

2018-2140

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

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**Arthrex, Inc.,**

*Appellant*

v.

**Smith & Nephew, Inc. and ArthroCare Corp.,**

*Appellees*

**United States,**

*Intervenor*

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**Appeal from the U.S. Patent & Trademark Office,  
Patent Trial and Appeal Board, *Inter Partes* Review No. 2017-00275**

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**PATENT OWNER ARTHREX, INC.'S CORRECTED SUPPLEMENTAL BRIEF**

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**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT****CERTIFICATE OF INTEREST****Case Number** 18-2140**Short Case Caption** Arthrex, Inc. v. Smith & Nephew, Inc.**Filing Party/Entity** Arthrex, Inc.

**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).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 01/12/2022Signature: /Anthony P. Cho/Name: Anthony P. Cho

<p><b>1. Represented Entities.</b> Fed. Cir. R. 47.4(a)(1).</p>	<p><b>2. Real Party in Interest.</b> Fed. Cir. R. 47.4(a)(2).</p>	<p><b>3. Parent Corporations and Stockholders.</b> 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 checked="" 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 checked="" type="checkbox"/> None/Not Applicable</p>
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Appellant Arthrex, Inc., respectfully submits this supplemental brief pursuant to the Court's order of December 2, 2021. ECF No. 156.

## INTRODUCTION

This case returns to the Court following a trip to the Supreme Court and a remand to the Patent and Trademark Office. This Court previously held that the Patent Trial and Appeal Board lacked authority to invalidate Arthrex's patent claims because the Board's members exercised the authority of principal officers without having been appointed by the President and confirmed by the Senate, as the Appointments Clause requires. The Supreme Court agreed. To remedy the problem, the Court ruled that the PTO Director—a properly appointed principal officer—must have unilateral authority to review Board decisions. This Court then remanded so Arthrex could seek that principal-officer review.

On remand, Arthrex never got the remedy the Supreme Court ordered. No presidentially appointed, Senate-confirmed principal officer decided Arthrex's petition for review of the Board's decision. Instead, the petition was denied by Commissioner for Patents Drew Hirshfeld—an agency official appointed only as an *inferior* officer by the Secretary of Commerce. That order violates multiple constitutional and statutory constraints.

First, the decision violates the Appointments Clause. The Supreme Court held that only presidentially appointed *principal* officers may issue final decisions that

represent the agency's final word. Yet the PTO repeated the exact same error that led to the Supreme Court's decision by allowing someone appointed as a mere *inferior* officer to conclusively resolve Arthrex's case.

Second, the decision violates the Federal Vacancies Reform Act. That statute permits an acting officer to exercise the functions and duties of a principal office temporarily, but only if the acting officer was the principal officer's deputy or was personally selected by the President. Commissioner Hirshfeld was neither.

Finally, the decision violates the separation of powers. The President must be able to remove the heads of executive agencies at will so he can supervise and be accountable for their exercise of executive power. Commissioner Hirshfeld has tenure protections that deny the President that authority.

For those reasons, as well as the grounds stated in Arthrex's principal briefs (ECF Nos. 18 & 40), the Court should reverse the Board's decision on the merits and vacate Commissioner Hirshfeld's order denying review.

## **BACKGROUND**

### **I. ARTHREX'S '907 PATENT**

This case concerns Arthrex's U.S. Patent No. 9,179,907, which covers a novel surgical device for reattaching soft tissue to bone. Appx578 (1:43-48). Early suture anchors required surgeons to tie knots to secure tissue—a tedious and cumbersome process. Appx578 (1:32-39). The '907 patent discloses a device for securing tissue

without knots, reducing surgery times and attendant complications. Appx578 (1:36-48), Appx581 (8:1-12), Appx582 (9:62-10:5).

The '907 patent stems from an application filed in 2001, No. 09/886,280. Appx1220-1266. That '280 application described an embodiment of the invention that uses a flexible eyelet (a “suture loop”) to position the suture where it can be secured without tying knots. Appx1224, Appx1226, Appx1232, Appx1238.

Following that application, the inventors filed a series of continuation and continuation-in-part applications refining their design. Appx1267-1377. Each application incorporated by reference the original '280 application and claimed priority based on that application. *See, e.g.*, Appx1268. Each application explained the same basic object of the invention: to allow surgeons to attach tissue to bone without tying knots by threading suture through an eyelet. *See, e.g.*, Appx1268-1270, Appx1294 (identifying eyelet as an “improved method” over knotted suture anchors). The applications also added improvements to the inventors’ original design, such as the use of a rigid rather than a flexible eyelet to facilitate sliding of the suture through the loop. *See, e.g.*, Appx1268-1269.

In 2014, Arthrex filed another continuation application that matured into the '907 patent. Appx595-642. That application, like the preceding ones, claimed priority to the '280 application. Appx595. Unlike the prior applications, it disclosed the original flexible-eyelet embodiment explicitly rather than incorporating it by

reference. Appx596-605. It also disclosed the improved rigid-eyelet embodiment. Appx604, Appx612, Appx615, Appx631. Rather than claim a particular type of eyelet, rigid or flexible, the inventors claimed in their independent claims a knotless surgical device with a generic “eyelet.” Appx610, Appx613.

The PTO issued the '907 patent on November 10, 2015. Appx559.

## **II. THE BOARD'S DECISION**

Arthrex sued Smith & Nephew, Inc. and its subsidiary ArthroCare Corp. for infringing the '907 patent. Appx3-4. The jury returned a verdict for Arthrex, finding the patent claims valid and infringed. *Id.* The parties then settled the litigation. *Id.*

While that lawsuit was pending, Smith & Nephew sought inter partes review. Appx2. It argued that the PTO's publication of *the inventors' own 2001 application* was prior art that anticipated the '907 patent. Appx18 n.7. An invention in a later application can benefit from the filing date of an earlier one only if the earlier one provides a written description of the same invention. 35 U.S.C. § 120. Smith & Nephew argued that the prior applications did not meet that standard. Appx15-16.

The Patent Trial and Appeal Board agreed. Though each prior application incorporated by reference the original disclosure of a knotless surgical device with an eyelet, the Board found the applications insufficient to describe the '907 patent's generic eyelet because they also mentioned the advantages of a rigid eyelet over a flexible one. Appx18-22, Appx27-30, Appx40-42.

The Board thus deemed the claims anticipated by the publication of the '280 application. Appx40, Appx42.

### **III. ARTHREX'S APPEAL TO THIS COURT**

Arthrex appealed on several grounds. First, Arthrex argued that the Board failed to give effect to its applications' incorporations by reference of the original disclosure. ECF No. 18 at 32-49. Second, Arthrex urged that the Board erred by failing to find adequate written description: Every application in the priority chain disclosed Arthrex's invention of a novel device that threads suture through an eyelet to secure tissue without knots, even if the later iterations disclosed an improved version that used a rigid rather than flexible eyelet. *Id.* at 49-53. Third, Arthrex contended that the Board improperly invalidated its patent claims for lack of written description, when the statute permits inter partes review only for anticipation or obviousness. *Id.* at 54-59 (citing 35 U.S.C. § 311(b)). Finally, Arthrex argued that the administrative patent judges who decided its case were appointed in violation of the Appointments Clause. *Id.* at 59-66.

This Court agreed with Arthrex's constitutional claim without reaching the other three arguments. *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). The Appointments Clause, it explained, requires that principal officers be appointed by the President and confirmed by the Senate; only inferior officers may be appointed by department heads. *Id.* at 1327 (citing U.S. Const. art. II, § 2).

APJs are appointed by the Secretary of Commerce, a method appropriate only for inferior officers. *Id.* (citing 35 U.S.C. § 6(a)). But APJs, the Court concluded, exercised the authority of principal officers: No superior officer could review their decisions, and the Secretary could remove them only for cause. *Id.* at 1329-34. As a remedy, the Court severed APJs’ tenure protections. *Id.* at 1335-40.

#### **IV. THE SUPREME COURT’S DECISION**

The Supreme Court affirmed the finding of a constitutional violation. “[T]he unreviewable authority wielded by APJs during inter partes review,” the Court held, “is incompatible with their appointment by the Secretary to an inferior office.” *United States v. Arthrex*, 141 S. Ct. 1970, 1985 (2021). Only a principal officer “may issue a final decision binding the Executive Branch.” *Id.*

Rather than sever APJs’ tenure protections, the Court granted the Director unilateral authority to review APJ decisions. 141 S. Ct. at 1986-88. The Patent Act generally vests the PTO’s “powers and duties,” including review powers, in the Director. 35 U.S.C. § 3(a)(1). But Section 6(c) provides that “[o]nly the Patent Trial and Appeal Board may grant rehearings” and that Board panels must consist of “at least 3 members.” *Id.* § 6(c). Because the Director is merely one member of the Board, those provisions precluded him from unilaterally reviewing Board decisions. The Court held that “Section 6(c) cannot constitutionally be enforced to the extent that its requirements prevent the Director from reviewing final decisions rendered



by APJs.” *Id.* at 1987. “Section 6(c) otherwise remains operative as to the other members of the PTAB.” *Id.*

The Supreme Court opined that “a limited remand to the Director provides an adequate opportunity for review by a principal officer.” 141 S. Ct. at 1987-88. This Court therefore remanded to the PTO “for the limited purpose of allowing [Arthrex] the opportunity to request Director rehearing.” ECF No. 144 at 2. The Court stayed proceedings on the remaining issues on appeal. *Id.*

## **V. PROCEEDINGS ON REMAND**

On remand, the PTO was unable to provide the principal-officer review the Supreme Court directed. The office of Director was vacant. So was the office of Deputy Director. The PTO was instead being run by the Commissioner for Patents, Drew Hirshfeld. *See* Ian Lopez, *Hirshfeld Takes Up PTO Chief Duties as Biden Enters White House*, Bloomberg Law, Jan. 20, 2021 (quoting an email from Commissioner Hirshfeld to PTO staff explaining that, “[u]pon a vacancy of the Director and Deputy Director of the USPTO, the Commissioner for Patents performs the functions and duties of the . . . USPTO Director,” and that Commissioner Hirshfeld therefore “began performing those functions and duties” upon former Director Andrei Iancu’s resignation).

