No. 16-712

In the Supreme Court of the United States

OIL STATES ENERGY SERVICES, LLC, PETITIONER

v.

GREENE'S ENERGY GROUP, LLC, ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR ASSOCIATION FOR ACCESSIBLE MEDICINES AS AMICUS CURIAE SUPPORTING RESPONDENTS

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INTEREST OF AMICUS CURIAE*

The Association for Accessible Medicines (AAM), formerly the Generic Pharmaceutical Association, is a

* No counsel for a party authored this brief in whole or in part, and no person other than amicus or its counsel has made a monetary contribution intended to fund the preparation or submission of the brief. The parties have entered blanket consents to the filing of amicus briefs, and copies of their letters of consent are on file with the Clerk.

nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic drug products and bulk active pharmaceutical ingredients, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide consumers with generic and biosimilar medicines that are just as safe and effective as their brand-name counterparts, but substantially more affordable. Generic drugs account for roughly 89% of all prescriptions dispensed in the United States but only 26% of total drug costs. Over the last decade, they have generated $1.67 trillion in savings for patients and taxpayers.

AAM's core mission is to improve the lives of consumers by providing timely access to affordable medicines. To further that mission, AAM regularly participates in litigation as amicus curiae. See, *e.g.*, *Sandoz Inc.* v. *Amgen Inc.*, 137 S. Ct. 1664 (2017); *TC Heartland LLC* v. *Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223 (2013).

This case involves the inter partes review procedure, an important tool established by Congress in the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, for efficiently weeding out invalid patents. The America Invents Act was designed to address "a growing sense that questionable patents are too easily obtained and are too difficult to challenge." H.R. Rep. No. 98, Pt. 1, 112th Cong., 1st Sess. 39 (2011) (*House Report*). In creating inter partes review, Congress sought "to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproduc-

tive litigation costs." *Id.* at 40. Because manufacturers of brand-name prescription drugs can and frequently do use patents of dubious validity to prevent the introduction of competing generics, inter partes review is an important continuation of Congress' longstanding effort "to get generic drugs into the hands of patients at reasonable prices—fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir.), cert. denied, 502 U.S. 906 (1991). The resolution of this case is therefore of particular importance to AAM and its members.

SUMMARY OF ARGUMENT

Non–Article III tribunals may adjudicate cases in which "the claim at issue derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority." *Stern* v. *Marshall*, 564 U.S. 462, 490 (2011). Inter partes review involves claims that qualify under both components of that test.

First, patent rights "exist only by virtue of statute," and the patent system is a federal regulatory scheme entrusted to the expert administration of the United States Patent and Trademark Office (PTO). *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 229 n.5 (1964). It is undisputed that Congress may assign the issuance of patents to an administrative agency, and it follows that Congress may also give the agency authority to reconsider its decisions and correct its own mistakes by revoking patents that should not have issued. Inter partes review, which allows the PTO to take "a second look at an earlier administra-

tive grant of a patent," does exactly that. *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2144 (2016).

Second, inter partes review is essential to the limited regulatory objective of eliminating invalid patents that block valuable products like low-cost generic medicines. Patents are issued "in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). Faced with heavy caseloads and limited time and resources to review patent applications, the PTO inevitably issues some patents it should not. Inter partes review was established to "provid[e] a more efficient system for challenging patents that should not have issued." *House Report* 39-40. Compared to litigation in federal court, the process offers the benefits of a relaxed standing requirement, more focused discovery, streamlined evidentiary and hearing procedures, and rapid deadlines for adjudication. At the same time, it retains significant safeguards to protect the holders of valid patents.

An efficient system for challenging invalid patents is particularly important to the continued provision of low-cost, high-quality generic and biosimilar medicines, which are frequently denied to patients due to invalid patents. Generic drugs are therapeutically identical to their brand-name counterparts, and they offer significant savings to patients and the taxpayers. None of the benefits of generic medicines can be realized, however, until after the brand-name manufacturer's patent claims—even dubious ones—have been resolved. Delay in removing improperly awarded patents therefore leads to substantially higher drug

costs to our Nation. A speedy and efficient mechanism to challenge improvidently granted patents is essential to the timely provision of generic and biosimilar medicines.

