

Nos. 2019-1871, -1873, -1875, -1876, -2224

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IN THE  
**United States Court of Appeals**  
**for the Federal Circuit**

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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.

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

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**COMBINED PETITION FOR PANEL REHEARING AND/OR  
REHEARING EN BANC**

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March 6, 2020

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*Merck Sharp & Dohme Corp.*

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## CERTIFICATE OF INTEREST

Counsel for Appellee Merck Sharp & Dohme Corp. hereby certifies as follows:

1. The full name of every party represented by me is: **Merck Sharp & Dohme Corp.**
2. The real parties in interest are: **Merck Sharp & Dohme Corp.**
3. All parent corporations and any publicly held companies that own 10% or more of the stock of the parties I represent are as follows:

**Merck Sharp & Dohme Corp.** is a subsidiary of Merck & Co., Inc., which is a publicly traded company. No publicly held company owns 10% or more of Merck & Co., Inc.'s stock.

4. The names of all law firms and the partners or associates that appeared for the parties now represented by me in the trial court or that are expected to appear in this court are:

**Hogan Lovells US LLP:** Catherine E. Stetson, Arlene L. Chow, Thomas P. Schmidt, and Ernest Yakob.

**Jones Day:** Anthony M. Insogna, Nikolaos C. George, Ryan B. McCrum, Jennifer L. Swize, and Jennifer J. Chheda.

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: *Merck Sharp & Dohme Corp. v. Pfizer Inc. & Wendy J. Watson*, Case No. 2:19-cv-02011-JS (E.D. Pa.).

Dated: March 6, 2020

/s/ Catherine E. Stetson  
Catherine E. Stetson

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## FEDERAL CIRCUIT RULE 35(b) STATEMENT

Based on my professional judgment, I believe this appeal requires an answer to the same precedent-setting questions of exceptional importance on which all parties have sought rehearing in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), and on which the Federal Government has sought rehearing in *Polaris Innovations Ltd. v. Kingston Technology Co.*, 792 F. App'x 820, 820 (Fed. Cir. 2020): Whether the Administrative Patent Judges of the Patent Trial and Appeal Board were appointed in violation of the Constitution, when such a constitutional challenge must be raised, and what the proper remedy for any violation is.

/s/ Catherine E. Stetson  
Catherine E. Stetson

*Counsel for Appellee*  
*Merck Sharp & Dohme Corp.*

## INTRODUCTION

Appellees Merck Sharp & Dohme Corp., Sanofi Pasteur Inc., and SK Chemicals Co., Ltd. successfully challenged claims 1-45 of U.S. Patent No. 9,492,559 (“the ’559 Patent”) in an *inter partes* review proceeding before the Patent Trial and Appeal Board. Before filing its opening brief, the patent owner—Appellant Pfizer, Inc.—moved to vacate the Board’s decision under *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), which was decided while the appeal was pending. Pfizer had not raised any Appointments Clause challenge before the Board. In a short, unpublished order, this Court granted the motion, “vacat[ing]” the Board’s decision and “remand[ing]” the case “to the Board for proceedings consistent with this court’s decision in *Arthrex.*” ECF No. 53 at 2. All three parties in *Arthrex*—the Patent and Trademark Office (PTO), Arthrex, and Smith & Nephew—have sought rehearing en banc of the panel’s decision.

Merck now petitions for panel rehearing or rehearing en banc, in light of the pending rehearing petitions in *Arthrex* and a rapidly growing number of related cases. As the papers in those cases show, the questions decided in *Arthrex* are hugely consequential, and have already generated divisions among the Judges of this Court. Given those divisions, and the clear importance of the issues involved, further review by this Court or the Supreme Court is likely. To remand this case to the Board now for a do-over that may prove entirely unnecessary would be

wasteful and inefficient. This Court should therefore simply hold this petition for panel rehearing or rehearing en banc until it finally resolves the Appointments Clause and related issues raised by the *Arthrex* panel decision. If the *Arthrex* panel decision is reversed on the Appointments Clause or remedy question, then this Court's remand order should be vacated too, and the appeal reinstated. Similarly, if the Court determines that an Appointments Clause challenge to the PTAB may be forfeited in circumstances applicable here, the panel's order should likewise be vacated.

