No. 16-341

IN THE

Supreme Court of the United States

TC HEARTLAND LLC, D/B/A HEARTLAND FOOD PRODUCTS GROUP,

Petitioner,

v.

KRAFT FOODS GROUP BRANDS LLC,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*[1] AND SUMMARY OF ARGUMENT

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA members' research and development (R&D) efforts produce the innovative medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day. From 2000 to 2015, PhRMA members obtained approval for over 550 new medicines and invested over half a *trillion* dollars in R&D. In 2015 alone, PhRMA members' R&D expenses exceeded an estimated $58.8 billion—or roughly one quarter of total domestic sales of pharmaceuticals. PhRMA seeks to protect these significant financial investments by supporting public policies that foster, reward, and protect innovation. To that end, PhRMA frequently participates as an *amicus* in cases that affect the pharmaceutical industry and particularly those that involve important issues affecting intellectual property and protecting patent rights.

This is one of those cases. Since Congress amended the relevant statutory provisions in 1988—and again in 2011—it has been clear that an infringement claim against a corporate defendant may be brought in any district where the company is subject to personal jurisdiction. 28 U.S.C. §§ 1391(c)(2), 1400(b). Section

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[1] Pursuant to Rule 37.6, PhRMA affirms that no counsel for a party authored this brief in whole or in part and that no person other than PhRMA, its members, or their counsel made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to Rule 37.3(a), counsel of record for both parties have consented to the filing of this amicus brief.

1391(c) *defines* residency as coterminous with personal jurisdiction for "all venue purposes." There is nothing in the structure or history of the statute or in any interpretive canon that supports Petitioner's attempt to avoid the straightforward reading of these provisions.

Petitioner and its *amici*, however, do not like the regime that Congress has twice enacted, largely because an extraordinary number of patent lawsuits are filed in a single district court in Texas. But that *policy* concern cannot legitimately override Congress's statutory text. Worse still, the policy concerns that animate Petitioner and its *amici* simply ignore the many reasons why *changing* the current statutory regime would lead to chaotic results that Congress could not possibly—and plainly did not—intend. Because Congress has legislated in the face of such policy concerns and made a decision, any change to that decision—if there is one—ought to come from Congress, not the courts.

One glaring illustration of the problems posed by the regime Petitioner advocates is litigation over Abbreviated New Drug Applications (ANDAs), which is governed by the Hatch-Waxman Act. Among that statute's carefully crafted balances is a process through which generic drug makers can piggyback on patent holders' expensive clinical testing efforts and, simultaneously, force accelerated litigation over the relevant patents. In particular, ANDA filings incentivize generic companies to allege that the innovators' patents are invalid, unenforceable, or would not be infringed by the proposed generic. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute then creates "a highly artificial act of infringement that consists of submitting an ANDA … that is in error as to whether commercial manufacture, use, or sale of the new [ge-

neric] drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 678 (1990); see also 35 U.S.C. § 271(e)(2). Bringing such a "highly artificial" infringement claim in a timely manner automatically stays generic approval for up to 30 months to allow for expeditious resolution of the dispute.

These ground rules effectively invert the normal litigating posture by allowing the would-be infringer to trigger a lawsuit. ANDA filings overtly initiate conflict with patent holders, and yet the filing generic companies almost always wind up as defendants in these cases because the innovator manufacturer has little practical choice but to sue to protect its patents. The Hatch-Waxman Act's particular definition of infringement thus repositions patent holders from defendants in a declaratory judgment action to plaintiffs in name only.

The current venue provisions fully and fairly accommodate the features of ANDA litigation. Approval of a new, patented medicine is regularly followed by multiple ANDAs—sometimes more than a dozen—all challenging the innovating manufacturer's patents. However, inventors can usually consolidate the ensuing and virtually identical litigation into a single district, yielding obvious and substantial economies. Ordinarily, there is at least one venue in which each patent challenger is subject to personal jurisdiction. The availability of a single forum allows for coordination of discovery and briefing and conserves judicial resources, thereby upholding a fundamental purpose of procedural law: "to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1.

Petitioner TC Heartland and *amicus* Generic Pharmaceutical Association (GPhA) nevertheless ask

this Court to supplant Congress's definition of "reside" with a just-for-patent-law definition that would force pharmaceutical patent holders to chase ANDA filers all over the country. The result would be redundant litigation over the same drug, which serves no purpose except to invite harassment, enable and encourage inconsistent results, and waste the innovator's time and resources. ANDA filings represent the generic companies' request for approval to sell a drug *nationwide*, yet the generic companies argue that venue is not proper wherever personal jurisdiction exists over them. GPhA Br. 3, 10–11. GPhA's unhappiness with recent decisions concerning the scope of personal jurisdiction in ANDA litigation, *id.*, does not remotely justify contorting the plain language of the venue statute to guarantee cumbersome and wasteful litigation.

At bottom, this case is nothing more than a request for an ill-conceived, one-size-fits-all judicial end-run around existing legislative policy decisions. If there is any change to the venue rules—and there should not be—Congress is the branch properly suited to weigh the many complex considerations at play and is, indeed, already well aware of these very issues. Because Petitioner's and GPhA's preferred result is irreconcilable with the text, structure, and history of the statutes and would lead to harmful and wasteful consequences, the Court should affirm.

