

No. 2018-2140

IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

ARTHREX, INC.,

Appellant,

v.

SMITH & NEPHEW, INC., ARTHROCARE CORP.,

Appellees,

UNITED STATES,

Intervenor.

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

APPELLEES' CORRECTED SUPPLEMENTAL RESPONSE BRIEF

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**UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CERTIFICATE OF INTEREST

Case Number 2018-2140

Short Case Caption Arthrex, Inc. v. Smith & Nephew, Inc. and ArthroCare Corp.

Filing Party/Entity Smith & Nephew, Inc. and ArthorCare Corp.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box.** Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

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<p>1. Represented Entities. Fed. Cir. R. 47.4(a)(1).</p>	<p>2. Real Party in Interest. Fed. Cir. R. 47.4(a)(2).</p>	<p>3. Parent Corporations and Stockholders. Fed. Cir. R. 47.4(a)(3).</p>
<p>Provide the full names of all entities represented by undersigned counsel in this case.</p>	<p>Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.</p> <p><input type="checkbox"/> None/Not Applicable</p>	<p>Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.</p> <p><input type="checkbox"/> None/Not Applicable</p>
<p>Smith & Nephew, Inc.</p>	<p>Smith & Nephew, Inc.</p>	<p>Smith & Nephew PLC</p>
<p>ArthroCare Corp.</p>	<p>ArthroCare Corp.</p>	<p>Smith & Nephew PLC</p>

Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

None/Not Applicable Additional pages attached

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court’s decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

None/Not Applicable Additional pages attached

VirnetX, Inc. v. Mangrove Partners Master Fund, Ltd. et al	CAFC No. 2020-2271	
Cellspin Soft, Inc. v. Canon U.S.A. Inc. et al.	CAFC No. 2020-1947	

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable Additional pages attached

Additional Information regarding Question 5:

Counsel for appellees are aware of two cases in which issues similar to those raised in appellant's Supplemental Brief have been briefed: *VirnetX, Inc. v. Mangrove Partners Master Fund, Ltd. et al.*, No. 2020-2271 and *Cellspin Soft, Inc. v. Canon U.S.A. Inc. et al.*, No. 2020-1947. Further, if the Court credited appellant's contentions, every appeal from a PTAB final written decision ("FWD") or rehearing request decided between January 19, 2021 and the present would be impacted. So would all cases concerning patents issued from at least November 21, 2013 to January 13, 2014 (e.g., Utility Patent Nos. 8,590,062 to 8,627,511), June 7, 2017 to February 7, 2018 (e.g., Utility Patent Nos. 9,674,996 to 9,888,620), and January 20, 2021 to the present (e.g., Utility Patent Nos. 10,897,842 to 11,259,451 (as of February 23, 2022)).

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Arthrex’s challenge to the denial of its rehearing request on remand contradicts the letter of the Supreme Court’s decision, the text of the Federal Vacancies Reform Act (“FVRA”), and centuries of precedent from both the Supreme Court and the Patent Office (“PTO”). If credited, Arthrex’s arguments would imperil the ability of the PTO and indeed the entire federal government to function during Presidential transitions. Arthrex’s extreme position contradicts even Arthrex’s own previous representation to the Supreme Court that “inferior” officers can “wield principal-officer powers” on a temporary basis. S&N Add. Ex. A at 7.

Arthrex received exactly what the Supreme Court ordered: unilateral review by the executive branch official responsible for patentability determinations. The Court credited Arthrex’s Constitutional challenge to the extent FWDs rendered in IPRs were “expressly ordering the Director to undo his prior patentability determination when a PTAB panel of unaccountable APJs later disagrees with it.” *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1985 (2021). To remedy that imbalance, *Arthrex* held 35 U.S.C. § 6(c) unenforceable “insofar as it prevent[ed] the Director from reviewing the decisions of the PTAB on his own” rather than as one of a multi-member panel. *Id.* at 1987. Arthrex got exactly that relief on remand.

Nothing in the Supreme Court’s decision requires the Director to consider rehearing requests personally—just as no law requires the Director to examine patent applications personally. All that matters is that there be “discretion” to perform such actions by the holder of the office (or his or her delegee), ensuring that the “President remains responsible for the exercise of executive power.” *Arthrex*, 141 S. Ct. at 1988. The FVRA itself confirms that responsibility, including the President’s ability to remove Hirshfeld’s delegated responsibilities at any point. This ensures the President’s ultimate responsibility for both issuing and cancelling patent franchises.

Moreover, the Supreme Court expressly contemplated that the “Acting Director”—neither nominated by the President nor confirmed by the Senate—would handle *Arthrex*’s rehearing request on remand. This mandate echoes *Arthrex*’s own acknowledgment to the Court that “inferior” officers can “wield principal-officer powers” on a temporary basis. S&N Add. Ex. A at 7. It also tracks centuries of history. When Congress first authorized the Patent Office in 1836, it expressly provided for an “inferior officer” to superintend the Office when the principal office was vacant.

This is also exactly the scenario recognized in *Eaton*, which the Supreme Court cited in a context directly refuting *Arthrex*’s erroneous suggestion that *Eaton* applies only to acting officials the President personally appoints. Prior to leaving

his post, the consul general to Siam tasked a missionary (Eaton) with superintending the consulate, leaving Eaton in charge of U.S. governmental interests in Bangkok.

Here, likewise, the former Director and Deputy Director resigned pursuant to a formal delegation regime tasking the Commissioner of Patents (Hirshfeld) with superintending the PTO until the President selected a permanent successor. The same has occurred in multiple previous transitions following the FVRA's passage. In the last decade alone, over half a million patents have been issued in the name of PTO superintendents who were neither a "principal officer's deputy" nor "personally selected by the President" (Arthrex Supp. Br. at 2). Arthrex's arguments would wrongly cloud all such patents. Further, the IPR process "involves the same basic matter as the grant of a patent" and is simply "a second look" at the earlier grant. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1368 (2018) (quoting *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279 (2016)). There is no difference between finalizing IPR decisions and finalizing initial patentability decisions. Both are essential PTO functions that would grind to a halt—along with the rest of the Executive Branch—if Arthrex's arguments were credited.

BACKGROUND

Arthrex's "Background" discussion ranged well beyond the authorized subject (i.e., "denial of Director review" (ECF No. 156 at 2)) to discuss Arthrex's underlying patent and the Board's unpatentability determination. S&N incorporates its Counterstatement (ECF No. 33 at 5-21) and addresses only Arthrex's most extreme distortions and omissions.

I. ARTHREX'S '907 PATENT

"Knotless" suture anchors have been commercially available since the 1990s—before Arthrex's first provisional in 2000. *See id.* at 6.

Arthrex's 2000 and 2001 Applications described a particular "flexible loop" design for knotless anchors. *Id.* at 8-10.

Arthrex's 2003-2013 Applications discuss the 2001 Application in the Background and explain how this "flexible loop configuration ... disadvantageously impedes sliding of the suture or graft." *Id.* at 10. The 2003-2013 Applications describe the "present invention" as "overcom[ing]" the above "disadvantages of the prior art ... by providing an eyelet implant" that locks into an interference device and includes a "fixed aperture for receiving a suture attached to a graft, such that the suture is able to freely slide through the aperture." *Id.* at 11. Arthrex concedes that this "prior art" is the 2001 Application's flexible loop, which the 2003-2013 Applications incorporate in their Background sections. *Id.*

The '907 Patent application (filed in 2014) is materially different from all of the earlier applications. Arthrex rewrote the “Background”—dropping the incorporation of the 2001 Application and deleting all suggestions that the flexible loop configuration disadvantageously impeded suture sliding and risked bone damage. Arthrex also removed all suggestions of a need for a device permitting sutures to slide freely. *Id.* at 12-13.

II. S&N’S IPR PETITION AND THE BOARD’S DECISION

S&N’s IPR petition challenged '907 Patent claims covering both “flexible loop” and “rigid implant” anchors. S&N relied on the publication corresponding to Arthrex’s 2001 “flexible loop” application and also an unrelated 2002 publication describing the “rigid implant” design. Both published before Arthrex’s 2003 Application and well before Arthrex’s '907 Patent application.

After 25 pages of detailed analysis (Appx14-40), the Board determined that the effective filing date of the disputed claims was the '907 Patent’s May 8, 2014 filing date. Appx40. That was indisputably dispositive. The Board’s priority analysis was a routine exercise of its duty under 35 U.S.C. § 311(b) to determine the scope of the relevant “prior art” to the '907 Patent.

Far from relying only on the “advantages of a rigid eyelet” (Arthrex Supp. Br. at 4) described in the 2003-2013 Applications, the Board drew on extensive expert testimony, made detailed factual findings, analogized the situation to

previous Federal Circuit decisions, and concluded that the 2003-2013 Applications did not support claims covering flexible loop designs. The incorporation-by-reference of the 2001 Application came “only in the Background section, and only in order to introduce the disadvantage of that structure that the invention overcomes.” Appx28-29.

III. SUPREME COURT’S DECISION

In reviewing Arthrex’s Appointments Clause challenge, the Supreme Court found a problem with the “restrictions on review reliev[ing] the Director of responsibility for the final decisions rendered by APJs purportedly under his charge.” *Arthrex*, 141 S. Ct. at 1981. The statutory scheme, which allowed rehearings of FWDs only by multi-member panels, obscured “on whom the blame” for dubious decisions “really ought to fall.” *Id.* at 1982.

By contrast, there was no such confusion concerning patent issuance, which had been controlled by the “single officer” superintending the Patent Office since its creation in 1836. *Id.* at 1984-86. To this day, that official—now known as the Director—retains “the ultimate authority regarding the granting of patents.” *Id.* at 1985 (quoting *In re Alappat*, 33 F.3d 1526, 1535 (Fed. Cir. 1994) (en banc) (plurality opinion)). Yet IPRs could require “the Director to undo his prior patentability determination when a PTAB panel of unaccountable APJs later disagrees with it.” *Id.*

To remedy this imbalance, the Supreme Court ordered this case remanded “to the Acting Director for him to decide whether to rehear the petition.” *Id.* at 1987. What mattered was an executive official’s “discretion to review decisions rendered by APJs,” ensuring the President’s responsibility for “the exercise of executive power” and—“through him”—accountability “to the people.” *Id.* at 1988.

IV. ARTHREX’S REHEARING REQUEST

Arthrex requested rehearing on August 27, 2021 (Arthrex Add. Ex. B)—the last possible day per this Court’s Order. ECF No. 144 at 2.

Arthrex’s request dwelled on *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), and *Paice LLC v. Ford Motor Co.*, 881 F.3d 894 (Fed. Cir. 2018)—two irrelevant decisions Arthrex never mentioned before the Board rendered the decision Arthrex now challenges.¹

Arthrex’s rehearing request was referred to Commissioner Hirshfeld, who was performing the functions and duties of the PTO Director—just as earlier Commissioners had performed these duties during past transitions.

