Nos. 19-1434, 19-1452, and 19-1458

IN THE
Supreme Court of the United States

UNITED STATES OF AMERICA,
Petitioner,

v.

ARTHREX, INC., ET AL.,
Respondent.

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

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS IN NOS. 19-1434 AND 19-1452

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(For Continuation of Caption, See Inside Cover)

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19-1452

SMITH & NEPHEW, INC. AND ARTHROCARE CORP.,

Petitioner,

v.

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INTERESTS OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines (AAM) is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute 90% of all prescriptions dispensed in the United States, yet generics account for only 20% of total drug spending. AAM regularly participates in litigation as *amicus curiae*.

AAM and its members have a significant interest in the questions presented, and in the existence and smooth functioning of the *inter partes* review process. AAM's members depend on fair and prompt adjudication of patent claims that seek to block their efforts to bring lower-cost drug options to patients. The *inter partes* review process is thus essential to the work of AAM's

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[1] Pursuant to Supreme Court Rule 37.3(a), counsel for all parties consented to the filing of this brief. Pursuant to Supreme Court Rule 37.6, no party authored this brief in whole or in part, no fee has been paid or will be paid for preparing this brief, and no person or entity other than *amicus curiae* and its counsel made any monetary contribution to the preparation or submission of this brief.

members and to the patients who depend on generic and biosimilar medicines.

INTRODUCTION AND SUMMARY OF ARGUMENT

Inter partes review (IPR) is a critical tool for quickly and efficiently eliminating invalid patents. When it adopted the current IPR system in 2011, Congress recognized that patent examiners—laboring under an intense workload—frequently issue patents that are invalid. IPR allows the Patent and Trademark Office (PTO) to fix those mistakes without forcing competitors to undertake lengthy, expensive litigation to defeat patents that never should have been granted in the first place.

Perhaps no segment of the public benefits more from IPR than the patients who depend upon generic and biosimilar medications. Branded drug manufacturers often seek to extend their monopolies unlawfully by filing multiple patents intended to keep more affordable generic and biosimilar medicines off the market. AAM's members rely on IPR to efficiently root out those invalid drug patents. The ultimate winners from those IPR proceedings are the patients (and taxpayers) who are able to obtain less expensive, safe generic and biosimilar medicines without undue delay. It is because of successful IPR proceedings that cheaper generic and biosimilar alternatives to fight diseases like Alzheimer's, Parkinson's, and prostate cancer, have reached the market far more quickly than they otherwise would have. *See, e.g.*, *Novartis AG v. Noven Pharms. Inc.*, 853

F.3d 1289 (Fed. Cir. 2017); *see also BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063 (Fed. Cir. 2019).

In the decision below, the Federal Circuit held that the administrative judges who preside over IPR proceedings are principal officers who hold their position in violation of the Appointments Clause. AAM urges the Court to reverse that ruling for the reasons the government and Smith & Nephew have set out, and writes separately to emphasize that the Federal Circuit's merits ruling has already caused delay by mandating rehearing of potentially hundreds of IPR decisions. Branded drug patent-holders have jumped at the opportunity to re-litigate the validity of patents already found invalid through the IPR process. And members of the public must now wait even longer to benefit from generic and biosimilar alternatives that do not infringe any lawful patent. Reversing the Federal Circuit's incorrect merits determination would correct this problem.

If the Court nonetheless concludes that the IPR judges are principal officers, it should reject Arthrex's contention that a *more* sweeping remedy is needed. Arthrex asks this Court to invalidate the entire IPR system subject to Congress's decision to reauthorize the system if Congress so chooses. Arthrex leaves no doubt that it would be happy to see the IPR system never return from its trip to the Capitol, but eliminating IPR, even temporarily, would have deleterious consequences for the patients who seek cost-effective medications and the generic and biosimilar manufacturers who must

make investment decisions about what products to bring to market.

There is no legal justification for treating any Appointments Clause violation as a basis for dismantling the entire IPR system, and doing so would re-impose the very hurdles to addressing invalid patents that Congress sought to eliminate. Those patents would continue to serve as an illegitimate barrier to cheaper generic and biosimilar alternatives. This Court should allow the IPR system to continue to serve the goals that Congress intended and to work on behalf of all Americans, including the millions who benefit from cost-effective generic and biosimilar medicines.

ARGUMENT

I. *Inter Partes* Review Is Essential to Eliminating Invalid Patents, Which In Turn Enables Patient Access to More Affordable Generic and Biosimilar Medicines.

A. *Inter Partes* Review Is Essential to Eliminating Invalid Patents.

IPR allows competitors to quickly and cheaply eliminate improvidently granted patents that are blocking valuable technology from reaching the market. This Court has recognized that "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, 815-16 (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.