### **FACTUAL AND PROCEDURAL BACKGROUND**

Merck, Sanofi, and SK Chemicals petitioned for *inter partes* review of claims 1-45 of the '559 patent, which is owned by Pfizer. The Board granted the petitions. *See* IPR Nos. IPR2017-02131, IPR2017-02132, IPR2017-02136, IPR2017-02138, and IPR2018-00187. And it found that all of the challenged claims were unpatentable as obvious under 35 U.S.C. § 103. At no point during the PTAB proceedings did Pfizer raise its Appointments Clause challenge.

Pfizer appealed the Board's decisions, and this Court consolidated the appeals. ECF No. 19. Pfizer's opening brief was initially due on August 23, 2019, but after multiple extensions the due date was set as December 12, 2019. *See* ECF Nos. 17, 18, 38, 40. In the interim, on October 31, 2019, a panel of this Court decided *Arthrex*, which held that the Administrative Patent Judges (APJs) who



constitute the Patent Trial and Appeal Board were appointed in violation of the Appointments Clause. 941 F.3d at 1325. The Court also held that the Appointments Clause challenge was not forfeited by failing to raise it in the PTAB. *Id.* at 1326-27. To remedy the constitutional violation, the *Arthrex* panel “sever[ed] the portion of the Patent Act restricting removal of the APJs.” *Id.* at 1325. It then vacated the Board’s decision in that case and remanded to the Board for a new hearing before “a new panel of APJs.” *Id.* at 1325, 1340.

After *Arthrex* was decided, Pfizer filed a motion to vacate and remand under Federal Circuit Rule 27(f). ECF No. 41. Merck, Sanofi, and SK Chemicals all opposed. ECF Nos. 44, 46. The PTO filed a Notice of Intervention, ECF No. 47, which the Court granted. And, like Appellees, the PTO opposed the motion to vacate and remand on the ground that en banc reconsideration of *Arthrex* was likely and that to shunt this case back to the PTAB would be “inefficient and burdensome.” ECF No. 48 at 3.

This Court granted Pfizer’s motion. In a summary, unpublished order, it vacated the Board’s decision and remanded the case to the Board “for proceedings consistent with this court’s decision in *Arthrex*.” ECF No. 53 at 2.

## ARGUMENT

### I. THE COURT SHOULD GRANT PANEL REHEARING OR REHEARING EN BANC.

There are compelling reasons to grant the pending petitions for rehearing en banc in *Arthrex*. Accordingly, this Court should hold the present petition for panel rehearing or rehearing en banc, and vacate the panel's order to the extent rehearing is granted in *Arthrex* or one of the related cases.

1. The parties in *Arthrex* all agree on the need for en banc review: The Government, the appellants, and the appellees in *Arthrex* have *all* filed separate petitions seeking rehearing en banc. *See* U.S. Petition for Rehearing En Banc 2-3, *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 18-2140 (Fed. Cir. Dec. 16, 2019), ECF No. 77 (arguing that en banc review is warranted because the panel erred in its interpretation of the Appointments Clause and in the remedy it ordered); Appellees' Petition for Rehearing En Banc 2-4, *Arthrex*, No. 18-2140 (Fed. Cir. Dec. 16, 2019), ECF No. 79 (same); Appellant *Arthrex, Inc.*'s Combined Petition for Rehearing and/or Rehearing En Banc 4, *Arthrex*, No. 18-2140 (Fed. Cir. Dec. 16, 2019), ECF No. 78 (arguing that the panel erred because it did not invalidate the portion of the statute governing *inter partes* review). On top of that, two amicus briefs have been filed in support of en banc review. *See* N.Y. Intellectual Prop. Law Ass'n Amicus Br., *Arthrex*, No. 18-2140 (Fed. Cir. Dec. 30, 2019), ECF No. 92; Ass'n for Accessible Medicines Amicus Br., *Arthrex*, No. 18-2140 (Fed.

Cir. Dec. 31, 2019), ECF No. 99. The fact that all sides in *Arthrex* agree on the need for en banc review confirms that the case is an obvious candidate for it.