Commissioner Hirshfeld denied Arthrex’s request on October 15, 2021—only nine months into the current Administration.

¹ *Paice* was decided after Arthrex filed its original response, but before the oral hearing. Arthrex never submitted a notice of supplemental authority. *Cf.* Appx546-548 (Arthrex notice of supplemental authority concerning different case).

ARGUMENT

Arthrex has obtained exactly what the Supreme Court ordered: unilateral review of the PTAB's decision by a politically accountable officer responsible for patentability determinations and, given the Supreme Court's decision, also responsible for reviewing PTAB final written decisions reconsidering patentability determinations.

Arthrex's insistence that only a "principal officer" could decide Arthrex's rehearing request contradicts not only binding authority and the Supreme Court's remand to the "Acting Director," but also Arthrex's own representation to the Court that "inferior" officers can "wield principal-officer powers" on a temporary basis. S&N Add. Ex. A at 7.

I. COMMISSIONER HIRSHFELD'S EXERCISE OF DELEGATED AUTHORITY IS CONSISTENT WITH THE APPOINTMENTS CLAUSE.

Centuries of precedent confirm that inferior officers such as Commissioner Hirshfeld may perform the duties of a principal Officer "for a limited time[] and under special and temporary conditions" without "transform[ing]" the office into one requiring Senate confirmation. *United States v. Eaton*, 169 U.S. 331, 343 (1898). That is exactly what happened here. Commissioner Hirshfeld has been delegated the Director's powers for the special and temporary time while there is no Senate-confirmed Director superintending the PTO.

Arthrex’s unprecedented reading of the Appointments Clause would paralyze the entire Executive Branch during Presidential transitions, when political appointees confirmed by the Senate resign *en masse* on or near the last day of a President’s term. Delegations of authority are essential to avoid disrupting essential governmental functions, such as issuing patents and taking “a second look” at earlier grants via IPRs. *Cuozzo*, 579 U.S. at 279.

A. The President’s Unfettered Ability to Replace Commissioner Hirshfeld Ensures Political Accountability.

Neglecting these realities, Arthrex wrongly asserts that “the buck stops with Commissioner Hirshfeld.” Arthrex Supp. Br. at 13. Not so. The buck stops with the President, who remains responsible for the actions of delegees pending the confirmation of new Officers to fill the relevant vacancies. The FVRA itself confirms the President’s unfettered ability to name Acting Officers—superseding delegees such as Hirshfeld. For example, the President could have removed Hirshfeld’s authority and named Secretary of Commerce Raimondo, who already directly supervises the PTO and provides “policy direction” pursuant to 35 U.S.C. § 2(a). Since March 3, 2021, she has “serve[d] in an office for which appointment is required to be made of the President, by and with the advice and consent of the Senate.” 5 U.S.C. § 3345(a)(2).

Given the President’s power to remove Hirshfeld’s delegated authority without cause, the President indisputably bears responsibility for politically

controversial PTAB decisions cancelling patent claims—just as with politically controversial patents issuing in the first place. Under the longstanding delegation regime at the PTO, Commissioner Hirshfeld has the unilateral power to rehear PTAB decisions—just as he has “the ultimate authority regarding the granting of patents.” *Alappat*, 33 F.3d at 1535. And he exercises that power at the President’s pleasure. See *Edmond v. United States*, 520 U.S. 651, 664 (1997) (“It is conceded by the parties that the Judge Advocate General may also remove a Court of Criminal Appeals judge from his judicial assignment without cause.”). The President may remove Commissioner Hirshfeld from his delegated assignment without cause. Therefore, the buck on issuing and cancelling patent claims stops with the President.

By contrast, prior to *Arthrex*’s original Appointments Clause challenge, “the President [could] neither oversee the PTAB himself nor ‘attribute the Board’s failings to those whom he *can* oversee.’” *Arthrex*, 141 S. Ct. at 1982 (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 496 (2010)). The PTAB was issuing FWDs, and 35 U.S.C. § 6(c) required multi-member panels for rehearing requests. There was no transparent way the Director or the Director’s designee—and thus by extension the President—could unilaterally intercede. Following *Arthrex*’s partial invalidation of § 6(c), the Director—or another official vested with the authority of the Director—may do so. The President, who appoints

the Director and may revoke any delegations, thus bears ultimate responsibility for any purported PTAB failings.

B. *Eaton* Approved Exactly What Arthrex Denies.

Arthrex mischaracterizes *Eaton*, which approved precisely what Arthrex denies it permits: “delegating the agency head’s duties and functions to the agency’s preferred successor.” Arthrex Supp. Br. at 16. *Eaton* permitted such delegation for a limited period to avoid the “evil consequences” that would otherwise result while awaiting a permanent successor. 169 U.S. at 342.

Specifically, the consul general to Siam had become ill and needed to leave his post. Under “consular regulations” applicable when both the “consul and vice consul” offices were vacant, the consul general appointed Lewis Eaton—a missionary—“to perform temporarily the duties of the consulate.” *Id.* at 338. These regulations ensured “unbroken performance of consular duties,” without which the “public interest” would “inevitably suffer.” *Id.* at 339, 342.

Here, likewise, delegating the Director’s functions and duties to Commissioner Hirshfeld was necessary to protect the patent system after the former Director and Deputy Director both resigned immediately before the current President’s inauguration. Agency Organization Order 45-1 (ECF No. 161 Ex. 1) addresses this scenario and was promulgated pursuant to 35 U.S.C. § 3(b)(3)(B) (authorizing Director to “delegate to [subordinate officials] such of the powers

vested in the Office as the Director may determine”) and section 4745 of the Patent and Trademark Office Efficiency Act, Pub. L. No. 106-113, 113 Stat. 1501A-572, 1501A-587 (1999) (codified at 35 U.S.C. § 1 note). This is no different from promulgating the applicable “consular regulations” pursuant to Congressional authorization in *Eaton*. 169 U.S. at 337.

Arthrex wrongly tries to distinguish *Eaton* because “the President never appointed Commissioner Hirshfeld.” Arthrex Supp. Br. at 16. But the President never appointed Eaton either—the consul general did. 169 U.S. at 331-32; *see also Morrison v. Olson*, 487 U.S. 654, 672 (1988) (noting that *Eaton* “approved” regulations permitting “*executive officials* to appoint a ‘vice-consul’ during the temporary absence of the consul”).² In Arthrex’s own words, the consul general “handed [Eaton] a blank check before packing up and shipping out.” Arthrex Supp. Br. at 15. Eaton’s authority was later recognized by the “state department.” 169 U.S. at 339. Here, likewise, the Commerce Department recognizes Commissioner Hirshfeld as performing the functions and duties of PTO Director. S&N Add. Ex. B; *see also* S&N Add. Ex. C (May 11, 2021, statement by Secretary Raimondo noting PTO’s “momentous benchmark” of issuing U.S. Patent No. 11,000,000 under Hirshfeld).

² Emphasis added unless indicated.

Arthrex’s proposed distinction also contradicts the Supreme Court’s reliance on *Eaton* when explaining why it had been permissible for eighteenth and early nineteenth-century arbitrators and examiners to make final decisions on patent issues. They exercised their powers under “special and temporary conditions”—just like the missionary in *Eaton*, which settled that “an inferior officer can perform functions of principal office on [an] acting basis.” *Arthrex*, 141 S. Ct. at 1985 (citing *Eaton*, 169 U.S. at 343).³ Further, the arbitrators and examiners were indisputably appointed by “the Secretary of State,” not the President. *Arthrex*, 141 S. Ct. at 1985.

Nor can *Arthrex* distinguish *Eaton* based on how long Commissioner Hirshfeld has performed the Director’s functions and duties. Hirshfeld denied *Arthrex*’s rehearing request on October 15, 2021—his 268th day in the role. By comparison, *Eaton* performed consular duties for 309 days before being replaced by a Senate-confirmed official—from July 12, 1892 to May 17, 1893. 169 U.S. at 334. Moreover, while the letter of the FVRA is inapplicable as discussed in Section II.A *infra*, the spirit is relevant insofar as Congress recognized that 300 days was a reasonable time allowance for nominations following Presidential transitions. *See* 5 U.S.C. § 3349a.

³ The Supreme Court’s reliance on *Eaton* when addressing how early arbitrators and examiners made final determinations on patent issues likewise refutes any attempt to minimize *Eaton* as only concerning “intragovernmental” disputes.

C. Long-Standing Patent Office Practice Confirms Commissioner Hirshfeld’s Delegated Authority.

Notwithstanding Arthrex’s suggestion that “[o]nly a principal officer can wield” Patent Office powers (Arthrex Supp. Br. at 17-18), history confirms the long-standing practice of “protect[ing] the interests of the government” by relying on inferior officers to superintend the Patent Office when the lead position is vacant. *Eaton*, 169 U.S. at 332. Such “historical practice” bears “significant weight” when interpreting constitutional provisions concerning “the allocation of power” between Congress and the Executive Branch. *NLRB v. Noel Canning*, 573 U.S. 513, 524 (2014).

When creating the Patent Office in 1836, Congress authorized the Commissioner of Patents and Secretary of State to appoint an “inferior officer.” Act of July 4, 1836, ch. 357, § 2, 5 Stat. 117, 118. Congress also authorized that inferior officer to “perform the duties of Commissioner” in “the necessary absence of the Commissioner, or when the said principal office shall become vacant.” *Id.*

Pursuant to this authority, inferior officers in times of transition routinely made final rejections, issued patents, and authorized patent extensions. *See, e.g., N.Y. & Md. Line R Co v. Winans*, 58 U.S. 30, 41 (1854) (rejecting challenge to patent extension signed by acting commissioner: “The court will take notice judicially of the persons who from time to time preside over the patent office, whether permanently or transiently.”); *Comm’r of Pats. v. Whiteley*, 71 U.S. 522

(1866) (crediting application for reissue filed with Acting Commissioner); *Woodworth v. Hall*, 30 F. Cas. 577, 578 (C.C.D. Mass. 1846) (“[T]he chief clerk, since July, 1836, has been accustomed to perform, under this section, all the duties of commissioner during his necessary absence ... [M]any patents during that period have been signed, and many records certified, by the chief clerk, as acting commissioner, under the 2d section of the patent law, and which must become invalid if this one be so pronounced, for that cause.”); *In re Bishop*, 3 F. Cas. 452, 453 (C.C.D.D.C. 1857) (affirming final rejection made by “acting commissioner”).

The 1836 Patent Act reflects the same sort of contingency planning as the consular regulations confirmed in *Eaton*. Without “unbroken performance” of patent examination and issuance, competitors could misappropriate patentable inventions without consequence. Absent a signature from the Director or another officer exercising the Director’s authority, no patents could issue and no infringement actions could lie. *Marsh v. Nichols, Shepherd & Co.*, 128 U.S. 605, 616 (1888); *see also* 35 U.S.C. § 153.

