No. 2019-2402

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., KAKEN PHARMACEUTICAL CO., LTD.,

Plaintiffs-Appellants,

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LTD., MYLAN INC.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of New Jersey in Case No. 3:18-cv-14305-PGS-LHG, Judge Peter G. Sheridan

BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) IN SUPPORT OF REHEARING *EN BANC* AND REVERSAL

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December 21, 2020

CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America certifies the following:

1. Represented Entities. Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case.

Pharmaceutical Research and Manufacturers of America

2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2). 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.

None.

3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3). 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.

PhRMA has no parent corporation and no publicly held corporation owns 10% or more of its stock. However, its membership includes companies that have issued stock or debt securities to the public. A list of PhRMA's members is available at: www.phrma.org/about/member-companies.

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. 47.4(a)(4).

None.

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).

Valeant Pharmaceuticals North America LLC, et al. v. Zydus Pharmaceuticals (USA) Inc., et al. ("*In re Julia*"), No. 18-cv-13635 (D.N.J.)

Bausch Health US, LLC et al. v. Mylan Pharmaceuticals Inc., et al., No. 20-cv-02749 (D.N.J.)

Valeant Pharmaceuticals North America LLC, et al. v. Mylan Pharmaceuticals, Inc., et al., Nos. 18-cv-184, 19-cv-37 (N.D. W. Va.)

Bausch Health US, LLC et al. v. Mylan Pharmaceuticals Inc., No. 20-cv-46 (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.

Dated: December 21, 2020

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing leading research-based pharmaceutical and biotechnology companies.[2] PhRMA's members are the primary source of the many new medicines introduced each year and play a key role in extending longevity and improving the quality of human life.

Given the risky biopharmaceutical research and development process, which has a significant failure rate, and the substantial requirements to demonstrate safety and efficacy of new products, those results come at a significant cost to PhRMA's members. Since 2000, PhRMA members have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019. PhRMA members make these investments in reliance on a legal system that protects their intellectual property, a core component of which is the ability to choose the forum for litigation about patents covering their products before generic drugs are launched.

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[1] PhRMA certifies that no party or party's counsel authored this brief in whole or in part or contributed money that was intended to fund the preparation or submission of this brief, and no person—other than PhRMA or its members—contributed money that was intended to fund the preparation or submission of this brief.

[2] PhRMA's members are listed at http://www.phrma.org/about/members.

PhRMA has a substantial interest in this case because its members regularly bring infringement suits under 35 U.S.C. §271(e)(2) to protect their patent rights and need clarity on where such suits can be filed in the wake of *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017).

SUMMARY OF THE ARGUMENT

The *en banc* Court should grant rehearing because the panel's decision is inconsistent with the text and purpose of both the Hatch-Waxman Act and 28 U.S.C. §1400(b). The error in the panel's decision and the assumptions underlying it will exacerbate the burdens faced by innovator pharmaceutical companies in the wake of *TC Heartland*. The fragmented litigation required by the panel decision reduces judicial efficiency and significantly increases the costs of Hatch-Waxman cases—particularly now that such cases frequently have many defendants.

PhRMA supports the petition's interpretation of §271(e)(2), which necessarily includes in the venue analysis hypothetical future acts of infringement that the generic defendant is presumed to commit by filing an Abbreviated New Drug Application ("ANDA"). By excluding these acts, the panel interpreted §271(e)(2) in a manner that conflicts with the Hatch-Waxman Act's structure and purpose.

Moreover, *en banc* rehearing is warranted to review an exceptionally important question that was addressed only implicitly by the panel: Whether 28

U.S.C. §1400(b) governs §271(e)(2) actions. Section 1400(b) is an exception to the general venue statute, 28 U.S.C. §1391. It should be construed narrowly and extended to §271(e)(2) actions only if doing so is consistent with the text and purpose of both statutes. But the text of §1400(b) cannot be reconciled with §271(e)(2); the enacting Congress in 1897 did not contemplate hypothetical acts of infringement; and extending §1400(b) to §271(e)(2) actions would conflict with the Hatch-Waxman Act's purpose. Maxims of statutory interpretation therefore indicate that the general venue statute should govern §271(e)(2) actions.