ARGUMENT

This Court has long recognized that "there are matters, involving public rights, which may be presented in such form that the judicial power is capable of acting on them, and which are susceptible of judicial determination, but which [C]ongress may or may not bring within the cognizance of the courts of the United States, as it may deem proper." *Murray's Lessee* v. *Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1856). Public rights—those rights "arising 'between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments'"—are created by Congress, and Congress may commit their adjudication to administrative tribunals. *Stern*, 564 U.S. at 489 (quoting *Crowell* v. *Benson*, 285 U.S. 22, 50 (1932)); see *B&B Hardware, Inc.* v. *Hargis Indus., Inc.*, 135 S. Ct. 1293, 1316 (2015) (Thomas, J., dissenting) (noting that administrative agencies may "function as courts * * * with respect to claims involving public or quasi-private rights"). Under this "public rights doctrine," non–Article III tribunals may adjudicate cases in which "the claim at issue derives from a federal regulatory scheme, or in which resolution of the claim by an expert Government agency is deemed essential to a limited regulatory objective within the agency's authority." *Stern*, 564 U.S. at 490. Inter partes review involves claims that qualify under both components of that test.

A. Inter partes review governs claims derived from a federal regulatory scheme

Patent rights are public rights because they are derived from a federal regulatory scheme. As this Court has observed, patent rights "exist only by virtue of statute," and they can be conferred only by the government. *Sears*, 376 U.S. at 229 n.5. Unlike "a parcel of land" (Pet. Br. 29), they do not exist until established by Congress or an agency acting on its behalf. Congress may therefore commit their adjudication to an agency.

In the exercise of its Article I power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries," U.S. Const. art. I, § 8, cl. 8, Congress has directed the PTO to approve a patent application if "it appears that the applicant is entitled to a patent" under standards prescribed by law, 35 U.S.C. 131. By empowering the PTO to grant patents, Congress devised an "expert and inexpensive method for dealing with a class of questions of fact which are particularly suited to examination and determination by an administrative agency specially assigned to that task." *Stern*, 564 U.S. at 494 (quoting *Crowell*, 285 U.S. at 46); see *B&B Hardware*, 135 S. Ct. at 1317 (Thomas, J., dissenting) ("Because [trademark] registration is merely a statutory government entitlement, no one disputes that the [PTO] may constitutionally adjudicate a registration claim.").

Petitioner does not dispute that Congress may permissibly assign to the PTO the authority to issue a patent in the first instance. It follows that Congress

may also allow the PTO to revoke a patent if it determines that the issuance of that patent was erroneous. It has long been recognized that "[t]he power to reconsider is inherent in the power to decide." *Albertson* v. *FCC*, 182 F.2d 397, 399 (D.C. Cir. 1950). For that reason, this Court has held that courts have an inherent power to correct their own mistakes. See, *e.g.*, *Gagnon* v. *United States*, 193 U.S. 451, 456 (1904); see also *United States* v. *Denedo*, 556 U.S. 904, 912-913 (2009). And "[a]n agency, like a court, can undo what is wrongfully done by virtue of its order." *United Gas Improvement Co.* v. *Callery Props., Inc.*, 382 U.S. 223, 229 (1965).

For decades, the PTO has exercised the authority to reconsider its patenting decisions in appropriate circumstances. Before the America Invents Act, when more than one party sought to patent the same subject matter, the PTO conducted an "interference" proceeding to resolve the competing claims and determine which one was entitled to priority. 35 U.S.C. 135(a) (2006); see *Koninklijke Philips Elecs. N.V.* v. *Cardiac Sci. Operating Co.*, 590 F.3d 1326, 1334 (Fed. Cir. 2010). Interferences were not limited to competing applications but could be conducted whenever an applicant sought a patent that would "interfere with any pending application, *or* with any unexpired patent." 35 U.S.C. 135 (1952) (emphasis added). And for more than 70 years, the statute provided that if the agency determined that the applicant had priority, the proceeding could result in the "cancellation of the claims involved" in the already-issued patent. *Ibid.*; see, *e.g.*, *Hahn* v. *Wong*, 892 F.2d 1028, 1030 (Fed. Cir. 1989)

(describing procedure for interference between an application and a patent).

