

No. 19-1475

In the
Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

BIOMARIN PHARMACEUTICAL INC.,

Respondent.

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

PETITIONER'S REPLY BRIEF

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES.....	ii
PETITIONER’S REPLY BRIEF	1
I. The Federal Circuit’s Refusal to Apply <i>Arthrex</i> ’s Change in Law Is a Recurring Issue that Warrants This Court’s Review.....	3
II. The Director’s Delegation of Institution Authority to Administrative Patent Judges Acting as Principal Officers Is an Exceptionally Important Issue	6
A. Congress Did Not Sanction the Director’s Departure from Established Administrative Law Principles	6
B. <i>Arthrex</i> Did Not Remedy the Director’s Violation of 35 U.S.C. § 314.....	9
C. The Director’s Delegation of Institution Authority to Principal Officers Should Be Considered Alongside or Held for <i>Arthrex</i>	10
III. The Federal Circuit’s Retreat from Objective Evidence of Nonobviousness Also Warrants Review	11
CONCLUSION	13

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Arthrex, Inc. v. Smith & Nephew, Inc.</i> , 941 F.3d 1320 (Fed. Cir. 2019)	<i>passim</i>
<i>Bedgear, LLC v. Fredman Bros. Furniture Co.</i> , 779 F. App'x 748 (Fed. Cir. 2019), <i>reh'g granted</i> , <i>judgment vacated</i> , 803 F. App'x 407 (Fed. Cir. 2020)	5
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 136 S. Ct. 2131 (2016)	7
<i>Curtis Publ'g Co. v. Butts</i> , 388 U.S. 130 (1967)	4
<i>Demaco Corp. v. F. Von Langsdorff Licensing Ltd.</i> , 851 F.2d 1387 (Fed. Cir. 1988)	12
<i>Ethicon Endo-Surgery, Inc. v. Covidien LP</i> , 812 F.3d 1023 (Fed. Cir. 2016) (Newman, J., dissenting), <i>cert. denied</i> , 137 S. Ct. 625 (2017)	6, 8, 11
<i>Ethicon Endo-Surgery, Inc. v. Covidien LP</i> , 826 F.3d 1366 (Fed. Cir. 2016)	9
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966)	3, 11, 12, 13
<i>Heckler v. Chaney</i> , 470 U.S. 821 (1985)	7

<i>Hormel v. Helvering</i> , 312 U.S. 552 (1941)	4, 10
<i>In re DBC</i> , 545 F.3d 1373 (Fed. Cir. 2008)	4
<i>Martin v.</i> <i>Occupational Safety & Health Review Comm'n</i> , 499 U.S. 144 (1991)	7
<i>Merck Sharp & Dohme Corp. v. Hospira, Inc.</i> , 874 F.3d 724 (Fed. Cir. 2017)	11
<i>SAS Inst. Inc. v. Iancu</i> , 138 S. Ct. 1348 (2018)	2
<i>Stryker Spine v. Biedermann Motech GmbH</i> , 684 F. Supp. 2d 68 (D.D.C. 2010)	4
<i>Trading Techs. Int'l, Inc. v. IBG LLC</i> , 771 F. App'x 493 (Fed. Cir. 2019)	5
<i>Univ. of Tex. Sw. Med. Ctr. v. Nassar</i> , 570 U.S. 338 (2013)	2
<i>Wong Yang Sung v. McGrath</i> , 339 U.S. 33 (1950)	7

Statutes & Other Authorities:

5 U.S.C. § 554(d)	6, 7
5 U.S.C. § 7513(a)	1, 8
35 U.S.C. § 314	9, 10, 11

35 U.S.C. § 314(a)	6
35 U.S.C. § 314(b)	2, 7
35 U.S.C. § 314(d)	7
35 U.S.C. § 316	8
35 U.S.C. § 316(c)	2, 6
35 U.S.C. § 319	7
37 C.F.R. § 42.4(a)	10
157 Cong. Rec. S1377 (daily ed. Mar. 8, 2011)	7
Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(a), 125 Stat. 284 (2011) (AIA)	2

PETITIONER'S REPLY BRIEF

This Court granted certiorari in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), to review (1) whether Administrative Patent Judges (APJs) are principal officers who must be appointed by the President with the Senate's advice and consent pursuant to the Appointments Clause; and (2) whether, if APJs 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) for those judges. 592 U.S. __ (Oct. 13, 2020) (Order List). These same questions implicate Duke's petition. And Duke's petition raises additional recurrent questions of exceptional importance that should be considered alongside this Court's review of *Arthrex*, or at least held for further consideration until after *Arthrex* is decided.