Similarly, there will be scenarios—including when no Senate-confirmed Director is in place—in which mistakenly issued patents impair legitimate competition. The IPR system corrects such mistakes by permitting “a second look at an earlier administrative grant of a patent.” *Cuozzo*, 579 U.S. at 279. Indeed, IPRs concern the “same basic matter as the grant.” *Oil States*, 138 S. Ct. at 1368.

But under Arthrex’s erroneous theory, IPRs must halt whenever the Director resigns. This is no more logical than suggesting that the PTO should stop issuing patents during such transitions. IPR is simply “an act by the [PTO] in reconsidering its own grant of a public franchise.” *Saint Regis Mohawk Tribe v. Mylan Pharm. Inc.*, 896 F.3d 1322, 1328 (Fed. Cir. 2018).

Issuing and cancelling such franchises are essential functions that “bind the Executive Branch.” *Arthrex*, 141 S. Ct. at 1985. As such, they implicate principal-officer powers. But as Arthrex itself previously acknowledged when citing *Eaton*, “inferior” officers can “wield principal-officer powers” on a temporary basis. S&N Add. Ex. A at 7-8. Commissioner Hirshfeld did so when denying Arthrex’s rehearing request—much like predecessors dating back to the Patent Office’s founding in 1836 when the permanent superintendent’s office was vacant.

D. The Supreme Court’s Remand to the “Acting Director” Directly Refutes Arthrex’s Position.

While Commissioner Hirshfeld is not literally the “Acting Director,” the Supreme Court’s remand to the “Acting Director,” *Arthrex* 141 S. Ct. at 1972, directly refutes Arthrex’s insistence that “[o]nly a principal officer” was capable of revoking Arthrex’s patent claims. Arthrex itself represented to the Supreme Court that “‘Acting’ officers are inferior even when they wield principal-officer powers.” S&N Add. Ex. A at 7. Yet Arthrex now disingenuously suggests that the parties “did not brief” the issue. *Arthrex Supp. Br.* at 17. On the contrary, Arthrex’s

express representation confirms that Commissioner Hirshfeld as an inferior officer was empowered to wield principal-officer powers temporarily and, during that time, revoke Arthrex's patent claims.

II. COMMISSIONER HIRSHFELD'S EXERCISE OF DELEGATED AUTHORITY IS CONSISTENT WITH THE FVRA.

Arthrex's FVRA arguments contradict both the letter and the spirit of the statute. If credited, they would throw the patent system into chaos and cloud the validity of hundreds of thousands of patents and countless other PTO actions.

A. Arthrex's Arguments Contradict the Letter of the FVRA.

The FVRA is inapplicable because the disputed function—reviewing a prior patentability determination—is non-exclusive. The FVRA applies only to functions and duties that a statute or regulation requires “to be performed by the applicable officer (and only that officer).” 5 U.S.C. § 3348(a)(2). Here, no statute or regulation requires the Director personally to decide rehearing requests.

By Arthrex's own characterization, its rehearing request was “[p]ursuant to Supreme Court and Federal Circuit mandate and 37 C.F.R. 42.71(d).” Arthrex Add. Ex. B at 1. Court mandates are neither “statute” nor “regulation.” And § 42.71(d) refers to the “Board”—not the Director. Further, the Supreme Court stressed that the “Director need not review every [PTAB] decision,” 141 S. Ct. at 1988—just like the Director need not review every patentability determination by examiners.

An “exclusive” function under the FVRA is the exception—not the rule. *E.g., Stand Up for California! v. U.S. Dep’t of the Interior*, 994 F.3d 616, 622 (D.C. Cir. 2021) (“Should Congress remain silent on the issue, however, the FVRA provides the Executive Branch with leeway to set out which functions or duties are exclusive and which are not.”); *Stand Up for California! v. U.S. Dep’t of Interior*, 298 F. Supp. 3d 136, 137 (D.D.C. 2018) (“[I]n practice, there are very few duties that cannot be delegated to . . . another who acts in the place of the principal pursuant to agency regulations or orders.”); *Kajmowicz v. Whitaker*, No. 2:19-CV-00187, 2021 WL 2200795, at *7 (W.D. Pa. June 1, 2021) (collecting cases); Guidance on Application of Fed. Vacancies Reform Act of 1998, 23 U.S. Op. Off. Legal Counsel 60, 72 (1999) (“Most, and in many cases all, the responsibilities performed by a PAS officer will not be exclusive, and the Act permits non-exclusive responsibilities to be delegated to other appropriate officers and employees in the agency.”).

By contrast, Arthrex’s cases are inapposite. *Bullock* concerned regulations requiring the relevant “Director alone to consider and resolve recommendations and protests.” *Bullock v. U.S. Bureau of Land Mgmt.*, 489 F. Supp. 3d 1112, 1128 (D. Mont. 2020). Here, nothing requires the PTO Director alone to resolve rehearing requests. Similarly, the relevant “function” in *L-M.M.* was assigned

“*only* to the USCIS Director.” *L.M.-M. v. Cuccinelli*, 442 F. Supp. 3d 1, 30 (D.D.C. 2020).

Further, *L.M.-M.* involved a transparent attempt to evade the FVRA by supplanting the previous first assistant in favor of someone who “did not hold another PAS position at the time of his designation” and had never even served anywhere in the federal government, but nevertheless was nominally appointed to a *new office* created *after* the vacancy arose. *Id.* at 25.

Here, by contrast, Hirshfeld had served in his previous PTO position for more than five years before the transition in administrations. S&N Add. Ex. D. And he is discharging the duties of the Director just as previous Commissioners discharged these duties during previous transitions. *See infra* Section II.C.

Under the PTO delegation regime, Hirshfeld is not currently serving as the “Commissioner for Patents” and thus is not presently one of the “other members of the PTAB” for whom 35 U.S.C. § 6(c)’s three-member-panel requirement “remains operative.” *Arthrex*, 141 S. Ct. at 1987. Instead, there is an “Acting Commissioner for Patents”—namely, the Deputy Commissioner for Patents. S&N Add. Ex. E. Any suggestion that Section 6(c) itself precludes the Commissioner from acting unilaterally pursuant to a delegation (*see Arthrex Supp. Br.* at 22) thus fails. It “remains operative” as to the PTAB, but a single responsible official may—and did here—review panel decisions as required by the Supreme Court.

B. Arthrex’s Arguments Contradict the Spirit of the FVRA and Subsequent Congressional Enactments.

Aside from contradicting the letter of the FVRA, Arthrex’s position neglects unmistakable Congressional intent.

Arthrex acknowledges that Congress passed the FVRA in 1998 “to help enforce the constitutional requirements of presidential nomination and Senate confirmation for principal officers.” Arthrex Supp. Br. at 19; *see also SW Gen., Inc. v. N.L.R.B.*, 796 F.3d 67, 70 (D.C. Cir. 2015) (noting that FVRA was “framed as a reclamation of the Congress’s Appointments Clause power”), *aff’d*, 137 S. Ct. 929 (2017).

The very next year, however, Congress passed the Patent and Trademark Office Efficiency Act, Pub. L. No. 106-113, 113 Stat. 1501A-572 (1999). The PTO Efficiency Act provided for a “Deputy Director” of the PTO appointed as an inferior officer—that is, by the “Secretary of Commerce, upon nomination by the Director.” *Id.* § 4713 (codified as 35 U.S.C. § 3(b)(1)). Congress also expressly “vested” the Deputy Director “with the authority to act in the capacity of the Director in the event of the absence or incapacity of the Director.” *Id.*

Simply put, the PTO Efficiency Act in 1999 took the Patent Office back to where it started in 1836—permitting Executive Branch officers (other than the President) to designate a second-in-command at the PTO and have that person act in the capacity of the Director when the office is vacant. *See supra* Section I.C.

As the *L.M.-M.* court acknowledged, “overreaching in filling vacancies for positions that have statutorily designated first assistants was not the primary problem that Congress had in mind” when passing the FVRA. 442 F. Supp. 3d at 29. That applies even more so when that first assistant is not a PAS position and Congress passed relevant legislation after the FVRA. *Cf.* Nina A. Mendelson, *The Permissibility of Acting Officials: May the President Work Around Senate Confirmation?*, 72 Admin. L. Rev. 533, 566 (2020) (discussing “contested zones of authority between the President and Congress”).

Unlike the gamesmanship in *L.-M.-M.*, the present situation involves garden-variety housekeeping: what happens when both the PAS position and the statutorily designated first assistant position are vacant following a Presidential transition? The Department of Commerce and PTO addressed this scenario in Agency Order 45-1, providing that when the positions of Director and Deputy Director are vacant, “the Commissioner for Patents ... will perform the non-exclusive functions and duties” of the Director position. The PTO Efficiency Act itself expressly provided for “delegation and assignment” within the PTO. § 4745, 113 Stat. at 1501A-587 (codified at 35 U.S.C. § 1 note). *See* 35 U.S.C. § 3(b)(3)(B) (authorizing Director to “delegate to [subordinate officials] such of the powers vested in the Office as the Director may determine”); 37 C.F.R. 11.1 (“USPTO Director means the Director of the United States Patent and Trademark

Office, or an employee of the Office delegated authority to act for the Director of the United States Patent and Trademark Office in matters arising under this part.”); *see also Schaghticoke Tribal Nation v. Kempthorne*, 587 F.3d 132, 135 (2d Cir. 2009) (rejecting FVRA challenge, citing regulation providing that Assistant Secretary could name “authorized representative”).

C. Arthrex’s Arguments Contradict Decades of Settled PTO Practice and the Issuance of Numerous Patents During Transitions.

Following passage of the FVRA in 1998 and the PTO Efficiency Act in 1999, the PTO has repeatedly relied on Agency Order 45-1 and/or similar earlier orders to ensure continuity of PTO operations during Presidential transitions and other periods without a Director or Deputy Director. These orders have ensured the PTO’s ability to examine patent applications and issue patent claims, including:

- collecting fees per 35 U.S.C. § 41 (“*the Director shall* charge ...”)
- examining patent applications per § 131 (“*The Director shall* cause an examination to be made ...”)
- notifying patent applicants of rejections per § 132 (“*The Director shall* notify the applicant thereof ...”)
- issuing patents per § 131 (“*the Director shall issue* a patent”); and

- signing patents per § 153 (“[p]atents ... shall be signed *by the Director* or have his signature placed thereon”).⁴

In the last decade alone, the PTO has issued over 668,000 patents during such transition periods—including 94 assigned to Arthrex:⁵

Time Period	Official Performing the Functions and Duties of Director	Total Number of Patents Issued	Number of Patents Issued Assigned to Arthrex
11/21/2013-1/13/2014	Margaret Focarino (Commissioner for Patents) ⁶	40,591	6
6/7/2017-2/7/2018	Joseph Matal (Associate Solicitor)	233,257	40
1/20/2021-present	Andrew Hirshfeld (Commissioner for Patents)	394,486 (as of 2/22/22)	48 (as of 2/22/22)

See, e.g., S&N Add. Ex. F (announcing delegation to Focarino: “This delegation of authority to the Commissioner for Patents during a period when the Director and Deputy Director positions are vacant has long been provided for ...”).