A patent "represents a legal conclusion reached by the Patent Office," "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 the 2020 fiscal year, fewer than 8,500 patent examiners were tasked with reviewing more than 650,000 patent applications. U.S. Patent and Trademark Office, *Performance and Accountability Report, Fiscal Year 2020*, at 189, 231 (2020) (*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 concluding 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. 107-120, at 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 existing *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. 12992 (2011) (statement of Sen. Leahy). And it noted "a growing sense that questionable patents are too easily obtained and are too difficult to challenge." H.R. Rep. No. 112-98, pt. 1, at 39 (2011), *as reprinted in* 2011 U.S.C.C.A.N. 67, 69. 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. Klobuchar) ("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.").

B. 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 and biosimilar 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. 1991) (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 of 2009, 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.

To be approved by the FDA, a generic medicine must have the same active ingredients as the brand-name drug and must meet the same rigorous standards of strength, quality, purity, and potency. *See* 21 U.S.C. § 355(j)(2)(A)(ii)-(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). Generics account for 90% of prescriptions dispensed in the United States, but only 20% of total drug costs. Association for Accessible Medicines, *2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 16 (2020). In total, generic medicines generated $313 billion in savings for the American healthcare system in 2019, and $2.2 trillion in savings over the last decade. *Id.* at 16, 18. In 2019 alone, generic medicines saved the Medicaid system $48.5 billion and the Medicare system $96 billion. *Id.* at 17.

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. Association for Accessible Medicines, *Generic Drug Access & Savings in the U.S.* 26 (2017). Generic drugs reduce the problem of lack of adherence because new patients are three times less likely to stop taking generic medicines than brand-name drugs. *Id.*

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 roughly half the brand-name price, and for medicines that attract a large number of generic manufacturers, the average generic price falls to less than 10% of the brand-name price. U.S. Food & Drug Admin., *Generic Competition and Drug Prices* (Dec. 13, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices.

2. Invalid Patents Can Block 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.'" *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (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 that 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," *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405-06 (2012).

A generic competitor hoping to enter the market must file an Abbreviated New Drug Application (ANDA). *See* 21 U.S.C. § 355(j). As part of that application, the generic manufacturer must identify any patents claiming the brand-name drug in the Orange Book and either wait for their expiration or show that they are not a barrier—for example, by certifying that they are "invalid or will not be infringed by the manufacture, use, or sale" of the proposed generic. *Id.* § 355(j)(2)(A)(vii).

Such a certification naturally "provoke[es] litigation," *see Caraco*, 566 U.S. at 407, and the brand-name manufacturer may file suit immediately, 35 U.S.C. § 271(e)(2)(A). When the brand-name manufacturer does sue, the FDA is automatically precluded from approving the proposed generic for 30 months, unless the case is dismissed or the court declares that the patent is invalid or not infringed before that time. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3)(viii).

In other words, whether or not the patent is eventually ruled invalid, litigation is "likely to keep the generic drug off the market for a lengthy period." *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 risks being held liable for substantial damages if the court later

rules against it. 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, 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 automatic 30-month stay does not depend on the strength of the brand-name manufacturer's patents or infringement claims, 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. *Id.* § 262(k)(7); *see Sandoz*, 137 S. Ct. at 1670. But by using 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 medicines shows that the costs of invalid patents are not merely theoretical. For example, when generic

manufacturers sought to introduce their versions of Zytiga, a brand-name prostate cancer drug, the brand-name manufacturer filed suit in district court. The generic manufacturers then sought *inter partes* review, where they defeated the patent claims on obviousness grounds. *See BTG Int'l Ltd.*, 923 F.3d at 1066-67. The Federal Circuit affirmed the Patent Trial and Appeal Board's decisions. *Id.* at 1066. While the generic manufacturers were successful in the end, the time spent litigating the patent claims was time in which the affordable, life-saving generics were not available to prostate cancer patients.

Brand-name drug companies can also use dubious patents to delay the entry of more affordable biologic medicines. *See, e.g.*, Cynthia Koons, *Guarding Big Pharma's Crown Jewel*, Bloomberg Businessweek 17 (Sept. 11, 2017) (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); *accord* Biosimilars Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients* 8 (June 2019) (highlighting that, absent settlements, late-stage patents would have extended AbbVie's patent protection for Humira until 2034, over thirty years after its approval).

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.

II. Administrative Patent Judges Are Not Principal Officers, But to The Extent The Court Concludes Otherwise, It Should Reject Arthrex's Request to Eliminate IPR Indefinitely.