Commissioner Hirshfeld is not a principal officer appointed by the President and confirmed by the Senate. He was appointed by the Secretary of Commerce—a

method appropriate only for *inferior* officers. 35 U.S.C. § 3(b)(2)(A). Nonetheless, in 2002, the PTO issued an internal order stating: “If the position of the Under Secretary is vacant, the Deputy Under Secretary will serve as Acting Under Secretary. If both the Under Secretary and the Deputy Under Secretary positions are vacant, *the Commissioner for Patents . . . will perform the functions and duties of the Under Secretary.*” U.S. Patent & Trademark Off., Agency Organization Order 45-1, § II(D) (June 24, 2002) (reproduced at Add. Ex. C) (emphasis added).<sup>1</sup>

Arthrex filed a petition for Director review of the Board’s decision. Add. Ex. B. Arthrex disputed Commissioner Hirshfeld’s authority to decide the petition, observing that he was “not a presidentially appointed principal officer” and that the absence of principal-officer review raised “serious issues under the Appointments Clause, separation of powers, and the Vacancies Reform Act.” *Id.* at 14-15.

The petition set forth multiple grounds for review. Principally, Arthrex urged that the Board disregarded the consistent disclosure of the “eyelet” function and the structure for that function throughout the priority chain. Add. Ex. B at 8-9. The

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<sup>1</sup> See also U.S. Dep’t of Commerce, Department Organizational Order 10-14, § 2.04 (Sept. 28, 2012) (replicating delegation); Teresa Stanek Rea, Deputy Director, U.S. Patent & Trademark Off., *Delegation To Perform the Non-Exclusive Functions and Duties of the Under Secretary and Deputy Under Secretary of Commerce for Intellectual Property and Director and Deputy Director of the United States Patent Office* (Nov. 15, 2013) (citing both orders); U.S. Patent & Trademark Off., *Notice of Delegation to Commissioner for Patents and Notice of Delegation to Commissioner for Trademarks* (Oct. 30, 2014) (explaining legal basis for delegation).

function of the “first member including eyelet” in the ’907 patent claims, Arthrex explained, was to thread suture. *Id.* at 8. The prior applications provided adequate written description for that function so long as “the disclosed function [was] sufficiently correlated to a particular, known structure.” *Id.* (quoting *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003)).

That test was met here. Each application in the priority chain disclosed the function of threading suture as well as a known structure for threading—initially a flexible eyelet and later also a rigid eyelet. Add. Ex. B at 8. The record was undisputed that both rigid and flexible eyelets existed in the prior art and were known to be interchangeable for the function of threading suture. *Id.* at 9. The Board improperly focused on the “free sliding” advantages of a rigid eyelet, even though the ’907 patent claims had nothing to do with free sliding. They only require an eyelet for threading suture, a function performed by both flexible and rigid eyelets. The Board overlooked those dispositive disclosures. *Id.*

Arthrex also renewed its argument that the Board failed to give effect to its incorporations by reference. Add. Ex. B at 10-14. And it reiterated that the Board circumvented the statutory limits on inter partes review. *Id.* at 14.

On October 15, 2021, Commissioner Hirshfeld denied Arthrex’s petition. Add. Ex. A. His order states simply: “It is ORDERED that the request for Director

review is denied; and FURTHER ORDERED that the Patent Trial and Appeal Board’s Final Written Decision is the final decision of the agency.” *Id.* at 1.

## **VI. FURTHER PROCEEDINGS ON APPEAL**

Arthrex notified this Court of Commissioner Hirshfeld’s decision and filed a supplemental notice of appeal. ECF Nos. 150, 151. It requested supplemental briefing and oral argument. ECF No. 150 at 1. Because the Appointments Clause dominated the prior oral argument, Arthrex urged that it had not had a full opportunity to argue the remaining points from its original appeal briefs. *Id.*

This Court lifted the stay of proceedings and ordered the case “rescheduled for oral argument in due course.” ECF No. 152. The Court permitted Arthrex to file this supplemental brief addressing the denial of review. ECF No. 156.

## **ARGUMENT**

The Supreme Court held the inter partes review scheme unconstitutional because it permitted APJs—mere *inferior* officers—to render the agency’s final word without any review by a principal executive officer. The Court ordered this case remanded to the PTO so Arthrex could seek principal-officer review. On remand, however, the agency failed to provide that remedy. Instead, it denied Arthrex’s petition in a decision by yet another person appointed as an *inferior* officer: Commissioner for Patents Drew Hirshfeld.

The agency's delegation of final decisionmaking authority to Commissioner Hirshfeld violates the Appointments Clause. It also violates the Federal Vacancies Reform Act by purporting to vest principal-officer authority in a subordinate not authorized to serve as Acting Director. And it violates the separation of powers by allowing an officer to run the agency while insulated from presidential control. If the Court does not reverse the Board's decision on the merits, it should vacate Commissioner Hirshfeld's decision and remand for proceedings that comply with constitutional and statutory limitations.

**I. COMMISSIONER HIRSHFELD LACKED AUTHORITY TO REVIEW ARTHREX'S PETITION UNDER THE APPOINTMENTS CLAUSE**

Commissioner Hirshfeld's order denying review violated the Appointments Clause. Commissioner Hirshfeld purported to exercise authority that may only be wielded by a presidentially appointed principal officer.

**A. Commissioner Hirshfeld Improperly Exercised the Authority of a Principal Officer**

The Appointments Clause provides that principal officers must be appointed by the President and confirmed by the Senate. U.S. Const. art. II, §2. Only inferior officers may be appointed by department heads. *Id.* Commissioner Hirshfeld was appointed by the Secretary of Commerce. 35 U.S.C. §3(b)(2)(A). Under the Appointments Clause, therefore, he could exercise only the powers of an inferior

officer—authority that does not include rendering an agency’s final decisions with no opportunity for review by any superior executive officer.

The Supreme Court made clear in this very case that only a *principal* officer may issue final agency decisions that are not subject to review by any superior officer. The Court held the inter partes review scheme unconstitutional because it gave *inferior* officers the last word: “[T]he unreviewable authority wielded by APJs during inter partes review,” the Court held, “is incompatible with their appointment by the Secretary to an inferior office.” *Arthrex*, 141 S. Ct. at 1985. “Only an officer properly appointed to a principal office may issue a final decision binding the Executive Branch . . . .” *Id.*; see also *Edmond v. United States*, 520 U.S. 651, 665 (1997) (holding that Coast Guard judges were inferior officers because they had “no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers”).

The Appointments Clause, the Court explained, ensures accountability for executive actions. “The President is ‘responsible for the actions of the Executive Branch . . . .’” *Arthrex*, 141 S. Ct. at 1978. “Assigning the nomination power to the President guarantees accountability for the appointees’ actions because the ‘blame of a bad nomination would fall upon the president singly and absolutely.’” *Id.* at 1979 (quoting *The Federalist No. 77* (Hamilton)). “[T]he Appointments Clause permits Congress to dispense with joint appointment, but *only* for inferior officers.”

*Id.* (emphasis added). Congress’s attempt to grant final authority to APJs, subject to no review by superior officers, “conflict[ed] with the design of the Appointments Clause ‘to preserve political accountability.’” *Id.* at 1982.

To remedy the violation, the Court severed the statutory restrictions that prevented the Director from unilaterally reviewing APJ decisions. *Arthrex*, 141 S. Ct. at 1987. The Court then remanded so *Arthrex* could seek *principal-officer* review: “[A] limited remand to the Director,” the Court held, “provides an adequate opportunity for *review by a principal officer.*” *Id.* at 1987-88 (emphasis added).

By assigning *Arthrex*’s petition to Commissioner Hirshfeld, the PTO once again denied *Arthrex* the constitutionally required opportunity for principal-officer review. Just like the panel of APJs who previously invalidated *Arthrex*’s patent claims, Commissioner Hirshfeld is an inferior officer appointed by the Secretary of Commerce. 35 U.S.C. § 3(b)(2)(A). Just like those APJs, he purports to issue final decisions that are not reviewable by any superior officer. The Court found the old regime unconstitutional because, “[i]n all the ways that matter to the parties who appear before the PTAB, the buck stops with the APJs, not with the Secretary or Director.” *Arthrex*, 141 S. Ct. at 1982. Now, the buck stops with Commissioner Hirshfeld. His exercise of that principal-officer power “conflicts with the design of the Appointments Clause ‘to preserve political accountability.’” *Id.*

## **B. The PTO's Delegation of Authority Does Not Avoid the Appointments Clause Violation**

The PTO cannot avoid the Supreme Court's holding on the theory that Commissioner Hirshfeld exercises only authority delegated by the PTO's Director. *See* pp. 7-8 & n.1, *supra*. Ordinarily, a principal officer may delegate tasks to a subordinate without running afoul of the Appointments Clause. The Framers expected the Executive Branch to "rely on subordinate officers for assistance." *Arthrex*, 141 S. Ct. at 1979. That arrangement, however, derives its "legitimacy and accountability" from a "clear and effective chain of command." *Id.* The principal officer "need not review every decision." *Id.* at 1988. But he must have "**discretion** to review decisions rendered." *Id.* (emphasis added).

Thus, where a principal officer delegates decisionmaking authority to a subordinate but retains the power to review the decisions or to revoke the delegation, the subordinate remains an inferior officer. *See In re Sealed Case*, 829 F.2d 50, 56 (D.C. Cir. 1987) (holding that Iran/Contra independent counsel was an inferior officer because "the Attorney General may rescind th[e] regulation [creating the office] at any time"); *e.g.*, 85 Fed. Reg. 13,186, 13,188 (Mar. 6, 2020) (providing for Secretary of Labor review of Administrative Review Board decisions where Secretary had previously delegated final authority to the Board). The principal officer's continuing power to supervise or revoke the delegation preserves the accountability the Appointments Clause requires.