ARGUMENT

Through amendments enacted over recent decades, Congress has expanded venue options in suits against corporate defendants, bringing clarity while ensuring a baseline of fairness. See, *e.g.*, 14D Charles A. Wright & Arthur R. Miller et al., *Federal Practice and Procedure* § 3802, at 37 (4th ed. 2013) (Congress

has "nearly eliminate[d] venue as a separate restriction in cases against corporations"). Petitioner wants a different rule—one that returns to a patent-specific venue standard long ago abrogated by Congress. See *Fourco Glass Co.* v. *Transmirra Prods. Corp.*, 353 U.S. 222 (1957). This textually unsupported proposal would result in duplication and waste throughout high-stakes ANDA litigation. The Court should reject it.

I. SECTION 1391(C)'S DEFINITION OF RESIDENCY EXPRESSLY APPLIES TO PATENT INFRINGEMENT LITIGATION.

Certain groups principally concerned about cases concentrated in the Eastern District of Texas have mounted a campaign to convince federal courts that §§ 1391(c) and 1400(b) mean something very different from what they say.[2] But the arguments behind that campaign are hollow: they avoid the plain text and rest on canons of statutory construction that have no applicability to the provisions as they exist today.

A. The Statutes' Meaning Is Clear.

The plain meaning of §§ 1391(c) and 1400 is more than sufficient to dispose of this case. Section 1391(c) provides that, "[f]or *all* venue purposes," a corporate

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[2] *See*, *e.g.*, *Script Sec. Sols. L.L.C.* v. *Amazon.com, Inc.*, 170 F. Supp. 3d 928, 930–34 (E.D. Tex. 2016); *Gro Master, Inc.* v. *Farmweld, Inc.*, 920 F. Supp. 2d 974, 985–87 (N.D. Iowa 2013); *Saint-Gobain Calmar, Inc.* v. *Nat'l Prods. Corp.*, 230 F. Supp. 2d 655, 657–58 (E.D. Pa. 2002); *Haddad Bros.* v. *Little Things Mean A Lot, Inc.*, No. 00CIV.0578, 2000 WL 1099866, at *6–7 (S.D.N.Y. Aug. 4, 2000); *PKWare, Inc.* v. *Meade*, 79 F. Supp. 2d 1007, 1017–18 (E.D. Wis. 2000); *Braden Shielding Sys.* v. *Shielding Dynamics of Tex.*, 812 F. Supp. 819, 821 (N.D. Ill. 1992); *Kinetic Inst., Inc.* v. *Lares*, 802 F. Supp. 976, 987–88 (S.D.N.Y. 1992); *Injection Research Specialists* v. *Polaris Indus., L.P.*, 759 F. Supp. 1511, 1512–16 (D. Colo. 1991).

defendant shall be deemed to reside "in any judicial district in which such defendant is subject to the court's personal jurisdiction with respect to the civil action in question." 28 U.S.C. § 1391(c)(2) (2012) (emphasis added). For patent infringement cases, § 1400(b) then provides that venue is proper "in the judicial district where the defendant resides." *Id.* § 1400(b). Together, these statutes mean that a corporate defendant in a patent infringement case "resides" in any district where it is subject to personal jurisdiction. Since Congress first amended the relevant provisions in 1988, that has been the rule, and it was reaffirmed once again in the decision below. See also Resp. Br. 18–22.

B. There Is No General-Versus-Specific Interpretation At Issue.

Hoping to leverage this Court's sixty-year-old, superseded decision in *Fourco Glass Co.* v. *Transmirra Products Corp.,* 353 U.S. 222 (1957), Petitioner asserts that the question presented is "the same as the issue decided in *Fourco*: Whether 28 U.S.C. § 1400(b) … is not to be supplemented by 28 U.S.C. § 1391(c)." Pet. Br. i. And Petitioner later insists that the Court should continue to apply the "specific" provision of § 1400(b) over the "general" provision of § 1391(c), as it did in *Fourco*. *Id.* at 26–28.

This formulation, however, ignores the fundamental differences between § 1391 in 1952 and § 1391 today. The version of § 1391(c) at issue in *Fourco* was a substantive provision, specifying where a defendant "may be sued." 28 U.S.C. § 1391(c) (1952). That provision thus "specifically dealt with" the same issue as § 1400(b), which provided for (and still does) where a patent infringement action "may be brought." See *Fourco*, 353 U.S. at 223, 228. Faced with such a conflict—two statutes providing differing answers as to

where a lawsuit "may be" brought—this Court applied the more specific provision in § 1400(b) over the general substantive provision in § 1391(c). *Id*. at 228–29.

Congress subsequently eliminated the conflict that animated *Fourco* when it undertook "significant" revisions to § 1391 in 1988 and again in 2011. 14D Wright & Miller, *supra*, § 3802, at 36–37, 42–44. Through these amendments, § 1391(c) is now "purely definitional." Paul R. Gugliuzza & Megan M. La Belle, *The Patently Unexceptional Venue Statute*, 66 Am. L. Rev. (forthcoming 2017) (manuscript copy at 10). The statute no longer purports to delimit where a corporation "may be sued" but instead defines where a corporation "shall be deemed to reside." 28 U.S.C. § 1391(c)(1) (2012). Although *other* subsections of § 1391 still provide for substantive venue rules, including § 1391(b), which broadly concerns where "[a] civil action may be brought," § 1391(c) does not. And because § 1400(b) does not purport to define corporate "reside[ncy]," there is no conflict with § 1391(c); the latter simply fits hand in glove with the former.