⁴ Commissioner Hirshfeld’s signature is applied pursuant to a delegation of authority—as has been true for decades. 661 O.G. 13 (Aug. 5, 1952) (“Designation of Attesting Officers”).

⁵ All figures were obtained by searching the PTO Patent Full-Text and Image Database (available at <https://patft.uspto.gov/netahtml/PTO/search-adv.htm>) by issue date.

⁶ This is not even counting the period between 1/14/2014 and 1/12/2015, when Michelle Lee oversaw the PTO after being appointed as Deputy Director. Lee’s appointment by the Secretary of Commerce followed the nomination by Margaret Focarino pursuant to 35 U.S.C. § 3(b)(1). Focarino was exercising the authority delegated to her.

Should PTO examiners allow an application that Commissioner Hirshfeld believes contrary to law, the functions and duties delegated to him since January 20, 2021, have included the “obligation” to refuse to grant such patent. *Alappat*, 33 F.3d at 1535 (“The Commissioner⁷ has an obligation to refuse to grant a patent if he believes that doing so would be contrary to law.”). This ensures the requisite political accountability. If the President does not approve of Hirshfeld’s performance—for example, his willingness to permit certain patents to grant—the President is free to name an Acting Director to take over under the FVRA. *See* 5 U.S.C. § 3345(a)(2).

Here again, there is no relevant difference between determining that a patent application satisfies the requirements for patentability (leading to issuance) and determining that the initial patentability determination was erroneous (leading to cancellation). Any such distinction would contradict *Oil States*. 138 S. Ct. at 1374 (IPR process “involves the same basic matter as the grant of a patent”); *see also Saint Regis*, 896 F.3d at 1328 (IPR involves PTO “reconsidering its own grant”).

The Supreme Court’s *Arthrex* decision itself stressed how the IPR system had previously raised the specter of “expressly ordering the Director to undo *his prior patentability determination* when a PTAB panel of unaccountable APJs later

⁷ *Alappat* was decided before the 1999 PTO Efficiency Act, which reorganized the Office and caused it to be headed by a “Director” rather than a “Commissioner.”

disagrees with it.” 141 S. Ct. at 1985. Now, however, a politically accountable official—here, Commissioner Hirshfeld, whose delegated authority the President can remove without cause—is responsible for both patentability determinations and final IPR decisions taking a “second look” (*Cuozzo*, 579 U.S. at 279) at such determinations. If Commissioner Hirshfeld’s denial of Arthrex’s rehearing request truly lacked “force or effect” (Arthrex Supp. Br. at 22-23) the same would be true of all patentability determinations over the last year. *See Arthrex*, 141 S. Ct. at 1977 (noting that Patent Act of 1836 left “initial determination of patentability to the Executive Branch ... where it remains today”). The power to cancel patents is (and must be) every bit as delegable as the power to issue them.

While Arthrex dwells on the Supreme Court’s reference to “the Director” (Arthrex Supp. Br. at 22),⁸ this same language appears in § 131 (governing patent issuance) and repeatedly elsewhere in the Patent Act. Indeed, examining and issuing patents is just one of the numerous duties Congress allocated to the “Director,” but with the power to delegate. Others include:

- augmenting patent terms per 35 U.S.C. §§ 154(b)(3)(B) and 156(d);

⁸ Further, the Supreme Court’s mandate specifically referenced “the Acting Director”—confirming the Court’s recognition that the holding concerning § 6(c) was not literally limited to a Senate-confirmed Director. Arthrex’s disingenuous suggestion that this was a mere “passing reference” (Arthrex Supp. Br. at 17) neglects how the Supreme Court was echoing Arthrex’s own briefing. *See supra* Section I.D.

- correcting issued patents per §§ 254-256;
- initiating and concluding post-issuance proceedings including:
 - derivations (§ 135);
 - supplemental examination (§ 257);
 - reexamination (§§ 303 & 307);
 - *inter partes* review (§§ 314(b) & 318(b));
 - post grant review (§§ 324(c) & 328(b)); and
- appointing PTAB panels per § 6(c).

Under Arthrex’s misguided interpretation of the FVRA, *none* of these functions could occur when the Director and Deputy Director positions are vacant (as has occurred repeatedly, including 696 days (almost 20 percent of the total) during the last decade alone. For all intents and purposes, the PTO’s doors would be closed.

Even this Court would be impacted. Appeals of PTAB decisions require a “certified list,” which “the Director shall transmit.” 35 U.S.C. § 143. Under Arthrex’s theory, no such lists could have been transmitted for the past thirteen months.

III. COMMISSIONER HIRSHFELD’S EXERCISE OF DELEGATED POWERS IS CONSISTENT WITH THE SEPARATION OF POWERS

Arthrex’s separation-of-powers arguments fail for similar reasons and neglect that Commissioner Hirshfeld is performing the functions and duties of the Director at the President’s pleasure. The FVRA itself confirms as much. *See*

supra Section I.A. Whether or not Hirshfeld is removable from government employment without cause is beside the point—just as with other inferior officers who temporarily perform the functions and duties of Senate-confirmed positions during Presidential transitions. Indeed, Arthrex’s arguments would invalidate many of the succession lines prescribed by the FVRA, rendering the Executive Branch as a whole unworkable during periods of Presidential transition.

Tellingly, Arthrex makes no attempt to cabin its arguments to IPR rehearing requests or otherwise deny the havoc Arthrex’s theory would wreak on the PTO—much less other agencies. Instead, Arthrex emphasizes Commissioner Hirshfeld’s “sole authority” (Arthrex Supp. Br. at 25) over patent issuance (i.e., the flipside of IPR determinations, as previously discussed). Under Arthrex’s mistaken theory, hundreds of thousands of patents issued during transition periods (*supra* Section II.C) would be Constitutionally suspect. The President is unconstrained in his ability to “supervise Commissioner Hirshfeld’s discharge of the Director’s executive duties” (Arthrex Supp. Br. at 23). The President therefore bears ultimate responsibility both for the issuance of patent claims (such as the 48 patents Arthrex has secured under Commissioner Hirshfeld’s stewardship) and later determinations that the original issuance was a mistake (such as the IPR here).

The removal restrictions at issue in *Seila* and *Collins* (Arthrex Supp. Br. at 24-26) are inapplicable. They had nothing to do with the FVRA and/or

Presidential transitions. Instead, they concerned permanent appointments and unusual structures of newfangled agencies. Commissioner Hirshfeld, in contrast, is continuing a long history of settled PTO practice.

CONCLUSION

For the foregoing reasons, as well as those in S&N's original responsive brief (ECF No. 33), the Court should affirm the Board's decision on the merits and the denial of Arthrex's rehearing request.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation specified in ECF No. 156. The relevant portions of the brief (i.e., excluding the portions exempted by Fed. R. App. P. 32(f) and Fed. Cir R. 32(b)(2)) contain 5968 words, as determined by Microsoft Word 365.

The brief also 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). The brief has been prepared using 14-point Times New Roman font (i.e., a proportionally spaced typeface).

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CERTIFICATE OF SERVICE AND FILING

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ADDENDUM

Exhibit	Description/Source
A	Reply Brief for Arthrex, Inc. in <i>United States v. Arthrex, Inc.</i> , Nos. 19-1434, 19-1452, and 19-1458 (U.S.)
B	U.S. Department of Commerce, Leadership (as of February 22, 2022) https://www.commerce.gov/about/leadership?q=/about/leadership&page=1
C	PTO Press Release 21-04, USPTO issues patent number 11,000,000 (May 11, 2021) https://www.uspto.gov/about-us/news-updates/uspto-issues-patent-number-11000000
D	PTO Executive Biographies, Drew Hirshfeld (as of February 22, 2022) https://www.uspto.gov/about-us/executive-biographies/drew-hirshfeld
E	PTO Executive committee (as of February 22, 2022) https://www.uspto.gov/about-us/executive-biographies
F	Notice of Delegation to Commissioner for Patents and Notice of Delegation to Commissioner for Trademarks https://www.uspto.gov/patents/patents-announcements/notice-delegation-commissioner-patents-and-notice-delegation

EXHIBIT A

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.,
Respondents.

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

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(additional captions on inside cover)

SMITH & NEPHEW, INC., ET AL.,
Petitioners,

v.

ARTHREX, INC., ET AL.,
Respondents.

ARTHREX, INC.,
Petitioner,

v.

SMITH & NEPHEW, INC., ET AL.,
Respondents.

QUESTIONS PRESENTED

1. Whether, for purposes of the Appointments Clause, U.S. Const. art. II, §2, cl. 2, administrative patent judges of the U.S. Patent and Trademark Office are principal officers who must be appointed by the President with the Senate’s advice and consent, or “inferior Officers” whose appointment Congress has permissibly vested in a department head.

2. Whether, if administrative patent judges are principal officers, the court of appeals properly cured any Appointments Clause defect in the current statutory scheme prospectively by severing the application of 5 U.S.C. §7513(a) to those judges.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, Arthrex, Inc. states that the corporate disclosure statement included in its opening brief remains accurate.

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IN THE
Supreme Court of the United States

NO. 19-1434

UNITED STATES OF AMERICA,
Petitioner,

v.

ARTHREX, INC., ET AL.,
Respondents.

NO. 19-1452

SMITH & NEPHEW, INC., ET AL.,
Petitioners,

v.

ARTHREX, INC., ET AL.,
Respondents.

NO. 19-1458

ARTHREX, INC.,
Petitioner,

v.

SMITH & NEPHEW, INC., ET AL.,
Respondents.

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

REPLY BRIEF FOR ARTHREX, INC.

PRELIMINARY STATEMENT

Neither the government nor Smith & Nephew cites a single case where this Court has upheld, much less imposed, a regime remotely similar to the one the Federal Circuit imposed below. The standard federal model for

agency adjudication has long granted tenure protections to ensure the impartiality of administrative judges, while granting transparent review power to accountable agency heads. The court below created a regime that has *neither* impartiality *nor* accountability.

Administrative patent judges make final decisions involving billions of dollars of intellectual property that shape the course of innovation across entire industries. But they now face the threat of being fired if their superiors—for reasons unknown to the parties—disagree. Their rulings may be driven, not by the facts and law, but by a desire to please their bosses. Superiors, meanwhile, must interfere behind the scenes to try to achieve desired outcomes, because the statute denies them any transparent power of review. Superiors thus avoid accountability for their actions—to the President and the public alike. That structure is anathema to a constitutional provision “designed to preserve political accountability” so the public knows whom to blame for poor decisions. *Edmond v. United States*, 520 U.S. 651, 663 (1997).