In addition, since 1980, the PTO's ex parte reexamination procedure has allowed "[a]ny person at any time" to "file a request for reexamination" of an issued patent by the PTO. 35 U.S.C. 302. If the PTO identifies "a substantial new question of patentability," it can reexamine the patent and revoke it if appropriate. 35 U.S.C. 303(a); see *Cuozzo*, 136 S. Ct. at 2137. And in 1999, Congress established an inter partes reexamination procedure under which third parties had the right to participate in the reexamination proceedings and challenge the validity of a patent. See Optional Inter Partes Reexamination Procedure Act of 1999, Pub. L. No. 106-113, Tit. IV, Subtit. F, 113 Stat. 1501A-567. That procedure is the direct antecedent of the inter partes review process established by the America Invents Act.

Petitioner attempts to distinguish those traditional procedures, but its efforts are unavailing. Petitioner points out (Br. 49-50) that interference decisions are subject to judicial review, but so are the results of inter partes review. 35 U.S.C. 319. Petitioner also observes (Br. 50) that ex parte reexamination is not "an adversarial proceeding with all the trappings of litigation." That may be true, but petitioner does not explain why a relatively informal procedure for reconsidering an agency's decision is constitutionally permissible while one that offers *greater* procedural protections to affected parties is not.

Whether it takes place in an interference proceeding, through ex parte reexamination, or through inter partes review, the PTO's revocation of a patent does

not entail constitutionally impermissible adjudication. It does not resolve questions of whether a patent has been infringed. Instead, it is merely an exercise of the agency's inherent power to correct its own mistakes and to take "a second look at an earlier administrative grant of a patent." *Cuozzo*, 136 S. Ct. at 2144. For that reason, the claims involved are "so closely integrated into a public regulatory scheme as to be a matter appropriate for agency resolution." *Granfinanciera, S.A.* v. *Nordberg*, 492 U.S. 33, 54 (1989) (quoting *Thomas* v. *Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 594 (1985)).

B. Inter partes review is essential to the limited regulatory objective of eliminating invalid patents

The inter partes review process is also "essential to a limited regulatory objective within the agency's authority," *Stern*, 464 U.S. at 490, namely, quickly and cheaply eliminating patents that were improvidently granted and are blocking valuable technology from reaching the market. This Court has recognized that the "possession and assertion of patent rights are 'issues of great moment to the public,'" and that "[t]he far-reaching social and economic consequences of a patent * * * give the public a paramount interest in seeing that patent monopolies * * * are kept within their legitimate scope." *Precision Instrument Mfg. Co.* v. *Auto. Maint. Mach. Co.*, 324 U.S. 806, 815-816 (1945) (quoting *Hazel-Atlas Glass Co.* v. *Hartford-Empire Co.*, 322 U.S. 238, 246 (1944)). The PTO frequently issues invalid patents, and Congress established the inter partes review process to remedy those

mistakes. Inter partes review simplifies and accelerates the process of weeding out invalid patents, while retaining significant protections for valid patents.

1. The PTO often issues invalid patents

This Court has observed that a patent "simply represents a legal conclusion reached by the Patent Office" that is "predicated on factors as to which reasonable men can differ widely" and reached "in an *ex parte* proceeding, without the aid of the arguments which could be advanced by parties interested in proving patent invalidity." *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 670 (1969). Unfortunately, the examiners conducting those ex parte proceedings have heavy caseloads: In 2016, fewer than 9,000 patent examiners were tasked with reviewing more than 650,000 patent applications. U.S. Patent and Trademark Office, *Performance and Accountability Report, Fiscal Year 2016*, at 15, 179 (2016) (*PTO Report*). On average, patent examiners have only about 20 hours to evaluate a patent application, which requires reading the application, searching for prior art, communicating with the applicant, evaluating patentability, and writing up their conclusions. Michael A. Carrier, *Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act*, 45 U.C. Davis L. Rev. 103, 107 (2011). It is no surprise, therefore, that the PTO frequently issues patents later found to be invalid. See Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents?: Evidence from a Quasi-Experiment*, 67 Stan. L. Rev. 613, 615, 676 (2015) (describing consensus that the PTO "is issuing too many invalid patents" and con-

cluding that "the Agency is in fact biased toward granting patents"). Indeed, one recent study found that federal courts hold challenged patents to be invalid 43% of the time. John R. Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1801 (2014).

