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 *AMICUS CURIAE* OF THE GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONER

BERT W. REIN
Counsel of Record
JAMES H. WALLACE, JR.
MARK A. PACELLA
BRIAN H. PANDYA
WESLEY E. WEEKS
WILEY REIN LLP
1776 K Street, N.W.
Washington, DC 20006
(202) 719-7000
BRein@wileyrein.com

Attorneys for Amicus Curiae Generic Pharmaceutical Association

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TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES

Page

Cases

Cited Authorities

Cited Authorities

Page

Statutes

Other Authorities

Cited Authorities

Page

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae the Generic Pharmaceutical Association ("GPhA") is a non-profit, voluntary association comprising nearly 100 manufacturers and distributors in the generic pharmaceutical industry, which manufactures over 88 percent of the prescription drugs dispensed in the United States each year. GPhA's members provide American patients with safe and cost-effective medicines that are bioequivalent to, and have the same safety, efficacy, and therapeutic benefit as, their brand-name counterparts. These products significantly improve public health while cutting annual healthcare costs by billions of dollars.

GPhA's core purpose is to improve the lives of patients by providing timely access to affordable pharmaceuticals. Toward this end, GPhA advances the interests of its members through initiatives in the scientific, regulatory, federal and state forums and in the public affairs arena. GPhA also regularly participates as amicus curiae in cases before the Federal Circuit and the Supreme Court.

Other amici have noted that the Federal Circuit's misinterpretation of 35 U.S.C. §§ 1331 and 1400(b) has caused an overconcentration of lawsuits in the Eastern District of Texas. GPhA writes to highlight two

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae, or its counsel, made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief, either by express written consent or by filing a letter documenting consent with the Court.

different issues. First, the Federal Circuit's expansive interpretation of the venue statutes creates inconsistency with a similar venue provision found in the Hatch-Waxman Act concerning venue for declaratory judgment actions raising patent issues filed by generic drug companies. Second, the Federal Circuit's statutory misinterpretation has resulted in adverse consequences in the context of patent suits arising under the Hatch-Waxman Act. Because the Federal Circuit previously held that generic drug applicants are subject to personal jurisdiction virtually nationwide based on the filing of an application with the FDA, the Federal Circuit's misinterpretation of the venue statutes allows patent holders to hand-pick their preferred forum. Unsurprisingly, that unconstrained choice has led to the overconcentration of such cases in two district courts that are favored by pharmaceutical patent holders.

GPhA has a direct interest in preserving the Hatch-Waxman Act's careful balance between patent rights and the public's need for low-cost generic drugs, which is skewed by the decision below. GPhA often has members who have varied interests in such matters. However, the association has a vested interest in a predictable and consistent system for litigants engaged in Hatch-Waxman Act litigation.

SUMMARY OF THE ARGUMENT

For reasons Petitioners have explained, the decision below misconstrues the venue statutes and must be reversed. GPhA fully endorses the statutory analysis in Petitioner's brief.

In addition, the Federal Circuit's expansion of venue in patent cases by importing Section 1391 into Section 1400(b) is at odds with Congress's decision to *limit* venue for patent cases brought under the Hatch-Waxman Act. Specifically, Congress limited venue in declaratory judgment actions brought by generic drug applicants under the Hatch-Waxman Act, mirroring the limitations imposed on patent infringement cases under Section 1400(b). The Federal Circuit's misinterpretation of Section 1391 erases that limitation in actions brought by patent holders—but not the limitation imposed on those challenging a patent in a declaratory judgment action—creating a significant statutory asymmetry.