In the case below, the Federal Circuit held that Administrative Patent Judges (APJs) of the Patent Trial and Appeal Board are principal officers who held their position in violation of the Appointments Clause. AAM urges the Court to reverse that merits determination for the reasons stated by the government and by Smith & Nephew in their opening briefs. AAM will not repeat those legal arguments here but emphasizes that the Federal Circuit's merits determination has required a large number of IPR decisions currently pending on appeal to be sent back to the IPR for re-adjudication by a new panel. *See* Pet. App. 223a-228a, No. 19-1434 (Patent Trial and Appeal Board, *General Order in Cases Remanded Under* Arthrex, Inc. v. Smith & Nephew, Inc., *941 F.3d 1320 (Fed. Cir. 2019)* (May 1, 2020)) (noting that the Federal Circuit had already vacated more than a hundred decisions by the Board in light of *Arthrex*, with more expected in the future). As the government has explained, there are now at least 139 cases in which an IPR determination has been vacated—not including cases currently pending in the Federal Circuit or cases to which the government is not a party. *See* Petition for a Writ of Certiorari 24-25, 25 n.2, *United States v. Image Processing Techs. LLC*, No. 20-74.

One casualty of that ruling is the recent IPR decisions invalidating unlawful branded drug patents. Armed with the Federal Circuit's principal officer determination, brand-name manufacturers have jumped at the opportunity to relitigate—and delay—IPR (re)determinations on the validity of their patents. *See, e.g.*, Order 1-2, *Amgen Inc. v. Iancu*, No. 2019-2171 (Fed. Cir. Mar. 24, 2020), ECF No. 48 (remanding to the Board in light of the Federal Circuit's decision below). The result is that patients and taxpayers must wait even longer to gain access to affordable generic and biosimilar alternatives that have *already* been adjudicated through the IPR process not to infringe on any valid patent. Indeed, so many Board decisions have been vacated in light of *Arthrex* that the Board has placed the cases in abeyance until the APJs' status is settled by the Supreme Court, further exacerbating the delay. Pet. App. 223a-228a, No. 19-1434 (Patent Trial and Appeal Board, *General Order in Cases Remanded Under* Arthrex, Inc. v. Smith & Nephew, Inc., *941 F.3d 1320 (Fed. Cir. 2019)* (May 1, 2020)).

But if this Court concludes that the APJs are in fact principal officers, AAM urges the Court to reject Arthrex's invitation to undermine the IPR process further by going beyond the Federal Circuit's remedial decision and disbanding the IPR system indefinitely unless and until Congress acts to reauthorize it. As Arthrex has set out both in its Federal Circuit briefing and its petition to this Court, Arthrex contends that the proper remedy for an Appointments Clause violation is to invalidate the entire IPR system, and permit

Congress to reauthorize it if Congress so chooses. Brief for Petitioner at 33-34, *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 19-1458 (June 30, 2020).

It would be legally groundless as well as harmful to the American public and the cost-effective generic and biosimilar medications the public relies upon to eliminate IPR, even temporarily. As Smith & Nephew has explained, the Federal Circuit's remedy lifting certain tenure protections is well in keeping with this Court's prior Appointments Clause jurisprudence. *See* Brief for Respondents Smith & Nephew, Inc. and ArthroCare Corp. at 10-18, Nos. 19-1434 and 19-1458 (July 23, 2020). And as explained above, the IPR system is crucial to ensuring that necessary and affordable generic and biosimilar medicines can quickly and efficiently be brought to market free of restraints from invalid patents. *See supra* Section I.

If IPR were unavailable, even just temporarily, it would deprive patients and drug manufacturers of all the efficiencies and benefits of IPR going forward. At-risk launches—where a generic company launches its product prior to resolution of patent issues at the risk of incurring damages should infringement liability ultimately be found—are already a perilous, time-sensitive proposition. Eliminating IPR would create further uncertainty and risk for generic and biosimilar drug manufacturers in determining what cost-effective alternatives they could bring to market. With an uncertain future for IPR and the concomitant risk of expensive litigation over patent scope, the companies that consider investing in and developing generic and

biosimilar alternatives may be forced to pull back from, or even abandon, plans to develop those medications. Patients and taxpayers would suffer from those unwarranted delays, and in some cases they would be deprived of generic and biosimilar alternatives altogether.

Rather than upend the IPR system, to the extent this Court finds an Appointments Clause violation at all (and it should not), it should affirm the Federal Circuit's targeted remedy for the violation, and refuse to eliminate the IPR mechanism that Congress intended as an important check on invalid patents.

CONCLUSION

For the foregoing reasons, the Court should reverse the Federal Circuit's determination that the APJs of the Patent Trial and Appeal Board are principal officers. And if the Court finds an Appointments Clause violation, it should affirm the Federal Circuit's remedy.

Respectfully submitted,

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