Appeal No. 2018-2140

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARTHREX, INC.,

Appellant,

v.

SMITH & NEPHEW, INC., ARTHROCARE CORP.,

Appellees,

UNITED STATES,

Intervenor.

Appeal from the United States Patent and Trademark Office Patent Trial and Appeal Board in No. IPR2017-00275

BRIEF FOR THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF REHEARING *EN BANC*

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December 30, 2019

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* Association for Accessible Medicines certifies:

1. The full name of every party or amicus represented by me is:

Association for Accessible Medicines

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

See above.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the amicus curiae represented by me are:

Not applicable.

4. The names of all law firms and the partners or associates that appeared for the amicus curiae now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

Not applicable.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal is:

There are no pending cases involving the patent-in-suit known to me. However, numerous cases will be affected by the constitutional issues raised in the pending appeal. *See, e.g.*, *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 783 F. App'x 1029, 1030 (Fed. Cir. 2019) (Dyk, J., concurring) (noting that panel decision here will "requir[e] potentially hundreds of new proceedings").

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INTEREST OF THE *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 22% of total drug spending. AAM regularly participates in litigation as *amicus curiae*. Pursuant to Fed. R. App. P. 29(b)(3), AAM files contemporaneously herewith its unopposed motion for leave to file this amicus brief.

AAM and its members have a significant interest in the constitutional issues central to the parties' petitions for rehearing *en banc* here. AAM's

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1 No counsel for any party authored this brief in any part, and no party, counsel, or person other than AAM, its members, and its counsel contributed money to fund the preparation and submission of this brief. *See* Fed. R. App. P. 29(a)(4)(E).

members depend on fair and prompt adjudication of patent claims that seek to block their efforts to bring lower-cost drug options to patients. By casting into doubt scores of *inter partes* review ("IPR") decisions from the Patent Trial and Appeal Board ("PTAB") and requiring new proceedings, the panel's decision mires AAM's members in uncertainty and burdensome duplicative proceedings. The result will be delay in bringing cost-effective generic and biosimilar drugs to market, and increased costs for consumers. AAM believes *en banc* review is necessary to correct the panel's error and to dispel the cloud of uncertainty over the IPR system. *En banc* review here can also obviate the possibility of rehearings in other cases in this Court where patent holders are now raising various challenges to the IPR system in light of the panel's ruling. *See supra* pp. 5-8.

ARGUMENT

I. The Panel's Erroneous Decision Has Created Disarray And It Poses Particular Harm For Manufacturers And Distributors Of Generic And Biosimilar Drugs And The Patients Who Depend On Them.

The government and Smith & Nephew have ably set out the reasons why the panel's determination that Administrative Patent Judges ("APJs") are "principal officers" is incorrect, and AAM will not repeat those arguments at length here. As those parties have explained in their petitions

for rehearing (D.I. 77 at 6-11; D.I. 79 at 8-18), the Director has, among other powers, the authority to issue guidance that APJs are bound to follow in adjudicating an IPR; the authority to decide which, if any, matters a particular APJ will handle; and the authority to terminate an APJ to "promote the efficiency of the [PTO]." D.I. 69, slip op. at 13, 15-17; 35 U.S.C. § 6(c). In light of these powers, the APJs are "inferior officers" bound to follow the Director's guidance and their appointments pass constitutional muster. *See Edmond v. United States*, 520 U.S. 651, 662-63 (1997) ("Whether one is an 'inferior' officer depends on whether he has a superior.").

AAM writes instead to emphasize the urgent need for this Court's review in light of the widespread confusion that reigns in the wake of the panel's decision and the particular harms that decision creates for the manufacturers and distributors of generic and biosimilar drugs, and ultimately for the patients who depend upon them. *En banc* review is needed to restore stability and prevent wasteful shuttling of patent challenges across the PTAB and this Court. *See* slip op. at 5 ("The issue presented today has a wide-ranging effect on property rights and the nation's economy. Timely resolution is critical to providing certainty to

rights holders and competitors alike who rely upon the *inter partes* review scheme to resolve concerns over patent rights.").