The practical consequence of the decision below is clear and harsh: It delays the public's access to low cost generic drugs. In combination with the Federal Circuit's jurisdictional decision in *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016), *cert. denied*, No. 16-360, 2017 WL 69716 (U.S. Jan. 9, 2017), it effectively subjects every generic drug applicant to nationwide jurisdiction in litigation brought by patent holders under the Hatch-Waxman Act, regardless of whether the generic drug company has any connection to the forum selected by the patent holder. This has caused an undue concentration of such cases in the two small home districts favored by branded drug companies, the Districts of Delaware and New Jersey, where 73 percent of all such suits are now filed. This in turn has resulted in crowded dockets and delayed trials, directly contrary to Congress's intent to "speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012).

The consequences of concentrating most Hatch-Waxman cases in two courts go beyond delay from overcrowded dockets. Pharmaceutical patent cases raise issues of claim interpretation, infringement, and invalidity that do not arise in other patent cases. Leaving most pharmaceutical patent cases to judges in two districts, whose decisions are then appealed to a single national appellate court, deprives patent law of the diversity of approaches needed to advance the law. *Cf. Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.* 841 F.3d 1288, 1294 (Fed. Cir. 2016) (analogizing the development of patent law doctrines to "the classic common law methodology for creating law") (citing Karl N. Llewellyn, *The Common Law Tradition: Deciding Appeals* (1960)). And the ability of brand manufacturers to select their preferred forums undermines the venue statutes' goal of promoting a level playing field.

ARGUMENT

I. The Federal Circuit's Decision Is Contrary to the Court's Decisions in *Stonite Products Co. v. Melvin Lloyd Co.* and *Fourco Glass Co. v. Transmirra Products Corp.*

This case is the third time this Court has been called on to answer the same question: whether the express terms of the patent venue statute is the exclusive source of venue for patent infringement suits. This Court should reaffirm its previous decisions and answer this question in the affirmative.

As the Court previously explained, "Congress adopted the predecessor to § 1400(b) as a special venue statute

in patent infringement actions 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." *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 262 (1961) (quoting *Stonite Prods. Co. v. Melvin Lloyd Co.*, 315 U.S. 561, 563 (1942)). Thus, Congress determined to limit venue in patent actions to those where defendants were "at home" by reason of incorporation or commercial establishments, and to do so, "define[d] the exact jurisdiction of the . . . courts in these matters," which does not "dovetail with the general (venue) provisions." *Id.* (internal quotation marks and citations omitted). Recognizing this Congressional intent, the Court held in *Fourco Glass Co. v. Transmirra Products Corp.* that § 1400(b) was "not to be supplemented by the provisions of 28 U.S.C. § 1391(c)." 353 U.S. 222, 229 (1957).

Because Congress has not substantively amended § 1400(b), the Federal Circuit's decision to "enlarge upon the mandate of the Congress as to venue in such patent actions" in disregard of this Court's teaching in *Fourco* is an unjustified "intrusion into the legislative field." *Schnell*, 365 U.S. at 263.

The petitioner has fully explained in its opening brief why the decision under review wrongfully attributes substantive significance to technical changes in 28 U.S.C. § 1391. As explained below, Petitioner's argument is further strengthened by Congress's enactment of legislation under the Hatch-Waxman statutory regime to permit ANDA applicants to bring declaratory judgment actions against drug patent holders seeking to establish non-infringement or invalidity. There, Congress expressly limited venue to judicial districts where the patent holder "has its principal

place of business or a regular and established place of business." 21 U.S.C. §§ 355 (c)(3)(D)(i)(II); (j)(5)(C)(i)(II). This attempt to create venue equality between generic drug applicants and patent holders mirrors the venue limitation of § 1400(b) confirmed in *Stonite* and *Fourco*.

For these reasons, the decision below should be reversed.

II. The Federal Circuit's Expansive Interpretation of the Patent Venue Statute Is At Odds With Congress's Restriction of Venue In the Hatch-Waxman Act.