Here, the delegation has no such effect. The offices of Director and Deputy Director are both vacant. As a result, no superior officer at the PTO can review Commissioner Hirshfeld's decisions or rescind his authority in the event he abuses or neglects his powers. It makes no difference whether Commissioner Hirshfeld has the agency's last word because Congress gave him that power directly or because his superior handed him a blank check before packing up and shipping out. Either way, the buck now stops with Commissioner Hirshfeld. "Only an officer properly appointed to a principal office may issue a final decision binding the Executive Branch . . . ." *Arthrex*, 141 S. Ct. at 1985. Commissioner Hirshfeld exercises that authority but was never appointed as the Constitution requires.

Nor can the PTO avoid the Supreme Court's decision by analogizing Commissioner Hirshfeld to the acting officers in cases like *United States v. Eaton*, 169 U.S. 331 (1898). *Eaton* addressed whether "[C]ongress [could] vest *in the president* the appointment of a subordinate officer called a 'vice consul,' to be charged with the duty of temporarily performing the functions of the consular office." *Id.* at 343 (emphasis added). The Court held that Congress could do so because 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 thereby transformed into the superior and permanent official." *Id.*

*Eaton* thus governs situations where Congress authorizes the **President** to appoint a temporary acting officer. 169 U.S. at 343 (addressing whether Congress could “vest in the president” power to appoint acting officer); *see also NLRB v. SW Gen.*, 137 S. Ct. 929, 935 (2017) (“Since President Washington’s first term, Congress has given **the President** limited authority to appoint acting officials to temporarily perform the functions of a vacant [principal] office without first obtaining Senate approval.” (emphasis added)). Those arrangements preserve the President’s oversight by placing appointments squarely in his hands.

Here, by contrast, the President never appointed Commissioner Hirshfeld as Acting Director. The PTO came up with the delegation of authority all on its own. Nothing in *Eaton* authorizes an agency to exempt its leadership from presidential nomination and Senate confirmation by delegating the agency head’s duties and functions to the agency’s preferred successor.

Commissioner Hirshfeld, moreover, is hardly performing the Director’s duties “for a limited time, and under special and temporary conditions.” *Eaton*, 169 U.S. at 343. Under the agency’s delegation, Commissioner Hirshfeld serves indefinitely until a successor is appointed, and he has already discharged the powers of Director for nearly a year. *See pp. 7-8, supra; cf. SW Gen.*, 137 S. Ct at 946 n.1 (Thomas, J., concurring) (finding “nothing ‘special and temporary’ about [an officer’s] appointment” where officer “served for more than three years in an office limited by

statute to a 4-year term”); *United States v. Smith*, 962 F.3d 755, 764 n.3 (4th Cir. 2020) (noting that “a statute may authorize an acting tenure so lengthy that it exceeds the ‘special and temporary conditions’ contemplated by *Eaton*”); *Designating an Acting Attorney General*, 2018 WL 6131923, at \*14 (O.L.C. Nov. 14, 2018) (acting appointment must not “continue beyond a reasonable time”).

Finally, the PTO cannot rely on the Supreme Court’s one passing reference to “a remand to the *Acting* Director to decide whether to rehear the petition.” *Arthrex*, 141 S. Ct. at 1972 (emphasis added). By the PTO’s own admission, a Commissioner for Patents exercising the powers of Director is not an “Acting Director” at all. *See* U.S. Patent & Trademark Off., *Notice of Delegation to Commissioner for Patents and Notice of Delegation to Commissioner for Trademarks* (Oct. 30, 2014) (Commissioner “has not been, and need not be, appointed ‘Acting Director’ of the USPTO under the Vacancies Reform Act”). The parties, moreover, did not brief in the Supreme Court whether Commissioner Hirshfeld could exercise the powers of Director. The Court’s opinion does not resolve that issue. *See Cooper Indus., Inc. v. Aviall Servs., Inc.*, 543 U.S. 157, 170 (2004) (“Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are not to be considered as having been so decided as to constitute precedents.”).

The law is clear: The PTO cannot revoke Arthrex’s patent claims through a final and unreviewable decision by a panel of APJs. It cannot do the same thing

through a decision of its Commissioner for Patents, who is likewise appointed as a mere inferior officer. Only a principal officer appointed by the President and confirmed by the Senate can wield those powers.

## **II. COMMISSIONER HIRSHFELD LACKED AUTHORITY TO REVIEW ARTHREX'S PETITION UNDER THE FEDERAL VACANCIES REFORM ACT**

The Federal Vacancies Reform Act (“FVRA”) restricts the circumstances in which a subordinate can temporarily exercise the powers of a vacant principal office. It thereby prevents agencies from evading the constitutional requirements for appointment of principal officers. Commissioner Hirshfeld’s denial of Arthrex’s petition violated those statutory limitations too.

### **A. Commissioner Hirshfeld Was Not Appointed Pursuant to the Federal Vacancies Reform Act**

The FVRA sets forth “the *exclusive* means for temporarily authorizing an acting official to perform the functions and duties” of a vacant principal office. 5 U.S.C. § 3347(a) (emphasis added). If a principal officer “dies, resigns, or is otherwise unable to perform the functions and duties of the office,” those functions and duties shall be performed by (1) the “first assistant to the office”; (2) another principal officer, if the President so directs; or (3) another high-level officer or employee in the same agency, if the President so directs. *Id.* § 3345(a)(1)-(3). The statute defines “function or duty,” in relevant part, as a function or duty that is “established by statute” and “required by statute to be performed by the applicable

officer (and only that officer).” *Id.* § 3348(a)(2)(A). Actions taken in violation of the FVRA “shall have no force or effect.” *Id.* § 3348(d).

Congress enacted the FVRA to help enforce the constitutional requirements of presidential nomination and Senate confirmation for principal officers, “a critical ‘structural safeguard . . . of the constitutional scheme.’” *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 935 (2017). The statute followed years of attempts to evade those requirements through the prolific use of “acting” appointments. *Id.* at 935-37.

Consistent with that design, courts have rejected attempts to evade the FVRA through regulatory delegations. For example, in *Bullock v. U.S. Bureau of Land Management*, 489 F. Supp. 3d 1112 (D. Mont. Sept. 25, 2020), *injunctions vacated as moot*, No. 4:20-cv-00062, Dkt. 52 (D. Mont. Nov. 1, 2021), the court rejected an attempt to delegate the Director of the Bureau of Land Management’s authority to a subordinate during a vacancy. *Id.* at 1124-30. The delegations, the court held, “represent[ed] unlawful attempts to avoid the constitutional requirements of the Appointments Clause and the statutory requirements of the FVRA.” *Id.* at 1127; *see also L.M.-M. v. Cuccinelli*, 442 F. Supp. 3d 1, 29-34 (D.D.C. 2020) (rejecting argument that “mere existence of [a] vesting-and-delegation statute[.]” negated FVRA’s requirements), *appeal dismissed*, No. 20-5141, 2020 WL 5358686 (D.C.

Cir. Aug. 25, 2020). The practice of evading the FVRA through regulatory delegations has been the subject of extensive scholarly criticism as well.<sup>2</sup>

The PTO’s delegation of authority to Commissioner Hirshfeld is no different. Commissioner Hirshfeld does not qualify as an Acting Director under the FVRA. He is not the “first assistant” to the Director—the Deputy Director has that job. 5 U.S.C. §3345(a)(1); 35 U.S.C. §3(b)(1). He is not a principal officer. 5 U.S.C. §3345(a)(2). And the President did not personally select him to assume the Director’s duties. *Id.* §3345(a)(3). Commissioner Hirshfeld therefore cannot serve as Acting Director consistent with the FVRA.

**B. Commissioner Hirshfeld Purported To Perform Functions and Duties of the Director**

The PTO has nonetheless asserted that the FVRA does not apply when the Commissioner for Patents stands in for the Director, because the Commissioner is not actually performing any “function or duty” of the Director. The statute defines

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<sup>2</sup> See Nina A. Mendelson, *The Permissibility of Acting Officials: May the President Work Around Senate Confirmation?*, 72 Admin. L. Rev. 533, 558-63 (2020) (arguing that FVRA was intended to “eliminate agency use of internal delegation to avoid Vacancies Act limits on acting appointments”); Nina A. Mendelson, L.M.-M. v. Cuccinelli and the Illegality of Delegating Around Vacant Senate-Confirmed Offices, Yale J. on Reg.: Notice & Comment (Mar. 5, 2020) (citing “widespread” strategy of “delegat[ing] around a vacancy in a Senate-confirmed post, allotting the full suite of responsibilities to an unconfirmed individual, someone typically ineligible to ‘act’ under the FVRA’s qualifications”); Jody Freeman & Sharon Jacobs, *Structural Deregulation*, 135 Harv. L. Rev. 585, 647 (2021) (“Presidents have tried to circumvent the [FVRA’s] limitations by having agency heads delegate responsibilities to subordinates before vacating their offices.”).

“function or duty” to include only actions “required . . . to be performed by the applicable officer (and only that officer).” 5 U.S.C. § 3348(a)(2)(A). According to the PTO, “[a]ll of the Director’s duties under Titles 35 and 15 . . . are delegable (*i.e.*, non-exclusive)” because there is no “clear statutory language” saying otherwise. U.S. Patent & Trademark Off., *Notice of Delegation to Commissioner for Patents and Notice of Delegation to Commissioner for Trademarks* (Oct. 30, 2014) (emphasis added). Thus, even though Commissioner Hirshfeld has been single-handedly running the agency for almost a year, the PTO claims he is not exercising any “function or duty” of the Director at all. *See id.* (asserting that Commissioner “need not be[] appointed ‘Acting Director’ of the USPTO” because “[a]ppointment of a VRA-authorized ‘Acting Officer’ is only needed to allow an individual to perform duties . . . that are exclusive to [a] particular [principal] Officer”).