2. Congress established inter partes review to weed out invalid patents quickly and efficiently

Because the PTO will inevitably issue some patents that it should not, a speedy and inexpensive process for challenging patents of dubious validity is critical to the health of the entire patent regime. Congress has long recognized the need for an administrative mechanism to review improvidently granted patents. See H.R. Rep. No. 120, 107th Cong., 1st Sess. 3 (2001) (noting that the 1980 creation of a reexamination process was intended to "(i) settle validity disputes more quickly and less expensively than litigation; (ii) allow courts to refer patent validity questions to an agency with expertise in both the patent law and technology; and (iii) reinforce investor confidence in the certainty of patent rights by affording an opportunity to review patents of doubtful validity"). By 2011, when the America Invents Act was passed, Congress had concluded that the ex parte and inter partes reexamination procedures were "too lengthy and unwieldy to actually serve as an alternative to litigation when users are confronted with patents of dubious validity." 157 Cong. Rec. 12,992 (2011) (statement of Sen. Leahy). And it noted "a growing sense that questionable patents are too easily obtained and are too difficult to

challenge." *House Report* 39. As then-Senator Sessions explained, the goal of the America Invents Act was to "allow invalid patents that were mistakenly issued by the PTO to be fixed early in their life, before they disrupt an entire industry or result in expensive litigation." 157 Cong. Rec. at 3375 (statement of Sen. Sessions); accord *id.* at 2844 (statement of Sen. Leahy) ("The legislation also provides a modernized, streamlined mechanism for third parties who want to challenge recently issued, low-quality patents that should never have been issued in the first place.").

3. Inter partes review accelerates the process of weeding out invalid patents, while retaining significant protections for valid patents

To accomplish its goal of "improving patent quality and providing a more efficient system for challenging patents that should not have issued," Congress established a streamlined process for challenging patents through inter partes review. *House Report* 39-40; see *id.* at 47; see also *Cuozzo*, 136 S. Ct. at 2143-2144 (describing features of inter partes review that make the procedure "less like a judicial proceeding and more like a specialized agency proceeding," offering "a second look at an earlier administrative grant of a patent"). The inter partes review process contains a number of cost- and time-saving features designed to allow the PTO to identify improvidently granted patents—and correct its own mistakes—quickly and efficiently. Those benefits include

- **A relaxed standing requirement.** To challenge a patent in district court, the challenging

party must have Article III standing, which, among other things, requires the party to have suffered a concrete, particularized, and actual or imminent "injury in fact." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992). In contrast, inter partes review may be initiated by any person who is not the owner of the patent at issue. 35 U.S.C. 311(a); see *Cuozzo*, 136 S. Ct. at 2143-2144 ("Parties that initiate the proceeding need not have a concrete stake in the outcome; indeed, they may lack constitutional standing.") That relaxed standing requirement allows a prospective competitor—such as a prospective manufacturer of a generic drug—to resolve the validity of a blocking patent before devoting the substantial resources necessary to develop a competing product. That greatly increases the chance that invalid patents will be quickly identified and eliminated.

- **Focused discovery.** In contrast to the broad discovery allowed in federal courts by the Federal Rules of Civil Procedure, discovery in inter partes review proceedings is limited to the deposition of witnesses submitting affidavits or declarations and "what is otherwise necessary in the interest of justice." 35 U.S.C. 316(a)(5); see 37 C.F.R. 42.51(b). The process thus avoids "the potentially enormous expense of discovery" associated with litigation. *Bell Atl. Corp.* v. *Twombly*, 550 U.S. 544, 559 (2007).

- **Streamlined evidentiary and hearing procedures.** Proceedings before the Board are mostly conducted through the submission of written testimony and briefs. See 35 U.S.C. 316(a)(8). Testimony to the Board must be presented in the form of an affidavit. 37 C.F.R. 42.53(a). Similarly, cross-examination must be submitted in the form of a deposition transcript. *Ibid.* The parties are entitled to an oral hearing. 35 U.S.C. 316(a)(10).

- **Rapid deadlines for adjudication.** An inter partes review must be completed within one year of when it is instituted. 35 U.S.C. 316(a)(11). The PTO may extend the deadline only by six months, and only for good cause. *Ibid.* According to the PTO's annual Performance and Accountability Report, the office has succeeded in meeting the statutory deadlines. *PTO Report* 71; compare *House Report* 45 (district court litigation in patent cases is "often costly and protracted").