ARGUMENT

I. THE PANEL DECISION IMPROPERLY EXCLUDES AN ANDA FILER'S FUTURE CONDUCT FROM §271(E)(2)'S INFRINGING ACTS

As the petition describes, the panel's decision improperly excludes an ANDA filer's future conduct from §271(e)(2)'s infringing acts. A main purpose of §271(e)(2) is to "facilitate[] the early resolution of patent disputes between generic and pioneering drug companies by providing that the mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1283 (Fed. Cir. 2008). Claims under §271(e)(2) therefore have elements that are based both on actions during the approval process and on the intended marketing of the product if the ANDA is approved. Not only must the defendant have submitted an ANDA and manifested an intent to engage in the manufacture, use, or sale of the ANDA product before the patent expires, but

the ANDA product or its use, if approved, must infringe the patent. The latter is a necessary element of a §271(e)(2) claim because a court must "determine whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent." *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995).

This Court has recognized that these intended marketing acts are sufficient to establish personal jurisdiction. In *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016), the Court rejected Mylan's attempt to evade jurisdiction outside its home state because, among other things, when Mylan submits an ANDA, "Mylan seeks approval to sell its generic drugs throughout the United States." If the nationwide intended acts of infringement that Mylan is presumed to undertake when it files an ANDA are sufficient to establish personal jurisdiction nationwide, those same acts should be "acts of infringement" under §1400(b).

II. HATCH-WAXMAN CASES SHOULD BE ANALYZED UNDER THE GENERAL VENUE STATUTE

The *en banc* Court should also grant rehearing because the panel decision is based on a flawed premise. Actions under §271(e)(2) should be governed by the general venue statute, 28 U.S.C. §1391, and not by §1400(b). Although not addressed by the panel or the parties, this issue is exceptionally important because of the inefficiencies and gamesmanship that will result from splintering Hatch-

Waxman cases involving the same drug into districts across the country. The *en banc* Court should either resolve this threshold question or clarify that the panel decision leaves it open.[3]

A. Applying §1400(b) to Hatch-Waxman Actions Is Inconsistent with Both Statutes' Text, History, and Purpose

Venue in civil actions is generally governed by 28 U.S.C. §1391, but "in 1897 Congress placed patent infringement cases in a class by themselves, outside the scope of general venue legislation," by enacting §1400(b)'s predecessor. *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 713 (1972). The exception embodied in §1400(b) has been narrowly and literally construed: The Supreme Court has declined to extend it to actions against foreign defendants, *id.* at 710 & n.8, and other courts have declined to extend it to actions seeking declaratory judgments, *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1583 (Fed. Cir. 1990), *abrogated on other grounds*, *TC Heartland*, 137 S. Ct. at 1521 (collecting cases).[4] Those decisions are consistent with the maxim

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[3] Two district court decisions have declined to apply the general venue statute, but the issue has not been considered by this Court. *See Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, No. 17-cv-374-LPS, 2018 WL 5109836, at *5 (D. Del. Oct. 18, 2018); *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, No. 18-cv-1043-LPS, 2019 WL 2502535, at *2 (D. Del. June 17, 2019).

[4] Courts have continued to hold that "[v]enue in declaratory judgment actions for non-infringement of a patent is governed by the general venue statute" since *TC Heartland*. *See, e.g.*, *Apple Inc. v. VoIP-Pal.com, Inc.*, No. 20-cv-02460-LHK, 2020 WL 7319352, at *13 (N.D. Cal. Dec. 11, 2020).

of statutory construction that exceptions to general rules be narrowly construed, *see, e.g.*, *Commissioner of Internal Revenue v. Clark*, 489 U.S. 726, 739 (1989); 2A Norman J. Singer, *Sutherland Statutes and Statutory Construction* §47:11 (7th ed. Nov. 2020), and with the Supreme Court's guidance that venue statutes not "be given a 'liberal' construction," *see, e.g.*, *Olberding v. Illinois Cent. R. Co.*, 346 U.S. 338, 340 (1953).