A. The *inter partes* review system is now in disarray.

What was intended to be a "quick and cost effective alternative[] to litigation" (H.R. Rep. No. 112-98, pt. 1, at 48 (2011) , *as reprinted in* 2011 U.S.C.C.A.N. 67, 78) is now a quagmire. The panel prescribed that all "cases where final written decisions were issued [by the PTAB] and where litigants present an Appointments Clause challenge on appeal" are entitled to remand back to the PTAB before a new panel. Slip op. at 29. As Judge Dyk has already observed, this decision "imposes large and unnecessary burdens on the system of *inter partes* review, requiring potentially hundreds of new proceedings." *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 783 F. App'x 1029, 1030 (Fed. Cir. 2019); *see also* D.I. 68, Smith & Nephew Suppl. Br. at 8-9 (describing "over 160 such IPRs" that could be undone by the panel's ruling).

These burdens will fall primarily on the shoulders of the APJs, from whom the panel has now stripped away even basic employment protections. Slip op. at 25-26. These judges will have their past work undone, and must now review for a second time patents granted by individual examiners who

enjoy more autonomy and protection in issuing patents than the APJs charged with reviewing them.

While it is clear that the number of IPRs subject to remand is large, there remain many other unknowns. As an initial matter, it is unclear when on appeal a party must raise the constitutional issue to be entitled to a remand, with many parties now clamoring for remands even where they did not raise the issue in their opening briefs. *E.g.*, *Customedia Techs., LLC v. Dish Network Corp.*, No. 2019-1001, D.I. 61 (raising issue in motion to reconsider (recently denied with a dissent, D.I. 63)) (Fed. Cir. 2019); *Sanofi-Aventis Deutschland GmbH v. Mylan Pharm., Inc.*, Nos. 2019-1368, 2019-1369, D.I. 63 (Fed. Cir. 2019) (raising issue in petition for *en banc* rehearing following panel's holding that request for remand was waived).

Furthermore, did the APJ appointments become constitutional upon issuance of the panel's decision, such that PTAB decisions after that date are not subject to automatic remand? Or "[i]s it . . . when the mandate issues, when en banc review is denied, when certiorari is denied, or (if there is an en banc proceeding) when the en banc court affirms the panel, or (if the Supreme Court grants review) when the Supreme Court affirms the court of appeals decision?" *Bedgear*, 783 F. App'x at 1034 n.8.

Finally, upon remand, the scope of further proceedings is amorphous: the panel left it to "the Board's sound discretion" to decide whether a given remand should proceed on the already-developed record, or whether "additional briefing" or even "reopen[ing] the record" entirely is appropriate. Slip op. at 30.

The uncertainty generated by all of these open questions is heightened further by potential disagreement with the panel's ruling by other judges of this Court. Notably, at least one panel has questioned whether, even if this panel correctly found a constitutional defect, the new proceedings envisioned might still be invalid. *See Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 2018-1768, D.I. 90 at 2, (Fed. Cir. Nov. 8, 2019) (ordering supplemental briefing to "address[] the constitutional questions raised in these cases," including whether the panel's purported solution "sufficiently remedies the alleged unconstitutional appointment at issue" and, if so, whether it "obviates the need to vacate and remand for a new hearing, given the Supreme Court's holdings on the retroactive application of constitutional rulings").

B. Generic and biosimilar manufacturers, and the public, are particularly harmed by the uncertainty.

The uncertainty engendered by the panel's ruling is particularly injurious to AAM's members and the patients who benefit from their products. The aim of AAM's members is to bring affordable, lower-cost generic and biosimilar medicines to patients. 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. Because AAM members provide drugs at much lower costs than their brand-name competitors, the potential responsibility to compensate a brand-name drug patent holder for loss of large profits oftentimes keeps generic drugs off the market pending resolution of patent issues. *Cf.* IMS Institute, *Price Declines After Branded Medicines Lose Exclusivity in the U.S.* at 2 (Jan. 2016) (describing how typically "[g]eneric drugs greatly reduce the price of medicines" upon market entry), *available at* https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf; FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic*

Drug Prices at 2-3 (December 2019), *available at* https://www.fda.gov/media/133509/download.

