2019-1871, 2019-1873, 2019-1875, 2019-1876 and 2019-2224

United States Court of Appeals for the Federal Circuit

PFIZER INC.,

Appellant,

– v. –

MERCK SHARP & DOHME CORP.,
SANOFI PASTEUR INC., SK CHEMICALS CO., LTD.,

Appellees,

ANDREI IANCU, Director, U.S. Patent and Trademark Office,

Intervenor.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-02131, IPR2017-02132, IPR2017-02136, IPR2017-02138 and IPR2018-00187

COMBINED PETITION FOR REHEARING AND REHEARING *EN BANC* FOR APPELLEES SANOFI PASTEUR INC. AND SK CHEMICALS CO., LTD.

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CERTIFICATE OF INTEREST

Counsel for Appellees Sanofi Pasteur Inc. and SK Chemicals Co., Ltd. certifies the following:

1. The full name of every party represented by me is: Sanofi Pasteur Inc. and SK Chemicals Co., Ltd.

2. The names of the real parties in interest represented by me are: Sanofi Pasteur Inc., SK Chemicals Co., Ltd., and SK Bioscience Co., Ltd.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the parties represented by me are: Sanofi S.A. and SK Discovery Co., Ltd.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court and who are not already listed on the docket for the current case are:

Proskauer Rose LLP: Gerald E. Worth, Christine G. Espino

Sanofi Pasteur Inc.: Patricia Callanan, Jiang Lin.

5. The titles and numbers of all cases known to counsel to be pending in this or any other court or agency that will directly affect or be affected by the Court's decision in the pending appeal are: *Merck Sharp & Dohme Corp. v. Pfizer Inc. and Wendy J. Watson*, Case No. 2:19-cv-02011-JS (E.D. Pa.).

Dated: March 6, 2020

/s/ Fangli Chen

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RULE 35 STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following decisions of the Supreme Court of the United States or the precedent of this Court: *Harper v. Va. Dep't of Taxation*, 509 U.S. 86 (1993); *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477 (2010); and *Helman v. Dep't of Veterans Affairs*, 856 F.3d 920 (Fed. Cir. 2017).

Moreover, based on my professional judgment, I believe this appeal requires answers to one or more precedent-setting questions of exceptional importance:

(1) Whether Administrative Patent Judges ("APJs") of the Patent Trial and Appeal Board ("PTAB") are inferior or principal officers of the United States; and

(2) If APJs are principal officers, what remedy, if any, is warranted for any defect in their appointment.

Dated: March 6, 2020

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PRELIMINARY STATEMENT

The Panel disposed of this appeal before merits briefing had begun by vacating five final written decisions issued by APJs of the PTAB. The Panel's one-page order cited *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), which held that APJs are principal officers of the United States who were improperly appointed. The Panel remanded to the PTAB for further proceedings "consistent with . . . *Arthrex*."

Petitioners respectfully submit that *Arthrex*—and, thus, the Panel decision here—were wrongly decided and warrant review by the full Court. Petitioners are not alone in this view. The *Arthrex* decision has been widely criticized, including by judges of this Court. *See Polaris Innovations Ltd. v. Kingston Tech. Co.*, 792 F. App'x 820, 831 (Fed. Cir. 2020) (Hughes, J. and Wallach, J., concurring); *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 783 F. App'x 1029, 1034 (Fed. Cir. 2019) (Dyk, J. and Newman, J., concurring). Moreover, various parties—including the United States—have urged the full Court to reconsider *Arthrex* given the important issues at stake. Under *Arthrex* and the decision here, hundreds of cases that have already been decided will be sent back to the PTAB for further proceedings. The impact on litigants and the PTAB cannot be understated.

The decision in *Arthrex* is not final. Both the appellant and the appellee in *Arthrex*—as well as the United States as intervenor—have petitioned for rehearing

en banc. If the Court were to grant the petitions in *Arthrex*, it should likewise grant this petition. The decision here was based solely on *Arthrex* and is appropriate for *en banc* review for precisely the same reasons as that decision.

