No. 16-341

IN THE
Supreme Court of the United States

TC HEARTLAND, LLC,

Petitioner,

v.

KRAFT FOOD GROUP BRANDS LLC,

Respondent.

BRIEF OF THE BIOTECHNOLOGY INNOVATION ORGANIZATION AND THE ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICI CURIAE*

The Biotechnology Innovation Organization ("BIO") is a major trade association representing over 1,100 biotechnology companies, research institutions, technology incubators, and similar entities in the medical, agricultural, environmental and industrial biotechnology sectors.[1] In the healthcare sector alone, the biotechnology industry has more than 370 therapeutic products currently in clinical trials being studied to treat more than 200 diseases.

The Association of University Technology Managers (AUTM) is a nonprofit organization dedicated to bringing research to life by supporting and enhancing the global academic technology transfer profession through education, professional development, partnering, and advocacy. AUTM's more than 3,200 members represent managers of intellectual property from more than 300 universities, research institutions, and teaching hospitals around the world, as well as numerous businesses and government organizations.

BIO and AUTM have a strong interest in a balanced and fair patent enforcement system. The vast majority of BIO members, for example, are small companies that have yet to bring a product to market

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[1] Letters of consent have been filed with the Clerk. Pursuant to Supreme Court Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, and no person or entity other than *amici* and their counsel made a monetary contribution to the preparation or submission of this brief.

and attain profitability. Their potential to do so depends on their ability to enforce their patents. BIO has a strong interest in ensuring that these companies, and indeed all BIO members, can invoke venue rules that enable them to enforce their patents in convenient and logical forums – such as where they are engaged in efforts to commercialize their patented inventions. At the same time, BIO and AUTM recognize that manipulating patent venue in an abusive manner is not sound policy and is not necessary to protect the legitimate interests of patent holders.

A balanced approach is imperative. While BIO and AUTM recognize policy deficiencies that have materialized under the current approach to venue, they have an interest in ensuring that those deficiencies result in targeted reforms through congressional action, not a blunderbuss approach. Given the high failure rate of potential biotechnology, bioagricultural, and pharmaceutical products, for example, and the massive investment required to identify, develop and obtain regulatory approval for new products and bring them to market, the ability to efficiently and effectively enforce patents is critical to the biotechnology industry.

Both this Court and Congress have taken significant steps in recent years to rein in abusive patent litigation. Certainly, more can be done. But the other side of the equation is crucially important given the constitutional purpose at the heart of the patent system – to "promote the Progress of Science and

useful Arts." U.S. Const., Art. I, § 8, cl. 8. As the US PTO testified with respect to proposed legislative reform, any reform "must achieve a balance, preventing abuse while ensuring that any patent owner, large or small, will be able to enforce a patent that is valid and infringed." H.R. Rep. No. 114-235, at 83 (2015) (testimony of Michelle K. Lee, Director of the PTO, April 14, 2015).

SUMMARY OF ARGUMENT

Petitioner and its *amici* document issues caused by forum shopping that has resulted in a significant concentration of patent-infringement suits in the Eastern District of Texas. BIO and AUTM share this policy concern. BIO's members are often defendants in patent suits, not just plaintiffs. And BIO does not believe it is good for the system if more than 40% of patent cases come up through a single district. BIO's view stems not only from patent suits, but also from many other types of civil litigation where BIO members have been forced to defend themselves in inconvenient and disadvantageous forums.

But attempting to resolve those issues through this case would do significantly more harm than good. This case presents this Court with a binary choice limited to patent suits. Petitioner advocates one side of that choice: a return to the venue regime that prevailed prior to 1988. That would divorce venue decisions in patent cases from the balancing of convenience that occurs as part of transfer decisions in the present system – one of several mechanisms that currently limit the degree to which forum

shopping can skew convenience and fairness in plaintiffs' favor.

The pre-1988 regime limited venue options to a corporate defendant's place of incorporation or where it "has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b). That often left few possible forums, and potential defendants could effectively shop for those forums by careful selection of their state of incorporation and whether/where to have regular and established places of business. Patent owners engaged in heated battles in an uncertain effort to litigate anywhere outside the defendants' state of incorporation. And even if they prevailed, they often would still be limited to a venue in which the defendant had a regular and established place of business but to which they had no connection whatsoever. A return to this regime would greatly inconvenience patent owners (particularly those that are small businesses, like most BIO members), would increase the amount of patent litigation by frequently forcing patent holders to bring related claims in multiple separate actions, and would skew litigation in favor of accused infringers.

Congressional reform efforts in recent years demonstrate the undesirability of a return to the pre-1988 approach. *None* of the recent reform proposals has advocated a return to that approach. The multiple proposals considered in the last two Congresses, for example, all recognized the importance of including venue options tied to locations where the patent

owner is or was engaged in activities related to the patent. Congress should be left to proceed with those better calibrated reform efforts. This Court should either dismiss this case as improvidently granted or should affirm, rather than legislating an obsolete approach to venue that Congress has not endorsed.

ARGUMENT

I. Narrowing Venue To The Forums Permitted Before The 1988 Amendment Would Inconvenience And Unfairly Disadvantage Patent Owners And Detract From Judicial Economy.

This Court noted in 1972 that "changes in the general venue law ha[d] left the patent venue statute far behind." *Brunette Mach. Works, Ltd. v. Kockum Industries, Inc.*, 406 U.S. 706, 713 n.13 (1972). Restoring the patent-venue regime that then prevailed would divorce patent-venue law even further from modern business practices than was the case in 1972.

A. The Pre-1988 Regime Severely Constrained Venue While Leading To Pitched Battles Over What Fell Within The Narrow Limits.

The patent venue provision, 28 U.S.C. § 1400(b), authorizes a plaintiff to bring a patent-infringement action in "the district where the defendant resides or where the defendant has committed acts of infringement and has a regular and established place of business." In 1988, Congress amended the general

venue provision, 28 U.S.C. § 1391, to make clear that the broad definition of "resides" in that provision applied throughout the statutory chapter, which includes § 1400(b). The Federal Circuit then held that the term "resides" in § 1400(b) took on the broad meaning specified in § 1391(c). *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990). Petitioner now advocates a return to the pre-1988 regime in which § 1400 was interpreted as a stand-alone provision without reference to § 1391.