Petitioner's citation to *Radzanower* v. *Touche Ross & Co.*, 426 U.S. 148, 153 (1976), for the contention that the "specific" provision of § 1400(b) governs the "general" provision of § 1391(c), Pet. Br. 26–28, thus rests on a fundamental misunderstanding of what those provisions currently say. *Fourco* itself recognized that a "substantive change in that statute" could lead to a different result. 353 U.S. at 225. And that is precisely what happened: Congress "substantive[ly]" changed § 1391(c) in 1988 when it recast that statute as a definitional provision.[3]

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[3] Petitioner's view would also nullify the "[f]or purposes of this chapter" language enacted in 1988. That version of Chapter 87

Indeed, even before the 1988 amendments, this Court recognized that § 1400(b) is more "specific" than § 1391 only to the extent that the two statutes directly collide. In *Brunette Machine Works, Ltd.* v. *Kockum Industries, Inc.*, a U.S. corporation sued a Canadian corporation for patent infringement in Oregon. 406 U.S. 706, 707 (1972). The patentee asserted that venue was proper under 28 U.S.C. § 1391(d) (1972), which at the time provided "[a]n alien may be sued in any district." Relying on *Fourco*, the accused infringer argued that the provisions of § 1391 had no effect in patent infringement cases. This Court disagreed, holding that § 1391(d) was not "derived from the general venue statutes that § 1400(b) was intended to replace" but expressed "a principle of broad and overriding application" not contemplated by § 1400(b). *Brunette*, 406 U.S. at 713. So too here: because the conflict between §§ 1391(c) and 1400(b) no longer exists, the former's "broad and overriding" definition of residency applies to the use of that term in the latter.

C. The Statutory Text Provides A Clear Statement Of Congressional Intent.

Petitioner also argues that *Fourco*'s limitation on § 1391(c) should control because Congress did not make sufficiently clear its intention to abrogate

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used the term "resident," "residence," or "reside" 11 times outside of § 1391. *See* 28 U.S.C. §§ 1395(e), 1396, 1397, 1398, 1400(a) & (b), 1402(a)(1) & (b), 1408(1), 1409(b) (1988). These are all specific venue provisions governing matters like forfeiture of a vessel and bankruptcy. If specificity in other provisions precluded application of § 1391(c)'s definition, it would mean that § 1391(c) does not apply to *any* specific venue statute in Chapter 87 outside of § 1391, rendering meaningless the words "[f]or purposes of this chapter." The words of a statute, however, "cannot be meaningless, else they would not have been used." *United States* v. *Butler*, 297 U.S. 1, 65 (1936).

Fourco. Pet. Br. 28–31. That argument is based in part on the absence of any legislative history expressly stating Congress's intention concerning the fate of *Fourco*. See, *e.g.*, Pet. 4 ("[T]he legislative history of the 1988 Act gave no indication of any congressional intent to change the patent case venue statute.").

The task at hand, however, is "to apply the statute, not legislative history, and certainly not the absence of legislative history." *Chisom* v. *Roemer*, 501 U.S. 380, 406 (1991) (Scalia, J., dissenting). And sure enough, the statute and its amendment history provide the clear statement for which Petitioner claims to be searching. The 1988 revisions applied a new definition of residency "[f]or purposes of venue *under this chapter*." 28 U.S.C. § 1391(c) (1988) (emphasis added). That enactment was much broader than the initial proposal to define residency only "[f]or the purposes of Subsections (A) and (B)" of § 1391. Alan B. Rich et al., *The Judicial Improvements and Access to Justice Act: New Patent Venue, Mandatory Arbitration and More*, 5 High Tech. L.J. 311, 318 (1990) (emphasis omitted) (quoting Memorandum from Judge William W. Schwarzer (Feb. 22, 1985)). "[T]his chapter," of course, means Chapter 87, which includes § 1400.

The 2011 amendment then *broadened* the applicability of § 1391(c), from "[f]or purposes of venue under this chapter" to "[f]or *all* venue purposes." 28 U.S.C. § 1391(c) (2012) (emphasis added). As the House Report for the 2011 amendments noted, the revised § 1391(c) would apply "[u]niversally" to "all venue statutes, including venue provisions that appear elsewhere in the United States Code," whereas the 1988 version applied only "for purposes of venue under Chapter 87." H.R. Rep. No. 112-10, at 20 (2011).