STATEMENT OF THE CASE

This appeal arises from five final written decisions of the PTAB confirming the unpatentability of all claims in U.S. Patent No. 9,492,559. Before the parties submitted their merits briefs in this appeal, the Court decided *Arthrex*, holding that PTAB APJs are principal officers of the United States who were not appointed in compliance with the Appointments Clause of the United States Constitution. 941 F.3d at 1335 (citing U.S. Const. art. II, § 2, cl. 2). As a remedy, the *Arthrex* Panel severed a statutory provision protecting the APJs from removal, which going forward would transform them into inferior officers who did not need to be appointed by the President and approved by Congress. *Id.* at 1338. The *Arthrex* Panel nevertheless vacated the final written decision at issue because, in the Panel's view, the APJs were improperly appointed at the time the decision was issued. *Id.* at 1338–39.

The appellants and appellees in *Arthrex*, as well as the United States as intervenor, have filed petitions requesting that the full Court rehear *Arthrex*. Those petitions remain pending.

After *Arthrex* was decided, Appellant Pfizer Inc. moved to vacate the five final written decisions under review in this appeal based on *Arthrex*. Appellees opposed, as did the United States, which had moved to intervene. In opposition, the parties argued that it would be premature to vacate the five final written decisions based on *Arthrex* because *Arthrex* was the subject of several pending petitions for rehearing.

On January 21, 2020, a Panel of this Court (Moore, O'Malley, and Stoll, JJ.) issued a one-page order vacating the five final written decisions based on *Arthrex*. ADD2.[1] The Panel remanded the case to the PTAB "for proceedings consistent with this court's decision in *Arthrex*." *Id.*

REASONS FOR GRANTING THE PETITION

I. WHETHER APJS WERE PROPERLY APPOINTED AND THE APPROPRIATE REMEDY FOR AN APPOINTMENTS CLAUSE VIOLATION ARE ISSUES OF EXTRAORDINARY IMPORTANCE.

The importance of the issues implicated by the Panel's decision cannot be gainsaid. Relying exclusively on *Arthrex*, the Panel vacated five final written decisions by the PTAB and remanded for further proceedings before a new panel of APJs. ADD2. In adopting the rationale of *Arthrex*, the Panel implicitly held that (1) PTAB APJs are principal officers of the United States subject to the

[1] Citations to "ADD" are to the Addendum to the petition.

Appointments Clause and (2) the appropriate remedy for the improper appointment of an APJ is to vacate a final written decision and remand for further proceedings. Those holdings have widespread implications for patent litigants and the patent system as a whole.

Under the Panel's holding and *Arthrex*, hundreds of final written decisions issued by the PTAB are in danger of being summarily vacated on similar grounds. *See Bedgear*, 783 F. App'x at 1030 (Dyk, J. and Newman, J., concurring) (noting that *Arthrex* will result in "hundreds of new proceedings" at the PTAB). The upshot is that the entire patent system will be bogged down in needless additional litigation as hundreds of cases like this one that have already been resolved are sent back to the PTAB for further proceedings.

Arthrex and decisions relying on *Arthrex* like the one here therefore "impose[] large and unnecessary burdens on the system." *Id*. As the United States has explained, "hundreds of PTAB decisions could be remanded for adjudication before new PTAB panels, a massive undertaking imposing significant costs on the public fisc and impeding the agency's ability to complete IPR proceedings promptly. . . . [T]he burden of such remands will not fall on the government alone. Remands will force private, opposing parties who already fully litigated a PTAB trial to bear the costs of a new hearing." Pet'n for Reh'g En Banc by the United States in *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 18-2140, Dkt. No. 77, at 16

(Dec. 16, 2019). Even Congress recognized the significance of *Arthrex* when it convened a panel to examine the decision's implications.[2]

Review by the full Court is thus warranted both here and in *Arthrex* because of the important issues at stake. Petitioners respectfully submit that if the Court grants the petition to rehear *Arthrex*, it should likewise grant the petition here.