Under the pre-1988 regime, venue in patent cases was both severely constrained and subject to pitched battles. Prior to the 1988 amendments, this Court interpreted the term "resides" as limited to the defendant's place of incorporation. *See Fourco Glass Co. v. Transmirra Products*, 353 U.S. 222, 226 (1957). When that forum was inconvenient or undesirable for a patent owner, a plaintiff's only choice was to sue "where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b).

Courts generally agreed that a "regular and established place of business" required more than merely "doing business." *See, e.g., Knapp-Monarch Co. v. Casco Products Corp.*, 342 F.2d 622 (7th Cir. 1965). The locations of a company's parent or subsidiary did not count. And a number of courts held that the same was true for locations of independent contractors hired to sell the company's products -- at least if the contractors also sold products for other companies. This was so even if the company's name

appeared in the phone book and on the office door of the contractor. *See, e.g., Coleco Industries, Inc. v. Kransco Manufacturing, Inc.*, 247 F. Supp. 571 (S.D.N.Y. 1965). *See also Grantham v. Challenge-Cook Bros.*, 420 F.2d 1182 (7th Cir. 1969); *Hollub Indus., Inc. v. Wyche*, 290 F.2d 852 (4th Cir. 1961). A manufacturer thus could dramatically restrict the venues in which it could be sued by selling through such third-party agents.

The limitations were particularly severe with respect to infringement actions involving process patents. A party infringes a process patent only if it practices the process, not if it sells or uses the product that results from the process. *See, e.g., Merrill v. Yeomans*, 94 U.S. 568 (1876); *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770 (Fed. Cir. 1993); *Foster D. Snell, Inc. v. Potters*, 88 F.2d 611 (2d Cir. 1937). Thus, if a manufacturer practiced the process only in its state of incorporation, venue might be improper in any other location regardless of whether the manufacturer sold the product elsewhere. *See, e.g., Koratron Co. v. Lion Uniform, Inc.*, 449 F.2d 337 (9th Cir. 1971).

Beyond this, there was great uncertainty that was resolved through case-by case battles. "[B]y 1985, the pocket part to the United States Code Annotated had twenty-six columns of annotations on what was or was not a 'regular and established place of business.'" Sidney A. Rosenzweig, *Patent Venue Reform: Congress Takes Two Steps Back*, Progress & Freedom Foundation Progress on Point Paper (Feb. 2009),

https://ssrn.com/abstract=1368468. In the years when venue often turned on the regular-and-established-business provision, "[a]ll too often, patent infringement suits beg[a]n with a battle over where the war is to be fought." Richard C. Wydick, *Venue in Actions for Patent Infringement*, 25 STAN. L. REV. 551 (1973). In determining whether a company had a regular and established place of business in a district, courts weighed "many small shards of evidence," including "who pays the rent on defendant's office," whether the defendant's name appears in the telephone book, whether the defendant's name appears on an office door or the lobby board of a building, and what legend appears on the business cards carried by the defendant's salesmen. *See* Wydick, *supra*, at 574 (citations omitted).

The related venue requirement that "the defendant has committed acts of infringement" in the district was also the subject of extensive litigation. An act of infringement requires making, using or selling the invention. 35 U.S.C. § 154. Parties battled over whether, for example, a defendant was selling the invention in the district if it took orders in the district but did not complete the sale there. *Compare, e.g., Dow Chem. Co. v. Melton Corp.*, 281 F.2d 292, 294 (4th Cir. 1960) (holding that completed act of sale must be proved) *with Union Asbestos v. Evans*, 328 F.2d 949, 953 (7th Cir. 1964) (holding that solicitation of sales plus demonstration of device constitutes act of infringement for venue purposes).

These battles over venue often resulted in findings that venue was improper even in venues with substantial connections to the defendant and the litigation. *See, e.g., Jeffrey Gallon, Inc. v. Joy Manufacturing Co.*, 323 F. Supp. 261 (N.D. W. Va. 1971) (holding venue improper even though defendant had repair shop in district with 11 employees); *General Radio Co. v. Superior Electric Co.*, 293 F.2d 949 (1st Cir. 1961) (holding venue improper even though defendant had office with district sales manager and secretary). At times, it appeared that defendants could all too easily defeat venue by, for instance, simply installing infringing equipment on a truck and moving around between customer locations where infringing services were performed. *Phillips v. Baker*, 121 F.2d 752, 756 (9th Cir. 1941) ("The appellees merely conduct precooling operations in a box car temporarily standing at a railroad siding, which car is there one day and gone the next; appellees also move from place to place according to the locations of the various shippers.[…] The necessary element of permanency is lacking.") Other courts found venue more readily, emphasizing, for example, that "economic realities" guide the conclusion that while "a defendant's presence in the district must be permanent and ongoing, it need not be fixed in a physical location or office." *See, e.g., Brunswick v. Suzuki Motor Co.*, 575 F. Supp. 1412, 1424 (E.D. WI 1983).

The advent of the Federal Circuit, and its consideration of § 1400(b), did not curb these venue battles. The Federal Circuit interpreted § 1400(b) in

In re Cordis Corp., 769 F.2d 733 (Fed. Cir. 1985), when it considered a petition seeking mandamus from a district court venue decision. After citing the high threshold for mandamus, it held that the district court had not abused its discretion in finding that venue was proper based on the following facts: the defendant had sales representatives who lived in the district and worked out of home offices in which they stored products and brochures, and the sales representatives also acted as consultants during implantation of allegedly infringing devices during surgery. *Id*. at 736-37. The Federal Circuit narrowly distinguished prior court of appeals decisions that had held there was no venue on similar facts. For example, it distinguished *University of Illinois Foundation v. Channel Master*, 382 F.2d 514 (7th Cir. 1967), on the basis that in that case, the company's employee who worked from his home "kept no stock or samples of the products" in the district and there was no evidence that he demonstrated the specific product. *See Cordis*, 769 F.2d at 736. With respect to the regular and established business requirement, the Federal Circuit stated, the question is whether the corporate defendant has "a permanent and continuous presence" in the district, not "whether it has a fixed physical presence in the sense of a formal office or store." *Id.* at 737.