These enactments are clear-cut, and Congress's failure specifically to cite *Fourco* is no reason to discard the plain meaning of the statutory scheme. Congress, moreover, has been well aware of perceived forum-shopping concerns for a long time. See, *e.g.*, Pet. Br. 14–15 (citing a 2006 *New York Times* article describing the rise in patent litigation in the Eastern District of Texas). The issues were well-publicized in 2011, when Congress passed the most significant changes to the U.S. patent system in generations *and* made substantive changes to venue rules. See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011); Federal Courts Jurisdiction and Venue Clarification Act of 2011, Pub. L. No. 112-63, 125 Stat. 758. But Congress did not change the patent venue rules then, and it has considered but not enacted numerous proposals to amend the rules since. See, *e.g.*, Resp. Br. 57–58 (citing recent legislation to address patent forum shopping). In fact, just a couple of weeks ago, Senator Hatch—namesake of the Hatch-Waxman Act—reiterated that Congress will continue to study the issue notwithstanding the pendency of this case. Press Release, Orrin Hatch, Hatch Unveils Innovation Agenda for the 115th Congress (Feb. 16, 2017), http://www.hatch.senate.gov/public/index.cfm/2017/2/hatch-unveils-innovation-agenda-for-the-115th-congress. In short, Congress has provided a clear statement about patent venue rules in the statutory text, and, until Congress provides a different clear statement, that text (not *Fourco*) governs.

II. JUDICIALLY AMENDING THE VENUE STATUTES WOULD LEAD TO WASTEFUL AND REPETITIVE ANDA LITIGATION.

The not-so-subtle subtext of this case is the perceived problem of forum shopping in one type of patent litigation. See, *e.g.*, Pet. Br. 14–16; Intel Br. 24–

29; Texas Br. 7–15. PhRMA takes no position on the merits of these policy concerns in the abstract, but PhRMA does take issue with Petitioner's proposed blunt-instrument solution to a nuanced issue that would replace one perceived policy problem with a host of others. In the specific context of ANDA litigation, Petitioner's judge-made rule would mean dispersing parallel litigation over a single branded medicine to dozens of district courts nationwide. See also AIPLA Br. 9–10 (detailing problems proposed rule would cause for copyright litigation).

A. Innovating Pharmaceutical Companies Rely On ANDA Litigation To Protect Their Astronomical R&D Investments.

1. Biopharmaceuticals represent the most R&D-intensive sector of the U.S. economy. To discover new and innovative medicines, the industry invests on average six times more in R&D as a percentage of sales than all other manufacturing industries. Since 2000, PhRMA members alone have invested over half a *trillion* dollars in R&D, including nearly $60 billion in 2015. PhRMA, *2016 Biopharmaceutical Research Industry Profile* 47 (2016), http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf.

The leading driver of these costs is the long process required to obtain FDA approval to market a new drug. That entails, among other things, preclinical testing, animal studies, and at least three phases of clinical trials. If those tests show that a compound is safe and effective, the next step is to submit a New Drug Application (NDA). In addition to providing testing results, manufacturing plans, and labeling proposals, the NDA must list any patents that "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the

drug." 21 U.S.C. § 355(b)(1). If FDA scientists approve the NDA, the agency lists those patents in a publication called the Orange Book.

The drug development process is lengthy, expensive, and replete with potential for failure. The average time between drug discovery and FDA approval is 10 to 15 years. Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1*, 1 JACC: Basic to Translational Science 170, 171 (2016). The total cost of preapproval R&D is estimated at nearly $2.6 billion on average (2013 dollars). Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25–26 & fig.2 (2016). And despite these enormous outlays, approval is hardly a guarantee: just 11.8% of drugs that enter clinical trials receive FDA approval. *Id.* at 23. Moreover, for every ten drugs that are ultimately approved, roughly two actually produce revenues that exceed average R&D costs. John A. Vernon et al., *Drug Development Costs When Financial Risk is Measured Using the Fama–French Three-Factor Model*, 19 Health Econ. 1002 (2010).

2. The path of the would-be generic manufacturer is much easier. Its version of the NDA is "abbreviated" and allows the generic to bypass preclinical and clinical testing simply by showing bioequivalence to an approved pioneer medicine. 21 U.S.C. § 355(j)(2)(a)(iv). An ANDA filer must also certify how marketing the drug will affect any patents listed in the Orange Book. There are four choices, but the most well-known and potentially lucrative is the so-called "Paragraph IV" certification, through which the applicant claims that the patents are invalid, unenforceable, or not infringed. *Id.* § 355(j)(2)(a)(vii). The first generic applicant to file a substantially complete ANDA and make such a certification re-

ceives a 180-day exclusivity period against later applicants. *Id.* § 355(j)(5)(B)(iv).

That exclusivity period provides a significant incentive that encourages the filing of ANDAs. Generic manufacturers can make 60 to 80 percent of their total profits in the six-month exclusivity period. See Daniel F. Coughlin & Rochelle A. Dede, *Hatch-Waxman Game-Playing from a Generic Manufacturer Perspective*, 25 Biotech L. Rep. 525, 525–26 (2006). And even for manufacturers who are not the first to file an ANDA, there remain incentives to file an ANDA containing a Paragraph IV certification—for example, either to benefit from a ruling on invalidity or to be next in line in the event the first ANDA is withdrawn or forfeited. As a result, the approval of an NDA often (and quickly) results in many ANDAs concerning the same patented medication.