Further, four Judges on this Court have already publicly registered their disagreement with the panel decision in *Arthrex*. Just a week after the panel decision issued in *Arthrex*, Judges Dyk and Newman wrote a separate opinion in a different case to explain why they disagreed with the remedy ordered in *Arthrex*—namely, a remand for a new hearing before a new panel of APJs. See *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 783 F. App'x 1029, 1030 (Fed. Cir. 2019) (Dyk, J., joined by Newman, J., concurring in the judgment), *petition for rehearing or rehearing en banc filed* (Jan. 8, 2020). Similarly, Judges Hughes and Wallach later wrote separately in a third case to note that, while the panel was constrained to follow *Arthrex*, they “disagree with the merits and question the remedy of the *Arthrex* panel decision.” *Polaris Innovations Ltd. v. Kingston Tech. Co.*, 792 F. App'x 820, 820-821 (Fed. Cir. 2020) (Hughes, J., joined by Wallach, J., concurring), *petitions for rehearing en banc filed* (Feb. 20 & Feb. 28, 2020). That four Judges have already publicly voiced their doubts about *Arthrex* so close on the heels of the panel's decision is yet another strong signal that the panel's decision is likely to be reviewed en banc.

*Arthrex* also meets the traditional criteria for en banc review. The decision clearly involves “a question of exceptional importance.” Fed. Cir. Internal

Operating Procedure (IOP) 13.2(b). It modifies the structure of a key federal agency, deems a federal statute unconstitutional as written, and imposes substantial “burdens on the system of *inter partes* review, requiring potentially hundreds of new proceedings” before newly constituted panels of APJs. *Bedgear*, 783 F. App’x at 1030 (Dyk, J., concurring in the judgment); *see* U.S. Petition for Rehearing En Banc 16, *Arthrex*, No. 18-2140. *Arthrex* also may deepen “a conflict with another circuit.” Fed. Cir. IOP 13.2(d). As Judge Dyk noted, other Circuits have diverged from *Arthrex*’s holding as to the proper remedy for an Appointments Clause violation. *See Bedgear*, 783 F. App’x at 1032-33 & n.4 (Dyk, J., concurring in the judgment). Given these compelling reasons for granting en banc review, this case should not be sent back to the PTAB while the petitions in *Arthrex* and *Polaris*<sup>1</sup> remain pending.

2. Further, the pending petitions—and the separate writings from Judges of this Court—amply make the case for en banc review on the merits. The PTO has explained that “[t]he Director of the [PTO] has numerous means of control over APJs.” U.S. Petition for Rehearing En Banc 2, *Arthrex*, No. 18-2140. “In concluding that APJs are principal officers, the panel gave inadequate weight to the Director’s authority, particularly his power of removal—a potent means of

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<sup>1</sup> The PTO has asked the Court to rehear *Polaris* en banc in tandem with *Arthrex*. *See* U.S. Petition for Rehearing En Banc 6, *Polaris Innovations Ltd. v. Kingston Technology Co.*, No. 18-1831 (Fed. Cir. Feb. 20, 2020), ECF No. 99.

control.” *Id.*; see *Polaris*, 792 F. App’x at 821 (Hughes, J., concurring) (“The Director’s power to direct and supervise the Board and individual APJs, along with the fact that APJs are already removable under the efficiency of the service standard, suffices to render APJs inferior officers.”). As for the remedy, Judge Dyk has explained that, “[i]n Appointments Clause cases, the Supreme Court has required a new hearing only where the appointment’s defect had not been cured or where the cure was the result of non-judicial action.” *Bedgear*, 783 F. App’x at 1034 (Dyk, J., concurring in the judgment) (footnote omitted). “The contrary decision in *Arthrex* is inconsistent with binding Supreme Court precedent and creates a host of problems in identifying the point in time when the appointments became valid.” *Id.* Finally, the PTO has argued that a “patent owner” who “fail[s] to present its Appointments Clause challenge to the Board[] forfeit[s] that challenge.” U.S. Petition for Rehearing En Banc 3, *Arthrex*, No. 18-2140. These arguments, too, reinforce the case for en banc review, and this Court should not remand this case before the pending en banc petitions are decided.

3. In light of the likelihood that the Court will grant the petitions for rehearing en banc in *Arthrex* or *Polaris*, remanding this case to the Board *before* the pending petitions are resolved would risk imposing substantial and needless burdens on the parties and the Board. Any proceedings on remand will be unnecessary if this Court grants rehearing en banc in *Arthrex*: This Court’s typical

practice is to vacate the panel's decision upon granting rehearing en banc. *See, e.g., Wi-Fi One, LLC v. Broadcom Corp.*, 851 F.3d 1241, 1241 (Fed. Cir. 2017) (per curiam) (vacating the panel opinion upon granting a petition for rehearing en banc). Moreover, after hearing the case en banc, the full Court may decide to reverse the panel's decision, either with respect to the underlying Appointments Clause violation or with respect to the remedy. The en banc Court may also make clear that Pfizer has forfeited its Appointments Clause challenge. Any of those dispositions would obviate any need for new proceedings before the Board.