After the *Cordis* decision, district court venue decisions continued to be unpredictable and often narrow. Some courts pointed to *Cordis* as a justification to find venue on particular facts. *See, e.g., Minnesota Mining & Mfg. v. Johnson & Johnson*

Products, 1 U.S.P.Q.2d 1992 (D. Minn. 1986) (upholding venue in Minnesota due to defendant's "substantial presence in the forum despite absence of a fixed location"). But other courts emphasized that *Cordis* was a mandamus case that itself depended on very specific factual analysis, and continued to deny venue on similar facts. In *Schoofs v. Union Carbide Corp.*, 228 U.S.P.Q. 540 (E.D. Cal. 1985), for example, the court held that a company's employment of a full-time salesperson in the district did not establish a regular and established place of business where the "totality of the activities" he performed were not "factually similar" to those in *Cordis*. In *Herbert v. Diagnostic Products*, 1986 WL 6781 (S.D.N.Y. 1986), the court held that a company whose sales representatives used their homes as offices did not have a regular and established place of business in the district where "usage of the homes is less than that in *Cordis*" – "no inventories are maintained" there, for example. *Id*. at * 4.

Herbert relied in part on a line of cases that read a 'regular and established place of business' to mean "a permanent physical location which defendant maintains, controls and pays for, and from which substantial business is conducted." *Id.* (citations omitted). Other cases also reiterated rigorous limitations. For example, *MAGICorp. v. Kinetic Presentations, Inc.,* 718 F. Supp. 334 (D.N.J. 1989), held that even in a case in which the defendant leases office space in the district, "it is necessary for the court to inquire whether the plaintiff has proved that the defendant engages in a substantial part of its

ordinary business in a continuous manner in the district." *Id.* at 340. "[I]mportant factors include whether the defendant employs sales representatives in the district and, if so (1) whether these employees work exclusively for the defendant and (2) whether they are authorized to consummate sales as opposed merely to solicit orders within the district." *Id.* (internal quotation marks and citation omitted). Under that standard, a national manufacturer can ensure it is not subject to venue in a district simply by employing sales representatives who do not work exclusively for it, and who do not consummate sales in the district.

Thus, prior to the 1988 amendments to § 1391, § 1400(b) was often interpreted narrowly after costly and unpredictable battles focused on the application of abstract statutory terms to detailed fact patterns, rather than on the practicalities of where venue is sensible. And "since the shards of evidence [related to whether a business was fixed and established] can be arrayed in an endless variety of patterns, the law in this area tend[ed] to grow in bulk but not in substance." Wydick, *supra*, at 574. It remained unpredictable and battle-prone despite decades of application.

B. A Return To The Pre-1988 Regime Would Significantly Inconvenience Patent Owners And Detract From Judicial Economy.

1. Patent Owners Would Often Have To Litigate In Distant Geographic Locations Far From Witnesses And Evidence.

With a return to a pre-1988 patent venue regime, all the confusing caselaw described above would once again become important precedent. Not only would this provide virtually unlimited fodder for unproductive litigation – *all* this precedent is *at least* 30 years old, grounded in long-superseded commercial practices from an economy that predates computers, e-commerce, and biotechnology. A return to the pre-1988 regime for patent venue would likely leave patent owners with even fewer venue options today than they had in 1988. In today's world of internet sales, a wide array of businesses (including, for example, online pharmacies) often can avoid having multiple regular and established offices, making it significantly more likely today than pre-1988 that a stand-alone interpretation of § 1400(b) would leave patent owners with no venue options other than a venue based on defendant's state of incorporation.

That stand-alone interpretation would substantially inconvenience patent owners. Many patent owners, including most of amicus BIO's members, are small companies. It is often costly and inconvenient to be forced to sue in a location that could well be on the other side of the country and

could be one where none of the relevant witnesses or documents are located. Even infringement suits involving larger entities are often more reasonably and conveniently brought in a proximate geographic location. Moreover, the federal courts in the available venue might be significantly backlogged or lack any experience with patent cases. Petitioners and their *amici* express understandable concern over the burden and inconvenience of having to defend infringement suits in faraway locations. But those concerns must be balanced against legitimate needs to enforce patents in logical locations, where the harm from infringement occurred and is most acutely felt, and where litigation can be efficiently resolved.

Such considerations are particularly important for BIO's members, who invest heavily to develop patentable inventions and whose businesses often depend on the intellectual property they represent. Developing a single therapy requires a fully capitalized average investment approaching $2.6 billion and consumes more than six years. *See* DiMasi JA, Grabowski HG, Hansen RA. *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,* J. HEALTH ECON. 47: 20-33 (2016). And the risk is huge. There is only a one in 5,000 chance that a biopharmaceutical medicine will advance from the laboratory bench to production. *See* Secretary of Health and Human Services Tommy G. Thompson, Remarks at the Milken Institute's Global Conference (Apr. 26, 2004), available at www.hhs.gov/news/speech/2004/040426.html. As a

result of these costs and risks, the development of experimental compounds is significantly impacted by the enforceability of patent protection. Benjamin Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEXAS L. REV. 503 (2009).

A small company may hold a limited number of patents and manufacture its biopharmaceutical products in a single state, where its headquarters are also located. If faced with patent infringement, the state of the company's residence is the most logical forum for suit – the place where the harm of infringement can most naturally be said to occur and the place where relevant witnesses and documents are likely to be located. Such a result reflects a venue choice that would be available to a plaintiff in any other type of commercial action. And if the defendant believed that the state was an inconvenient forum, it could seek to transfer the litigation.