- **Decisions rendered by a panel of experts.** Inter partes review is conducted before a three-member panel consisting of specialized administrative patent judges appointed to the Patent Trial and Appeal Board by virtue of their "competent legal knowledge and scientific ability." 35 U.S.C. 6(a), (c); 35 U.S.C. 316(c); see *Kappos* v. *Hyatt*, 566 U.S. 431, 445 (2012) (noting that "the PTO has special expertise in evaluating patent applications"). If the matter is not dis-

missed, the panel must issue a written decision. 35 U.S.C. 318(a).

Despite the efficiency of inter partes review, significant protections remain to protect legitimate patents. For example, the PTO may grant a petition for inter partes review only if the information presented in the petition shows that "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged"—a standard designed to eliminate frivolous or meritless petitions. 35 U.S.C. 314(a). Similarly, a petitioner may not seek inter partes review if it has previously filed a civil suit challenging the validity of the same claim, 35 U.S.C. 315(a)(1), or if it was served with a complaint alleging infringement of the patent more than one year before, 35 U.S.C. 315(b). Moreover, the scope of inter partes review is narrowly focused on the correction of erroneously issued patents. A petitioner in an inter partes review may request to cancel a patent claim only based on obviousness or lack of novelty, and only based on prior-art patents and publications. 35 U.S.C. 311(b). Other issues, such as infringement or invalidity on other grounds, must be adjudicated in federal court. Finally, the Board's written decision on patentability is subject to appeal to the United States Court of Appeals for the Federal Circuit. 35 U.S.C. 319.

C. Eliminating invalid patents is necessary to permit patient access to more affordable generic and biosimilar medicines

Pharmaceutical patents provide a compelling illustration of the need for an efficient mechanism for the PTO to retract improvidently issued patents. Inter

partes review is essential to ensure patient access to low-cost generic medicines that would otherwise be blocked by invalid patents.

1. The availability of generic and biosimilar medicines saves money and provides greater patient access to critical medicines

Congress has recognized the benefits offered by generic medicines, and it sought to encourage their introduction by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Amendments. See *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (Congress sought "to enable new drugs to be marketed more cheaply and quickly"); *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir.) (purpose of Hatch-Waxman was "to get generic drugs into the hands of patients at reasonable prices—fast"), cert. denied, 502 U.S. 906 (1991). More recently, Congress sought to speed up the introduction of biosimilar medicines by enacting the Biologics Price Competition and Innovation Act, Pub. L. No. 111-148, Tit. VII, Subtit. A, 124 Stat. 804. See generally *Sandoz Inc.* v. *Amgen Inc.*, 137 S. Ct. 1664 (2017). Patient access to low-cost, high-quality generic and biosimilar medicines remains critically important today given the high cost of healthcare in the United States.

By definition, generic drugs are therapeutically equivalent to their brand-name counterparts. To be approved by the FDA, generic medicines must have the same active ingredients and must meet the same rigorous standards of strength, quality, purity, and

potency. 21 U.S.C. 355(j)(2)(A)(ii), (iii), (iv). Likewise, a biosimilar medicine has "no clinically meaningful differences" in "safety, purity, and potency" from the brand-name biologic product. 42 U.S.C. 262(i)(2)(B).

The principal difference between generic or biosimilar medicines and brand-name prescription drugs or biologic products is cost. Association for Accessible Medicines, *Generic Drug Access & Savings in the U.S.* 24 (2017) (*Generic Drug Access*). Generics account for 89% of prescriptions dispensed in the United States, but only 26% of total drug costs. *Id.* at 16. In total, generic medicines generated $253 billion in savings for the American healthcare system in 2016, and $1.67 trillion in savings over the last decade. *Id.* at 20. Every year, generic medicines save the Medicaid system $37.9 billion and save the Medicare system $77 billion. *Id.* at 21.