Smith & Nephew invokes Congress’s need for “flexibility in defining and filling federal offices.” S&N Reply 51. The Appointments Clause does grant Congress flexibility—but only within constitutional bounds. And that flexibility is precisely why the court of appeals erred by imposing its own preferred remedy rather than letting Congress decide. The court’s remedy is unrecognizable in the annals of American administrative law. The Appointments Clause does not permit it. Congress never would have enacted it. The court’s severance remedy should be reversed.

ARGUMENT**I. THE COURT OF APPEALS' SEVERANCE REMEDY WAS INSUFFICIENT TO CURE THE VIOLATION**

Even shorn of tenure protections, APJs still issue the Executive Branch's final word, revoking valuable property rights with no opportunity for review by any superior officer. That power alone makes them principal officers. The court of appeals' remedy was no remedy at all.

A. The Appointments Clause Requires Review of Administrative Patent Judges' Decisions by Superior Executive Officers

The government does not dispute that neither the Director nor any other superior executive officer can review APJ decisions. Only the Board can grant rehearing. 35 U.S.C. §6(c). And only the Federal Circuit can review decisions on appeal. *Id.* §141. No superior executive officer can "single-handedly review, nullify or reverse [an APJ's] decision." Pet. App. 10a. That remains the case, whether APJs have tenure protections or not.

1. That absence of review cannot be squared with precedent. *Edmond* treats review of decisions as an indispensable element of supervision for administrative judges: "What is significant is that the judges * * * have no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers." *Edmond v. United States*, 520 U.S. 651, 665 (1997). *Edmond* thus makes clear that review and correction by a principal officer are required.¹

¹ Arthrex never "agree[d]" that severance would cure the violation. Compare Gov't Reply 33 with Arthrex Pet. in No. 19-1458, at 13 n.2.

Smith & Nephew quotes *Edmond*'s observation that there is no "exclusive criterion" for inferior officers. S&N Reply 21. But the fact that different considerations may be relevant for different types of officers does not mean that for *this* category—administrative judges who do nothing but decide cases—Congress can eliminate the one oversight mechanism crucial to ensure accountability. That *Edmond* considered other oversight mechanisms in addition to review proves only that review alone may not be *sufficient* to make administrative judges inferior officers—not that Congress can eliminate review entirely. Arthrex Br. 24-25.²

The Constitution's other uses of the term "inferior" confirm as much. Cf. S&N Br. 21. Article III refers to lower federal courts as "inferior" *precisely because* their decisions are subject to this Court's review. See Steven G. Calabresi & Gary Lawson, *The Unitary Executive, Jurisdiction Stripping, and the Hamdan Opinions*, 107 Colum. L. Rev. 1002, 1006-1007 (2007). Courts that issued unreviewable decisions in minor matters might be "lesser" in quality or rank. But they would not be "inferior." See *Edmond*, 520 U.S. at 662-663.

The government does not deny that this Court has *never* held an administrative judge to be an inferior officer absent some superior who could review his decisions. Smith & Nephew argues otherwise based on *Freytag v. Commissioner*, 501 U.S. 868 (1991). Even though the Tax Court could review special trial judge decisions, it

² For policymakers, removal may well be sufficient: Removing the policymaker changes the policy. By contrast, removing an administrative judge does not alter decisions already made. Those decisions stand as the Executive Branch's final word. Arthrex Br. 22.

claims, that court was not an Executive Branch entity and never actually reviewed any decisions. S&N Reply 27-28. That is wrong on both counts. The Tax Court *is* an Executive Branch entity. See *Kuretski v. Comm’r*, 755 F.3d 929, 939-945 (D.C. Cir. 2014) (“[T]he Tax Court exercises its authority as part of the Executive Branch.”), cert. denied, 135 S. Ct. 2309 (2015); William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511, 1563-1567 (2020). And it *has* reviewed special trial judge orders—dozens if not hundreds of times. See, e.g., *Guerra v. Comm’r*, 110 T.C. 271, 271-272 (1998); *Givens v. Comm’r*, 90 T.C. 1145, 1145 (1988); Tax Ct. R. 182(d).

2. The government and Smith & Nephew find no support in Patent Office history. Gov’t Reply 25-30; S&N Reply 5-12. For more than a century, Congress lodged final decisionmaking authority in presidentially appointed, Senate-confirmed officers like the Commissioner and examiners-in-chief. Arthrex Br. 3-4. The handful of supposed counterexamples crumble upon inspection.

The arbitrators who decided interferences and other limited matters under the 1793 and 1836 statutes were nothing like APJs. Cf. Gov’t Reply 25-26; S&N Reply 6-7. They acted in only *one specific case*. An arbitrator who decides a single case is not an “officer,” let alone a principal officer, because “[h]is position is without tenure, duration, continuing emolument, or continuous duties, and he acts only occasionally and temporarily.” *Auffmordt v. Hedden*, 137 U.S. 310, 327 (1890); see also *Constitutional Limitations on Federal Government Participation in Binding Arbitration*, 19 Op. O.L.C. 208, 216-219 (1995) (“arbitrators are not officers” because “their service does not bear the hallmarks of a constitutional office—tenure, duration, emoluments, and continuing duties” and they “do not occupy a position of employment

within the federal government”); *Officers of the United States Within the Meaning of the Appointments Clause*, 31 Op. O.L.C. 73, 100-111 (2007) (canvassing Framing-era authorities). At most, the temporary and narrow nature of the assignments makes arbitrators inferior officers, even absent agency review. See *Morrison v. Olson*, 487 U.S. 654, 672 (1988) (independent counsel “appointed essentially to accomplish a single task”).³

The patent examiners who consider patent applications are irrelevant too. Cf. Gov’t Reply 28; S&N Reply 7. Their decisions have always been subject to agency review. The 1870 statute provided that “*the commissioner shall cause an examination to be made * * * and if on such examination it shall appear that the claimant is justly entitled to a patent * * * issue a patent therefor.*” Act of July 8, 1870, ch. 230, §31, 16 Stat. 198, 202 (emphasis added); see also Act of July 4, 1836, ch. 357, §7, 5 Stat. 117, 119-120. The current statute is almost identical. 35 U.S.C. §131. That language does not grant examiners *any* unreviewable authority. “Unlike an IPR, which by statute the Board must ‘conduct,’ examination is entirely within the control of the Director,” who has “sole authority over the decision whether to grant the requested patent.” U.S. Supp. Br. in *In re Boloro Glob. Ltd.*, No. 19-2349, Dkt. 27, at 3, 7-9 (Fed. Cir. filed Mar. 20, 2020) (citation omitted); see also 37 C.F.R. §1.181(a)(1) (permitting peti-

³ Arbitrations under the early statutes were exceedingly rare. See P.J. Federico, *Early Interferences*, 19 J. Pat. Off. Soc’y 761, 762 (1937) (about one case per year under 1793 statute); P.J. Federico, *Evolution of Patent Office Appeals*, 22 J. Pat. Off. Soc’y 838, 841 (1940) (nine cases total under short-lived 1836 statute). Arbitrations under the 1793 statute, moreover, had little effect: The losing party could obtain a patent regardless. See Federico (1937), *supra*, at 763.

tions for Director review). Unlike here, the Director has the final word.⁴

The 1927 statute eliminating appeals from examiners-in-chief to the Commissioner is beside the point. Cf. Gov't Reply 27-28; S&N Reply 7-8. Examiners-in-chief themselves remained presidentially appointed, Senate-confirmed officers until 1975. Arthrex Br. 4. The Commissioner's role as "chief officer" does not prove Congress understood examiners-in-chief to be inferior officers. Cf. Gov't Reply 27-28. The Framers recognized, for example, that there could be "Superior Officers below Heads of Departments." 2 *The Records of the Federal Convention of 1787*, at 627 (Max Farrand ed., 1911) (Madison). The best evidence of Congress's understanding of the status of examiners-in-chief is that Congress gave them power to render the Patent Office's final word while providing for their appointment in the manner required for principal officers. Arthrex Br. 4.⁵

Finally, the 1952 statute permitting examiners to "act as a member of the Board" for up to six months is no precedent either. Cf. Gov't Reply 28-29. "Acting" officers are inferior even when they wield principal-officer powers: "[A] subordinate officer * * * charged with the performance of the duty of the superior for a limited time and under special and temporary conditions * * * is not

⁴ Smith & Nephew urges that examiners had the "*de facto* last word" because, as a practical matter, the Commissioner could not review every decision. S&N Reply 7. But the *power* to review, not its exercise, is what matters. Arthrex Br. 26-27. The Director has that same broad power over reexaminations too. 35 U.S.C. § 305; 35 U.S.C. § 314(a) (2006).

⁵ Smith & Nephew's claim that "Arthrex does not actually dispute" Congress's intent is thus wrong. S&N Reply 6.

thereby transformed into the superior and permanent official.” *United States v. Eaton*, 169 U.S. 331, 343 (1898); see *Designating an Acting Attorney General*, 2018 WL 6131923, at *5-17 (O.L.C. Nov. 14, 2018).⁶

3. The government and Smith & Nephew scour other agencies for counterexamples. Gov’t Reply 23; S&N Reply 26. Those efforts come up short. There is no serious dispute that the “vast majority” of agency adjudication regimes permit superior officer review. Christopher J. Walker & Melissa F. Wasserman, *The New World of Agency Adjudication*, 107 Calif. L. Rev. 141, 157 (2019). The Board is a sharp break from that tradition.

Smith & Nephew cites one study reporting that certain agency hearings “permit no administrative appeal at all.” S&N Reply 26. By the study’s own account, however, “[t]he matters in which the [officer] could issue a final decision without the possibility of any appellate review were limited to what appear to be extremely low-volume adjudications: CFTC wage-garnishment proceedings, labor arbitrations within the Alcohol and Tobacco Tax and Trade Bureau of Treasury, public/private partnerships with NASA, and certain license-transfer agreements before the NRC.” Kent Barnett, *et al.*, Admin. Conf. of the U.S., *Non-ALJ Adjudicators in Federal Agencies* 35 (Sept. 24, 2018). Moreover, *none* of those four examples actually supports Smith & Nephew’s position. Two are situations where the agency had *authority* to provide review, but chose not to. See 31 U.S.C.

⁶ The 1939 statute permitting bills in equity likewise proves nothing. Cf. S&N Reply 8. Parties still had the *right* to seek administrative review. Arthrex Br. 33-34. Lower federal courts are “inferior” to this Court even though parties might decline to appeal.

§ 3720D(c) (wage-garnishment proceedings); 5 U.S.C. § 572 (authority for NASA ombudsman). The other two involve arbitrations or orders that *are* subject to principal officer review. See 5 U.S.C. §§ 7121-7122 (labor arbitrations); 10 C.F.R. § 2.1320(b)(2) (NRC license-transfer orders).