Such convenience factors are ordinarily a critical part of venue determinations. Constitutional limits on personal jurisdiction protect all defendants from having to defend themselves in jurisdictions that are outside the bounds of "traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). Venue statutes are then designed "to allocate suits to the most appropriate or convenient federal forum." *Brunette Mach. Works, Ltd. v. Kockum Industries, Inc.*, 406 U.S. 706, 710 (1972).

Under the general venue provision, a plaintiff suing a corporate defendant can select the forum so

long as there is personal jurisdiction, but the defendant can then seek transfer under 28 U.S.C. § 1404(a) based on the convenience of *both* parties including "relative ease of access to sources of proof; availability of compulsory process for attendance of unwilling, and the cost of obtaining attendance of willing, witnesses. . . and all other practical problems that make trial of a case easy, expeditious and inexpensive." *Piper Aircraft Co. v. Reyno* , 454 U.S. 235, 241, n.6 (1981) (internal quotation marks omitted). Courts can also consider public-interest factors including "the administrative difficulties flowing from court congestion . . . ." *Id.* The transfer provision "reflects an increased desire [by Congress] to have federal civil suits tried in the federal system at the place called for in the particular case by consideration of convenience and justice." *Van Duesen v. Barrack*, 376 U.S. 612 (1964).

Prior to passage of the transfer statute, convenience also was important, but it was the plaintiff's convenience that was front and center. Under the traditional doctrine of *forum non conveniens*, "a real showing of convenience by a plaintiff who has sued in his home forum will normally outweigh the inconvenience the defendant may have shown." *Koster v. Lumbermens Mutual Co.*, 330 U.S. 518, 524 (1947). *See also Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508 (1947) ("[U]nless the balance is strongly in favor of the defendant, the plaintiff's choice of forum should rarely be disturbed.")

But Petitioner now proposes re-imposition of an approach to patent venue under which considerations of the plaintiff's convenience and justice become irrelevant. The only available venue(s) may not be the site of any of the operative facts or include *any* of the evidence or witnesses. The courts in those venues could also be backlogged and could lack any experience with patent cases. Indeed, forums that would undoubtedly meet both private and public venue transfer factors would often be precluded.

This very case is an illustration. Respondent sued in the jurisdiction where it is incorporated and thus to which it has strong ties and one in which it alleges Petitioner infringed. Petitioner was unable to show that the balance of convenience justified transfer elsewhere. But it now asks this Court to impose venue requirements that would render irrelevant Respondent's connection to the district and the balance of factors that the district court determined counsel against transfer.

2. Patent Owners Would Be Restricted In Their Ability To Bring Significantly Related Claims In A Single Action.

A return to the pre-1988 regime could further inconvenience patent owners – and detract from judicial economy – by significantly limiting the ability of patent owners to litigate closely related claims in a single action.

Often patentees bring suit on multiple related patents in a single action. For example, defendants frequently infringe method and product patents

simultaneously. But, as explained in § I *supra*, some courts applying the pre-1988 regime held that the only proper venue for suit on a method patent (outside the place of incorporation) is the place where the method is practiced, not where the resultant product is sold. Some of these courts dismissed method claims brought in other venues even when plaintiffs were properly proceeding on product claims in those venues. *See, e.g., Kalvar Corp. v. Memorex Corp.*, 386 F. Supp. 273 (E.D. La. 1974) (holding venue was proper only as to product claim, not method claim); *Schroeder v. Owens-Corning Fiberglas Corp.*, 326 F. Supp. 594 (C.D. Cal. 1971). A return to the pre-1988 venue regime thus could result in separate and duplicative litigation of claims based on product and method patents.

Even with respect to multiple product claims, the patent owner could be severely limited in its ability to sue on related patents in the same forum. In *Dow Chem. Co. v. Metlon Corp.*, 281 F.2d 1960 (4th Cir. 1960), for example, the plaintiff alleged that defendant had infringed two of its patents through the sale of certain yarns. The court found that that there was no venue with respect to the claims under one of the patents, because there was no evidence of sale of the particular yarns alleged to violate that patent. The patent owner was permitted to proceed in the existing forum with only a subset of its claims; the rest had to be litigated elsewhere.

One particularly important type of patent litigation would be significantly impacted by a return

to the pre-1988 venue regime: litigation based on abbreviated new drug applications ("ANDAs") that generic competitors file with the FDA seeking permission to market a generic version of a brand drug. *See Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404-05 (2012) (describing the process). This form of litigation was created by the 1984 Hatch Waxman Act and thus was not long subject to the pre-1988 venue regime. (BIO and AUTM are not aware of any decisions interpreting §1400(b) in Hatch-Waxman ANDA cases while the pre-1988 regime was in effect.)

Under the Hatch-Waxman Act, if competitors wish to produce a generic form of a brand drug before expiration of patents on the brand drug, they may submit a "Paragraph IV certification" stating that the relevant brand patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Often many manufacturers of generics submit applications. In 2005, for example, an average of eleven applications were submitted the first day that doing so was permissible *See F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2246 (2013) (Roberts, C.J., dissenting) (citing data from Brief for Generic Pharmaceutical Association). After the patent owner receives notice of the ANDA filings, it has 45 days to sue for infringement, which then automatically entitles it to a thirty month stay. 21 U.S.C. § 355(j)(5)(B)(iii).

When multiple ANDAs have been filed for the same brand drug, it is generally advantageous for the

patent owner, as well as judicially efficient, to bring infringement actions against the applicants in a single district because such cases involve the same timelines and highly similar issues across defendants. *See, e.g., Pfizer Inc. v. Teva Pharmaceuticals USA, Inc.*, 444 Fed. Appx. 961 (Fed. Cir. 2014) (case with ten defendants); *Eli Lilly and Co. v. Actavis Elizabeth LLC*, 2010 WL 3374123 (Fed. Cir. 2007) (seven defendants); *Sanofi-Aventis v. Sandoz, Inc.*, 405 Fed. Appx. 493 (Fed. Cir. 2009) (twenty-three defendants). As the Federal Circuit has explained, permitting adjudication of multiple ANDA infringement actions in a single district "will serve the interests of the plaintiffs and the judicial system in efficient resolution of litigation." *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals Inc.*, 817 F.3d 755 (Fed. Cir. 2016). This avoids the need to educate multiple courts on what are often complex technical issues. As one court explained in the context of a discussion of personal jurisdiction:

> it would be a significant burden on Plaintiffs if required to bring lawsuits against each ANDA filer in the defendants' respective home states. In this case, Plaintiffs initially filed suit against approximately forty generic drug companies that reside in a variety of locations. Such a result would be inconsistent with the balance that Congress sought to create in passing the Hatch-Waxman Act.