The resource concerns presented by a hasty remand are especially acute in light of the mushrooming number of pending appeals in this Court in which parties have raised Appointments Clause challenges to the Board's composition in light of *Arthrex*. This Court has already vacated and remanded more than 50 cases.<sup>2</sup> There

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<sup>2</sup> *See Bedgear, LLC v. Fredman Bros. Furniture Co., Inc.*, No. 18-2170 (Fed. Cir.) (rehearing petition filed Nov. 8, 2019); *Uniloc 2017 LLC v. Facebook, Inc.*, No. 18-2251 (Fed. Cir.) (rehearing petition filed Dec. 2, 2019); *Bedgear, LLC v. Fredman Bros. Furniture Co., Inc.*, Nos. 18-2082, 18-2083, 18-2084 (Fed. Cir.) (rehearing petition filed Jan. 8, 2020); *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 18-1831 (Fed. Cir.) (rehearing petition filed Feb. 21, 2020); *VirnetX, Inc. v. Cisco Sys., Inc.*, No. 19-1725 (Fed. Cir.) (rehearing petition filed Feb. 24, 2020); *Uniloc 2017 LLC v. Cisco Sys., Inc.*, No. 18-2431 (Fed. Cir.) (rehearing petition filed Feb. 24, 2020); *Uniloc 2017 LLC v. Cisco Systems, Inc.*, No. 19-1064 (Fed. Cir.) (rehearing petition filed Feb. 24, 2020); *Image Processing Techs., LLC v. Samsung Elecs. Co.*, No. 18-2156 (Fed. Cir.) (rehearing petition denied Feb. 24, 2020); *Image Processing Techs., LLC v. Samsung Elecs. Co.*, Nos. 19-1408, 19-1485 (Fed. Cir.) (rehearing petition denied Feb. 24, 2020); *Luoma v. GT Water Prods., Inc.*, No. 19-2315 (Fed. Cir.) (rehearing petition filed Mar. 2, 2020); *Mirror Imaging, LLC v. Fidelity Info. Servs., LLC*, Nos. 19-2026, 19-2027, 19-

is no sound reason to burden the Board with a cascade of remands that may be entirely obviated by an en banc decision in *Arthrex* or by Supreme Court review.

Further, Pfizer would not suffer any undue prejudice by holding this case and then

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2028, 19-2029 (Fed. Cir.) (rehearing petition filed Mar. 2, 2020); *Stuart v. Rust-Oleum Corp.*, Nos. 19-1994, 19-2238 (Fed. Cir.) (rehearing petitions due Mar. 6, 2020); *Vilox Techs., LLC v. Unified Patents, Inc.*, No. 19-2057 (Fed. Cir.) (rehearing petitions due Mar. 6, 2020); *Agrofresh, Inc. v. UPL Ltd.*, No. 19-2243 (Fed. Cir.) (rehearing petitions due Mar. 9, 2020); *Concert Pharm., Inc. v. Incyte Corp.*, No. 19-2011 (Fed. Cir.) (rehearing petitions due Mar. 9, 2020); *Document Sec. Sys. v. Seoul Semiconductor Co.*, No. 19-2281 (Fed. Cir.) (rehearing petitions due Mar. 9, 2020); *Vaporstream, Inc. v. Snap, Inc.*, Nos. 19-2231, 19-2290, 19-2337, 20-1030 (Fed. Cir.) (rehearing petitions due Mar. 9, 2020); *Vaporstream, Inc. v. Snap, Inc.*, No. 19-2339 (Fed. Cir.) (rehearing petitions due Mar. 9, 2020); *VirnetX, Inc. v. Cisco Sys., Inc.*, No. 19-1671 (Fed. Cir.) (rehearing petitions due Mar. 9, 2020); *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 19-1202 (Fed. Cir.) (rehearing petitions due Mar. 12, 2020); *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 18-1768 (Fed. Cir.) (rehearing petitions due Mar. 16, 2020); *Sound View Innovations, LLC v. Unified Patents Inc.*, No. 20-1154 (Fed. Cir.) (rehearing petitions due Mar. 19, 2020); *Sound View Innovations, LLC v. Hulu, LLC*, No. 20-1155 (Fed. Cir.) (rehearing petitions due Mar. 19, 2020); *Document Sec. Sys., Inc. v. Seoul Semiconductor Co.*, No. 19-2430 (Fed. Cir.) (rehearing petitions due Mar. 19, 2020); *Intel Corp. v. Alacritech, Inc.*, Nos. 19-1443, 19-1447, 19-1449, 19-1450 (Fed. Cir.) (rehearing petitions due Apr. 6, 2020); *Intel Corp. v. Alacritech, Inc.*, No. 19-1464 (Fed. Cir.) (rehearing petitions due Apr. 6, 2020); *Alacritech, Inc. v. Intel Corp.*, Nos. 19-1444, 19-1445, 19-1466 (Fed. Cir.) (rehearing petitions due Apr. 6, 2020); *VirnetX, Inc. v. Iancu*, Nos. 17-2593, 17-2594 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020); *Promptu Sys. Corp., v. Comcast Cable Commc'ns, LLC*, Nos. 19-2368, 19-2369 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020); *Promptu Sys. Corp., v. Comcast Cable Commuc'ns, LLC*, No. 20-1253 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020); *High 5 Games, LLC v. Iancu*, No. 20-1024 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020); *Drone-Control, LLC v. SZ DJI Tech. Co.*, Nos. 19-2210, 19-2223, 19-2276, 19-2318 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020); *Protiva Biotherapeutics, Inc. v. Moderna Therapeutics, Inc.*, No. 20-1183 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020); *Iron Oak Techs., LLC v. Unified Patents Inc.*, No. 19-2388 (Fed. Cir.) (rehearing petitions due Apr. 13, 2020).