The Hatch-Waxman Act was designed by Congress "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs.*, 566 U.S. at 405. To achieve this goal, the Act authorized generic companies to file a less expensive Abbreviated New Drug Application ("ANDA"), eliminating the need to repeat safety and efficacy studies. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (citing 21 U.S.C. § 355). This abbreviated pathway created the modern generic drug industry. *See id.* The Hatch-Waxman Act also provides a mechanism for branded and generic pharmaceutical companies to timely litigate disputes relating to patent infringement, validity, and enforceability. *See id.* Under the Act, ANDA filers may be sued for patent infringement based on the "highly artificial act of infringement" of "submitting" an ANDA with a certification that the ANDA does not infringe the branded company's listed patents. *Id.* at 678;[2] *see also* 35 U.S.C. § 271(e)(2).

2. As the Court explained in *Lilly*, "an act of infringement had to be created for these ANDA . . . proceedings. That is what

If the patent owner does not timely sue the ANDA applicant, the applicant may file a declaratory judgment action against the patent holder in "the judicial district where the [patent owner] has its principal place of business or a regular and established place of business."[3] 21 U.S.C. §§ 355 (c)(3)(D)(i)(II); (j)(5)(C)(i)(II). This mirrors the limited venue language of 1400(b), creating a logical symmetry between the venues where the ANDA applicant can be sued for infringement and the venues where the patent owner can be sued to resolve issues relating to an ANDA application.

The decision below upsets this careful balance. Now, generic companies are subject to nationwide lawsuits whereas patent owners may only be sued where they are "at home." *Cf. Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014). This incongruous result underscores the error in the Federal Circuit's conclusion that Section 1391 effectively displaced the limited venue for patent cases under 1400(b), contrary to the Court's longstanding precedents.

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is achieved by § 271(e)(2)—the creation of a highly artificial act of infringement that consists of submitting an ANDA . . . containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent." *Eli Lilly & Co.*, 496 U.S. at 678.

3. If the patent owner does not sue an ANDA applicant within 45 days after receiving notice of the ANDA, the ANDA applicant may file a declaratory judgment action against the patent owner to obtain patent certainty. *See* 21 U.S.C. §§ 355 (c)(3)(D); (j)(5)(C).

III. The Federal Circuit's Decision Has Caused an Undue and Unhealthy Concentration of ANDA Patent Cases in Two District Courts.

The generic drug industry is vitally important to the nation's healthcare system and its economy. In 2014, 3.8 billion prescriptions were filled in the United States with generic drugs, accounting for 88 percent of all prescriptions filled. *See* GPhA Report, Generic Drug Savings in the U.S. at 1 (2015).[4] And over the last 10 years, generic drugs have been responsible for $1.68 trillion in healthcare system savings, including $76.1 billion in savings for the United States Government's Medicare program in 2014 alone. *Id.* at 1, 5-6. The decision below profoundly burdens this vital industry.

A. ANDA patent cases are particularly complex and resource intensive.

Cases brought under the Hatch-Waxman Act are not like other patent cases. Typically, an action for patent infringement may only be filed against a party who "without authority makes, uses, offers to sell, or sells . . . or imports into the United States any patented invention during the term of the patent," or induces or contributes to such actions. 35 U.S.C. § 271(a)-(c). Generic drug cases, however, are typically adjudicated long before the accused infringing product is sold in the United States based on the filing of an ANDA with a patent certification, as explained above.

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4. *Available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

The filing of a patent infringement suit under the Hatch-Waxman Act triggers a 30-month stay of final FDA approval of an ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent owner prevails in the lawsuit, the FDA may not approve the ANDA until the valid and infringed patents expire, even if all other health and safety requirements for FDA approval are met. If the ANDA holder prevails in litigation, it may launch its product upon FDA approval. If the 30-month stay expires before the completion of litigation, the FDA may approve the ANDA. If approved, the ANDA holder may then launch its generic drug product "at risk," if not preliminarily enjoined from doing so.