Eli Lilly and Co. v. Mylan Pharmaceuticals, Inc., 96 F. Supp. 3d 824, 835 (S.D. Ind. 2015).

But if Petitioner prevails, patent owners will not be able to prosecute ANDA-based infringement actions in a single district unless (1) the generic manufacturers are all incorporated in the same state or (2) they all have regular and established places of business in the same district and they have all committed acts of infringement there. Those conditions are very unlikely to be met in most cases. Generic manufacturers are incorporated all over the country. *See, e.g., id.* at 835 (noting that the forty generic manufacturers sued "reside in a variety of locations"). Mylan Pharmaceuticals, for example, is incorporated in West Virginia (and has its principal place of business in Morgantown West Virginia) where no other generics are incorporated.[2] It is also unlikely the manufacturers would all have regular and established places of business in the same district. And the "acts of infringement" requirement could also be a significant barrier. It is not clear where a defendant in an ANDA case has committed an act of infringement, because the sole act of infringement in such cases is the artificial one of filing the ANDA application. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990).[3]

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[2] Mylan has previously challenged litigation against it in other jurisdictions. *See, e.g., id.*; *see also Acorda Therapeutics,* 817 F.3d at 764 (holding there was personal jurisdiction over Mylan in ANDA litigation brought in Delaware).

[3] For purposes of personal jurisdiction, the Federal Circuit has held that the filing of the ANDA application with the FDA did not confer personal jurisdiction at the FDA's location in

Moreover, even if patent owners believed they could establish that each generic competitor has committed an act of infringement and had a regular and established place of business in a single venue, the patent owners would face significant risks if they brought all the suits in that venue. If they brought the suits in one district and some were dismissed on venue grounds, the owners might not be able to re-file because the 45-day window would have expired. *Pfizer, Inc. v. Sandoz, Inc.*, 2010 WL 256548, at * 3 (D. Del. 2010). That puts "patent holders 'between a jurisdictional rock and a hard place: file suit in the forum of choice but risk losing patent protection if the suit is dismissed for personal jurisdiction, or file suit in the only known safe forum(s)," which would likely differ for each generic. *Id.* (quotation omitted).[4]

C. A Return To The Pre-1988 Regime Would Unfairly Disadvantage Patent Owners Relative To Accused Infringers.

Most of the policy justifications advanced by Petitioner and its *amici* for narrow venue in patent-

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Maryland. *Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829 (Fed. Cir. 1999). Instead, it has held that minimum contacts can be established based on where the ANDA applicants intended to conduct future infringing activities (such as selling the generic). *Acorda Therapeutics.*, 817 F.3d at 763. Whether this standard would carry over to assess where an act of infringement occurred for venue purposes is unclear.

[4] In some cases, patent owners file protective suits in the generic's home district in an attempt to ward off this problem. Even if successful, however, this tactic results in wasteful, duplicative litigation.

infringement actions are arguments against enabling plaintiffs to engage in forum shopping. BIO and AUTM understand that concern. BIO's members have been subjected to suit in distant forums that plaintiffs believed were uniquely advantageous in all sorts of actions, including patent actions. But the disadvantage to patent owners from a return to the pre-1988 regime would be significantly greater than any disadvantages to defendants that exist today.

Under the pre-1988 regime, patent owners would only be able to sue in districts in which the defendants are in some sense at home – districts in which they are either incorporated or in which they have a regular and established place of business and have committed acts of infringement. That provides defendants some home field advantage as a matter of course. Moreover, entities that know they are likely to be defendants in patent actions can engage in their own forum shopping by choosing their state of incorporation based on perceived litigation advantages. They can then take steps to distribute their product without establishing regular and established places of business in any venues they do not view as advantageous. That is particularly easy in today's world of internet sales.

This Court has noted the risk that "[t]hrough its choice of the State of incorporation, a corporation could manipulate federal court jurisdiction, for example, opening the federal courts' doors in a State where it conducted nearly all its business by filing incorporation papers elsewhere." *Hertz Corp. v.*

Friend, 559 U.S. 77, 85-86 (2010). As Congress has recognized in considering patent-venue reform proposals, venue rules should not permit a party to "manufacture venue" by choosing its state of incorporation. S. Rep. No. 110-259, at 26 (2008). The Senate Judiciary Committee amended one proposed reform bill by adding multiple venue options to ensure that "a company cannot establish venue in a given State simply by incorporating there." *Id.* Similarly, the House Judiciary Committee amended a reform proposal so that it explicitly directed that "a party shall not manufacture venue by assignment, incorporation, joinder, or otherwise primarily to invoke the venue of a specific district court." H.R. 1908, 110th Cong. § 11 (Sept. 7, 2007). A return to the pre-1988 regime enables just the sort of forum shopping the congressional committees were seeking to avoid.

As evident from the *Acorda Therapeutics* and *Eli Lilly* cases, Mylan may have already selected the states of incorporation and principal places of business of particular Mylan entities in an effort to control the forum of infringement litigation against it. Two Mylan entities associated with production of generics – Mylan Pharmaceuticals, Inc. and its parent Mylan Inc. – are incorporated in West Virginia and Pennsylvania respectively with their principal places of business in those states – even though twenty of Mylan Inc.'s subsidiaries are incorporated in Delaware. *Acorda Therapeutics, Inc. v. Mylan Pharmaceuticals Inc.*, 78 F. Supp. 3d 572 (D. Del. 2015), *aff'd.* 817 F.3d 755 (Fed. Cir. 2016). The Mylan

entities incorporated in West Virginia and Pennsylvania have subsequently challenged personal jurisdiction in infringement suits outside these states. The challenges have generally failed. *See id.*, 817 F.3d at 764; *Eli* Lilly, 96 F. Supp. 3d at 835; *but cf. Acorda Therapeutics*, 78 F. Supp. 3d at 598 (holding jurisdictional discovery necessary with respect to Mylan Inc.). But these entities could recast them in future cases as venue arguments – were this Court to revive the pre-1988 venue regime.