3. The Act provides two ways to litigate the confrontation embedded in an ANDA, but virtually all litigation follows the same course. In particular, upon receiving notice of the ANDA, the patent holder can—and effectively must—sue for patent infringement under ANDA-specific infringement provisions. 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e). Filing the infringement suit within 45 days of receiving notice triggers an automatic 30-month stay of approval of the ANDA—an important pause on generic entry—and that is usually just enough time for a court to resolve the case. See Brian C. Howard & Jason Maples, Lex Machina, *Hatch-Waxman/ANDA Litigation Report 2015*, at 16 (2016) (on file with authors) (reporting a median time to trial of 27 months).

Alternatively, an ANDA filer can bring a lawsuit if the patent holder does not, 35 U.S.C. § 271(e)(5); 21 U.S.C. § 355(c)(3)(D)(i), but that almost never happens. See, *e.g.*, Lex Machina, *Legal Analytics for*

ANDA Litigation, https://lexmachina.com/wp-content/uploads/2014/12/ANDA-Datasheet.pdf?utm_source=website&utm_medium=datasheets&utm_campaign=resources (last visited Mar. 8, 2017) (under 5% of all ANDA litigation). In all but a tiny number of exceptional cases, therefore, ANDA litigation is an infringement action brought by a innovating patent holder against a host of ANDA applicants. Cf. *Eli Lilly*, 496 U.S. at 678 (describing "highly artificial act of infringement" designed to facilitate litigation of Paragraph IV certifications).

B. A Judicially Crafted Venue Rule Would Result In Wasteful, Duplicative, And Abusive ANDA Litigation.

Congress enacted the Hatch-Waxman Act in 1984, shortly before the first of its recent venue amendments in 1988. Congress was thus presumably aware of the Hatch-Waxman Act when it amended the venue laws, and both statutes coexist to allow patent holders facing multiple ANDAs to litigate those cases efficiently and in the same place.

Petitioner's counter-textual construction of the relevant venue provisions would upend this orderly and sensible process by requiring innovating patent holders to litigate the same cases many times over in different places. Venue for each ANDA would be permissible only in the State where the ANDA filer happens to be incorporated or where it maintains "a regular and established place of business." Identical validity arguments about the same patents, therefore, would be multiplied across numerous different judicial districts for absolutely no good reason. That is directly contrary to the Hatch-Waxman Act's clear intent to resolve ANDA litigation promptly and efficiently—an intent reflected, among other places, in the automatic but compressed 30-month stay of ge-

neric entry after litigation begins. 21 U.S.C. § 355(j)(5)(B)(iii); *supra* § II.A.

Recent and ongoing ANDA litigation is illustrative of the practical impact of Petitioner's proposed changes. On the one hand, some cases offer a preview of the kind of inefficiencies that would become mandatory in Petitioner's world. In litigation over the drug Adderall XR, for example, before the scope of personal jurisdiction in ANDA cases had been clarified, patent holders filed protective suits against ANDA filers in at least seven different jurisdictions.[4] The same happened in litigation over Clarinex, where the patent holder (Schering) sued 21 ANDA filers in New Jersey but also filed protective complaints in Florida and Michigan against four of those companies due to concerns about establishing personal jurisdiction in New Jersey.[5] Petitioner would have the Court adopt a rule that could lead to litigation in as many as 21 different jurisdictions, rather than just one.

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[4] *Shire Labs., Inc.* v. *Teva Pharm. Indus. Ltd.*, No. 2:06-cv-00952 (E.D. Pa. filed Mar. 2, 2006); *Shire Labs., Inc.* v. *Andrx Pharm., LLC*, No. 06-cv-61699 (S.D. Fla. filed Nov. 13, 2006); *Shire LLC* v. *Sandoz, Inc.*, No. 1:07-cv-00197 (D. Colo. filed Jan. 26, 2007); *Shire LLC* v. *Watson Pharm., Inc.*, No. 1:11-cv-02340 (S.D.N.Y. filed Apr. 5, 2011); *Shire LLC* v. *Neos Theraputics, Inc.*, No. 3:13-cv-01452 (N.D. Tex. filed Apr. 11, 2013); *Shire LLC* v. *Corepharma, LLC*, No. 1:14-cv-05694 (D.N.J. filed Sept. 12, 2014); *Shire LLC* v. *Amerigen Pharm. Ltd.*, No. 1:14-cv-06095 (D.N.J. filed Oct. 1, 2014); *Shire LLC* v. *Par Pharm., Inc.*, No. 1:15-cv-01454 (D.N.J. filed Feb. 26, 2015); *Shire LLC* v. *Abhai LLC*, No. 1:15-cv-13909 (D. Mass. filed Nov. 20, 2015).

[5] *See Schering Corp.* v. *Zydus Pharm., USA, Inc.*, No. 3:06-cv-04715 (D.N.J. filed Sept. 29, 2006) (naming 21 ANDA filers); *Schering Corp.* v. *Caraco Pharm. Labs., Ltd.*, No. 2:06-cv-14386 (E.D. Mich. filed Oct. 5, 2006) (naming two ANDA filers who were also defendants in *Zydus*); *Schering Corp.* v. *GeoPharma, Inc.*, No. 8:06-cv-01843 (M.D. Fla. filed Oct. 5, 2006) (same).