Courts and litigants generally prefer to avoid at-risk launches. From the perspective of the district courts, at-risk launches often generate time-sensitive and resource-draining motions for temporary restraining orders and preliminary injunctions. From the perspective of ANDA applicants, a party that launches at risk only to be later found liable for patent infringement may face a crippling damages award.

To avoid such scenarios, district courts often attempt to schedule trial and resolve ANDA cases sufficiently in advance of the expiration of the 30-month stay. While that diligence is commendable, it stretches judicial resources to the maximum. Because lawsuits occur before the sale, marketing, or import of the accused infringing generic drug, monetary damages are not at stake, and thus, most Hatch-Waxman Act cases are bench trials. Most trials are multi-day (if not multi-week) affairs, often involving multiple patents, where the district judge is required to carefully hear and weigh highly technical testimony related to the alleged infringement of sophisticated

pharmaceutical formulations and the alleged obviousness of new chemical structures. Upon completion of trial, in addition to resolving the usual flurry of post-trial motions, the judge must then issue written findings of facts and conclusions of law. Put simply, few cases place greater burden on the federal judiciary than cases brought under the Hatch-Waxman Act.[5]

B. ANDA patent cases should not be concentrated in two jurisdictions.

T.C. Heartland is the latest attempt by the Federal Circuit to expand patent jurisdiction and venue, contrary to this Court's decisions. In *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755, the Federal Circuit held that generic drug companies effectively are subject to nationwide jurisdiction for patent infringement claims based on their filing of an ANDA with the FDA in Maryland seeking approval to market their products. *Acorda* also conflicts with the teachings of this Court. Just three years ago, this Court decided *Daimler AG v. Bauman*, where it described a similar assertion of nationwide jurisdiction as "unacceptably grasping." 134 S. Ct. at 761. Although *Daimler* addressed general jurisdiction, it made crystal clear that subjecting

5. Cases brought under the Hatch-Waxman Act commonly involve multiple unrelated generic drug applicant defendants having discrete defenses, and lengthy findings of fact and conclusions of law are routine. *See, e.g.*, *Avanir Pharms., Inc. v. Actavis S. Atl. LLC*, 36 F. Supp. 3d 475 (D. Del. 2014) (63 pages); *Warner Chilcott Labs. Ireland Ltd. v. Impax Labs., Inc.*, No. 2:08-civ-06304-WJM, 2012 WL 1551709 (D.N.J. Apr. 30, 2012) (67 pages); *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381 (S.D.N.Y. 2007) (368 pages).

defendants to nationwide jurisdiction based on nationwide sales does not comport with due process because it does not "permit out-of-state defendants to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit." *Id.* at 762 (quotation marks and citation omitted); *see id.* at 750–51 (calling the exercise of jurisdiction in that case "exorbitant" because "the same global reach would presumably be available in every other State in which [defendant's] sales are sizeable.").

In combination, *Acorda* and *T.C. Heartland* expand the reach of both personal jurisdiction and venue far beyond what the Constitution and statutes allow, effectively subjecting generic defendants to suit in any district in the nation based solely on the filing of an application with the FDA seeking approval to make future sales. This is so regardless of whether that defendant has any connection with or presence in the Plaintiffs' chosen forum. The fundamental unfairness caused by the decision below raises serious issues under the Due Process clause of the Fifth Amendment.

The petitioner and several amici make clear that the Federal Circuit's misinterpretation of 28 U.S.C. §§ 1391 and 1400 has caused an undue concentration of patent infringement cases in the Eastern District of Texas. The Federal Circuit's current jurisdictional and venue regime has also caused an undesirable concentration of ANDA patent cases in two district courts. In fact, between 2009 and 2015, 73 percent of all ANDA suits were filed in either the District of Delaware or the District of New Jersey.[6]