The Federal Circuit's holding in *Arthrex* was an intervening change in law while Duke's appeal was still pending. Nevertheless, the court refused to apply it here. Respondent urges this Court to excuse the Federal Circuit's misapplication of forfeiture because, according to Respondent, Duke should have predicted the change before it happened. But Respondent is incorrect in both its premises and conclusion—clairvoyance has never been a prerequisite for invoking a constitutional protection, and the Federal Circuit *rejected* the same Appointments Clause challenge at least twice before deciding *Arthrex*.

The problems with APJs acting as principal officers are not limited to the Appointments Clause violation that this Court will review in *Arthrex*. In

enacting the Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 6(a), 125 Stat. 284, 300, 303 (2011) (AIA), Congress deliberately created a bifurcated process—sole authority to *institute* inter partes reviews rests with the Director, 35 U.S.C. § 314(b), while the authority to *conduct* them rests with the Patent Trial and Appeal Board (Board), 35 U.S.C. § 316(c). Notwithstanding these plainly delineated roles, the Director has surrendered his institution authority to the Board, where APJs acting as principal officers decide institution outside of the Director’s ability to “review, vacate, or correct.” *Arthrex*, 941 F.3d at 1335. But “[j]ust as Congress[s] choice of words is presumed to be deliberate’ and deserving of judicial respect, ‘so too are its structural choices.’” *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) (quoting *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 353 (2013)). The Director cannot replace Congress’s choice with his own.

Respondent’s only defense of the Director’s *ultra vires* delegation rests on a fundamental misreading of *Arthrex*. According to Respondent, the *Arthrex* court fixed any problem with the Director’s delegation of institution authority by “requiring the Director to appoint a Board member to rehear or reverse any [inter partes review].” BIO 13. But the court did no such thing. What the court actually did was sever Title 5 tenure protections. *Arthrex*, 941 F.3d at 1335-40. And that was no remedy at all—APJs continue to institute inter partes review as principal officers, without Director review. The aggrandizement of both adjudication *and institution* authority with unconfirmed APJs acting as unreviewed principal

officers violates the statute and warrants this Court's review alongside *Arthrex*.

Respondent's opposition to reviewing the third question presented only confirms the need for review. Under this Court's precedent, decision makers must consider objective "indicia" as part of the obviousness inquiry. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). By requiring Duke to prove a negative and show that its commercial success and industry praise were *not* due to all other imaginable factors, the Board's decision—summarily affirmed by the Federal Circuit—treats the fourth *Graham* factor as a meaningless platitude. This Court's intervention is needed to restore objective indicia to its proper place in the obviousness inquiry.

I. The Federal Circuit's Refusal to Apply *Arthrex's* Change in Law Is a Recurring Issue that Warrants This Court's Review

Respondent does not dispute that *Arthrex* "was decided while Duke's appeal was pending," but after Duke filed its opening brief. BIO 3. Nor does Respondent dispute that *Arthrex* literally changed the law, holding that "APJs are principal officers under Title 35 and, as a result, that they must be appointed by the President and confirmed by the Senate" consistent with the Appointments Clause. BIO 6. Under this Court's precedent, it does not matter whether Duke possessed the clairvoyance to raise an Appointments Clause challenge before *Arthrex* actually changed the law—"the mere failure to interpose [a constitutional] defense prior to the announcement of a decision which might support it cannot prevent a litigant from later invoking such a

ground.” *Curtis Publ’g Co. v. Butts*, 388 U.S. 130, 142-43 (1967); *see also Hormel v. Helvering*, 312 U.S. 552, 558-59 (1941) (holding that an exception to the waiver rule exists where “there have been judicial interpretations of existing law after decision below and pending appeal—interpretations which if applied might have materially altered the result”). Yet notwithstanding this Court’s unmistakable exception to forfeiture, the Federal Circuit has refused to apply *Arthrex’s* change in law to pending appeals unless an Appointments Clause challenge was raised in an opening appeal brief. Pet. 16-19.

