly, Valeant never tries to reconcile its "conceptual" reading (Pet. 12) with the text of § 1400(b) or the many precedents holding that "the requirement of venue is specific and unambiguous," "not one of those vague principles which, in the interests of some overriding policy, is to be given a liberal construction." Op. 10 (citations omitted).

We need not dwell on the fact that § 1400(b) looks backward in time, as it is obvious and Valeant supposedly accepts it. Op. 13. Indeed, after citing § 1400(b) in its Rule 35 statement, Valeant never again *mentions* the patent venue statute. Yet that omission is telling: Valeant acts as though its "act of infringement" analysis can be divorced from § 1400(b). It cannot. To establish venue, Valeant must satisfy both § 271(e)(2) and § 1400(b). Whatever infringement means, "the acts accused of infringement must have already occurred." *Id.*

B. The text, structure, and purpose of Section 271(e) further support the panel's unanimous decision.

Section 271(e) as a whole powerfully supports the panel's holding. As Valeant itself alleges, the ANDA filing is an "act of infringement" under § 271(e)(2). Appx153-154. Seizing on § 271(e)(2)'s "purpose" language, however, Valeant says that straightforward act should be reconceptualized as embodying a raft of "future

acts" allegedly "intended" by that submission. Pet. 5-6. According to Valeant, those *yet-to-happen acts* are "*what* the act of infringement is under section 271(e)(2)." Pet. 6. Valeant is mistaken.

1. Section 271(e)(2) makes it "an act of infringement to submit [an ANDA]" to FDA "if the purpose of such submission is to obtain approval … to engage in the commercial manufacture, use, or sale" of the ANDA product. The only "purpose" that Congress required is to obtain FDA approval, not to market the drug in any particular market, much less "nationwide." Pet. 2. And while Congress made the "purpose" of obtaining FDA approval a *condition* for treating the ANDA filing as an infringing act, "[t]he patent statute treats such a filing as itself an act of infringement." *Caraco*, 566 U.S. at 407.

Section 1400(b), moreover, focuses on the *location* where the defendant "has committed an act of infringement." A "purpose" is a mental state, not a place. In short, § 271(e)(2) "does not … turn potential future acts into past infringement" for venue purposes; rather, as the panel understood, "it is the submission of the ANDA, and only the submission, that constitutes an act of infringement"—and here, that happened in West Virginia. Op. 14.

2. The structure of § 271(e) confirms the ordinary meaning of § 271(e)(2). Take § 271(e)(1), which Valeant references only in passing. Pet. 8. To facilitate testing generic drugs for bioequivalence with their branded counterparts, Congress

crafted a safe harbor for pre-launch generic drug development that otherwise might infringe. 35 U.S.C. § 271(e)(1) (such activity "shall not be an act of infringement"). As a result, however, "an[other] act of infringement had to be created" to "enable … judicial adjudication" of infringement claims before the product launch becomes imminent. *Medtronic*, 496 U.S. at 678. Enter § 271(e)(2), which defines the ANDA submission as an "act of infringement."

Once § 271(e)(2) is understood as creating a substitute for other *pre-launch* "acts of infringement," it makes perfect sense to limit venue to the place where the pre-launch ANDA submission occurs. That approach treats Hatch-Waxman plaintiffs the same as other patentees seeking to enjoin, say, pre-launch manufacturing; to establish venue in such cases, it is insufficient to allege possible future sales in the district; venue is limited to where the defendant already "has committed" infringement. *See Liqui-Box Corp. v. Reid Valve Co.*, 672 F. Supp. 198, 199 (W.D. Pa. 1987) (dismissing for lack of past manufacturing or sales in the district); *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc.*, 2018 WL 2387234, at *8 (E.D. Tex. Mar. 7, 2018) (dismissing for improper venue after concluding that the alleged acts of infringement involved clinical trial activity covered by the safe harbor).