6. Ryan Davis, *Mylan Ruling Cements Del., NJ As Top ANDA Venues*, http://www.law360.com/articles/774236/mylan-

Congress intended the Hatch-Waxman Act to "speed the introduction of low-cost generic drugs to market." *See Caraco Pharm. Labs.*, 566 U.S. at 405. But the concentration of ANDA patent cases in just two district courts creates a potential backlog of these cases. For example, consider Mylan Pharmaceuticals, which is headquartered in the Northern District of West Virginia. Compared to the District of Delaware, Mylan's home district is much less congested and more expeditious to trial:[7]

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ruling-cements-del-nj-as-top-anda-venues (last visited Feb. 4, 2017) (reporting statistics on cases filed between 2009 and 2015) (citing data from Lex Machina); *see also* Brian C. Howard & Jason Maples, Lex Machina, Hatch-Waxman/ANDA Litigation Report 2015, at 3–4 (Apr. 2016).

This figure actually understates the extent of concentration, as patent holders often file duplicative suits in ANDA filers' home districts as protection in the event their chosen court grants a motion to dismiss on jurisdiction or venue. For example, in 2015-16, Mylan was sued 36 out of 42 times on ANDA filings in Delaware and New Jersey. In 24 of those 36 Delaware and New Jersey cases, the patent holder filed a duplicative suit against Mylan in the Northern District of West Virginia.

The decision below, if affirmed, will not put an end to inefficient motions practice over venue in Hatch-Waxman cases. Subject to nationwide venue and jurisdiction, ANDA filers will predictably file venue transfer motions when sued in inconvenient districts. This will divert time and resources from adjudicating the merits of these cases.

7. U.S. District Courts–Nat'l Judicial Caseload Profile - Combined Civil and Criminal Federal Court Management Statistics (Sept. 30, 2016), 12-Month Period Ending September 30, 2016, *also available at* http://www.uscourts.gov/sites/default/files/data_tables/fcms_na_distprofile0930.2016.pdf.

Statistic	District of Delaware	District of New Jersey	Northern District of West Virginia.
Time From Filing to Trial (Civil)	24.5 Months	42.0 Months	17.3 Months[8]
Number of Pending Cases per Judgeship	472	628	298
Number of Filings Weighted by Difficulty per Judgeship[2]	496	494	310
Percentage of Civil Cases Over 3 Years Old	13.1 Percent	6.3 Percent	1.2 Percent

Given Congress's desire for ANDA litigation to speed generics to market, the concentration of ANDA patent cases in congested districts is concerning. Delaware

8. As of September 30, 2015. 2016 data is not available for time to trial in the Northern District of West Virginia.

9. "Weighted filings statistics account for the different amounts of time district judges require to resolve various types of civil and criminal actions." Federal Court Management Statistics, Explanation of Selected Terms, at 1 available at http://www.uscourts.gov/sites/default/files/explanation-of-selected-terms-september-2014_0.pdf

and New Jersey judges should not be disproportionately burdened with these complex ANDA patent cases. Any delay in trial slows the entry of generic drugs into the marketplace. Given the number of generic prescriptions filled each year, even a several month delay in generic market entry results in substantial additional healthcare costs. Restoring the exclusivity of 28 U.S.C. § 1400(b) as the source of venue in patent infringement cases will help correct the undue concentration of ANDA patent cases and advance the public health.

Moreover, there is no efficiency or party convenience reason why the vast majority of ANDA patent cases are filed in New Jersey and Delaware. To the contrary, there are compelling reasons to be skeptical about this concentration. If the Federal Circuit implicitly sought to create specialist ANDA patent courts, it invaded an area of complex balancing that should be left to Congress.[10]

When Congress wants to establish specialized courts, it knows how to do so. *See, e.g.*, 28 U.S.C. § 1491

10. *See, e.g.*, Administrative Conference of the United States, Recommendation 91-9, at 1 (Dec. 13, 1991), *available at* https://www.acus.gov/sites/default/files/documents/91-9.pdf (recommending against a proposal to create specialized courts for review of all administrative law cases, recognizing that the creation of a specialist court requires "a complex balancing of various factors: the need for uniform law versus the benefits of 'percolation' in the decentralized circuits; the value of expert decision makers versus the broader perspective of generalists; the efficiency of specialization versus the risk of bias that specialization entails."); *see also* Diane P. Wood, *Generalist Judges in A Specialized World*, 50 S.M.U.L. Rev. 1755, 1767 (1997) (arguing that the benefits of generalist judges weigh against further specialization in the federal judiciary).