The government points to another study to claim “substantial variety” in review structures. Gov’t Reply 23 (citing Michael Asimow, Admin. Conf. of the U.S., *Federal Administrative Adjudication Outside the Administrative Procedure Act* app. A (2019)). Mere “variety” does not imply elimination of review entirely. “In addition to the PTAB, [only] two agencies out of Asimow’s ten case studies * * * lacked higher-level agency reconsideration of their decisions.” Walker & Wasserman, *supra*, at 172 (citing draft). And *neither* helps the government.⁷

The government cites three statutes that designate subordinates’ decisions as “final” without expressly providing for principal officer review. Gov’t Reply 23. But the government itself has repeatedly denied that such language precludes review. In 1991, the Office of Legal Counsel ruled that the Secretary of Education could review ALJ decisions despite a statute stating that they “shall be considered * * * final agency action.” *Secretary of Education Review of Administrative Law Judge Decisions*, 15 Op. O.L.C. 8, 13 (1991). A contrary construction, it noted, “would raise serious questions under the Appointments Clause” because “[a]n ALJ whose decision could not be reviewed by the Secretary * * * would

⁷ One was the Board of Veterans’ Appeals; its decisions are reviewable by an administrative court. Arthrex Br. 31. The other was the Civilian Board of Contract Appeals, one of the government’s three examples discussed next.

appear to be acting as a principal officer.” *Id.* at 14 (emphasis added); see also *Special Master for Troubled Asset Relief Program Executive Compensation*, 34 Op. O.L.C. 219, 233-237 (2010) (“final and binding” order subject to “secretarial review”); *Arthrex Br.* 32 n.4.

In any event, the government’s purported counterexamples are all recent, narrow, obscure, or some combination of the three.⁸ In *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183 (2020), the Court found a “telling indication of [a] severe constitutional problem” despite a similar handful of outliers. *Id.* at 2201-2202. History justifies the same conclusion here.

4. Smith & Nephew urges that APJs issue only “narrow decisions that do not set policy.” S&N Reply 26. The scope of an officer’s authority, however, “marks, not the line between principal and inferior officer,” but “the line between officer and nonofficer.” *Edmond*, 520 U.S. at 662. Besides, deciding the fate of billions of dollars of intellectual property is hardly inconsequential. APJs’ authority is all the more striking because APJs have the power to overrule the Director’s decision to grant a patent in the first place. Smith & Nephew cites no other context where purportedly “inferior” officers could overrule their own agency head.

⁸ See Pub. L. No. 109-163, § 847(a), (d)(2)(B), 119 Stat. 3136, 3391-3394 (2006) (creating Civilian and Postal Service Boards of Contract Appeals); cf. Pub. L. No. 95-563, § 8(a)(1), 92 Stat. 2383, 2385 (1978) (authorizing but not requiring such boards); Pub. L. No. 99-603, § 102(a), 100 Stat. 3359, 3374-3379 (1986) (one narrow category of discrimination claims); Pub. L. No. 92-576, § 15(a), 86 Stat. 1251, 1261 (1972) (creating Benefits Review Board for longshoremen and harbor workers); cf. Pub. L. No. 803, § 21(a), 44 Stat. 1424, 1436 (1927).

B. Other Oversight Powers Are Not Substitutes for Review

The government and Smith & Nephew “brainstorm[] [other] methods of * * * control.” *Seila Law*, 140 S. Ct. at 2207. None of them is an adequate substitute for review.

1. Smith & Nephew urges that the Director can “informally recommend[]” that the Board grant rehearing, S&N Reply 14, or “intervene” on appeal, *id.* at 15. But trying to cajole other officers or a court into correcting an APJ’s mistakes does not make the APJ a subordinate. The Appointments Clause requires direction and supervision, not hortatory recommendations to third parties.

The Director, of course, is the one who ultimately cancels a patent at the conclusion of an inter partes review. S&N Reply 17. If the Board finds a claim invalid, “the Director *shall* issue and publish a certificate canceling [the] claim.” 35 U.S.C. §318(b) (emphasis added). That mandatory and ministerial duty does not give the Director any power to review Board decisions. It permits the *Board* to control the *Director*.

Judicial review does not matter either. Cf. S&N Reply 17. Administrative judges’ decisions must be reviewable by “Executive officers,” not federal judges. *Edmond*, 520 U.S. at 665. If judicial review were enough, even cabinet secretaries would be inferior officers.⁹

⁹ Review by other *inferior* officers is likewise insufficient. Cf. S&N Reply 29. *Edmond* requires oversight (direct or indirect) by officers “appointed by Presidential nomination with the advice and consent of the Senate.” 520 U.S. at 663. Nor does the Board include other officers “whose appointments Arthrex does not question.” S&N Reply 30. The Deputy Director’s and Commissioners’ appointments are invalid too. See Arthrex Cert. Reply in No. 19-1458, at 6-7.

2. The government exaggerates the scope of other powers. Even after the statutory removal restrictions are severed, for example, due process limits removal as a tool of control. Removing or threatening to remove an administrative judge to change the outcome of a case raises obvious due process concerns. See *Arthrex Br. 63-64*; *Pet. App. 16a-17a n.3*; *Utica Packing Co. v. Block*, 781 F.2d 71, 78 (6th Cir. 1986). The government insists those concerns are insubstantial because agency heads can personally adjudicate disputes despite being removable at will. Gov’t Reply 15. But the *use* of removal power to alter the outcome of a case by secretly threatening to fire the judge if he does not rule a particular way presents distinct due process problems. It is also flatly inconsistent with the statute, which charges the Board, not the Director, with adjudicating cases. *Arthrex Br. 39-41*.¹⁰

The government overstates the Director’s rulemaking power. Gov’t Reply 11. Even after *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), “the Director has no substantive rule making authority with respect to interpretations of the Patent Act.” *Facebook, Inc. v. Windy City Innovations, LLC*, 973 F.3d 1321, 1353 (Fed. Cir. 2020) (additional views); see also U.S. Br. in *Cuozzo*, No. 15-446, at 14 (Mar. 2016) (“Congress has declined to authorize the PTO to issue rules interpreting the substantive patentability criteria * * * .”). Applying new substantive rules to pending cases could also raise serious retroactivity concerns. See *Doerre Br. 29-35*.

¹⁰ The government dismisses *Abrams v. Social Security Administration*, 703 F.3d 538 (Fed. Cir. 2012), as involving the removal standard for ALJs. Gov’t Reply 7-8. But *Abrams* relied on the separate APA provision that prohibits agency interference in pending cases—the same constraint the statute imposes here. 703 F.3d at 545-546.

The government admits that policy guidance is *not binding* on the agency. Gov't Reply 12. The Patent Office may "expect[]" APJs to follow it. *Ibid.* But the fact that aggrieved parties cannot complain surely hampers the Director in identifying departures and holding APJs accountable. The government admits, moreover, that the Director cannot use rules or policy guidance to "simply *tell* the Board how to rule." *Id.* at 15.

Finally, the Director cannot de-institute review merely because he disagrees with how the Board may rule. Cf. Gov't Reply 13. The Board, not the Director, decides cases on the merits. 35 U.S.C. §318(a). The government points to situations where the agency genuinely reconsidered an institution decision. See, e.g., *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1383-1386 (Fed. Cir. 2016) (petition did not name all real parties in interest), cert. dismissed, 137 S. Ct. 2113 (2017). The Director cannot use that reconsideration authority to invade the Board's statutory role. See *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1361 (Fed. Cir. 2008).

3. Even if the Director had all the powers claimed, they would still be poor substitutes for review. Removing an APJ does not vacate decisions already made. Nor does issuing rules or policy guidance. The government admits the Director cannot de-institute review after the Board rules. Gov't Reply 13. None of those powers permits the Director to correct a decision an APJ has already issued as the Executive Branch's final word.

Nor can the Director compel particular outcomes beforehand. The Director cannot realistically predict every way an APJ may go astray. And terminating a proceeding by de-instituting review is no remedy at all when the Director thinks the *petitioner* should prevail. None of

the Director's powers ensures that he can stand behind, and be held accountable for, everything the agency says.

The government proposes a contrived scheme in which Board panels must circulate draft opinions so that, if the Director disagrees, he can either de-institute review or issue policy guidance dictating a different result (threatening to fire APJs if they object). Gov't Reply 13-14. It is hard to imagine a more blatant evasion of the statute and due process. The Board, not the Director, decides inter partes reviews. *Arthrex Br.* 39-41.

The government's comparison to pre-circulation rules on courts of appeals is inapt. All judges on a court of appeals have the right to call for en banc review; pre-circulation facilitates that process. See, *e.g.*, Fed. Cir. IOP 10.5, 14.3. By contrast, requiring pre-circulation so the Director can overrule the Board subverts rather than advances the statutory design.

II. THE COURT OF APPEALS' SEVERANCE REMEDY DEFIES CONGRESSIONAL INTENT

Even if the court of appeals' severance remedy were sufficient to cure the defect, Congress never would have adopted it. Congress would not have enacted the statute without tenure protections for APJs. And the sheer number of potential remedies makes severance inappropriate. This Court normally severs invalid provisions to avoid judicial policymaking. Where the Court can only speculate about Congress's preferences, severance has the opposite effect.

A. Congress Would Not Have Enacted the Statute Without Tenure Protections

Congress has long considered tenure protections essential for administrative judges, traditionally pairing them with transparent review by an accountable agency

head. Arthrex Br. 48-52. Those protections became even more important when Congress enacted the AIA, putting APJs in charge of new adjudicative proceedings under a statutory structure designed to ensure the Board's independence. *Id.* at 52-56. Congress would not have enacted a regime that includes *neither* tenure protections for APJs *nor* transparent review by an accountable agency head. Requiring APJs to decide cases subject to unseen pressures to please superiors is fundamentally contrary to what Congress envisioned.

The government urges that the Constitution does not *require* tenure protections, noting that “agency heads who are removable at will [may] personally adjudicate cases.” Gov’t Reply 34. But the question is not whether tenure protections are constitutionally required. It is whether Congress would have enacted the statute without them. See *Bowsher v. Synar*, 478 U.S. 714, 735 (1986) (severing removal restrictions impermissible if it would “lead to a statute that Congress would probably have refused to adopt”). Congress has long insisted on tenure protections for administrative judges who do no more than adjudicate cases, even while striking a different balance for agency heads with broad policymaking responsibilities. Arthrex Br. 48-52.¹¹

True, Congress did not give APJs the same tenure protections it gave ALJs. Gov’t Reply 35-36. But Congress clearly understood that APJs’ civil service protec-

¹¹ Even the government’s few counterexamples are a mixed bag. Gov’t Reply 35-36. Section 7511(b)(8) exempts employees only from *that subchapter’s* civil service protections; tenure protections still apply to ALJs. See 5 U.S.C. § 7521; *e.g.*, 39 C.F.R. § 3013.2(a). Postal Service Board members have tenure protections too. See 41 U.S.C. § 7105(b)(3), (d)(2).

tions would “insulate these quasi-judicial officers from outside pressures and preserve integrity within the application examination system.” H.R. Rep. No. 104-784, at 32 (1996). Making APJs removable for political reasons, or for no reason at all, would undermine Congress’s goal of “creat[ing] a patent system that is clearer, fairer, more transparent, and more objective.” 157 Cong. Rec. 12,984 (Sept. 6, 2011) (Sen. Kyl).