That argument defies the FVRA’s basic structure. Agency organic statutes routinely authorize agency heads to delegate their duties. *See L.M.-M.*, 442 F. Supp. 3d at 34 (statutes “pervasive”). Treating an agency head’s generic delegation authority as sufficient to exempt the officer’s entire panoply of powers from the FVRA renders the statute’s careful limits meaningless in the vast majority of cases. *See pp. 19-20 & n.2, supra.*

In any case, whatever the merits of the PTO’s counterintuitive theory as to *other* actions Commissioner Hirshfeld might take, the theory falls flat here. The

Director’s unilateral power to review Board decisions *is* an exclusive, non-delegable function. The Supreme Court made that clear in this case already.

The Supreme Court observed that the Patent Act’s vesting of the PTO’s “powers and duties” in the Director would ordinarily authorize him to review APJ decisions. *Arthrex*, 141 S. Ct. at 1986 (citing 35 U.S.C. § 3(a)(1)). That review power, however, was hedged by the statute’s mandate that “only the [Board] may grant rehearings” and that the Board must sit in panels of “at least 3 members.” *Id.* at 1986-87 (citing 35 U.S.C. § 6(c)). To remedy the constitutional violation, the Court severed those latter restrictions, but *only* as applied to the Director: “Section 6(c) cannot constitutionally be enforced to the extent that its requirements prevent *the Director* from reviewing final decisions rendered by APJs. . . . The *Director* accordingly may review final PTAB decisions . . . .” *Id.* at 1987 (emphasis added). “Section 6(c) otherwise remains operative *as to the other members of the PTAB.*” *Id.* (emphasis added).

After the Supreme Court’s decision, the Patent Act permits the Director—and only the Director—to exercise a unilateral power to review Board decisions. The Director cannot delegate that unilateral power to other PTO officers because “Section 6(c) otherwise remains operative” as to those other officers—they are *statutorily prohibited* from unilaterally reviewing Board decisions. *Arthrex*, 141 S. Ct. at 1987. The Director’s unilateral power to review Board decisions is therefore



a power “established by statute” and “required by statute to be performed by the applicable officer (and only that officer).” 5 U.S.C. § 3348(a)(2)(A). It is a “function or duty” within the meaning of the FVRA. *Id.* Consequently, even apart from constitutional constraints, the FVRA deprives Commissioner Hirshfeld’s decision of any “force or effect.” *Id.* § 3348(d)(1).

### **III. COMMISSIONER HIRSHFELD’S EXERCISE OF THE DIRECTOR’S AUTHORITY VIOLATES THE SEPARATION OF POWERS**

The PTO’s attempt to install Commissioner Hirshfeld as head of the agency creates yet another constitutional problem. Article II of the Constitution vests the “executive Power” in the President and directs him to “take Care that the Laws be faithfully executed.” U.S. Const. art. II, §§ 1, 3. Those provisions require that the President have broad power to remove heads of executive agencies. Commissioner Hirshfeld now runs a major federal agency that wields vast executive powers, setting policy and administering operations that affect billions of dollars of intellectual property. But unlike a presidentially appointed Director, who is removable at will, 35 U.S.C. § 3(a)(4), Commissioner Hirshfeld “may be removed from office” only for “misconduct or nonsatisfactory performance under [his] performance agreement,” *id.* § 3(b)(2)(C). Those restrictions violate the separation of powers by impeding the President’s ability to supervise Commissioner Hirshfeld’s discharge of the Director’s executive duties.

In *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S. Ct. 2183 (2020), the Supreme Court invalidated a provision prohibiting the President from removing the Director of the Consumer Financial Protection Bureau except for “inefficiency, neglect of duty, or malfeasance in office.” *Id.* at 2193, 2197-207. The President’s duty to ensure due execution of the laws, the Court held, “generally includes the ability to remove executive officials, for it is ‘only the authority that can remove’ such officials that they ‘must fear and, in the performance of [their] functions, obey.’” *Id.* at 2197. The removal restrictions impeded the President’s ability to supervise the Director’s executive functions. *Id.* at 2200-07.

Similarly, in *Collins v. Yellen*, 141 S. Ct. 1761 (2021), the Court held unconstitutional a statute that prohibited the President from removing the Director of the Federal Housing Finance Agency except “for cause.” *Id.* at 1771. “[T]he Constitution,” the Court held, “prohibits even ‘modest restrictions’ on the President’s power to remove the head of an agency with a single top officer.” *Id.* at 1787; *see also Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 492-98 (2010) (holding that dual for-cause restrictions on President’s authority to remove PCAOB members violated separation of powers).

Those same principles apply here. Commissioner Hirshfeld heads a major federal executive agency. He wields all the “powers and duties of the United States Patent and Trademark Office.” 35 U.S.C. § 3(a)(1). He is “responsible for providing

policy direction and management supervision.” *Id.* § 3(a)(2). He may issue binding regulations. 35 U.S.C. § 2(b)(2). He has “sole authority over the decision whether to grant [a] 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). After the Supreme Court’s decision in this case, he may unilaterally “review final PTAB decisions and . . . issue decisions himself.” *Arthrex*, 141 S. Ct. at 1987. He has even promulgated rules governing his exercise of that review power. *See* U.S. Patent & Trademark Off., *USPTO Implementation of an Interim Director Review Process Following Arthrex* (June 29, 2021). *Seila Law* and *Collins* require that he be removable at will.

The Court has recognized only two exceptions to the President’s authority to remove executive officers. Neither applies here. First, Congress may grant tenure protections to “***multimember*** expert agencies that do not wield substantial executive power.” *Seila Law*, 140 S. Ct. at 2198-20 (emphasis added). That exception plainly does not apply. Commissioner Hirshfeld is the ***sole*** head of an agency with broad executive powers.

Second, the Court has permitted Congress to provide tenure protections to “inferior officers with limited duties and no policymaking or administrative authority.” *Seila Law*, 140 S. Ct. at 2199-2200. Commissioner Hirshfeld is currently exercising the powers of a ***principal*** officer. *See* pp. 11-18, *supra*. But even if he were only an inferior officer, he could not remotely be described as an “inferior

officer[] *with limited duties and no policymaking or administrative authority.*”  
*Seila Law*, 140 S. Ct. at 2199-2200 (emphasis added). So long as he stands in for the Director, he has vast policymaking and managerial authority over an entire federal agency. *See pp. 24-25, supra*. That he allegedly exercises those powers only on an interim basis does not reduce their scope or diminish the need for presidential oversight. *Cf. Collins*, 141 S. Ct. at 1781 (construing statute not to restrict President’s authority to remove Acting Director of FHFA).

The separation of powers requires that someone with Commissioner Hirshfeld’s current level of authority be removable at will. For that reason too, Commissioner Hirshfeld lacked authority to deny Arthrex’s petition.

## **CONCLUSION**

For the foregoing reasons, as well as those in Arthrex's principal briefs, the Court should reverse the Board's decision on the merits and vacate Commissioner Hirshfeld's denial of review.

Respectfully submitted,

CARLSON, GASKEY & OLDS, P.C.

Dated: January 12, 2022

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**CERTIFICATE OF COMPLIANCE**

I, Anthony P. Cho, counsel for Appellant, certify that the foregoing Corrected Supplemental Brief complies with the type-volume limitation set forth in the Court’s Order, ECF No. 156.

Specifically, this brief contains 5,987 words (excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2)) as determined by the word count feature of the word processing program used to create this brief.

I further certify that the foregoing brief complies with the typeface requirements set forth in Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6). Specifically, this brief has been prepared using a proportionally spaced typeface using Microsoft Word 2019, in 14-point Times New Roman font.

Dated: January 12, 2022

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**CERTIFICATE OF SERVICE**

I hereby certify that on January 12, 2022, I electronically filed the foregoing document using the Court's CM/ECF system, which sent notification of such filing to all counsel of record as follows:

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# **ADDENDUM**

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# **EXHIBIT A**

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE OFFICE OF THE UNDERSECRETARY AND DIRECTOR OF  
THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SMITH & NEPHEW, INC. and  
ARTHROCARE CORP.,  
Petitioner,

v.

ARTHREX, INC.,  
Patent Owner.

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IPR2017-00275  
Patent 9,179,907 B2

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Before ANDREW HIRSHFELD, *Commissioner for Patents, Performing the  
Functions and Duties of the Under Secretary of Commerce for Intellectual  
Property and Director of the United States Patent and Trademark Office.*

ORDER

IPR2017-00275  
Patent 9,179,907 B2

The Office has received a request for Director review of the Final Written Decision in this case. Ex. 3100. The request was referred to Mr. Hirshfeld, Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

It is ORDERED that the request for Director review is denied; and  
FURTHER ORDERED that the Patent Trial and Appeal Board's Final Written Decision is the final decision of the agency.

IPR2017-00275  
Patent 9,179,907 B2

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## **EXHIBIT B**

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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SMITH & NEPHEW, INC. &  
ARTHROCARE CORP.,  
Petitioners

v.

ARTHREX, INC.,  
Patent Owner.

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Case IPR2017-00275  
Patent 9,179,907

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**PATENT OWNER ARTHREX, INC.'S REQUEST FOR REHEARING BY  
THE DIRECTOR**



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## I. INTRODUCTION

Pursuant to Supreme Court and Federal Circuit mandate and 37 C.F.R. 42.71(d), Arthrex requests Director review of the Board’s Final Written Decision (“FWD,” Paper 36) finding unpatentable claims 1, 4, 8, 10–12, 16, 18, and 25–28 of U.S. Patent No. 9,179,907 B2 (“the ‘907 Patent”). The entire basis for this finding stems from the Board’s incorrect conclusion that the inventors of the ‘907 Patent abandoned the very ground-breaking idea for knotless surgery they sought to preserve in every single patent application leading up to the ‘907 Patent. Only in this way could the Board find this idea to be prior art and even a new disclosure to the patent in spite of the dictates of 35 U.S.C. § 120.