granting rehearing as appropriate: This appeal is still at an early stage, and Pfizer itself received multiple months of extensions on its opening brief. Pfizer has never pointed to any reason that an expeditious remand to the Board is necessary.

Indeed, in its reply in support of its motion to vacate, while Pfizer argued that it would be prejudicial to “resume briefing” on the merits appeal, it did not argue that a *stay* would be prejudicial. Rather, it agreed that, in the absence of vacatur, “the Court should defer ruling . . . until after the conclusion of any rehearing proceedings in *Arthrex*.” ECF No. 52 at 4. That is all Merck asks for here.

4. The Court should therefore hold this petition for rehearing (and thus its remand order) in abeyance and dispose of the case in accord with its en banc decision(s) in *Arthrex* and *Polaris*. Until this Court acts on the petition for rehearing, issuance of the mandate will be stayed, *see* Fed. R. App. P. 41(b), and the Board will not be saddled with a do-over that may prove unwarranted. The Court should not deny the petition and send the case back to the Board now, before this Court has finally resolved the Appointments Clause question and allied issues of remedy and forfeiture. In addition, if, at that time, there is any uncertainty as to whether Pfizer is entitled to vacatur, Merck respectfully requests the opportunity to file a supplemental brief. Indeed, Pfizer itself previously requested supplemental briefing in light of the en banc disposition of *Arthrex*. ECF No. 52 at 4-5.



**CONCLUSION**

The Court should hold this petition for panel rehearing or rehearing en banc in abeyance until it disposes of the pending petitions in *Arthrex* and *Polaris*. When those cases are resolved, the Court should grant panel rehearing or rehearing en banc if those cases make clear that Pfizer is not entitled to vacatur on merits, remedy, or forfeiture grounds. If there is any uncertainty about the proper disposition at that point, Merck respectfully requests that the Court order the parties to submit supplemental briefs regarding how to proceed in this appeal in light of the new developments.

March 6, 2020

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

1. This petition complies with the type-volume limitations of Rules of Appellate Procedure 35(b)(2) and 40(b) because it contains 2,982 words.
  
2. This petition complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Office Word in Times New Roman 14-point font.

/s/ Catherine Stetson

## **ADDENDUM**

NOTE: This order is nonprecedential.

**United States Court of Appeals  
for the Federal Circuit**

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**PFIZER INC.,**  
*Appellant*

v.

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

**ANDREI IANCU, Director, U.S. Patent and Trade-  
mark Office,**  
*Intervenor*

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

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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.

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**ON MOTION**

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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

**CERTIFICATE OF SERVICE**

I certify that on March 6, 2020, I caused a copy of the foregoing document to be served by electronic means via the Court's CM/ECF system on all counsel registered to receive electronic notices.

/s/ Catherine E. Stetson