Respondent contends that the Federal Circuit’s departure from *Curtis* and *Hormel* is justified because “Duke [h]ad [r]easonable [k]nowledge” of the Appointments Clause issue *before* the *Arthrex* decision. BIO 3-5. But this argument fails in every particular. Forfeiture has never turned on whether parties had “[r]easonable [k]nowledge” that a change in law might be coming. And even if it did, the cases Respondent relies on did nothing to signal the unique problem in *Arthrex*—the unconstitutional appointment of APJs to decide patentability under the AIA. *See In re DBC*, 545 F.3d 1373, 1380-81 (Fed. Cir. 2008) (recognizing that Congress had taken remedial action to address a pre-AIA Appointments Clause issue); *Stryker Spine v. Biedermann Motech GmbH*, 684 F. Supp. 2d 68, 88 (D.D.C. 2010) (pre-AIA Appointments Clause issue cured on rehearing by a properly constituted panel).

Not even the Federal Circuit saw this change coming. In fact, the court summarily rejected *the same* Appointments Clause challenge at least twice before

Arthrex. See *Trading Techs. Int'l, Inc. v. IBG LLC*, 771 F. App'x 493 (Fed. Cir. 2019); *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 779 F. App'x 748 (Fed. Cir. 2019), *reh'g granted, judgment vacated*, 803 F. App'x 407 (Fed. Cir. 2020). *Bedgear* in particular shows why Respondent is wrong: it came out one way before *Arthrex* (summarily denying the Appointments Clause claim), and the other way after *Arthrex* (granting rehearing, vacating, and remanding).

According to Respondent, the forfeiture issue is unlikely to reoccur because the Federal Circuit has fixed the Appointments Clause problem by “requir[ing] the Director to appoint a single Board member to hear or rehear any [inter partes review] including appeals.” BIO 6 (citing *Arthrex*, 941 F.3d at 1336). But Respondent misstates the holding of *Arthrex*. While the court of appeals considered allowing the director to appoint a single Board member to hear or rehear any inter partes review, it was ultimately “uncomfortable with such a sweeping change,” and instead severed the APJs removal protections under Title 5. *Arthrex*, 941 F.3d at 1336-38. Even after *Arthrex*, APJs retain their power to issue final written decisions that are unreviewable by any other executive officer, whether or not they have tenure protections.

With this Court’s recent grant of certiorari in *Arthrex* and the potential for additional intervening changes in law, the Federal Circuit’s misapplication of forfeiture remains uncured. As things stand, the Federal Circuit requires parties to predict intervening changes in law before they happen. This Court should grant review to ensure that whatever it decides in

Arthrex applies to parties like Duke with pending appeals who similarly had their patent rights abrogated by unconstitutionally appointed APJs.

II. The Director’s Delegation of Institution Authority to Administrative Patent Judges Acting as Principal Officers Is an Exceptionally Important Issue

A. Congress Did Not Sanction the Director’s Departure from Established Administrative Law Principles

In enacting the AIA, Congress deliberately separated (1) institution decisions from (2) adjudicatory review proceedings that culminate in a final written decision. Indeed, “[t]he bifurcated design of post-grant review is clear not only from the language of [AIA] §§ 314(a) and 316(c), but pervades the structure of these post-grant proceedings. Congress unambiguously placed these separate determinations in different decision-makers, applying different criteria.” *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1036 (Fed. Cir. 2016) (Newman, J., dissenting), *cert. denied*, 137 S. Ct. 625 (2017).