Even beyond selecting their state of incorporation and controlling their regular and established places of business, likely infringement defendants could also control the forum through other means. Defendants could move for transfer among districts in which the plaintiff originally could have brought suit. *See, e.g., Kaiser Industries Corp. v. Wheeling-Pittsburgh Steel Corp.*, 328 F. Supp. 365, 368 (D. Del. 1971). If for some reason they deemed their home districts disadvantageous for particular litigation, they could bring their own action in a different district seeking a declaratory judgment that the patent is invalid or not infringed. Such declaratory judgment actions are governed by the general venue statute, *see, e.g., VE Holding Corp.*, 917 F.2d at 1583; *U.S. Aluminum Corp. v. Kawneer Co., Inc.*, 694 F.2d 193, 195 (9th Cir. 1982), and give a manufacturer charged with infringement "an equal start in the race to the courthouse." *Kerotest Mfg. Co. v. C-O-Two Fire Equipment Co.*, 342 U.S. 180, 185 (1952); *see also Genenntech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993), *rev'd on other grounds*, *Wilton v.*

Seven Falls Co., 414 U.S. 277 (1995). Indeed, in some cases, the manufacturer is entitled to priority even if it files second. *See, e.g., Codex v. Milgo Electronic Corp.*, 553 F.2d 735, 738 (1st Cir. 1977) (establishing rebuttable presumption that if patent owner sues manufacturer's customer for infringement and manufacturer then files a declaratory judgment action, the declaratory judgment action has priority); *Kahn v. General Motors Corp.*, 889 F.2d 1078, 1081 (Fed. Cir. 1989) (approving generally of the First Circuit's "customer-suit" exception to the first-filed rule but holding that it did not apply on the specific facts before it).

Thus, a return to the pre-1988 regime would require patent owners to sue in potentially inconvenient forums where defendants are in some sense at home, would enable defendants to exercise control over which forums those were, and would leave defendants with means to choose different forums in particular cases or on particular issues. Patent owners might have little or no ability to influence forum choice if the defendant limited its regular and established places of business.

Today, in contrast, neither party is subject to unconstrained forum shopping. While there is undoubtedly undesirable forum shopping by plaintiffs, potential defendants have mechanisms available to limit such forum shopping. They can file their own declaratory judgment actions of non-

infringement or invalidity.[5] They can avail themselves of the PTO's Inter Partes Review Process for review of validity issues. *See Cuozzo Speed Technologies, LLC*, 136 S. Ct. 2131, 2137 (2016) (describing process, which was created in 2011); *Murata Machinery U.S.A. v. Daifuku Co., Ltd.*, 830 F.3d 1357, 1362 (Fed. Cir. 2016) (explaining that district courts have authority to stay infringement actions while the PTO review proceeds). *See also* Vishnubhakat, S., Rai, A., and Kesan, J.*, Strategic Decision Making in Dual PTAB And District Court Proceedings*, 31 BERKELEY TECH. L.J. 45, 80 (2016)(noting that more than 50% of motions to stay district court litigation pending PTO review are granted in whole or in part). Defendants can also contest personal jurisdiction in any forum in which they do not have minimum contacts sufficient to satisfy traditional notions of fair play and substantial justice. And they can move for transfer on the basis of considerations of overall convenience and justice. In cases where district courts fail to transfer when they should, the Federal Circuit has increasingly exercised mandamus to order transfer. *See* Software & Information Industry Ass'n Br. at 26 (noting that Federal Circuit has ordered mandamus of transfer decisions 17 times since 2008).

Thus, the present venue rules provide multiple safety valves for accused infringers to constrain the

[5] The Federal Circuit recently held that personal jurisdiction in such actions can extend to jurisdictions where the patent owner has transmitted warning letters. *See Xilinx, Inc v. Papst Licensing GmbH & Co. KG*, 2017 WL 605307 (Fed. Cir. 2017).

effects of forum shopping by plaintiffs. Petitioner's proposed interpretation of § 1400, on the other hand, would result in venue rules leaving patent owners in many cases with inadequate ability to constrain forum shopping by defendants. That skewed system has nothing to recommend it.

D. There Is Nothing Unique About Patent-Infringement Actions That Justifies Narrow Venue As A Policy Matter.

As the ABA Patent Section previously concluded, there is no policy justification for a special rule for patent venue, much less for one as constraining as the pre-1988 interpretation of § 1400. *See* Peterson, *Repeal of the Patent Venue Statute*, 1989 A.B.A. Sec. Pat. Trademark and Copyright L. 240, 247.

The ABA has now changed its mind, pointing to forum shopping induced by patent-specific procedural rules adopted by particular districts. ABA Br. at 12-13. But if these non-uniform procedural rules are problematic, the proper solution is to change them or to require uniformity. It is not to change the interpretation of the venue statute to one that constrains patent owners to very limited venue choices.

Some of Petitioner's *amici* portray patent-infringement actions as subject to abuse by patent trolls. *See, e.g.,* Br. of Software & Information Industry Association at 22-25. But the possibility of abuse does not distinguish patent cases from other causes of action. Moreover, both Congress and this Court have taken many steps in recent years to

protect against abusive patent litigation. Congress has, for example, set up the Inter Partes Review System. And this Court has rendered decisions on patent-eligible subject matter (*see, e.g., Alice Corp. v. CLS Bank Int'l.*, 134 S. Ct. 2347 (2014)) and claim definiteness, *Biosig v. Nautilus*, 134 S. Ct. 2120 (2014), that have made it significantly easier to invalidate patents. It has also enabled more frequent award of attorney fees to prevailing parties, *see Octane Fitness LLC v. Icon Health & Fitness*, 134 S. Ct. 1449 (2014); *Highmark Inc. v. Allcare Health Management System*, 134 S. Ct. 1744 (2014).