In deciding this matter, the Board lost sight of the principal advantage of the claimed invention, knotless surgery, and instead wrongly focused on statements made in a later CIP that touted the benefits of a “free sliding” suture. According to the Board, this improvement negated the original idea as written description support because it spoke with a “much louder voice” drowning out the original idea. Hence, the benefit of a “free sliding” suture overwhelmed the advantage of knotless surgery. However, nothing within the claims requires “free sliding.” The Board thus wrongly focused on the “free sliding” improvement instead of the claimed invention.

Under the proper lens, , there was incontrovertible proof of written description support for the claims. In fact, there was only one claim term in dispute, “first

member including an eyelet oriented to thread suture.” Nothing within this term requires the eyelet be “free sliding.” All this claim term requires is an eyelet oriented to thread suture. No more, no less. And, as shown in more detail below, every application in the priority chain undisputedly disclosed this common function of the eyelet, i.e. the ability to “thread” the suture through the eyelet, and at least one structure for accomplishing this function, whether a flexible eyelet or a rigid eyelet. The Board overlooked this evidence and argument. For this reason alone, Director review is not only warranted but the flawed Board decision must be vacated and the claims found patentable.

Beyond this dispositive argument, the Board decision should be vacated for a second, independent reason. The Board also ignored written description support for the claimed eyelet by ignoring the flexible eyelet embodiment that threads suture disclosed in every application of the priority chain either expressly or by incorporation by reference. Rather than consider this embodiment, the Board believed statements made in the chain about the advantages of a “free sliding” rigid eyelet, in fact, nullified detailed disclosure of the flexible eyelet embodiment as support for an “eyelet” that merely threads suture. The Board erred as a matter of law by failing to consider this embodiment as support.

For these and other reasons set forth below, Director review is warranted.

## II. LEGAL STANDARD

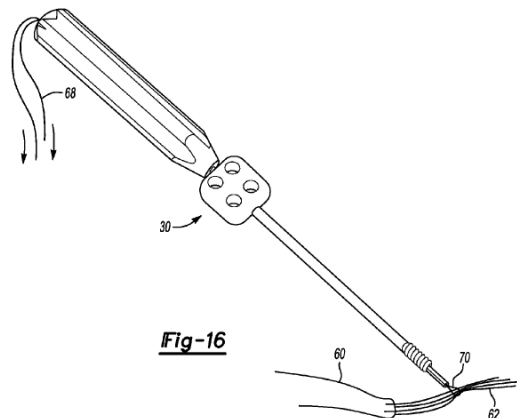
The Supreme Court has determined that final written decisions are reviewable by the Director of the PTO. *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1988 (2021). As explained in the Interim Rules following this decision, “[t]he Director’s review may address any issue, including issues of fact and issues of law, and will be *de novo*.” *Arthrex* FAQ A1 (*emphasis added*). Decisions may warrant review for, *inter alia*, material errors of fact or law, matters the Board misapprehended or overlooked, and novel issues of law or policy. *See Arthrex* Q&A D2.

## III. BACKGROUND

### A. The ‘907 Patent

Surgeons most commonly use a device known as a suture anchor to reattach torn tissue back to bone. [Paper 6, Patent Owner’s Preliminary Response at 3]. During an operation, a surgeon places the anchor into bone and then passes the ends of the suture through the torn tissue. [Exhibit 1019, Declaration of Dr. David McAllister at ¶¶47-49.] The surgeon knots the suture to secure the tissue in place so it may heal. [*Id.* at ¶49.] Knots formed from tying suture may cause irritation and discomfort for the patient and otherwise cause issues during surgery. [Exhibit 1001, ‘907 Patent at 1:34-36; Exhibit 2037, Declaration of Dr. Geoffrey B. Higgs, M.D., at ¶¶67-68.]

The main object of the invention of the '907 Patent, as well as every other application in the priority chain, was to create a suture anchor enabling surgeons to repair torn tissue knotlessly. [Ex. 1001 at 1:43-48; Exhibit 1003, Provisional Application No. 60/213,263 at 3-5, 9; Exhibit 1004, Application No. 09/886,280 at 4-5, 13; Exhibit 1005, Application No. 10/405,707 at 2-3, 8; Exhibit 1006, Application No. 12/022,868 at 2-3, 8; Exhibit 1007, Application No. 13/182,893 at 3-4, 8; Exhibit 1008, Application No. 13/756,218 at 1-2, 6.] As shown in the specification, the inventors accomplished this benefit by wedging suture in bone rather than tying knots in the suture itself. [Ex. 2037 at ¶¶76-88.] With reference to their original embodiment below, a surgeon passes suture 62 through the tissue 60 to be repaired and then threads that suture through an eyelet, here suture loop 70, claimed as a “first member including an eyelet.” [Ex. 1001 at 5:35-6:46; Fig. 16.]



The surgeon then places the captured portion of suture 62 into a hole in the patient's bone. [*Id.* at 5:48-62]. The surgeon uses the driver to lower an anchor into the hole,

thereby wedging suture 62 in place such as between the anchor and the side of the bone hole. [*Id.* at 5:64-6:15]. In this way, the innovative device permits suture to be locked in place without having to tie knots. [Ex. 2037 at ¶¶76-88.]

### **B. The ‘907 Patent Priority Chain**

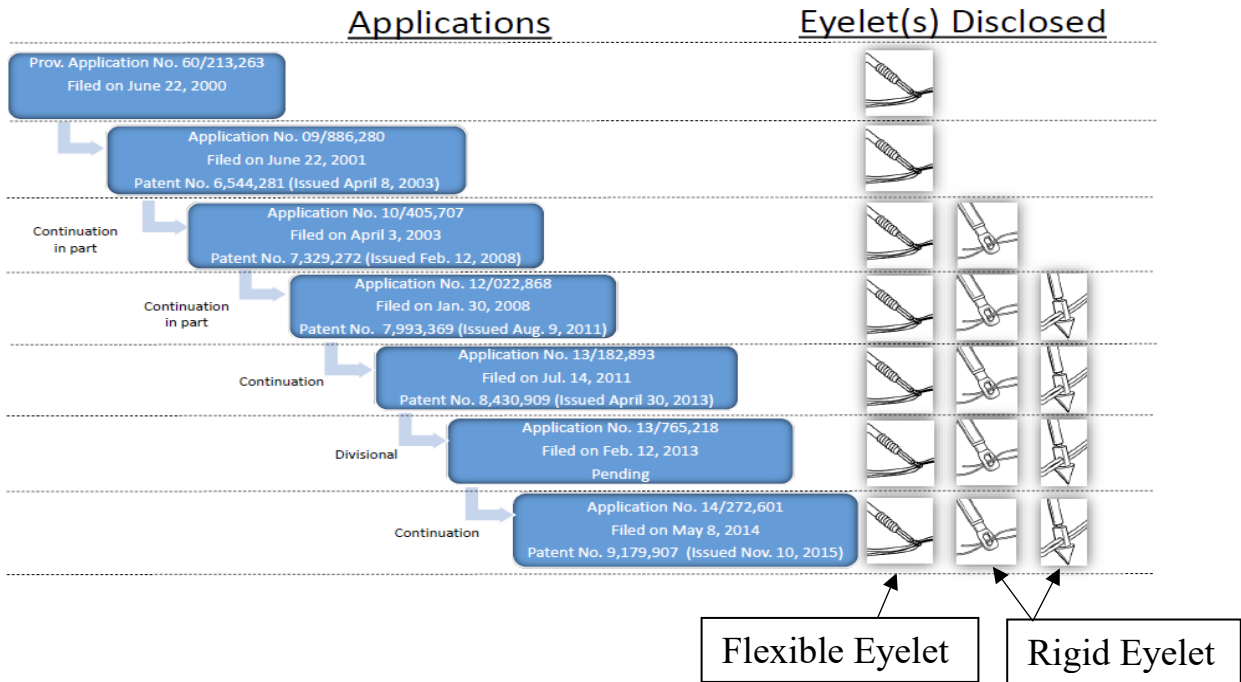
The idea for the innovative knotless suture anchor was first disclosed as a suture anchor assembly using a flexible eyelet (“suture loop”) in U.S. utility application 09/886,280 (“the ‘280 Application”) on June 22, 2001. [Ex. 1004.] Following this application, the inventors filed a series of continuations detailing improvements to their original idea for a knotless suture anchor prior to filing the ‘601 application, which became the ‘907 Patent. [Exs. 1005-1008, collectively, “the Intervening Applications.”] Each of the Intervening Applications incorporated by reference the ‘280 application with the same broad incorporating language, and each of the Intervening Applications continued to claim priority to the ‘280 application. [*Id.*] Importantly, each of the Intervening Applications explained the principal object of the invention, namely to allow a surgeon to use a suture anchor without tying knots by threading suture through an eyelet, placing the eyelet at the bottom of a bone hole, and then using the anchor, i.e. “second member,” to wedge the suture against the side of the bone hole. [*Id.*]

The first Intervening Application is Application No. 10/405,707 (“the ‘707 Application,” Ex. 1005) filed as a CIP of the ‘280 Application. In addition to



incorporating by reference the entirety of the ‘280 Application, the ‘707 Application, like later Intervening Applications, summarized the technique of the ‘280 Application and also disclosed threading suture through a “suture loop,” i.e., the flexible eyelet. [*Id.* at 3.] Hence, the ‘707 Application both describes the flexible eyelet embodiment in detail via the incorporated ‘280 Application and summarizes this embodiment in the background section of the application. The ‘707 Application undisputedly identifies this flexible eyelet embodiment as an “improved method” over the prior art knotted suture anchors. [*Id.* at 2-3.] Like the vast majority of CIPs, this application also discloses improvements over the original concept. Here, the ‘707 Application explains that the flexible loop “impedes sliding of the suture or graft which is fed through the suture loop.” [*Id.* at 3.] The application indicates this disadvantage of the inventors’ earlier work is overcome by providing an “eyelet implant” having a “fixed aperture for receiving a suture attached to a graft, such that the suture is able to freely slide through the aperture.” [*Id.*] Rather than describe “free sliding” as the only object of the invention, the ‘707 Application and every subsequent continuation continues to tout the main benefit of the ‘280 Application, knotless fixation, stating: “[a] *significant advantage* of the present invention is that the sutures attached to the graft or the graft itself can be securely attached to the bone without the need to tie knots.” [*Id.* at 8 (*emphasis added*).]