The benefits of more affordable generic and biosimilar medicines extend beyond mere cost savings. Lack of adherence to treatments is responsible for approximately 125,000 deaths annually. *Generic Drug Access* 26. Generic drugs reduce the problem of lack of adherence because new patients are three times less likely to stop taking generic medications than brand-name drugs. *Ibid.*

All of these benefits flow directly from the competition that generic and biosimilar medications provide to brand-name drugs that would otherwise enjoy monopoly status. The more competitors there are, the greater the savings: The entry of a second generic manufacturer into the market reduces the average generic price to nearly half the brand-name price, and for medicines that attract a large number of generic manufac-

turers, the average generic price falls to less than 20% of the branded price. U.S. Food & Drug Admin., *Generic Competition and Drug Prices* (May 13, 2015), http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm129385.htm.

2. Invalid patents can block the introduction of more affordable generic and biosimilar medicines

Patent law "strikes a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'" *Association for Molecular Pathology* v. *Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013) (quoting *Mayo Collaborative Servs.* v. *Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012)) (alteration in original). Especially in the pharmaceutical context, that balance is frequently upset by the assertion of invalid patents, which inevitably leads to lengthy and expensive litigation. Delay in removing improperly awarded patents can lead to substantially higher drug costs for patients, insurers, and taxpayers.

a. When a brand-name drug manufacturer submits an application to the FDA for approval of a new drug, it must include a list of every patent related to the drug that the patentee could reasonably assert would be infringed by the manufacture, use, or sale of a generic version of the drug. 21 U.S.C. 355(b)(1). Those patents are then listed in the FDA's "Orange Book," formally titled "Approved Drug Products with Therapeutic Equivalence Evaluations." See *Caraco Pharm. Labs., Ltd.* v. *Novo Nordisk A/S*, 566 U.S. 399, 405-406

(2012). Patents listed in the Orange Book represent significant barriers to the entry of generic competitors.

Under the Hatch-Waxman Amendments, a competitor hoping to enter the market with a generic version of an existing drug may file an Abbreviated New Drug Application (ANDA). See 21 U.S.C. 355(j). As part of the ANDA, the generic drug manufacturer must identify any patents claiming the brand-name drug in the Orange Book. 21 U.S.C. 355(j)(2)(A)(vii). For each listed patent that has been properly filed and has not expired, the generic drug manufacturer must either agree to wait for FDA approval until after the patent expires, 21 U.S.C. 355(j)(2)(A)(vii)(III), or certify that the "patent is invalid or will not be infringed by the manufacture, use, or sale" of the proposed generic, 21 U.S.C. 355(j)(2)(A)(vii)(IV).

Filing that latter certification, known as a Paragraph IV certification, "means provoking litigation." *Caraco*, 566 U.S. at 407. The ANDA filer must provide notice to the brand-name manufacturer "of the factual and legal basis" of its patent challenge, 21 U.S.C. 355(j)(2)(B)(iv)(II), and the brand-name manufacturer may immediately sue to enforce its patents, 35 U.S.C. 271(e)(2)(A). If the brand-name manufacturer files suit, the FDA is automatically precluded from approving the proposed generic drug for 30 months, unless the court declares that the patent is invalid or not infringed before that time. 21 U.S.C. 355(j)(5)(B)(iii). If the brand-name manufacturer prevails in its suit, the generic manufacturer's application cannot be approved until the patent expires. 35 U.S.C. 271(e)(4).

The Paragraph IV litigation process is thus "likely to keep the generic drug off the market for a lengthy period," whether or not the patent is eventually ruled invalid. *Caraco*, 566 U.S. at 408. Even after the 30-month stay has elapsed, a generic manufacturer that enters the market before the litigation is fully resolved does so at risk of being held liable for substantial damages if the court later rules in favor of the brand-name manufacturer. 35 U.S.C. 271(e)(4)(C). And when it comes to generic drugs, even modest delays have high costs. One study, for example, examined three different drugs and concluded that delays ranging from 21 to 33 months in the introduction of generic substitutes cost the Medicaid program alone more than $1.5 billion. Aaron S. Kesselheim et al., *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 Health Affairs 1637, 1643 (2006).

Because the 30-month stay in the Paragraph IV litigation process does not depend on the strength of the brand-name drug manufacturer's infringement claims or on the merits of its asserted patents, even invalid patents may block generic substitutes for lengthy periods of time. A speedy and efficient mechanism to challenge improvidently granted patents is therefore essential to the timely provision of generic medicines.