Some of Petitioner's *amici* point to a justification for special venue rules in patent cases that was first articulated by the Tenth Circuit in *Ruth v. Eagle-Picher Co.*, 224 F.2d 572, 577 (10th Cir. 1955), namely that the technical and intricate nature of patent cases justifies confining venue to places where the alleged acts of infringement occurred and defendant has a regular and established business. *See, e.g.,* Intel/Dell *amicus* Br. at 32-34. When Congress enacted § 1400, it did not rely on any such justification, however. Wydick, *supra*, at 564. That is for good reason. To the extent patent suits are uniquely technical, that would seem to argue *for* the concentration of litigation in a few experienced districts, not against it.

As for the location of evidence, most patent cases involve issues of invalidity and scope as well as infringement. On those issues, most of the evidence will be held by the patent owner, not the accused infringer. *Id.* at 565. Moreover, the pre-1988 regime

did not even ensure suit where *defendant's* evidence was located. The defendant's state of incorporation might have no nexus to the evidence, for example. As in other litigation, there is no fixed rule that can ensure a patent case is litigated in the most convenient forum.

Petitioner's proposed narrowing of venue in patent-infringement cases is not well tailored to the convenience issues it raises for the additional reason that there are many technical types of litigation that would remain outside its scope. This includes many cases involving *patent* issues such as declaratory judgment actions, as well as patent-infringement actions against aliens. *See Brunette Machine Works, Ltd. v. Kockum Industries, Inc.,* 406 U.S. 706, 714 (1972).

Common-law claims that encompass patent issues also potentially could continue to be brought outside the narrow constraints Petitioner proposes for § 1400(b)."[6] For example, a patent owner who believes that one of its licensees is violating the license might choose to sue for breach of the license agreement in

[6] This Court has held that at least in some cases, a state-law claim that turns on patent issues is not even subject to federal jurisdiction. *See Gunn v. Minton*, 133 S. Ct. 1059, 1066-67 (2013). It is not clear, however, how this applies to claims with forward-looking impact on patent enforcement. *Compare Forrester Environmental Services, Inc. v. Wheelabrator Technologies, Inc.,* 715 F.3d 1329, 1334-35 (Fed. Cir. 2013) *with MDS (Canada) Inc. v. Red Source Technologies, Inc.*, 720 F.3d 833, 842-43 (11th Cir. 2013).

state court or any federal court (assuming there is diversity jurisdiction), rather than declaring the license forfeited and suing for patent infringement. And a patent owner who believes that a third party is interfering with its relationship with its licensees might choose to sue for tortious interference with contractual relations rather than for induced infringement. *See, e.g., Koratron v. Deering Milliken, Inc.*, 418 F.2d 1314 (9th Cir. 1969) (holding suit for tortious interference was not constrained by § 1400(b)); *American Harley Corp. v. Irvin Industries, Inc*., 263 N.E.2d 552, 554 (N.Y. Ct. App. 1970) (holding that patent owner's suit for wrongful interference could proceed in state court). It would make little sense to force litigation over the same commercial dispute, involving the same facts, into different locations, depending only on whether the action involves tort, contract, or patent law. Yet, in some routine-types of patent litigation, the effect of a decision to adopt Petitioner's interpretation of § 1400 could be to skew the choice of patent owners of whether to bring common-law or patent-infringement claims without actually limiting venue choice.

II. Congressional Reform Efforts Show That Petitioner's Proposed Approach Is Unwise.

A. Congressional Reform Efforts Recognize The Need For Venue Options That Account For The Connections Of The *Plaintiff*, The Invention And The District.

Congress has given serious consideration in recent years to proposals to reform venue rules in

patent actions. *None* of the proposed legislation would have restricted venue to that in the pre-1988 regime. *Each* of the proposals would have provided plaintiffs with venue options based on their own locations, for example, where those were connected to the patent.

In the 2015-16 Congress, for example, the House Judiciary Committee approved patent reform legislation (including venue reform) that, the Committee said, was aimed at ensuring "that American manufacturing, small businesses, and start-up companies are protected against patent-enforcement abuse, while also ensuring that the patent system continues to protect and encourage American ingenuity." H.R. Rep. No. 114-235 at 23. The proposed legislation included provisions to reform patent venue, and the same provisions were introduced as a stand-alone bill in the Senate. United States Cong. Senate. *Venue Act*, 114th Cong. 2d sess. S. 2733. (March 17, 2016).

The proposed legislation specified multiple venue options. These included districts where the *plaintiff* has a regular and established physical facility and has undertaken significant activities related to the creation or practice of the patented invention – districts where *any* party has a:

> regular and established physical facility that such party controls and operates, not primarily for the purpose of creating venue, and has—
> (A) engaged in management of significant research and development of

> an invention claimed in a patent in suit prior to the effective filing date of the patent;
>
> (B) manufactured a product that embodies a tangible product that is alleged to embody an invention claimed in a patent in suit; or
>
> (C) implemented a manufacturing process that embodies manufacturing process for a tangible good in which the process is alleged to embody an invention claimed in a patent in suit;

Id.; see also H.R. REP. No. 114-235, at 6-7 (2015)**.**

The plaintiff could also sue in any jurisdiction "where an inventor named on the patent in suit conducted research or development that led to the application for the patent in suit." *Id*.

While the proposed legislation was an unfinished product, it was clearly intended to move patent law forward – not back to a pre-1988 regime. By including locations where the *plaintiff* (or inventor) has engaged in significant activities related to the patent, the proposed legislation sought to ensure that there would be at least some venue options that are convenient to the plaintiff, not just the defendant. The availability of these options also would have made it more difficult for the *defendant* to use the choice of a state of incorporation to limit venue to a chosen forum, as did inclusion of a venue option based on the defendant's principal place of business. But the forum

choices remained more than narrow enough to avoid the sort of forum shopping by plaintiffs of which Petitioner and its *amici* complain. And if a plaintiff selected a forum inconvenient for the defendant, the defendant retained the option to move to transfer.