3. Hatch-Waxman's remedial provisions further confirm the panel's interpretation. Citing the phrases "the patent *which has been infringed*" and "an infringer" in § 271(e)(4)(A)-(C), Valeant says Congress viewed the *proposed* acts of

marketing generic products "as having been committed in the past." Pet. 9. But obtaining any remedy requires proof, not just allegations. And Valeant's theory proves too much: if Hatch-Waxman "turn[s] potential future acts into past infringement" for remedial purposes (Op. 15), then § 271(e)(4)(C) would authorize "damages" in pre-launch suits, since the statute would *deem* "commercial manufacture, use, offer to sell, or sale" to have already occurred. Yet Valeant asserts no damages claim (Appx166-168)—powerful confirmation that no defendant here "has committed an act of infringement" beyond filing an ANDA, and that Valeant's reading of "acts of infringement" is divorced from its ordinary meaning, even elsewhere in Hatch-Waxman. *Compare also* § 271(e)(4)(B) (authorizing "injunctive relief … to prevent [§ 271(a) infringement]) *with* § 271(e)(4)(C) (authorizing "damages … only if there has been [§ 271(a) infringement]).

II. Valeant's claims of a conflict with precedent rest on far-afield cases and ignore the governing venue precedents.

Lacking support in the statute's text or structure, Valeant says the panel's decision conflicts with precedent. But *none* of Valeant's cases involve venue, let alone the second prong of § 1400(b). Some involve personal jurisdiction, some involve "extraterritorial infringement" (Op. 11 n.7), and some were not cited in its opening merits brief. Beyond the fact that theories based on the latter cases are forfeited, the panel rightly rejected Valeant's strained arguments from precedent. Op. 17.

Valeant's main claim of "conflict" rests on two non-venue infringement cases: *Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562 (Fed. Cir. 1997), and *Warner-Lambert Co. v. Apotex Corp*., 316 F.3d 1348 (Fed. Cir. 2003). Pet. 7, 10-11. But those cases address how to *prove* that an ANDA submission infringed, and all agree that "'the patentee's burden of proving ultimate infringement is not met by the filing of the ANDA.'" Pet. 5 (quoting *Glaxo*, 110 F.3d at 1570); *see also Warner-Lambert*, 316 F.3d at 1355-56 ("the statute does not make the filing of an ANDA prior to patent expiration an act of infringement unless the ANDA seeks approval to manufacture, use, or sell [an infringing] drug"). That does not distinguish Hatch-Waxman cases from other patent cases in which the patentee sues before the accused product is launched, seeking to *enjoin* future sales.

Indeed, *Glaxo* itself distinguishes what Valeant conflates: the "occurrence of the defined 'act of infringement'" and "the ultimate question whether what will be sold will infringe," which is another way of asking whether "the ANDA applicant's paragraph IV certification is incorrect." 110 F.3d at 1569. *Glaxo*'s analysis of the latter question—how to prove that a completed ANDA submission infringed in the unusual case where "the ANDA application" and its "extensive" supporting documentation are inconclusive—is irrelevant to the question here, which is *where* "the defined 'act of infringement'" occurred. *Id.* The panel preserved this distinction between the "merits" inquiry and the venue inquiry. Op. 15.

Next, Valeant (Pet. 11-13) invokes two other non-venue cases—*North American Philips Corp. v. American Vending Sales, Inc.,* 35 F.3d 1576 (Fed. Cir. 1994), a personal jurisdiction case, and *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc*., 617 F.3d 1296 (Fed. Cir. 2010), an extraterritorial infringement case. These decisions appeared nowhere in Valeant's opening merits brief (Dkt. 34) and need not be considered. *Commc'ns Test Design v. Contec, LLC*, 952 F.3d 1356, 1363 n.4 (Fed. Cir. 2020) ("[A]n issue not raised by an appellant in its opening brief is waived."). But regardless, they have nothing to do with Hatch-Waxman, and the panel rightly rejected the notion that they support venue in New Jersey. Op. 17.