On the other hand, different cases also demonstrate just how seriously burdensome both to litigants and courts these cases *could become* under Petitioner's rule. Innovating manufacturer Otsuka, for example, sued at least 19 different ANDA filers over a patented aripiprazole oral solution marketed as Abilify.[6]

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[6] *Otsuka Pharm. Co.* v. *Wockhardt Ltd.*, No. 3:13-cv-06604 (D.N.J. filed Oct. 31, 2013); *Otsuka Pharm. Co.* v. *Torrent Pharm. Ltd.*, No. 1:14-cv-01078 (D.N.J. filed Feb. 18, 2014); *Otsuka Pharm. Co.* v. *Alembic Pharm. Ltd.*, No. 1:14-cv-02982 (D.N.J. filed May 9, 2014); *Otsuka Pharm. Co.* v. *Zydus Pharm. USA Inc.*, No. 1:14-cv-03168 (D.N.J. filed May 16, 2014); *Otsuka Pharm. Co.* v. *Aurobindo Pharma Ltd.*, No. 1:14-cv-03306 (D.N.J. filed May 23, 2014); *Otsuka Pharm. Co.* v. *Intas Pharm. Ltd.*, No. 1:14-cv-03996 (D.N.J. filed June 20, 2014); *Otsuka Pharm. Co.* v. *Sun Pharm. Indus. Ltd.*, No. 1:14-cv-04307 (D.N.J. filed July 7, 2014); *Otsuka Pharm. Co.* v. *Mylan, Inc*, No. 1:14-cv-04508 (D.N.J. filed July 11, 2014); *Otsuka Pharm. Co.* v. *Zhejiang Huahai Pharm. Co.*, No. 1:14-cv-05537 (D.N.J. filed Sept. 4, 2014); *Otsuka Pharm. Co.* v. *Ajanta Pharma Ltd.*, No. 1:14-cv-05876 (D.N.J. filed Sept. 19, 2014); *Otsuka Pharm. Co.* v. *Intas Pharm. Ltd.*, No. 1:14-cv-06158 (D.N.J. filed Oct. 2, 2014); *Otsuka Pharm. Co.* v. *Sun Pharm. Indus. Ltd.*, No. 1:14-cv-06397 (D.N.J. filed Oct. 6, 2014); *Otsuka Pharm. Co.* v. *Teva Pharm. USA, Inc.*, No. 1:14-cv-06398 (D.N.J. filed Oct. 10, 2014); *Otsuka Pharm. Co.* v. *Aurobindo Pharma Ltd.*, No. 1:14-cv-06890 (D.N.J. filed Oct. 31, 2014); *Otsuka Pharm. Co.* v. *Lupin Ltd.*, No. 1:14-cv-07105 (D.N.J. filed Nov. 3, 2014); *Otsuka Pharm. Co.* v. *Actavis Elizabeth LLC*, No. 1:14-cv-07106 (D.N.J. filed Nov. 10, 2014); *Otsuka Pharm. Co.* v. *Zydus Pharm. USA Inc.*, No. 1:14-cv-07252 (D.N.J. filed Nov. 20, 2014); *Otsuka Pharm. Co.* v. *Alembic Pharm. Ltd.*, No. 1:14-cv-07405 (D.N.J. filed Nov. 26, 2014); *Otsuka Pharm. Co.* v. *Sciegen Pharm. Inc.*, No. 1:14-cv-08077 (D.N.J. filed Dec. 22, 2014); *Otsuka Pharm. Co.* v. *Apotex Corp.*, No. 1:14-cv-08074 (D.N.J. filed Dec. 24, 2014); *Otsuka Pharm. Co.* v. *Hetero Drugs Ltd.*, No. 1:15-cv-00161 (D.N.J. filed Jan. 8, 2015); *Otsuka Pharm. Co.* v. *Amneal Pharms LLC*, No. 1:15-cv-01585 (D.N.J. filed Mar. 2, 2015); *Otsuka Pharm. Co.* v. *Sandoz Inc.*, No. 1:15-cv-01716 (D.N.J. filed Mar. 9, 2015).

Each suit was brought in New Jersey and assigned to the same judge, rather than up to 19 different judges in 19 different courts around the country. The economies that such consolidation generates are self-evident. A single consolidated proceeding is more than enough for the patent holder to have to endure.[7]

Such inefficiencies could even require splitting up litigation over *the same ANDA*. Manufacturer UCB, for example, sued 17 ANDA filers about the patent-protected seizure medicine Vimpat.[8] One of these actions named both Venoot Pharmaceuticals and Venoot's marketing division, Breckenridge Pharmaceutical, which are incorporated in two different states. Compl. ¶¶ 5-6, 11, *UCB, Inc.* v. *Breckenridge*

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[7] There are countless other examples. Pfizer's branded drug Toviaz, for example, required 15 ANDA infringement actions in Delaware, *see, e.g.*, *Pfizer, Inc.* v. *Sandoz Inc., et al.*, No. 13-1110, 2016 WL 1611377 (D. Del. Apr. 20, 2016) (following consolidated bench trial, holding that the Toviaz patent is not invalid), while Sanofi's Multaq had 10 in the same court, *see, e.g.*, *Sanofi* v. *Glenmark Pharms, Inc., USA, et al.*, No. 14-264, 2016 WL 4569680 (D. Del. Aug. 31, 2016) (following a consolidated bench trial, concluding the Multaq patent at issue was valid and infringed), *appeal docketed*, No. 16-2722 (Fed. Cir. Sept. 29, 2016). Eli Lilly's Alimta led to 14 actions in the Southern District of Indiana. *See, e.g.*, *Eli Lilly* v. *Teva Parental Meds., Inc., et al.*, 845 F.3d 1357 (Fed. Cir. 2017) (affirming district court's judgments of infringement and no invalidity). Complete lists of these litigations are compiled in the Addendum of this Brief.