Section 1400(b) should not be construed to extend to §271(e)(2) actions because doing so is inconsistent with its plain meaning, lacks foundation in its history, and would frustrate the Hatch-Waxman Act's purpose.

First, as one district court has lamented, reconciling §1400(b)'s text with the language of §271(e)(2) presents "an almost impenetrable problem." *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, No. 17-cv-379-LPS, 2017 WL 3980155, at *6 (D. Del. Sept. 11, 2017). Section 1400(b) refers to the district "where the defendant has committed acts of infringement," but the panel's interpretation of §271(e)(2) does not line up with this text. For example, if the infringing act under §271(e)(2) is submission of an ANDA, as the panel held, §271(e)(2) is in tension with the plural "acts" in §1400(b) because an ANDA is generally submitted only once. This tension indicates that Congress did not intend for §271(e)(2) actions to fall within the general venue exception established by §1400(b).

Second, nothing in §1400(b)'s history suggests that Congress intended it to extend to cases about hypothetical acts of infringement, like §271(e)(2) actions. When Congress enacted §1400(b)'s predecessor in 1897, it carved out a certain category of cases—"suits brought for the infringement of letters patent"—from the general venue law. *See* Act of Mar. 3, 1897, ch. 395, 29 Stat. 695. At that time, infringement suits were limited to suits for invasion of the patentee's exclusive right to make, use, and vend the invention—in other words, infringement was limited to "the manufacture, use, or sale of the invention protected by the patent within the area and time described in the patent, by any person not duly authorized to do so by the patentee." 3 William C. Robinson, *Law of Patents for Useful Inventions* §890 (1890). The only acts that could infringe a patent—and therefore the only acts that triggered the §1400(b) exception—were acts taken in the real world. The law did not recognize an infringement cause of action premised upon future infringement in a hypothetical world until Congress passed the Hatch-Waxman Act in 1984. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (describing §271(e)(2) as "a new (and somewhat artificial) act of infringement for a very limited and technical purpose"); *see also* 10B Wright & Miller, Federal Practice and Procedure §2752 (Oct. 2020) (declaratory relief was unavailable until 1934). Because infringement under §271(e)(2) has no 1897 analogue, the history of §1400(b) provides no basis for construing it to capture §271(e)(2) actions.

Third, the structure of the Hatch-Waxman Act confirms that §271(e)(2) actions should be governed by the general venue statute. To encourage "immediate competition" by generics after patent expiration, the Act created a scheme to enable generics to litigate infringement and validity without launching a product and incurring damages. H.R. Rep. No. 98-857, pt. 1, at 46 (June 21, 1984). That scheme effectively creates a declaratory-judgment-like action in which the initial step—submitting a Paragraph IV certification—is taken by the ANDA filer and the relief is generally declaratory and injunctive. But the Hatch-Waxman Act gives the patent holder, not the ANDA filer, the ability to choose where the litigation is filed by giving it the first option file the action. 21 U.S.C. §355(j)(5)(C)(i)(I). This enables the patent holder to attempt to consolidate related cases in a single district. And even if the patent holder declines to file suit within the allotted 45-day period and the generic files a declaratory judgment action, the Act still indicates a preference for consolidation—a generic may only file such an action in the district where the *patent holder* has its "principal place of business or a regular and established place of business." 21 U.S.C. §355(j)(5)(C)(i)(II). Applying the general venue statute to §271(e)(2) actions would therefore be more consistent with the Hatch-Waxman Act's intent to allow the patent holder to choose the forum for Hatch-Waxman litigation.

B. Application of the General Venue Statute to §271(e)(2) Claims Is More Consistent with the Hatch-Waxman Act's Policy Goals

Application of the general venue statute to §271(e)(2) actions is also more consistent with one of the Hatch-Waxman Act's central goals—the orderly completion of litigation within the statutory 30-month stay of the FDA's approval of the generic's ANDA. *Caraco*, 527 F.3d at 1283. If litigation is not completed within this stay, preliminary relief is frequently necessary, which increases the burdens for litigants and the courts.