While the last of the Intervening Applications was still pending, Arthrex filed another continuation, U.S. Application No. 14/272,601 (“the ‘601 Application”), which resulted in the ‘907 Patent. [Exhibit 1002, File History of ‘907 Patent at 1-58.] Like every application in the priority chain, the ‘601 Application claimed priority to the ‘280 Application. [*Id.* at 5, 11.] In contrast to the Intervening Applications, however, rather than incorporate by reference the ‘280 Application, the ‘601 Application contains the disclosure of the ‘280 Application explicitly, including the flexible eyelet embodiment and its associated figures. [*Id.* at 12-21, Ex. 2037 at ¶¶233-239, 254-255.] The below chart illustrates the various embodiments disclosed within each application in the ‘907 Patent family:



[Paper 17, Patent Owner Response at 5; Exhibit 2036, Chart].

As shown above, the inventors always had possession of a “first member with an eyelet,” whether as a flexible eyelet or a combination of the flexible eyelet and a rigid eyelet. [Ex. 2037 at ¶¶193-195.]

**IV. THE BOARD OVERLOOKED EVIDENCE AND ARGUMENT OF COMMON DISCLOSURE OF THE FUNCTION OF THE EYELET AND STRUCTURE FOR THIS FUNCTION**

As explained above, the function of the “first member including eyelet” in the ‘907 Patent claims is to thread suture. The written description requirement for that claimed function is satisfied “if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1332 (Fed. Cir. 2003). On this basis, Arthrex offered evidence and argument that written description support existed for a generic “eyelet” because each of the applications of the ‘907 Patent chain discloses the function of threading suture tied to a known structure for threading, initially a flexible eyelet and then a rigid eyelet. [Paper 17 at 37-44; Ex. 2037 at ¶¶221-222.] The ‘280 Application itself disclosed the function of threading suture through the known structure of a flexible eyelet. [Ex. 1004 at 5, 11, 28.]

Likewise, the same function of threading suture was tied to the known structure of a rigid eyelet in every application from the ‘707 Application through the ‘601 Application, irrespective of any incorporation by reference of the ‘280 Application. [Exs. 1005-1008.] Accordingly, written description support existed for

the claimed “eyelet oriented to thread suture” because the disclosed function of threading suture was correlated to known structure for this function, either a flexible eyelet or a rigid eyelet, throughout the priority chain. *See In re Smythe*, 480 F.2d 1376, 1382-83 (C.C.P.A. 1973) (disclosure of a single species involving gas, which was used to separate liquid samples for analysis from one another, provided sufficient written description support for a generic claim requiring a “fluid,” even though “fluid” includes both gas and liquid, both of which have many different properties from one another). Indeed, the record was undisputed that both rigid and flexible eyelets existed in the prior art and were known to be interchangeable for the function of threading suture. [Paper 17 at 30; Exhibit 2015, U.S. Patent No. 5,569,306 at 2:64-3:8; Ex. 2037 at ¶¶71, 122, 260.]

All of this evidence was unrefuted by S&N. S&N’s expert even agreed that the function of the claimed eyelet is to thread suture; a point he could hardly dispute since that function is expressly required by the claim. [Ex. 1019 at ¶112.] Unfortunately, the Board overlooked this dispositive proof set forth in every application of the priority chain. This alone is grounds for review. *See In Re NuVasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016) (PTAB must “articulate a satisfactory explanation for its actions including a rational connection between the facts found and the choice made.”) (internal citations omitted).

**V. THE BOARD ERRED AS A MATTER OF LAW WHEN IT  
NEGATED THE BROAD INCORPORATION BY REFERENCE  
OF THE ‘280 PATENT APPLICATION**

There is a second, independent reason for the Director to review and reverse the Board’s decision. As part of its written description support for the claimed eyelet, Arthrex also relied on the incorporation by reference of the ‘280 Application to carry forward the content of its original concept for knotless fixation into subsequent applications in the priority chain.<sup>1</sup> There can be no dispute that the flexible eyelet embodiment disclosed in the ‘907 Patent is the same embodiment disclosed in the ‘280 Application. [FWD at 11-12]. Instead, at S&N’s urging, the Board ruled that criticism relating to the flexible eyelet species made in the Intervening Applications eliminated written description support for the flexible eyelet itself. [*Id.* at 40; Paper 1, Petition for *Inter Partes* Review at 6.] In so doing, the Board erred as a matter of law.

“To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found.” *Paice LLC v. Ford Motor Co.*, 881 F.3d 894, 906 (Fed. Cir. 2018) (internal citations and quotation marks omitted). Here, the specific

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<sup>1</sup> The application that became the ‘907 Patent restated the ‘280 Application rather than just incorporating it.

material incorporated is the entire ‘280 Application due to the following broad incorporation:

Application Serial No. 09/886,280 filed on June 22, 2001, the disclosure of which is incorporated by reference herein, discloses a surgical technique and associated instruments for securing soft tissue to bone which does not require the surgeon to tie suture knots to secure the tissue to the bone. [Ex. 1005; *see also* Exs. 1006-1008.]

*See Id.* at 907 (finding broad incorporation based on similar incorporating language).

This incorporation dictated the ‘280 Application must be considered for written description purposes. *See Id.* at 910 (question of written description support must examine host document together with incorporated reference therein).

Despite this broad incorporation by reference, the Board failed to give it effect, concluding that the ‘707 Application described the ‘280 Application as a “problematic background technique” that precluded the patentee’s reliance on the incorporation and any priority claim back to the ‘280 Application. [FWD at 30-31]. The Board’s decision is directly contrary to the Federal Circuit’s holding in *Paice* that a broad incorporation cannot be negated by later narrowing statements. *Paice*, 881 F.3d at 908. Even where the host patent criticizes the earlier inventions of an incorporated reference, legal error occurs by not incorporating the reference. *See Id.* This is so because differences between the invention of the incorporating application and the incorporated reference, such as prior art, are present in every case where “the host patent purports to improve upon that which it incorporates.” *Id.* (internal

citations omitted). This case is no different. It is a garden variety case where there is a subsequent improvement to certain aspects of the original invention. But as *Paice* teaches, that circumstance does not, in any way, change the fact that the original material is incorporated and serves as written description support. This conclusion is even more appropriate here because any criticisms of the flexible eyelet relating to slideability of suture have absolutely nothing to do with the claims of the '907 Patent, which are silent about the slideability of suture through the eyelet. Indeed, remarks about the slidability of suture never impacted the main object of knotless fixation or otherwise indicated that a flexible eyelet could not achieve this object. [Ex. 2037 at ¶¶87-88, 108, 118-121, 131-137, 141-145, 170-175.]

Even a characterization of the '280 application as “prior art” or “background” cannot preclude its availability for written description support under §112. In *Paice*, the incorporated patent was prior art and still capable of providing written description support. *Paice*, 881 F.3d at 899, 910. As the above demonstrates, whether the inventors characterized the '280 application as prior art, background or less effective in the Intervening Applications is simply irrelevant to the question of written description.

The Board's reliance on *Tronzo* and *Anascope* was misplaced. In *Tronzo*, the Federal Circuit held the parent patent disclosed “*only* conical shaped cups and nothing broader,” noting its failure to “disclose expressly” the “particular

hemispherical shape” of the claims. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998) (*emphasis in original*). In *Anascape*, the Federal Circuit likewise reviewed the entirety of the specification of the parent application for written description support before arriving at its conclusion, something that did not occur here. *See, e.g., Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1340 (Fed. Cir. 2010). By contrast, the Board refused to consider the express disclosure of the flexible eyelet of the parent application in its written description analysis because of disparaging statements made in later applications. In so doing, the Board failed to do what *Paice*, *Tronzo* and *Anascape* all teach – an examination of the entire disclosure for written description purposes.

The Board also negated the incorporation by reference of the ‘280 Application based on the testimony of Dr. David McAlister, Petitioners’ expert, and one of the inventors of the ‘907 Patent, Dr. Neal ElAttrache. Yet, there was no evidence that the two had even considered the incorporation by reference or realized its legal significance. In any case, testimony cannot override disclosure. *Homeland Housewares v. Whirlpool*, 865 F.3d 1372, 1378 (Fed. Cir. 2017) (“[W]e must disregard the testimony of an expert that is plainly inconsistent with the record....”) (internal citations omitted). Since whether and to what extent material has been incorporated by reference is a question of law, their testimony has no bearing on the



issue in any case. *See Paice*, 881 F.3d at 907 (internal citations omitted). Accordingly, the Board also committed legal error by relying on this testimony.

## **VI. THE PTAB DOES NOT HAVE STATUTORY AUTHORITY TO DECIDE AN IPR BASED ON 112 ISSUES**

The United States Code authorizes the PTAB to conduct IPRs “*only* on a ground that could be raised under §§ 102 or 103 and only on the basis of prior art consisting of patents and printed publications.” 35 U.S.C. §311(b) (*emphasis added*). Here, however, S&N raised only issues regarding compliance with 35 U.S.C. § 112 under the guise of a challenge under 35 U.S.C. § 102. S&N could not otherwise assert ElAttrache and Martinek as prior art. Thus, the entire Final Written Decision is only focused on a § 112 analysis.

The Director should grant review of this issue to make the PTO’s position clear on whether the PTAB can conduct what amounts to be a § 112 review in an IPR. *See Sarif Biomedical LLC v. Brainlab, Inc.*, 725 Fed. Appx. 996, 1000 (Fed. Cir. 2018)(unpublished)(“The PTAB does not have authority to institute an *inter partes* review under § 112.”) This case presents the perfect opportunity to make the PTO’s position known on whether § 112 can used as a basis for an IPR.