[8] *See UCB Files Vimpat Patent Claims Against 15 Companies*, PMLive (July 23, 2013), http://www.pmlive.com/pharma_news/ucb_files_vimpat_patent_claims_against_15_companies_491658 (noting suits against Glenmark, Apotex, Mylan, Ranbaxy, Sandoz, Sun Pharma, Watson, Zydus, ScieGen, Hetero, Breckenridge, Amneal, Alembic and Accord); *see also UCB, Inc.* v. *Aurobindo Pharma LTD*, No. 1:16-cv-00451 (D. Del. filed June 17, 2016); *UCB Inc.* v. *Teva Pharm. USA, Inc.*, No. 1:13-cv-01148 (D. Del. filed June 28, 2013).

Pharm., Inc., No. 1:13-cv-01211 (D. Del. filed July 10, 2013); see also Compl. ¶¶ 6–7, *UCB, Inc.* v. *Ranbaxy Labs. Ltd.*, No. 1:13-cv-01215 (D. Del. filed July 10, 2013) (naming co-defendants incorporated in Florida and Delaware). To accept Petitioner's argument would seemingly mean that UCB would have had to bring separate lawsuits in separate districts over the very same ANDA application. This kind of outcome can only be justified by clear congressional text commanding such a wasteful result. The venue provisions, however, provide for a much more orderly litigation process and one that does not countenance the kind of Balkanized litigation Petitioner proposes.

ANDA litigation thus provides a clear example why the question presented should be left to Congress. Venue statutes balance party and public interests that may vary widely based on the case, industry, or context. ANDA litigation is unique, implicating a different statutory framework and different dynamics and interests than are implicated in the run-of-the-mill infringement dispute between TC Heartland and Kraft or in the technology cases concentrated in the Eastern District of Texas. Weighing such competing and nuanced interests is for Congress, not the courts.[9]

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[9] If the Court does decide to alter the current venue rules—and it should not—it should avoid upsetting the current rule for ANDA litigation. Given the uniqueness of the Hatch-Waxman process, the stakes involved, and the artificial nature of these lawsuits, *see supra* § II.A–B, any change to the venue provisions affecting ANDA litigation should be decided in an ANDA case, where the courts can address the unique rules governing these cases.

C. GPhA's Arguments Ignore The Reality Of ANDA Litigation.

Generic manufacturers have filed a brief in support of Petitioner. Although that brief correctly recognizes that construction of the venue statutes could have significant repercussions for ANDA litigation, GPhA's arguments are misguided and otherwise erroneous.

For starters, many of GPhA's observations affirmatively support respondents. They note, for instance, that ANDA litigation is "particularly complex and resource intensive," and that trial in ANDA litigation is a "multi-day (if not multi-week) affair[], often involving multiple patents, where the district judge is required to carefully hear and weigh highly technical testimony." GPhA Br. 8–10. Moreover, they acknowledge that such cases "commonly involve multiple unrelated drug applicant defendants." *Id.* at 10 n.5. Although GPhA summarily states that those defendants might "hav[e] discrete defenses," *id.*, the defendants' positions have far more in common than not. And yet GPhA nowhere acknowledges what its preferred solution would mean for cases that "commonly involve multiple unrelated drug applicant defendants." GPhA's silence is telling because, as already explained, mandated case-splitting would multiply the cost and complexity of ANDA litigation and engender a game of legal Whack-a-Mole that would harm courts and biopharmaceutical companies with no corresponding benefit.

GPhA argues that the court of appeals' decision puts the venue statute "[a]t [o]dds" with ANDA venue provisions, whereas Petitioner's construction creates "symmetry" between how venue is determined depending on whether the brand or generic initiates suit. GPhA Br. 6–7. GPhA is wrong. There is no asymmetry under the existing statutes. By requiring

declaratory actions to be brought in the district of the patent holder's principal place of business or where the patent holder has a regular and established place of business, 21 U.S.C. § 355(j)(5)(C)(i)(II), Congress simply recognized that patent holders do not initiate the Hatch-Waxman process and in effect are the de facto defendants in ANDA cases—pushed into litigation by the *ANDA filers'* challenges to the patents as well as by the filers' efforts to sell their drugs nationwide. Litigation thus *should be* concentrated in one or few judicial districts where the patent holders have substantial ties, and that is precisely what happens now: the innovating manufacturer usually brings all lawsuits concerning a single drug in the district where it is based (or another district where the ANDA filers are all subject to personal jurisdiction). *Supra* at 15–18.