II. THE PANEL'S DECISION CANNOT BE RECONCILED WITH BINDING PRECEDENT PRESCRIBING THE REMEDY FOR AN APPOINTMENTS CLAUSE VIOLATION.

In addition to implicating issues of exceptional importance, the Panel's decision conflicts with binding precedent concerning the retroactive effect of court rulings and the proper remedy for a constitutional violation.

In *Harper v. Virginia Department of Taxation*, the Supreme Court held that a court's construction of a federal statute applies to all cases still open on direct review, regardless of whether the relevant events predate the construction. 509 U.S. 86, 97 (1993). In *Harper*, the Court had previously held in *Davis v. Michigan Department of Treasury* that a particular state tax exemption was unconstitutional. *Harper*, 509 U.S. at 89–90. Virginia nevertheless refused to apply the holding in *Davis* to taxes imposed before *Davis* was handed down. *Id.* at

[2] The Patent Trial and Appeal Board and the Appointments Clause: Implications of Recent Court Decisions: Hearing Before the Subcomm. on Courts, Intellectual Property & the Internet of the H. Comm. on the Judiciary, 116th Cong. (2019), https://judiciary.house.gov/legislation/hearings/patent-trial-and-appeal-board-and-appointments-clause-implications-recent-court.

90–91. The *Harper* Court held that Virginia must apply the *Davis* ruling to all pending tax cases, regardless of whether the taxes at issue were imposed before the exemption was declared unconstitutional. *Id.* at 100–01.

The Panel's decision flouts the retroactivity principle. In *Arthrex*, the Court construed the relevant statute in a manner that made APJs inferior officers. 941 F.3d at 1338. Under *Harper*, that statutory construction must apply to all cases that remain under direct review—including this one. *See Harper*, 509 U.S. at 97. In other words, the Panel here was required to hold that the APJs were inferior officers and thus properly appointed. Instead, the Panel implicitly held that the APJs were *improperly* appointed and vacated their final written decisions. ADD2. That approach runs directly counter to *Harper*, as two judges on this Court have recognized. *See Bedgear*, 783 F. App'x at 1032 (Dyk, J. and Newman, J., concurring) ("[T]o be consistent with *Harper*, the statute here must be read as though the PTAB judges had always been constitutionally appointed . . . .").

The Panel's decision likewise conflicts with *Free Enterprise Fund v. Public Co. Accounting Oversight Board*, which prescribed the proper remedy for when a delegation of power to a decision-maker violates the constitution. 561 U.S. 477 (2010). There, the Court struck down a two-level, for-cause removal protection held by members of the U.S. Securities and Exchange Commission's Public Company Accountability Oversight Board ("PCAOB") as contrary to the

Constitution's separation of powers. *Id.* After curing the constitutional defect by severing the offending portion of the statute, the Court did not vacate and remand the PCAOB decision at issue. Instead, it treated the Board members as if all along they had been "validly appointed" under the Court's construction of the statute. *Id.* at 510, 513.

Similarly, in *Helman v. Department of Veterans Affairs*, this Court found that the appointment of an administrative judge violated the Appointments Clause but declined to vacate the judge's decision. 856 F.3d 920, 927–30, 936–38 (Fed. Cir. 2017). In *Helman*, the statute made an administrative judge's determinations unreviewable by the Merit Systems Protection Board—which, according to the Court, transformed the administrative judge from an employee into an officer subject to the Appointments Clause. *Id*. at 929. Like in *Free Enterprise Fund* and *Arthrex*, the Court cured the constitutional violation by severing the provisions making the judge's determinations unreviewable. *Id.* at 936. The Court nevertheless left the judge's determination intact because its construction of the statute—including its severing of the offending provision—was held to have applied all along. *Id.* at 927, 936–38; *cf. Buckley v. Valeo*, 424 U.S. 1, 142-43 (1976) (per curiam) (holding prior actions of the Federal Elections Commission whose membership ran afoul of the Appointments Clause "de facto valid[]"),

superseded by statute, Bipartisan Campaign Reform Act of 2002, Pub. L. No. 107-155, 116 Stat. 81.