On the heels of the panel decision, however, brand-name drug manufacturers are now seizing on the panel's decision to urge remand for new IPR proceedings. *E.g.*, *Amgen Inc. v. Iancu*, No. 2019-2171, D.I. 22 at 70-71 (Fed. Cir. 2019); *Sanofi-Aventis Deutschland GmbH*, Nos. 2019-1368, 2019-1369, D.I. 63 at 2-3, 6-14; *see also Dr. Reddy's Labs., Inc. v. Horizon Pharma USA, Inc.*, No. IPR2018-00272, D.I. 75 (P.T.A.B. 2019). If these requests are granted, there could be at least another twelve months of proceedings regarding the validity of the challenged patents, during which time patients are deprived of more affordable medicines. *See* Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,756-48,757 (Aug. 14, 2012) (setting forth twelve-month timeline from institution of review to final decision).

In essence, the panel's decision could effectively amount to an unwarranted extension of the thirty-month statutory stay of FDA approval to which generic pharmaceutical manufacturers are subject upon commencement of patent litigation. Generic pharmaceutical manufacturers typically seek to have an IPR completed by the time the stay is lifted, but now, faced with a new round of IPR proceedings, generics may have to wait

at least another twelve months for clarity on patent issues, or else face the proposition of a perilous at-risk launch. This turns the purpose of an IPR on its head, transforming an intended "quick and cost effective" (*supra* p. 4) proceeding into yet another tool for delay by brand-name drug patent holders.

II. Even If There Were A Constitutional Violation (And There Was Not), The Panel's Remedy Is Overly Broad.

In ordering new PTAB panels to hear each and every case "where final written decisions were issued and where litigants present an Appointments Clause challenge on appeal" (slip op. at 29), the panel hung its hat on the tail ends of the Supreme Court's *Lucia* decision. In *Lucia*, after finding an Appointments Clause violation with respect to administrative judges at the SEC, the Court chose to "add today one thing more" and require that "another ALJ (or the Commission itself) must hold the new hearing to which Lucia is entitled." *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018). The panel here stretches *Lucia* well past its breaking point.

First, *Lucia* sought to ensure an "incentive to raise Appointments Clause challenges . . . by providing a successful litigant with a hearing before a new judge." *Id.* at 2055 n.5 (internal quotation marks and alterations omitted). But this incentive should apply only once—after the first

Appointments Clause challenge, there need not be any incentive for scores of other parties to copy the same argument. Thus, the panel's remedy of a new PTAB panel on remand should apply to one party only. At this time, that party is Arthrex, though perhaps there is a more deserving challenger—as the government and Smith & Nephew have explained, Arthrex's argument appears to have been lifted verbatim from another party (Polaris) that raised the argument earlier. (D.I. 68 at 9-10; D.I. 77 at 11-14.) Regardless, only one challenger, not many, is entitled to the special remedy of a new panel on remand.[2]

Second, even if more than one party is entitled to a new PTAB panel on remand, parties who failed to raise the issue below should not be so entitled. Here, the panel chose to excuse Arthrex's failure to raise its Appointments Clause challenge before the PTAB because the panel deemed this an "exceptional case." Slip op. at 5. But, again, the multitude of follow-on cases cannot also be exceptional. If a party did not raise a challenge before the PTAB, it has waived the right to enjoy the benefits of the

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[2] AAM members know well that an incentive to challenge is enjoyed by only the party who is first in line: to encourage challenges to drug patents, the Hatch-Waxman Act offers a six-month period of generic exclusivity to the first challenger(s). 21 U.S.C. § 355(j)(5)(B)(iv)(I). Subsequent challengers receive no such award.

challenge now. *See* slip op. at 4 (acknowledging the general rule that "a federal appellate court does not consider an issue not passed upon below" (quotation marks omitted)).

Thus, even if a constitutional defect exists (and it does not), its remedy should not engulf a vast array of PTAB decisions, including those involving AAM members. AAM urges *en banc* review to remove a source of substantial uncertainty on the patent landscape.

CONCLUSION

For the foregoing reasons, AAM requests that this Court undertake *en banc* review to vacate the panel's ruling.

Respectfully submitted,

Dated: December 30, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2019, I caused the foregoing brief to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which caused a copy of the foregoing to be delivered by electronic means to counsel of record.

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This Brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) because this Brief contains 2,167 words, excluding the parts of the Brief exempted by Fed. R. App. P. 32(f) and Federal Circuit Rule 32(b).

2. This Brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this Brief has been prepared in a proportionately spaced typeface using Microsoft Office Word 2013 in Century Expanded LT Std, Font Size 14.

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