Constitutional avoidance compels the same result. Arthrex Br. 62-64. Even if due process does not require tenure protections for agency adjudicators, firing or threatening to fire an administrative judge behind the scenes to achieve a desired outcome raises obvious due process concerns. See p. 12, *supra*. The court of appeals’ remedy not only permits but *encourages and relies upon* such abuse by forcing the agency head to use the threat of removal, rather than review, to supervise adjudications. Congress would not have strayed so close to the constitutional line.

B. Congress Should Determine the Appropriate Remedy

The sheer number of ways to fix the problem is reason enough to reject the Federal Circuit’s approach. The government does not deny there are at least *ten different ways* Congress could respond. Arthrex Br. 57-59. Selecting among them would invite rather than avoid judicial policymaking—the linchpin of this Court’s severability precedents. See *Barr v. Am. Ass’n of Pol. Consultants, Inc.*, 140 S. Ct. 2335, 2351 (2020) (plurality).

This is not a case like *Seila Law* or *Free Enterprise Fund v. Public Company Accounting Oversight Board*, 561 U.S. 477 (2010), where there were multiple ways to fix the problem, but one was clearly superior. Those cases involved agency heads, not administrative judges, and

the removal restrictions were the avowed targets of the claims. Arthrex Br. 60-62. This case challenges APJ *appointments*, and the Court can only speculate what Congress would prefer. Congress, not courts, should select among the many alternatives.

The government suggests that the Court sever 35 U.S.C. §6(c)'s directive that "[o]nly the Patent Trial and Appeal Board may grant rehearings." Gov't Reply 40-41. That approach would not fix the problem. Only the officer who makes a decision has inherent power to reconsider it. See *Tokyo Kikai Seisakusho*, 529 F.3d at 1360 ("The power to reconsider is inherent in the power to decide."). Eliminating the rehearing provision thus would not shift authority to the Director. It would leave that authority with the Board, the entity that decides inter partes reviews. 35 U.S.C. §318(a).

Even if the government's approach had its intended effect, it would be a drastic departure from Congress's intent. As the court of appeals recognized, "[t]he breadth of backgrounds and the implicit checks and balances within each three-judge panel contribute to the public confidence by providing more consistent and higher quality final written decisions." Pet. App. 25a. Allowing the Director to decide cases single-handedly would be "a significant diminution in the procedural protections afforded to patent owners" and "a radical statutory change to the process long required by Congress in all types of Board proceedings." *Id.* at 24a-25a.

Smith & Nephew's proposal to sever the appointment provision would not work either. S&N Reply 47. Eliminating secretarial appointments for APJs would not transfer authority to the President. Under the statute's default provision, it would transfer appointment authority to the Director. 35 U.S.C. §3(b)(3)(A). Like the govern-

ment's proposal, Smith & Nephew's speculation about what Congress would prefer only underscores that Congress should decide.

Deferring to Congress would not require the Court to revisit *Humphrey's Executor v. United States*, 295 U.S. 602 (1935). Cf. S&N Reply 32-35. There are many ways Congress could respond without making APJs principal officers—for example, by providing for agency-head review. Regardless, granting tenure protections to administrative judges does not raise serious constitutional questions, whether they are principal or inferior officers. See Arthrex Br. 48-50 & n.14; *e.g.*, 10 U.S.C. § 942(c) (Court of Appeals for the Armed Forces); 26 U.S.C. § 7443(f) (Tax Court); 38 U.S.C. § 7253(f) (Court of Appeals for Veterans Claims).

The government's feared impacts on other Board proceedings are overblown. Gov't Reply 36-37. Because the Director has plenary control over patent examinations, Congress need not alter the Board's role in appeals from those proceedings. See U.S. Supp. Br. in *Boloro*, *supra*, at 7-9 & n.2. The Board's remaining proceedings are rare compared to inter partes reviews.¹²

Smith & Nephew's legion of amici bemoan any disruption to their preferred method for challenging patents. S&N Reply 49. But there are two sides to that story.

¹² See Patent Trial & Appeal Board, *Trial Statistics* 5 (Sept. 2020) (1,429 petitions for inter partes review, 64 for post-grant review, and 20 for covered business method review in FY2020); Patent Trial & Appeal Board, *Appeal and Interference Statistics* 5, 7 (Sept. 30, 2020) (less than 90 reexamination appeals in FY2020; 10 interferences remaining); Anthony A. Hartmann, *PTAB Finds No Derivation in First Derivation Proceeding*, Finnegan AIA Blog (Mar. 25, 2019) (only 18 petitions for derivation proceedings ever).

Inter partes review has had a devastating impact on American innovation, particularly for small inventors. See, *e.g.*, 39 Aggrieved Inventors Br. 14-23; TiVo Br. 6-13; Malone Br. 1-3; U.S. Inventor Br. 1-2. Congress could well decide not to make an unfair process even less fair by eliminating tenure protections for APJs. Those policy debates belong before Congress, not this Court.

C. Arthrex Is Entitled to Dismissal

Smith & Nephew urges the Court not to dismiss this inter partes review even if the statutory provisions are not severable. S&N Reply 39-43. But if the entire statute is unsound and the defect not severable, the Court cannot send Arthrex back to the Board for more of the unconstitutional same. That would hardly create “incentives to raise Appointments Clause challenges.” *Lucia v. SEC*, 138 S. Ct. 2044, 2055 n.5 (2018) (alterations omitted). Arthrex’s argument is not a “letter to Santa Claus.” S&N Reply 36. Arthrex seeks only the unavoidable consequence of non-severability.¹³

Neither *Seila Law* nor *Northern Pipeline Construction Co. v. Marathon Pipe Line Co.*, 458 U.S. 50 (1982), holds otherwise. In *Seila Law*, the removal restrictions were severable. 140 S. Ct. at 2211 (plurality). Dismissal

¹³ Arthrex did not forfeit this claim. Cf. S&N Reply 40-42. Arthrex urged in the court of appeals that the statute is not severable. See Arthrex Pet. in No. 19-1458, at 13 n.2; S&N Cert. Resp. in No. 19-1458, at 10 (admitting preservation). It made the same argument in this Court. Arthrex Pet. in No. 19-1458, at 14-34. Arthrex’s argument for dismissal is not distinct from its argument against severability; those are two sides of the same coin. If the entire statute is invalid, this inter partes review necessarily cannot proceed. See Arthrex C.A. Reh’g Pet. 4 (“[T]he statute cannot be saved and must be ruled unconstitutional. Accordingly, the Final Written Decision here must be vacated and the case dismissed.”).

is appropriate here because the provisions are *not* severable. In *Northern Pipeline*, the lower court *did* dismiss the proceeding, *Marathon Pipeline Co. v. N. Pipeline Constr. Co.*, 12 B.R. 946, 947 (D. Minn. 1981), and this Court affirmed, 458 U.S. at 87-88 & n.40 (plurality). The Court should follow the same course here.¹⁴

III. SMITH & NEPHEW’S REMAINING ARGUMENTS ARE NOT PROPERLY BEFORE THE COURT

Smith & Nephew raises a host of other arguments. The Court need not address any of them.

1. Arthrex timely raised its constitutional claim. Cf. S&N Reply 36-39. The court of appeals “agree[d] with Arthrex that its Appointments Clause challenge was properly and timely raised before the first body capable of providing it with the relief sought.” Pet. App. 31a. The government sought this Court’s review of that timeliness ruling. Gov’t Pet. in No. 19-1434, at i. But the Court *denied review*. 141 S. Ct. 549 (2020). Neither of the two questions the Court granted covers the timeliness issue—either the government’s original version or the variation that Smith & Nephew now presents. Gov’t Br. i. The Court should not reach out to decide a ques-

¹⁴ Although the Court stayed its judgment in *Northern Pipeline*, 458 U.S. at 88-89 (plurality), it should not do so here. “A structural-redesign grace period implicitly tells Congress that it may blatantly violate the Constitution’s structural safeguards * * * and then later create a proper agency, if it acts fast enough, without any adverse consequences at all.” Kent Barnett, *To the Victor Goes the Toil—Remedies for Regulated Parties in Separation-of-Powers Litigation*, 92 N.C. L. Rev. 481, 530-536 (2014). The stay in *Northern Pipeline*, moreover, was cut from the same cloth as the Court’s decision to apply its holding prospectively only. 458 U.S. at 87-88 (plurality). The Court abandoned that approach in *Harper v. Virginia Department of Taxation*, 509 U.S. 86, 94-97 (1993).

tion the parties and amici have had no fair opportunity to address. S. Ct. R. 14.1(a).¹⁵

In any event, the court of appeals correctly held that Arthrex “properly and timely raised [its claim] before the first body capable of providing it with the relief sought.” Pet. App. 31a. Consistent with longstanding principles of administrative law, the Board has repeatedly held that it lacks authority to consider constitutional challenges to its own enabling statute, including Appointments Clause claims just like Arthrex’s. Arthrex Cert. Resp. in No. 19-1434, at 24-25 & n.6. Pressing this objection before the agency would have been futile. See *id.* at 23-30; Arthrex Cert. Reply in No. 19-1458, at 6-9.¹⁶

2. Dismissal would not violate the statutory bar on appealing institution decisions or the settlement agreement in separate infringement litigation. Cf. S&N Reply

¹⁵ Arthrex did not forfeit this objection at the petition stage. Cf. S&N Reply 37 n.5. Smith & Nephew nowhere asserted in its petition that the Court could consider its timeliness argument even if the Court *denied review* of the timeliness question. S&N Pet. in No. 19-1452, at 31-33. The first time Smith & Nephew made that argument was in response to Arthrex’s petition—and even then, it claimed only that the issue was somehow subsumed within the government’s first question, not *Arthrex’s* questions. S&N Cert. Resp. in No. 19-1458, at 4, 7. Arthrex promptly objected in reply. Arthrex Cert. Reply in No. 19-1458, at 10-11. Having done so, Arthrex was not required to renew the objection in its opening brief merely because Smith & Nephew made one fleeting reference to its intent to argue the point in a *future* submission. S&N Br. 49.

¹⁶ For the same reason, Arthrex was not required to seek dismissal before the Board. Cf. S&N Reply 41. Nor did Arthrex forfeit its claim by petitioning for inter partes review in unrelated cases. See Arthrex Cert. Reply in No. 19-1458, at 8-9.

39-40. Smith & Nephew forfeited both arguments at the petition stage. S. Ct. R. 15.2. And neither has merit.