In a similar vein, GPhA points to the fact that a majority of ANDA actions are brought in New Jersey and Delaware as evidence of undue concentration and a rule that ought to be changed. GPhA Br. 10–16. But GPhA neglects to point out that a majority of brand-name pharmaceutical companies are based in New Jersey or Delaware. Indeed, of the top 10 pharmaceutical companies in terms of revenue in 2016, six have their U.S. headquarters in New Jersey or Delaware, and the other four are incorporated in Delaware. See Arjun Datta, *Top 10 Pharmaceutical Companies in 2016*, ProClinical (Aug. 31, 2016), http://blog.proclinical.com/top-10-pharmaceutical-companies-2016; see also Corrinne Jurney, *2016 Global 2000: The World's Largest Drug and Biotech Companies*, Forbes Mag. (May 27, 2016), http://www.forbes.com/sites/corinnejurney/2016/05/27/2016-global-2000-the-worlds-largest-drug-and-biotech-companies/#165cd3c91d50; *Top 25 Pharma Companies by Global Sales*,

PM Live http://www.pmlive.com/top_pharma_list/global_revenues (last visited Mar. 8, 2017); John Carroll, *Top 15 Pharma R&D Budgets*, Fierce Pharma, http://www.fiercepharma.com/special-report/top-15-pharma-r-d-budgets (last visited Mar. 7, 2017). The apparent concentration of ANDA litigation is thus not evidence of patentee-friendly courts or anything untoward; it simply reflects a geographically concentrated industry.

Ultimately, GPhA's arguments are an apparent last-ditch effort to re-litigate a fight about the scope of *personal jurisdiction* in ANDA cases that GPhA recently lost (and on which this Court denied certiorari). Recycling arguments—sometimes verbatim[10]—that GPhA made unsuccessfully in support of *certiorari* in *Acorda Therapeutics, Inc.* v. *Mylan Pharmaceuticals, Inc.*, 817 F.3d 755 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017), GPhA vehemently argues that most ANDA litigation is not conducted in districts that GPhA prefers. These arguments did not prevail in *Acorda*, when personal jurisdiction was actually at stake, and they certainly offer no reason to rewrite the venue laws to try to reach the same outcome.

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[10] *Compare, e.g.*, GPhA Br. 10–11, *with* GPhA *Amicus* Brief at 6, *Mylan Pharm. Inc.* v. *Acorda Therapeutics Inc.*, 137 S. Ct. 625 (2017) (No. 16-360), *available at* 2016 WL 6247555.

CONCLUSION

For the foregoing reasons, and those stated by Respondent, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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ADDENDUM

Pfizer Toviaz (D. Del.)

ANDA Filer	Filed	Docket No.
Torrent	Feb. 2, 2017	1:17-cv-00112
Aurobindo	Sept. 30, 2016	1:16-cv-00886
Dr. Reddy's	Nov. 18, 2015	1:15-cv-01067
Mylan	Jan. 27, 2015	1:15-cv-00013
Hetero	Dec. 11, 2013	1:13-cv-02021
Apotex	Dec. 11, 2013	1:13-cv-02022
Wockhardt	Aug. 2, 2013	1:13-cv-01387
Lupin	June 28, 2013	1:13-cv-01153
Zydus	June 28, 2013	1:13-cv-01154
Accord	June 28, 2013	1:13-cv-01155
Amerigen	June 28, 2013	1:13-cv-01156
Amneal	June 28, 2013	1:13-cv-01157
Impax	June 28, 2013	1:13-cv-01158
Alkem	June 21, 2013	1:13-cv-01110
Sandoz	June 21, 2013	1:13-cv-01111

Sanofi Multaq (D. Del.)

ANDA Filer	Filed	Docket No.
Lupin	May 21, 2015	1:15-cv-00415
Alkem	Dec. 23, 2015	1:15-cv-01200
First Time	Dec. 23, 2015	1:15-cv-01205
Sandoz	Dec. 23, 2015	1:15-cv-01207
Sun	Dec. 23, 2015	1:15-cv-01208
Watson	Dec. 23, 2015	1:15-cv-01209
Unimark	July 3, 2014	1:14-cv-00876
Amneal	July 3, 2014	1:14-cv-00875
Alembic	Apr. 4, 2014	1:14-cv-00424
Glenmark	Feb. 26, 2014	1:14-cv-00264

Add3

Eli Lilly Alimta (S.D. Ind.)

ANDA Filer	Filed	Docket No.
Hospira	Dec. 21, 2016	1:16-cv-03460
Biocon	Feb. 26, 2016	1:16-cv-00469
Dr. Reddy's	Feb. 5, 2016	1:16-cv-00308
Emcure	Aug. 7, 2015	1:15-cv-01244
Mylan	July 10, 2015	1:15-cv-01083
Fresenius Kabi	Jan. 23, 2015	1:15-cv-00096
Sandoz	Dec. 5, 2014	1:14-cv-02008
Nang Kuang	Oct. 8, 2014	1:14-cv-01647
Glenmark	Jan. 23, 2014	1:14-cv-00104
Sun	Sept. 13, 2013	1:13-cv-01469
Accord	Feb. 28, 2013	1:13-cv-00335
Apotex	Apr. 17, 2012	1:12-cv-00499
App	July 15, 2011	1:11-cv-00942
Teva	Oct. 29, 2010	1:10-cv-01376