Philips and *Transocean* applied common-law sales concepts to conclude that (1) an infringing sale occurred at the buyer's location, thus supporting personal jurisdiction (*Philips*, 35 F.3d at 1579), and (2) in "extraterritorial infringement" cases, sales and offers for sale may be treated as occurring at the "location of anticipated performance" *and* "the location of contracting." Op. 11 n.7, 17 (citing *Transocean*, 617 F.3d at 1309-11). Valeant's position is "markedly more expansive," as it would require holding "that the literal act of infringement—submission of the ANDA—encompasses a vast 'conceptual' element of nationwide infringement." Op. 17. It would do so, moreover, in a context governed by specific statutory language—not by "common law"—yet without "any textual hook." *Id*. As the panel understood,

that is "a bridge too far." *Id.*; *see In re Cray Inc.*, 871 F.3d 1355, 1361 (Fed. Cir. 2017) (courts must not "conflate showings that may be sufficient for other purposes, *e.g.*, personal jurisdiction or the general venue statute, with the necessary showing to establish proper venue in patent cases.").

While invoking irrelevant cases, Valeant ignores critical precedent. It decries losing "36 years" of freedom to sue Hatch-Waxman defendants nationwide (Pet. 4), but never cites *TC Heartland*. And it criticizes the panel's "narrow reading" of "act of infringement" (Pet. 6), but ignores precedent holding that § 1400(b) is "unambiguous" and not "given a liberal construction." Op. 10. Those decisions control.

III. Valeant's policy arguments are unfounded, and would not warrant en banc review regardless.

Nor do Valeant's policy arguments warrant rehearing. For example, Valeant cites the hypothetical possibility that generics might try to "'game' the system" and obtain an advantage by filing ANDAs in places unconnected with their preparation. Pet. 4. As the panel recognized, even if that risk were real, it could not "trump the plain language of § 271(e)(2)" and "§ 1400(b)." Op. 18. But there was no gamesmanship here. The ANDA was prepared and submitted entirely from MPI's West Virginia headquarters, its home since the 1960s. Nothing happened in New Jersey. And as the panel recognized, if genuine gamesmanship issues arise, they can be addressed in "other cases where the precise contours are presented and briefed." Op. 19 n.8.

Where Congress's venue restrictions require brands to sue in multiple districts (Pet. 4), that is largely a collateral effect of *TC Heartland*; it does not justify rewriting § 1400(b).[3] Joinder and consolidation remain possible "where[ver] venue is proper." *In re EMC Corp.*, 677 F.3d 1351, 1360 (Fed. Cir. 2012); *see* Fed. R. Civ. P. 42(a) (permitting consolidation based on "common question[s] of law or fact"); Fed. R. Civ. P. 20(a) (allowing joinder in similar circumstances); 35 U.S.C. § 299 (exempting Hatch-Waxman cases from some limitations, *not* including venue, on consolidation and joinder). Further, "civil actions involving one or more common questions of fact … may be transferred to any district for coordinated or consolidated pretrial proceedings." 28 U.S.C. § 1407(a). And many aspects of separate lawsuits may be voluntarily coordinated—just as the parties did here.

Finally, if *Mylan* had sought a declaratory judgment here, it could not have sued nationwide, or even where Valeant "resides"—only "where [it] has its principal place of business or a regular and established" one. 21 U.S.C. § 355(j)(5)(C)(i)(II). There is no unfairness whatsoever in Congress's decision to impose comparable limitations on the locations where generics may be sued.

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[3] Valeant's lone amicus presses a theory that Valeant has abandoned: "Hatch-Waxman cases should be analyzed under the general venue statute." Br. 4–12. *TC Heartland* forecloses that view. 137 S. Ct. at 1519 ("§ 1400(b) 'is the sole and exclusive provision controlling venue in patent infringement actions'" and "'is not to be supplemented by … § 1391(c)'") (citation omitted) (ellipsis in original).

CONCLUSION

For the foregoing reasons, en banc rehearing should be denied.

Respectfully submitted,

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JANUARY 5, 2020

CERTIFICATE OF SERVICE

I certify that, on January 5, 2020, I caused the foregoing Corrected Brief for Defendants-Appellants to be electronically filed with the Clerk of Court using the CM/ECF system, and thereby served via CM/ECF on counsel for Plaintiffs-Appellees.

Date: JANUARY 5, 2020

/s/ Steffen N. Johnson
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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS, AND TYPE STYLE REQUIREMENTS

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3,819 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii) and Federal Circuit Rule 32(b).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word 2010.

Dated: JANUARY 5, 2020

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