Arthrex is not asking this Court to review the Director's decision "*whether to institute* an inter partes review." 35 U.S.C. §314(d) (emphasis added). It seeks a ruling that this inter partes review cannot proceed any further because the statute authorizing the proceeding is unconstitutional.

Nor is the settlement agreement relevant. While that agreement allowed the inter partes review to continue despite settlement of the infringement litigation, Arthrex did not agree to refrain from making otherwise valid arguments for dismissal. Cf. Pet. App. 86a.

3. Finally, retroactivity principles do not somehow render the Board's decision constitutional. Cf. S&N Reply 50. Smith & Nephew forfeited that claim too by not raising it at the petition stage. S. Ct. R. 15.2. And the government has rejected Smith & Nephew's argument, explaining that "retroactivity principles" do not bar relief where "APJs * * * did not at the time understand themselves to be subject to removal at will." U.S. Supp. Br. in *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 18-1768, Dkt. 96, at 12-15 (Fed. Cir. filed Jan. 6, 2020).

The principle that judicial decisions apply retroactively does not mean a party cannot complain when an adjudicator operates under a misunderstanding of governing law. See, e.g., *United States v. Booker*, 543 U.S. 220, 267-268 (2005) (remanding for resentencing under advisory guidelines despite applying holding retroactively to all pending cases). Saying what the law "is" does not avoid the need to require decisionmakers to adjudicate cases under a correct understanding of the law.

The APJs who decided Arthrex’s case were acting under the misimpression that the statutory restrictions on their oversight and accountability were valid. So too were their superiors. The agency would not even *consider* constitutional challenges to those restrictions. See Arthrex Cert. Resp. in No. 19-1434, at 24-25 & n.6. If this Court now holds the restrictions invalid, retroactivity would be a reason to *correct* the Board’s structural legal error, not to ignore it.¹⁷

CONCLUSION

The court of appeals’ judgment should be reversed with respect to the severance remedy.

¹⁷ Even where retroactivity is relevant, an exception applies if there are “alternative way[s] of curing the constitutional violation.” *Reynoldsville Casket Co. v. Hyde*, 514 U.S. 749, 759 (1995). Here, there are at least *ten different alternatives*.

Respectfully submitted.

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WASHINGTON—The United States Patent and Trademark Office (USPTO) today officially issued U.S. patent number 11 million, recognizing an important milestone in American innovation and ingenuity.

"This momentous benchmark is a reminder of the remarkable and enduring tradition of American innovation that has driven our nation forward for generations," said U.S. Secretary of Commerce Gina Raimondo. "Building our economy back stronger requires new ideas and innovative solutions from every sector. I am proud to recognize patent 11 million, its inventors, and its promise."

"Since the founding of our nation, American inventors have driven our culture and commerce with incredible ideas that have improved every function of our lives," said Drew Hirshfeld, performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO. "We owe a debt of gratitude to inventors who continue to show up day after day with solutions to the world's most pressing problems. We congratulate the inventors behind patent 11 million and all of the innovators who helped the country reach this milestone."

[Patent number 11 million](#), granted to co-inventors Saravana B. Kumar and Jason S. Diederich of 4C Medical Technologies, Inc. in Maple Grove, Minnesota, is for a utility patent that provides a new method for delivering, positioning, and/or repositioning a collapsible and expandable stent frame within a patient's heart chamber.

"We are incredibly excited and honored to be granted U.S. patent number 11 million for our invention," said inventor Saravana Kumar. "The 4C Medical beginning is a true story of American entrepreneurship, where Jason and I worked in a garage many nights and weekends to turn this idea into reality. We could not have gotten here without the support of so many, including my wife Katherine and 4C Medical's founder, physician Dr. Jeff Chambers. Currently, our team is actively working to demonstrate the benefits of our technology to treat patients with severe mitral regurgitation as part of a U.S. clinical trial."

"4C Medical's approach to inventing is simple—we identified a need, created a solution, and demonstrated its benefits. We are a team of highly driven and creative engineers who are committed to bringing lifesaving technologies to people who need it most," explained inventor Jason Diederich.

Background on the U.S. patent system

Patents predating the Patent Act of 1836 were unnumbered, identifiable only by the name of the patentee and the date of issue. These patents became known as "X-patents" after [Patent No. 1](#) was granted to Senator John Ruggles on July 13, 1836 for a traction wheel for steam locomotives—the first patent issued under the new law, which officially assigned patent numbers. A few months after the Patent Act of 1836 was enacted, a catastrophic fire at the Patent Office destroyed almost all of the records and models related to the X-patents. Efforts to reconstruct the records lost in the fire continue to this day.

Patent 11 million comes three years after the USPTO issued [patent number 10 million](#) in 2018. As part of that celebration, the USPTO redesigned the official U.S. patent cover—the seal-and-ribbon document awarded with each patent grant—paying homage to the classic elegance of its predecessors. A list of the patent milestones can be found [here](#).

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Drew Hirshfeld

Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the USPTO

Drew Hirshfeld currently performs the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (USPTO).

In this role, he serves as an advisor to the President, through the Secretary of Commerce, on national and various international intellectual property (IP) issues. He also manages more than 13,000 employees and executes the policies, priorities, and programs of one of the largest IP offices in the world, with an annual budget of nearly \$4 billion.

Named one of *Managing IP's* Top 50 Most Influential People in IP in 2021, Hirshfeld led the agency's response to the June 2021 *Arthrex* Supreme Court decision by implementing an interim Director review process that could be initiated sua sponte or by request from a party to a Patent Trial and Appeal Board (PTAB) proceeding, oversaw the implementation of the Trademark Modernization Act, and expanded the agency's education and outreach programming to a wider variety of audiences, among other notable accomplishments. Hirshfeld also serves as a member of the Precedential Opinion Panel (POP) deciding issues of exceptional importance to the PTAB.

Before leading the agency, Hirshfeld served as Commissioner for Patents from 2015 to 2021. During that time, he successfully managed efforts to ensure the consistency and reliability of patent grants, led a historic reorganization of the Patents division to better serve stakeholders, and implemented policies that provided all patent examiners with guidance and training to efficiently and effectively conduct quality examinations.

Prior to serving as Commissioner, Hirshfeld held the positions of Deputy Commissioner for Patent Examination Policy and Chief of Staff to the Under Secretary of Commerce for Intellectual Property and Director of the USPTO. He began his career in 1994 as a patent examiner and became a supervisory patent examiner in 2001. He was promoted to the Senior Executive Service in 2008 as a Group Director in Technology Center 2100.

Hirshfeld received a Bachelor of Science from the University of Vermont and a J.D. from Western New England College School of Law.

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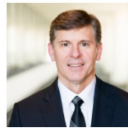
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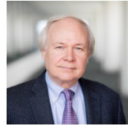
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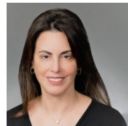
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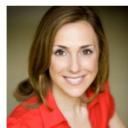
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Notice of Delegation to Commissioner for Patents and Notice of Delegation to Commissioner for Trademarks

Notice of Delegation to Commissioner for Patents

As previously established through the USPTO's Agency Organization Order 45-1, dated June 24, 2002, and pursuant to a further delegation issued on November 15, 2013, the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director, United States Patent Office (Under Secretary/Director) and the functions and duties of the Deputy Under Secretary/Deputy Director have been delegated to the Commissioner for Patents for any period when there is no Under Secretary/Director and the Deputy Under Secretary/Deputy Director, and when there is no Acting Director.

Therefore, effective upon the resignation of Deputy Under Secretary/Deputy Director Teresa Rea at 10:00 A.M. on November 21, 2013, the Commissioner for Patents Margaret A. (Peggy) Focarino began performing the functions and duties of the Under Secretary/Director and Deputy Under Secretary/Deputy Director.

Legal Basis for Such Delegations

This delegation of authority to the Commissioner for Patents during a period when the Director and Deputy Director positions are vacant has long been provided for under the Secretary of Commerce's [Department Organization Order 10-14](#) at § 2.04, and under the USPTO's [Agency Organization Order 45-1](#) at §II.(D). Similarly, the delegation was replicated by then-Deputy Director Teresa Rea, who signed an additional [delegation](#) to the Commissioner for Patents on November 15, 2013. Such general delegations are authorized within the Department of Commerce by [Reorganization Plan No. 5 of 1950](#), section 2, and within the USPTO by [35 U.S.C. § 3\(b\)\(3\)\(B\)](#), by the Patent and Trademark Office Efficiency Act, [Pub. L. No. 106-113, §4745](#) (1999), and by the inherent authority for such matters.

Commissioner Focarino has not been, and need not be, appointed "Acting Director" of the USPTO under the Vacancies Reform Act (VRA) of 1998. Appointment of a VRA-authorized "Acting Officer" is only needed to allow an individual to perform duties of a Presidentially Appointed, Senate Confirmed ("PAS") Officer that are exclusive to that particular PAS Officer. See [5 U.S.C. § 3348\(a\)\(2\)\(A\)\(i\) & \(a\)\(2\)\(B\)\(i\)](#). Department of Justice (DOJ) Guidance on this explains that "[m]ost, and in many cases all, the responsibilities performed by a PAS officer will not be exclusive, and the Act permits non-exclusive responsibilities to be delegated to other appropriate officers and employees in the agency." See [DOJ Guidance on Application of VRA](#), at Q. & A. #48. Congress allowed delegation of non-exclusive duties, recognizing that agencies might often find themselves without an "Acting Officer" pursuant to the VRA's terms, but not wanting an agency's business to be "seriously impaired" by such periods of vacancy. *Id.*

All of the Directors duties under Titles 35 and 15 (thus including, among many others, the duties to issue patents, register trademarks, and nominate a Deputy Director) are delegable (*i.e.*, non-exclusive) duties. Exclusive duties, by contrast, are recognizable by clear statutory language providing that *only* the PAS Officer in question can perform the duty (*e.g.*, "the Officer *exclusively* shall" or "only the Officer shall," or "the Officer *alone* shall"). See [Under Secretary of Treasury for Enforcement, 26 Op. Off. Legal Counsel 230, 233 \(2002\)](#); [Schaghticoke Tribal National v. Kempthorne, 587 F.Supp.2d 389, 420 \(D.Conn. 2008\)](#). The USPTO Director's duties specified above are delegable because they lack statutory language such as "only," "exclusively," or "alone."

Notice of Delegation to Commissioner for Trademarks

After assuming the functions and duties of the Under Secretary/Director by delegation on November 21, 2013, Commissioner for Patents Margaret A. Focarino further delegated to the Commissioner for Trademarks the Under Secretary/Director's function and duty under 15 U.S.C. §1057 to sign (or have her signature affixed to) Certificates of Registration of Trademarks. This delegation will remain in effect for any period when there is no Under Secretary/Director and Deputy Under Secretary/Deputy Director, and when there is no Acting Director.

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