B. The Genesis And History Of The Proposed Legislation Demonstrates A Wide Consensus Of The Importance Of Venue Options Predicated On The Patent Owners Connection With The Litigation.

The importance of including venue options tied to locations of the plaintiff that are connected to the invention was viewed by the House Judiciary Committee as "representing the emergence of a new consensus." H.R. Rep. No. 114-235, at 22 (2015) (discussing the package of reforms as a whole).

Those who dissented from the Committee's view did not advocate for narrower venue. Their general criticism of the proposed legislation was that it tilted the balance in patent litigation too far *towards* defendants, thus "imped[ing] rather than promot[ing] innovation," a view they explained was "shared by a broad cross-section of stakeholders in the patent system, representing a vast and diverse range of industry interests" including "organizations on behalf of the life sciences industries, the higher education community, agricultural interests, entrepreneurs, inventors, small businesses," and others. *Id*. at 167.

The genesis of the language on venue proposed by the Committee further demonstrates the shared understanding that patent owners who are not patent

trolls should have venue options based on their own connection to the patented invention. In 2015, the House Judiciary Committee tweaked the language on venue initially before it to add that a party's physical location could not be a source of venue where it was established "primarily for the purpose of creating venue." *Compare* H.R. 9, June 9 Amendment, pp. 19-20 *with* H.R. REP. No. 114-235, at 6-7 (2015)**.** That change restricted venue options somewhat. But the Committee Report made clear this additional language was aimed at patent trolls – entities whose interest in the patents they owned was litigation-related – and who were pursing litigation in venues like the Eastern District of Texas where there was a heavy concentration of patent cases.

"[C]ourts should consider the nature of the plaintiff," the Committee explained. H.R. Rep. No. 114-235, at 66 n. 160. Where the entity is an operating company – a company that had a substantial non-litigation interest in the patent – it "should be presumed to undertake its activities primarily in pursuit of those operations, and discovery into its motives for establishing its facilities in an area is unnecessary." *Id.* Even entities that "lack[] a substantial interest in the patent other than asserting it in litigation," should be presumed to have a bona fide motive unless the district chosen is "disproportionately burdened with patent cases." *Id*.

The Committee thus made clear that companies like respondent and *amicus* BIO's members should be able to sue where they have facilities connected to

their inventions or maintain business operations that are harmed by the infringement. The interest of BIO members in the patents they own is generally based on massive research they performed to obtain a patentable method or drug and in efforts to commercialize the resultant patents.

In 2007, the House Judiciary Committee had similarly recognized the importance of including venue options based on locations of the plaintiff. It considered an approach to venue with similarities to the 2015 proposals. H.R. 1908, 110th Cong. § 10 (Apr. 18, 2007). At that time, the House Judiciary Committee explained that:

> simply returning to the 1948 venue framework would be too strict for modern patterns of technology development and global commerce. Accordingly, venue requirements are relaxed by providing venue based on ***plaintiff's residence*** in many cases. In this way venue in patent cases should optimize convenience to all parties.

H.R. Rep. No. 110-314, at 40 (2007) (emphasis added).

C. A Decision By This Court To Return To The Pre-1988 Regime Would Likely Interfere With Congressional Reform Efforts.

The bills proposed in recent Congresses were subject to serious consideration. The 2015 bill introduced in the House was the subject of hearings with testimony from multiple witnesses, was marked

up by the House Judiciary Committee, which approved amendments and passed the bill out of Committee on a bipartisan vote of 24-8.

Senator Flake then proposed the Senate bill, which was limited solely to the venue provision. That bill was referred to the Judiciary Committee. After the Federal Circuit issued its opinion in this case, Senator Flake urged his colleagues to act on the basis that the "decision has only made need for congressional action on venue even more important." 162 Cong. Rec. S5066 (July 13, 2016). But since this Court granted *certiorari*, no further action has been taken. A decision in Petitioner's favor is likely to forestall further reform.

This Court has recognized "[t]he customary deference accorded the judgments of Congress," as well as the wisdom of deferring to Congress' superior fact-finding capabilities. *Rostker v. Goldberg*, 453 U.S. 57, 64 (1981). Congress is better equipped than this Court to calibrate the competing policy interests that underlie venue rules. Congress is also uniquely able to make a publicly accountable decision. Moreover, Congress can modify legislative reforms over time as required by experience and changing conditions, without the difficulties that attend reversing a ruling by this Court.

This Court should therefore either dismiss this case as improvidently granted or should affirm. Instructive here is the practice of state courts to decline proposals to alter the common law when similar proposals are under consideration by the state

legislature. *E.g.*, *Murphy v. American Home Prods. Corp.*, 448 N.E.2d 86, 90 & n. 1 (N.Y. 1983) (declining to recognize tort for wrongful discharge, in part because relevant state legislation "has been proposed but not adopted"); *O'Callaghan v. Waller & Beckwith Really Co.*, 155 N.E.2d 545, 547 (Ill. 1958) (declining to adopt rule regarding exculpatory clause in lease in light of state legislative activity on landlord-tenant issues).

This Court should adopt the same approach.

CONCLUSION

While a regime that concentrates patent cases in the Eastern District of Texas is undesirable, a return to the pre-1988 venue regime would be even worse. It would lead to renewed battles about venue divorced from practical considerations, would harm patent owners (particularly small entities like most BIO members), would prevent related claims from being efficiently litigated together, and would enable forum shopping by defendants without giving plaintiffs any of the mechanisms that defendants have today to limit – or limit the consequences of – forum shopping by plaintiffs.

This Court should leave reform efforts to Congress, which understands these concerns and has the capacity to adopt a balanced approach. It should either dismiss this case as improvidently granted or uphold the decision of the Federal Circuit.

Respectfully submitted.

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