Under *Free Enterprise* and *Helman*, the remedy for any Appointments Clause violation here is clear: If the statute can be construed in a manner that resolves the constitutional problem consistent with congressional intent, that construction should be adopted and the action of the official at issue preserved. The Panel's decision to vacate the APJs' final written decisions when there existed a statutory construction that would resolve the Appointments Clause violation is thus in irreconcilable conflict with settled law.

III. THE PANEL'S DECISION MISAPPLIES BINDING PRECEDENT DISTINGUISHING INFERIOR OFFICERS FROM PRINCIPAL OFFICERS.

The Panel's decision also misapplies Supreme Court precedent distinguishing between principal officers—who must be appointed by the President and approved by the Senate—and inferior officers, who are not subject to such a requirement. *See* U.S. Const. art. II, § 2, cl. 2 (creating an exception to the Appointments Clause for "inferior Officers"); *see also Edmond v. United States*, 520 U.S. 651, 660 (1997) (discussing the "Excepting Clause" within the Appointments Clause).

An officer is inferior if "he has a superior." *Edmond*, 520 U.S. at 662. Stated another way, an inferior officer is one whose work is "directed and

supervised at some level by [a principal officer]." *Id.* at 663. Several factors are relevant to identifying an inferior officer: (1) whether the officer was subject to removal by a higher officer; (2) the scope of the officer's duties; (3) the scope of the officer's jurisdiction; and (4) the length of the officer's tenure. *Id.* at 661; *see also Morrison v. Olson*, 487 U.S. 654 (1988) (holding that an independent counsel under the Ethics in Government Act is an inferior officer).

In *Edmond*, the Court held that judges on the Coast Guard Court of Criminal Appeals were inferior officers because they were supervised by a principal officer—the Judge Advocate General ("JAG")—and the Court of Appeals for the Armed Forces ("CAAF"). *Id.* at 664. The JAG supervised the judges by prescribing uniform rules of procedure, developing policies and procedures for particular cases, and, in appropriate cases, removing a judge from judicial assignment without cause. *Id.* Similarly, the CAAF supervised the judges in cases in which (1) the death penalty is involved; (2) the JAG orders review; or (3) the CAAF grants a petition. *Id.* at 664–65.

The Court reached a similar conclusion with respect to judges on the Tax Court in *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868, 881–82 (1991). As with the APJs here, the duties, salary, and appointment of the Tax Court judges were "established by law." *Id.* at 881. Significantly, the Court held that the Tax Court judges were inferior officers despite being authorized to render decisions of

the Tax Court; conduct and rule on the admissibility of evidence; and execute their duties with broad discretion. *Id*. at 881–82.

The Panel's decision cannot be reconciled with *Edmond* and *Freytag*. By relying on *Arthrex*, the Panel implicitly held that APJs are principal officers subject to the Appointments Clause. ADD2. However, the APJs are subject to a similar level of supervision as the judges in *Edmond* and *Freytag*, who were held to be inferior officers. Specifically, the APJs are supervised by the Director of the PTO (a principal officer) in the following ways:

- The Director has the power to control the process and substance of APJs' decision-making by promulgating regulations governing the conduct of IPRs. 35 U.S.C. § 316.
- The Director has the power to reconsider or cancel any proceeding instead of allowing it to proceed to a final decision. 35 U.S.C. § 314(d); *BioDelivery Scis. Int'l v. Aquestive Therapeutics, Inc*., 935 F.3d 1362, 1366 (Fed. Cir. 2019).
- The Director "has the power to issue policy directives and management supervision," such as "instructions that include exemplary applications of patent laws to fact patterns," which apply when APJs confront "factually similar cases." *Arthrex*, 941 F.3d at 1331 (citing 35 U.S.C. § 3(a)). Such policy directives are "binding on any and all USPTO employees." Patent Trial and Appeal Board Standard Operating Procedure 2 (revision 10) at 2.
- The Director has the power to designate APJs to a panel, as well as the power to reassign and de-designate APJs. 35 U.S.C. § 6(c); Patent Trial and Appeal Board Standard Operating Procedure 1 (revision 15) at 1–2.
- The Director controls which (if any) PTAB decisions are designated precedential and thus binding on future panels. *Arthrex*, 941 F.3d at 1330 (citing Patent Trial and Appeal Board Standard Operating Procedure 2 (revision 10) at 8).