## **VII. AUTHORITY AND TIMING**

Finally, Arthrex respectfully asserts certain challenges, also raised in other cases to preserve them for further review. *See, e.g., Mobility Workx, LLC v. Unified Patents, LLC*, No. 20-1441, Dkt. 85, at 1-3, 5-6 (Fed. Cir. July 8, 2021). First, there

is a dispute over Commissioner Hirshfeld’s authority to decide the petition because he is not a presidentially appointed principal officer nor even a properly appointed acting officer, and instead exercises only authority purportedly delegated from an office that is currently vacant and therefore cannot supervise his work. He is also removable only for cause. 35 U.S.C. § 3(b)(2)(C). Those arrangements undermine presidential accountability and raise serious issues under the Appointments Clause, separation of powers, and the Vacancies Reform Act, 5 U.S.C. 3345.

Second, the AIA imposes a deadline of 18 months for any “final determination in an inter partes review.” 35 U.S.C. § 316(a)(11). That deadline has already passed. Arthrex respectfully preserves that timing objection too.

### **VIII. CONCLUSION**

For the reasons stated above, the Director should grant review of this matter, vacate the Board decision, and find the claims in dispute patentable.

Respectfully Submitted,

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Dated: August 27, 2021

**CERTIFICATE OF SERVICE**

The undersigned certifies that a copy of the foregoing document was served electronically via email on August 27, 2021, in its entirety on the following:

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Michael N. Rader  
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Petitioners have consented to electronic service.

Date: August 27, 2021

/s/           Jessica Fleetham

## **EXHIBIT C**

**UNITED STATES PATENT AND TRADEMARK OFFICE**

**AGENCY ORGANIZATION ORDER 45-1**

**Agency Organization Order Series**

**Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office**

**Date of Issuance:**

**Effective Date:**

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- II. Appointment and General Authority of Director and Commissioners
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**VI. UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY  
AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**I. PURPOSE**

- A. This Agency Organization Order (AOO) sets forth the authority and functions of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (the Under Secretary), and provides for the organizational structure of the United States Patent and Trademark Office (USPTO).
- B. This AOO is issued upon the termination of the Memorandum of Understanding (MOU), dated March 29, 2000, between the U.S. Department of Commerce and the USPTO, and the clarification and incorporation of its provisions, as appropriate, into this AOO.

**II. APPOINTMENT AND GENERAL AUTHORITY OF DIRECTOR AND  
COMMISSIONERS**

- A. On November 29, 1999, the President signed into law the Patent and Trademark Office Efficiency Act (PTOEA), which establishes the USPTO as an agency of the United States, within the Department of Commerce.
- B. The Under Secretary is appointed by the President, by and with the advice and consent of the Senate, and reports to the Secretary of Commerce (the Secretary) with respect to policy matters. The Under Secretary, as established by 35 U.S.C. § 3, is responsible for providing policy direction and management supervision for the USPTO and the issuance of patents and registration of trademarks, and for consulting with the Patent Public Advisory Committee and the Trademark Public Advisory Committee.
- C. The Under Secretary will be assisted by the Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office (Deputy Under Secretary) who will act in the capacity of the Under Secretary in the event of the absence or incapacity of the Under Secretary. The Deputy Under Secretary is appointed by the Secretary upon consideration of individuals nominated by the Under Secretary.
- D. If the position of the Under Secretary is vacant, the Deputy Under Secretary will serve as Acting Under Secretary. If both the Under Secretary and the Deputy Under Secretary positions are vacant, the Commissioner for Patents and the Commissioner for Trademarks, in that order, will perform the functions and duties of the Under Secretary. In the event there is no Commissioner appointed under 35 U.S.C. § 3(b)(2), the Administrator for External Affairs, the Chief Financial Officer and Chief Administrative Officer or General Counsel of the USPTO, in order of length of service in those positions, will perform the functions and duties of the Under Secretary.

- E. In the event of the absence of the Under Secretary, the Deputy Under Secretary will serve as the Acting Under Secretary. In the event of the absence of the Under Secretary and Deputy Under Secretary, the following officials may be designated to perform the functions and duties of the Under Secretary: the Commissioner for Patents; the Commissioner for Trademarks; the Administrator for External Affairs; the Chief Financial Officer and Chief Administrative Officer; or the General Counsel for USPTO.
- F. A Commissioner performing the functions and duties of the Under Secretary will not assist the Secretary in evaluating the performance of the Commissioners.
- G. The Secretary will appoint a Commissioner for Patents and a Commissioner for Trademarks, each of who will serve for a five-year term. The Secretary may reappoint a Commissioner to subsequent five-year terms in accordance with PTOEA.
- H. The Under Secretary will appoint such other officers, employees and agents of the Office as deemed necessary to carry out the functions of USPTO.
- I. In accordance with the Act and Title 35, U.S.C., in carrying out its functions, USPTO will be subject to the policy direction of the Secretary, but otherwise will retain responsibility for decisions regarding the management and administration of its operations and will exercise independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions, in accordance with applicable provisions of the law.
- J. USPTO will have a Patent Public Advisory Committee and a Trademark Public Advisory Committee. The Secretary will appoint nine members to each committee who will serve at the pleasure of the Secretary. The Secretary will designate a chair of each Advisory Committee, each of whom will serve for a three-year term. In addition to the voting members, each Advisory Committee will include a representative of each labor organization recognized by USPTO.
- K. The Under Secretary will consult with the Patent Public Advisory Committee on a regular basis on matters relating to the patent operations of USPTO, will consult with the Trademark Public Advisory Committee on a regular basis on matters relating to the trademark operations of USPTO, and will consult with the respective Public Advisory Committee before submitting budgetary proposals to the Office of Management and Budget or changing or proposing to change patent or trademark user fees or patent or trademark regulations which are subject to the requirement to provide notice and opportunity for public comment under Title 5, U.S.C. § 553, as the case may be.

### **III. SPECIFIC AUTHORITIES**

- A. Pursuant to the authority vested in the Secretary and the Under Secretary by law, and in recognition of USPTO's responsibility for decisions regarding management and

administration of its operations and its independent control of its budget allocations and expenditures, personnel decisions and processes, procurements, and other administrative and management functions in accordance with the Act and applicable provisions of law, the Under Secretary will exercise the responsibilities relating to USPTO operations and functions including:

1. The functions prescribed by 17 U.S.C. § 914 regarding the privilege of foreign national, domiciliaries, and sovereign authorities to make interim registrations for mask works pursuant to Chapter 9 of Title 17 and by Executive Order (E.O.) 12504 regarding regulations for the presentation to the President of requests for issuance of proclamations described in such Chapter;
2. The functions, other than the appointment of Commissioners, prescribed for the Secretary by 35 U.S.C. § 3(b)2, including recommendation of Commissioners for the Secretary to appoint, formulation of the annual performance plans for the Commissioners, supervision of the Commissioners, and evaluation of the Commissioners with prompt notice to the Secretary of the evaluations;
3. The functions, other than appointment of members and designation of chairs, prescribed for the Secretary by 35 U.S.C. § 5, including recommendation of public advisory committee members for the Secretary to appoint, recommendation of public advisory committee chairs for the Secretary to designate, and provision of such support to the public advisory committees as required by statute or otherwise as the Under Secretary deems appropriate;
4. The functions prescribed for the Secretary by Chapter 17 of Title 35, U.S.C., except for the appellate function under 35 U.S.C. § 181 (see DOO 10-6, "Office of the General Counsel," §4.01i);
5. Except as otherwise specified herein, the Director will exercise the following administrative and management responsibilities:
  - a. Performing the responsibilities of agency head pertaining to USPTO, including the following examples:
    - i. 31 U.S.C. § 3325(a) regarding the certification of vouchers for disbursement of government funds;
    - ii. Any procurement-related authority;
    - iii. Title 5, U.S.C. (Government Organization and Employees);
    - iv. Title 40, U.S.C. (Public Buildings, Property, and Works);
    - v. Title 41, U.S.C. (Public Contracts); and



- vi. Title 44, U.S.C. (Public Printing and Documents);
- b. Carrying out responsibilities under Title VI of the Civil Rights Act of 1964, the Equal Employment Opportunity Act of 1972 and all applicable statutes, E.O.s, and regulatory provisions;
- c. Carrying out responsibilities under:
  - i. The Federal Advisory Committee Act (5 U.S.C. Appendix 2);
  - ii. The Privacy Act (5 U.S.C. § 552a) and implementing directives of the General Services Administration and the Office of Management and Budget;
  - iii. The Budget and Accounting Procedures Act of 1950, subject to §3.01f, below;
  - iv. The CFO Act of 1990;
  - v. The Government Management Reform Act of 1994, P.L. 103-356;
  - vi. The Government Performance and Results Act of 1993 (P.L. 103-62);
  - vii. The Federal Records Act;
  - viii. The Government Paperwork Elimination Act;
  - ix. The Paperwork Reduction Act of 1995 (P.L. 104-13);
  - x. OMB Circular A-130, "Management of Federal Information Resources;" and Sections 5 and 6 of the Computer Security Act of 1987 (P.L. 100-235) regarding Federal computer systems security training, identification of systems containing sensitive information, and a plan for computer system security and privacy;
  - xi. The Freedom of Information Act (5 U.S.C. § 552);
  - xii. 30 U.S.C. §§ 351-359 and 40 U.S.C. §§ 319-319c, regarding granting easements and other rights of access to real property, or consenting to the lease of mineral rights;
  - xiii. The Competition in Contracting Act (part of P.L. 98-369);