Much the same is true of biosimilar medicines. By statute, the FDA may approve such products as "interchangeable" with a brand-name biologic product. 42 U.S.C. 262(k). Such approval is permitted only after a 12-year period of exclusivity for the brand-name product. 42 U.S.C. 262(k)(7); see *Sandoz*, 137 S. Ct. at 1670. But by using estates of multiple patents, even

patents of doubtful validity, brand-name biologic manufacturers can delay the introduction of biosimilar products until well after the expiration of that 12-year period.

b. Recent experience with efforts to introduce generic drugs and biosimilar medicines shows that the costs of invalid patents are not merely theoretical.

Prilosec is the brand-name version of omeprazole, which is approved by the FDA to treat peptic ulcer disease and some forms of gastroesophageal reflux disorders. Daniel I. Gorlin, *Staving Off Death: A Case Study of the Pharmaceutical Industry's Strategies to Protect Blockbuster Franchises*, 63 Food & Drug L.J. 823, 832-833 (2008). Omeprazole was first patented in 1979 by a predecessor to AstraZeneca PLC. In 1998, it became the world's largest selling pharmaceutical product, and by 2001 it enjoyed $5.7 billion in annual sales. *Id.* at 834.

When AstraZeneca first sought FDA approval for omeprazole, it listed only the original patent in the Orange Book. Gorlin, 63 Food & Drug L.J. at 836. In an effort to extend its monopoly even after the expiration of that patent, it soon added additional patents covering, among other things, making the drug into a pill that could be taken orally and using the drug to treat certain infections. Ultimately, the Orange Book listed ten different patents covering the drug. *Ibid.* In adding those additional patents to the Orange Book, AstraZeneca sought "to create a situation where generic drug manufacturers must litigate 90 claims on six patents, making it impossible to resolve any dispute within the thirty month stay." *Id.* at 837 (quoting *Examining Issues Related to Competition in the*

Pharmaceutical Marketplace: A Review of the FTC Report, "Generic Drug Entry Prior to Patent Expiration": Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 107th Cong. 25 (2002) (prepared statement of Business for Affordable Medicines)).

In 1998, four generic drug companies filed ANDAs under the Hatch-Waxman Amendments, submitting Paragraph IV certifications and asking the FDA to approve their versions of omeprazole. Gorlin, 63 Food & Drug L.J. at 836. AstraZeneca sued its would-be generic competitors for patent infringement, triggering the 30-month stay enjoining the FDA from approving their applications. *Ibid.*

Of the six patents AstraZeneca sued to enforce, most were ultimately found to be invalid. See *In re Omeprazole Patent Litig.*, 258 F. Supp. 2d 221 (S.D.N.Y. 2001). And the valid patents were determined not to be infringed by a bioequivalent version of omeprazole. *Astra Aktiebolag* v. *Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 547-560 (S.D.N.Y. 2002). Nevertheless, the multitude of listed patents had their intended effect: Although the generic competitors filed their applications in 1998, a consolidated trial on AstraZeneca's patent infringement claims did not even start until December 2001—more than three years later. Gorlin, 63 Food & Drug L.J. at 836. By then, both the original patent on omeprazole and the 30-month stay on generic entry under the Hatch-Waxman Amendments had expired; the first generic manufacturer to file an application had received final approval from the FDA, but no generic version of

Prilosec had been introduced to the market. *Id.* at 838.

A generic version of the drug was finally introduced in December 2002, 14 months after the expiration of AstraZeneca's original patent. Gorlin, 63 Food & Drug L.J. at 839. Those 14 months allowed AstraZeneca to collect billions of dollars in extra revenue, at a cost to the taxpayers of hundreds of millions of dollars. *Ibid.*; see Kesselheim et al., 25 Health Affairs at 1642.

Brand-name drug companies could employ similar techniques to delay the entry of more affordable biologic medicines. See, *e.g.*, Cynthia Koons, *Guarding Big Pharma's Crown Jewel*, Bloomberg Businessweek, Sept. 11, 2017, at 17 (noting that AbbVie Inc., has secured more than 75 ancillary patents on its best-selling rheumatoid arthritis drug Humira, most within several years of the expiration of the original patent).

By allowing speedier resolution of patent validity—and prompt correction by the PTO of its own mistakes—inter partes review avoids unnecessary delays and furthers the congressional goal of ensuring that the patent monopoly on brand-name medicines be of limited duration, thus bringing more affordable treatment options to patients sooner.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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OCTOBER 2017