(conferring jurisdiction on the Court of Federal Claims); 28 U.S.C. § 1581 (conferring jurisdiction on the Court of International Trade); 26 U.S.C. § 7441 (establishing the United States Tax Court). Indeed, Congress has considered the question of specialization in patent law, and determined that specialization should occur only at the intermediate appellate level. *See* 28 U.S.C. § 1295 (conferring exclusive jurisdiction on the Court of Appeals for the Federal Circuit).

But Congress never suggested that trial of Hatch-Waxman Act patent cases should be limited to specialized "ANDA courts." By concentrating ANDA patent litigation at the district court level, the Federal Circuit has stymied the development of case law for the complex legal issues arising in ANDA patent cases. *See* Brief Amicus Curiae of Paul Michel in Supp. of Cert. at 6 ("Because there is a single patent court at the intermediary appellate level, it is critically important to receive a wide range of views from the district courts."); *cf,* Richard A. Posner, The Federal Courts: Challenge and Reform 257 (1996) ("[T]he Supreme Court will not have the benefit of competing judicial answers to choose among when deciding questions within the domain of the specialized court, except when there is a dissenting opinion in that court."). ANDA patent cases raise issues that are common to ANDA cases generally but do not arise in other patent cases. *See, e.g.*, *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005) (lead compound analysis); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059 (Fed. Cir. 2010) (relevance of ANDA labeling to specific intent to induce infringement); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1368–69 (Fed. Cir. 2012) (clinical trials not required to prove obviousness); *Santarus, Inc.*

v. Par Pharm., Inc., 694 F.3d 1344, 1354 (Fed. Cir. 2012) (holding that the "blood serum concentration resulting from administering a [drug] is an inherent property of the formulation, and an obvious formulation cannot become nonobvious simply by administering it to a patient and claiming the resulting serum concentrations."); *Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1342 (Fed. Cir. 2004) (holding that "the mere filing of an ANDA cannot constitute an act of willful infringement").

If more district courts confront these issues, the Federal Circuit will benefit from competing views. This in turn benefits ANDA filers, patent owners, and by extension, the patient population. The Federal Circuit's erroneous ruling, by contrast, would have the opposite result.

As the Court has explained, "the purpose of statutorily specified venue is to protect the defendant against the risk that a plaintiff will select an unfair or inconvenient place of trial." *Leroy v. Great W. United Corp.*, 443 U.S. 173, 183–84 (1979). Little could be more "unfair" than the Federal Circuit's one-sided venue rule, which allows brand manufacturers to funnel almost all ANDA litigation into their preferred districts. In the Hatch-Waxman Act, Congress attempted to strike a "careful balance" between patent holders and generic drug applicants. *See Janssen Pharmaceutica, N.V. v. Apotex,* 540 F.3d 1353, 1361 (Fed. Cir. 2008). Petitioner's reading of patent venue statutes would restore the balance that Congress intended.

CONCLUSION

For the reasons set forth herein and in the Petition, amicus curiae GPhA respectfully requests that the Court reverse the judgment of the Federal Circuit.

Respectfully submitted,

BERT W. REIN
Counsel of Record
JAMES H. WALLACE, JR.
MARK A. PACELLA
BRIAN H. PANDYA
WESLEY E. WEEKS
WILEY REIN LLP
1776 K Street, N.W.
Washington, DC 20006
(202) 719-7000
BRein@wileyrein.com

Attorneys for Amicus Curiae Generic Pharmaceutical Association

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