Because of the rapid growth of the generic industry, particularly over the last decade, Hatch-Waxman cases are getting bigger: Since 2016, at least 20 medications have each generated 10 or more separate suits; four have even generated §271(e)(2) claims against more than 20 generics.[5] The only efficient way to litigate cases against this many parties within the 30-month stay is to consolidate the cases in one district. If even some of these cases were scattered across the country, the costs to the patent holder would balloon, the inventors would spend much of their time in duplicative depositions and trials, numerous courts would have to hear complex cases involving essentially the same disputes and evidence, and parties would have to grapple with complex estoppel issues

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[5] Those four cases involved Tecfidera®, Eliquis®, Aubagio®, and Farxiga®, for which the FDA reports 29, 25, 21, and 20 first-filers, respectively. FDA, *Paragraph IV Certifications*, at 4, 16, 21, and 68, https://www.fda.gov/media/133240/download.

arising from potentially inconsistent decisions about the same patents in various district courts. Applying the general venue statute to §271(e)(2) actions avoids these outcomes by enabling the patentee to consolidate all related cases in a single district.

Subjecting §271(e)(2) actions to §1400(b) also heightens the risk that one incorrect decision anywhere in the country will, as a matter of collateral estoppel, allow generics across the country to enter the market. For example, in *Biogen International GmbH v. Amneal Pharmaceuticals LLC*, No. 17-cv-823-MN, 2020 WL 5549084 (D. Del. Sept. 16, 2020), the court conducted a trial in Delaware involving numerous generics. Mylan then went to trial alone in the Northern District of West Virginia and secured a judgment of invalidity. Because of the Mylan judgment, the Delaware court held that it was compelled to enter judgment against the patent owner. *Id.* at *8. Multiple generics were thus able to enter the market even while the decisions were on appeal. Moreover, the consequences of an incorrect decision are heightened in the pharmaceutical industry because generic substitution laws ensure that a generic launch rapidly and irreparably harms the market for the innovator's drug. Splitting litigation across multiple districts increases the chances of an erroneous decision, creating greater business uncertainty and thus chilling the incentive to invest in new therapeutics.

The panel decision suggested that these effects could be mitigated by resorting to multidistrict litigation, Op. 21 n.10, but MDLs are an imperfect solution because consolidated pre-trial proceedings do not solve the problem of inconsistent judgments. Moreover, MDLs require many months to create, and the process of remanding and scheduling trials requires more time after completion of discovery. Since *TC Heartland* was decided, five Hatch-Waxman MDLs have been created.[6] In those cases, it has taken an average of 6 months from the filing of the first complaint to MDL consolidation and 7.7 months from filing to entry of the scheduling order. The first trials in these action are scheduled for an average of 31.4 months after filing, so the average time to the *first* trials—not trials in all of the member cases—already exceeds 30 months (the period within which the Hatch-Waxman Act contemplates completion of litigation).

Applying the general venue statute to §271(e)(2) actions would also prevent gamesmanship. If an ANDA filer can be sued only where it is incorporated or where it submits the ANDA, generic companies may set up subsidiaries in atypical jurisdictions for this purpose; this would enable the generic to seize control of the filing of the litigation—a right the Hatch-Waxman Act gives the patent holder—and force suits into jurisdictions with procedural rules, case timelines, or judges

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[6] MDL Nos. 2884, 2896, 2902, 2912, and 2930.

that the generic deems favorable. Such behavior would upset the balance created by the Hatch-Waxman Act by allowing generics to employ ballooning litigation costs as leverage.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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December 21, 2020

CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of December, 2020, I filed the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

The foregoing filing complies with the relevant type-volume limitation of the Federal Rules of Appellate Procedure and Federal Circuit Rules because:

1. The filing has been prepared using a proportionally-spaced typeface and includes 2,600 words, excluding the parts of the brief exempted by Federal of Appellate Procedure 32(f).

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