- xiv. E.O. 12088 regarding compliance with pollution control standards at USPTO facilities;
- d. Exercising responsibilities regarding finance, accounting, fiscal management, budgeting, and planning, subject to § III(B)(6), below;
- e. Procuring real or personal property or goods and services of any kind by USPTO under any Federal law, regulation, directive or order;
- f. Performing the responsibilities for managing any real property USPTO may acquire, lease, purchase, or acquire responsibility in, including environmental compliance reports;
- g. Developing and issuing agency administrative orders, policies, standards and procedures for administrative functions in USPTO;
- h. Providing publications and printing, (e.g. micropublishing, design, graphics, editorial, promotional, distribution, and publishing control), library, mail, messenger, and distribution services for USPTO;
- i. Managing USPTO computer services and electronic mail systems and coordinating with DOC to ensure interoperability;
- j. Monitoring, overseeing, reviewing, managing, maintaining, procuring, or evaluating of USPTO Information Technology (“IT”) programs, performance, risks, acquisitions, initiatives, resources, personnel, training, or management;
- k. Setting goals for improving the efficiency or effectiveness of USPTO IT operations;
- l. Approving strategic and operational information technology plans and developing information technology policies and procedures, including security;
- m. Managing and maintaining USPTO IT systems for administrative and program management including property and procurement management systems;
- n. Protecting USPTO’s assets, operations and personnel;
- o. Managing USPTO’s programs for safeguarding national security information (E.O. 12958), C-1 personnel security (E.O.s 10450 and 12968), national industrial security (E.O.s 10865 and 12829), physical

facility security, and other programs for protecting USPTO's assets, operations, and personnel;

- p. Carrying out responsibilities regarding special studies, reports, technical information, and other related functions under 15 U.S.C. §§ 525-1527 (P.L. 91-412);
- q. Ensuring USPTO compliance with:
  - i. The provisions of the Federal Managers Financial Integrity Act of 1982 (P.L. 97-255) and acting as the designated senior official for the implementation of OMB Circular A-123, "Internal Control Systems," and OMB Circular A-127, "Financial Management Systems;"
  - ii. The Drug-Free Work Place Act (P.L. 100-690) and the procurement integrity provisions of the Office of Federal Procurement Policy Act Amendments of 1988 (P.L. 100-679);
- r. Establishing policies and procedures for the development and operation of financial management, financial information, and internal control systems;
- s. Providing direction, formulation, analysis, coordination, and implementation of USPTO's financial management policies and procedures;
- t. Developing and issuing policies, standards, measures, and procedures for the issuance of patents and the registration of trademarks, and provide functional appraisal and supervision in the conduct of its functions;
- u. Developing and administering the personnel management policies and programs of USPTO, including the direction, administration, and processing of all matters involving personnel, payroll, and occupational safety and health;
- v. Executing all functions relating to all elements of all USPTO officers' and employees' annual performance plans, rewards and promotions, except for the plans, bonuses, and agreements of the Director, the Deputy Director, the Commissioner for Patents, and the Commissioner for Trademarks;
- w. Developing, implementing, and improving management structures, systems, tools, and practices to achieve the highest degree of management efficiency, operational effectiveness, and economy, and to limit the opportunity for fraud and mismanagement;

- x. Coordinating preparation of national emergency plans and the development of preparedness programs required by E.O. 12656 and Federal Preparedness Circular No. 10; and serving as the PTO's Emergency Coordinator, as required by E.O. 12656.
6. The Director shall have the authority to provide appropriate communication and coordination, when appropriate, with all other agencies and offices of the Federal Government directly on applicable USPTO matters, including as examples, the Office of Management and Budget, subject to the provisions in section III(D) of this Order and the proviso in this paragraph, the Department of the Treasury, the Office of Personnel Management, the General Accounting Office, the General Services Administration, and other Executive Branch or independent agencies; the House Government Operations Committee, the Budget Committees, Appropriations Committees, and Judiciary Committees of the Congress, the Joint Committee on Printing, the Government Printing Office, and other Legislative Branch committees, offices, and agencies. The Director shall transmit the USPTO budget directly to the Office of Management and Budget (OMB), provided, however, that the Director shall first timely provide the Secretary in advance with the proposed USPTO budget in order to receive the Secretary's policy review and direction before USPTO transmits the budget to OMB; and
  7. Such functions under other authorities of the Secretary as are applicable to performing the functions assigned in this Order.
- B. Exercise of the authorities delegated in paragraph A of this section shall be subject to the policy direction, and such functions, powers, duties and responsibilities as are retained by the Secretary, as are set forth in paragraph D, below.
  - C. The Under Secretary may, except as precluded by law or regulation, redelegate the authorities in this section to officers and employees of USPTO, subject to such conditions in the exercise of the delegated authorities as the Secretary or Under Secretary may prescribe.
  - D. Functions, powers, duties, and responsibilities retained by the Secretary, as policy direction or incidental thereto, include:
    1. Policy direction as provided in 35 USC § 1;
    2. The power to accept gifts and bequests on behalf of the USPTO valued at greater than \$25,000;
    3. USPTO shall remain subject to the oversight responsibilities of the Inspector General;
    4. Legal services related to the following:

- a. Legislation and matters related thereto, as provided in Departmental Organizational Order 10-6 as in effect on the date of this agreement;
- b. Review of regulations subject to the following procedures:
  - i. USPTO shall notify the DOC Office of the General Counsel of all planned rulemaking activity in a timely manner,
  - ii. The DOC Office of the General Counsel may review any rulemaking that it, the USPTO, or the Office of Management and Budget determines to be significant or to implicate policy matters, and
  - iii. The USPTO may otherwise promulgate rules relating to agency management or personnel, agency organization, agency procedures or practices, or public property, benefits, or contracts without further review;
- c. Authorities of the Secretary provided in Chapter 40 of title 15, U.S.C., except with regard to:
  - i. The use of undesignated general gift funds;
  - ii. The conduct of studies, reports, technical information, and other related functions under 15 U.S.C. § 1525 (first paragraph) et seq.; and
  - iii. Review of joint projects under the 15 U.S.C. § 1525 (second paragraph) et seq.;
- d. Appellate liaison with the Civil Appellate Section of the United States Department of Justice regarding all appeals of court litigation including litigation for which USPTO otherwise is responsible;
- e. All functions of the Department's Designated Agency Ethics Official (DAEO) and agency-head review of all ethics-related collective bargaining agreements or portions thereof, and any ensuing litigation due to the agency-head review, except as USPTO is authorized by statute or other authority to have its own DAEO;
- f. Department-wide and other litigation which may affect USPTO as an operating unit of the Department as well as other operating units of the Department;

- g. Gifts, other than the use of undesignated gift funds;
- h. Review of Department Organization Orders and Department Administrative Orders;
- i. Restrictions on expenditures intended or designed to influence Congress on legislation;
- j. Qui tam actions;
- k. Advice on grand jury and Congressional investigations.

E. Payment for Services

1. After fiscal year 2002, the USPTO shall make reimbursements for services provided by the Department into the Working Capital Fund, the Advances and Reimbursements Fund, or other Departmental funds as may be necessary to support the Secretary's policy direction of USPTO and other functions, powers, duties, and responsibilities retained by the Secretary.
2. In fiscal year 2001, the USPTO shall enter into agreements with the Department for services valued at not less than \$5.6 million, subject to the availability of funds. In fiscal year 2002, the USPTO shall enter into agreements with the Department for services valued at not less than \$2.3 million, subject to the availability of funds.
3. Except as provided in subsection (E)(1) of this section, after fiscal year 2002, USPTO shall receive services from the Department on the basis of mutual agreements entered into under authority of 35 U.S.C. § 2(b)(5), and shall reimburse the Department for services received according to the terms of such agreements.
4. USPTO may enter into agreements under authority of 35 U.S.C. § 2(b)(5) to use services, equipment, personnel, and facilities of other departments, agencies, and instrumentalities of the Federal Government, on a reimbursable basis.

**IV. FUNCTIONS**

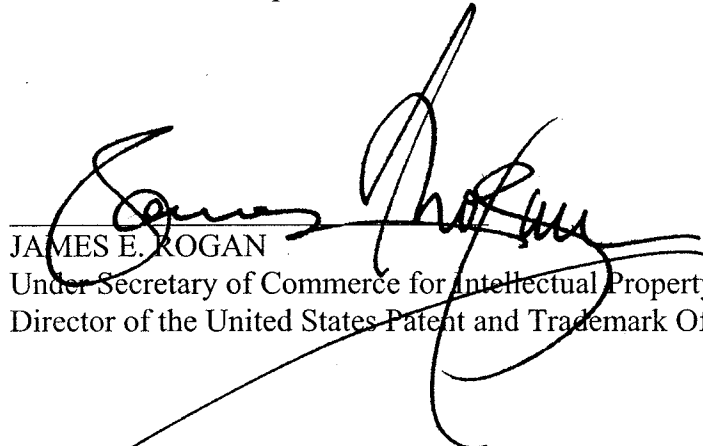
The Under Secretary performs the following functions:

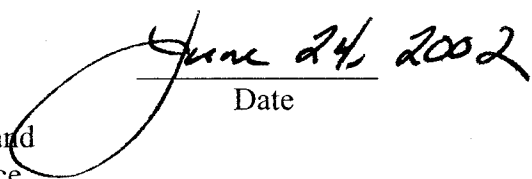
- Administers the laws relating to the granting and issuing of patents;
- Administers the laws relating to the registration of trademarks;
- Administers the laws relating to the dissemination to the public of information with

- F. Conducts cooperative programs with nongovernmental organizations, foreign intellectual property offices and international intergovernmental organizations;
- G. Serves as focal point within the Department and is prepared, when requested by appropriate authority and subject to the policy direction of the Secretary, to serve as spokesperson for the Executive Branch on the broad range of domestic and international intellectual property issues confronting the Nation; and
- H. Performs other functions required or deemed necessary and proper by the Under Secretary in exercising the authority delegated herein.

V. **EFFECT ON OTHER ORDERS**

This AOO supersedes the Memorandum of Understanding (MOU), dated March 29, 2000, between the U.S. Department of Commerce and the USPTO.

  
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JAMES E. ROGAN  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

  
\_\_\_\_\_  
Date