- The Director has the power to convene the Precedential Opinion Panel to review a panel decision and order rehearing. *Id.* (citing Patent Trial and Appeal Board Standard Operating Procedure 2 (revision 10) at 4-5).
- The Director controls APJs' pay. 35 U.S.C. § 3(b)(6).
- The Director has the power to remove APJs "for such cause as will promote the efficiency of the service." 5 U.S.C. § 7513(a); *Arthrex*, 941 F.3d at 1320 n. 4; *see also Polaris*, 792 F. App'x at 827 (Hughes, J. and Wallach, J., concurring) ("The efficiency of the service standard allows supervisors to discipline and terminate employees for arguably even a wider range than [good cause] standards . . . including failure or refusal to follow the Director's policy or legal guidance.").

Because their work is extensively directed and supervised by a principal officer, the APJs are inferior officers under *Edmond* and *Freytag*. *See Polaris*, 792 F. App'x at 821 (Hughes, J., and Wallach, J., concurring) ("I believe that viewed in light of the Director's significant control over the activities of the Patent Trial and Appeal Board and Administrative Patent Judges, APJs are inferior officers already properly appointed by the Secretary of Commerce."). The Panel's error in holding otherwise further warrants review by the full Court.

CONCLUSION

For the foregoing reasons, the Petition should be granted.

Dated: March 6, 2020

/s/ Fangli Chen

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ADDENDUM

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

PFIZER INC.,
Appellant

v.

MERCK SHARP & DOHME CORP., SANOFI PASTEUR INC., SK CHEMICALS CO., LTD.,
Appellees

ANDREI IANCU, Director, U.S. Patent and Trademark Office,
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2019-1871, -1873, -1875, -1876, -2224

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2017-02131, IPR2017-02132, IPR2017-02136, IPR2017-02138, and IPR2018-00187.

ON MOTION

Before MOORE, O'MALLEY, and STOLL, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

O R D E R

Pfizer Inc. moves to vacate the decision of the Patent Trial and Appeal Board and remand for further proceedings in light of *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). Merck Sharp & Dohme Corp., Sanofi Pasteur Inc., and SK Chemicals Co. Ltd. oppose the motion. The Director of the United States Patent and Trademark Office intervenes and requests that the court hold any decision on the motion in abeyance pending en banc consideration of *Arthrex*.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The Director of the United States Patent and Trademark Office is added as an intervenor. The revised official caption is reflected above.

(2) The motion to vacate and remand is granted. The Patent Trial and Appeal Board's decision is vacated, and the case is remanded to the Board for proceedings consistent with this court's decision in *Arthrex*.

(3) Each side shall bear its own costs.

FOR THE COURT

January 21, 2020
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

s24

CERTIFICATE OF SERVICE

I, hereby certify pursuant to Fed. R. App. P. 25 that, on March 6, 2020 the foregoing Combined Petition for Rehearing and Rehearing *En Banc* for Appellees Sanofi Pasteur Inc. and SK Chemicals Co., Ltd. was filed through the CM/ECF system and served electronically on parties in the case.

/s/ Fangli Chen
Fangli Chen

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE REQUIREMENTS AND TYPE STYLE REQUIREMENTS

1. This petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2)(A) or Federal Rule of Appellate Procedure 40(b).

The petition contains 2,766 words, excluding the parts of the petition exempted by Rule.

2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32.

__X__ The petition has been prepared in a proportionally spaced typeface using MS Word 2013 in a 14 point Times New Roman font or

____ The petition has been prepared in a monospaced typeface using _____in a ___ characters per inch_____ font.

March 6, 2020
Date

/s/ Fangli Chen
Fangli Chen
Counsel for Appellees
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SK Chemicals Co., Ltd.