This bifurcated structure is not unique to the AIA—it is a longstanding principle of administrative law. As the *Ethicon* majority recognized, *id.* at 1030 n.3, the Administrative Procedure Act generally precludes the combination of executive and adjudicative functions below the level of agency head. *See* 5 U.S.C. § 554(d) (prohibiting an “employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case” from

“participat[ing] or advis[ing] in the decision”); *Martin v. Occupational Safety & Health Review Comm’n*, 499 U.S. 144, 151 (1991) (“[U]nder the Administrative Procedure Act (APA)[, an agency] generally must divide enforcement and adjudication between separate personnel.” (citing 5 U.S.C. § 554(d))). Congress enacted this provision to “ameliorate the evils from the commingling of functions” by separating the “discretionary work of the administrator,” like “initiat[ing] action,” from the work “of the [administrative] judge.” *Wong Yang Sung v. McGrath*, 339 U.S. 33, 42, 46 (1950) (citation omitted).

Consistent with these core tenets of administrative law, Congress vested sole authority to institute inter partes review with the Director. 35 U.S.C. § 314(b) (“The Director shall determine whether to institute an inter partes review . . .”). Because the Director’s gatekeeping institution decision is discretionary and unreviewable, it is a quintessentially executive function, separate from the Board’s adjudicatory decisions, which are directly appealable to the Federal Circuit. *See* 35 U.S.C. §§ 314(d), 319; *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016). And that is precisely the bifurcated structure that Congress intended. *See* 157 Cong. Rec. S1377 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (explaining that the AIA reflects a legislative judgment that it is better to turn away some petitions that otherwise satisfy the threshold for instituting review than for the Board to develop a backlog); *cf. Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (an agency decision whether to initiate an enforcement action “often involves a complicated balancing of a number of factors,”

including “not only . . . whether a violation has occurred, but whether agency resources are best spent on this violation or another,” whether taking action “best fits the agency’s overall policies,” and “whether the agency has enough resources”).

Notwithstanding Congress’s express intent, the *Ethicon* majority affirmed the Director’s delegation of institution authority to APJs—the same ones who issue final decisions as Board members. *Ethicon*, 812 F.3d at 1031-33. The majority justified the Director’s delegation because the APJs were supposedly “subordinate officers.” *Id.* But *Arthrex* revealed that the majority was wrong—the Director has delegated his institution authority to APJs acting as principal officers that he cannot properly “review, vacate, or correct.” *Arthrex*, 941 F.3d at 1335.

Respondent’s attempts to recast APJs as inferior officers, BIO 7-12, are unavailing for all the reasons stated in *Arthrex* itself. *See Arthrex*, 941 F.3d at 1327-35; Pet. 14-16. While the Director has authority to promulgate regulations governing inter partes review, 35 U.S.C. § 316, and designate certain Board decisions as “precedential” and thus binding on future Board panels, Pet. 15, “[t]here is no provision or procedure providing the Director the power to single-handedly review, nullify or reverse a final written decision issued by a panel of APJs.” *Arthrex*, 941 F.3d at 1329. And before the court of appeals severed the fundamental protections afforded by Title 5, Pet. 23-24, APJs could be removed “only for such cause as will promote the efficiency of the service.” *Arthrex*, 941 F.3d at 1333 (quoting 5 U.S.C. § 7513(a)).

At bottom, the Director’s comingling of institution with merits adjudication in a single body—a Board of APJs acting as unreviewable principal officers—departs from unambiguous congressional intent as well as settled administrative law. Pet. 26-28. Even more, it “imperils the public confidence in the fairness and correctness of these proceedings.” *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 826 F.3d 1366, 1366 (Fed. Cir. 2016) (en banc) (Newman, J., dissenting from denial of reh’g). Left unchecked, it invites other agency heads to flout Congress’s structural choices in the name of convenience.

B. *Arthrex* Did Not Remedy the Director’s Violation of 35 U.S.C. § 314

Respondent does not dispute that it is improper for the Director to delegate institution authority to principal officers operating outside his review. BIO 12-14. Instead, Respondent asserts that any problem with APJs acting as principal officers was remedied when the Federal Circuit required the Director to initiate a new review process. BIO 12-13. Respondent again pins its arguments on a misreading of *Arthrex*. Instead of adding another layer of review, what the court actually did was sever the APJ’s removal protections under Title 5 and remand cases for a new hearing before a different panel of APJs. *Arthrex*, 941 F.3d at 1335-40. Severing Title 5 protections, however, did not make APJs inferior officers, and only created new due process problems. Pet. 23-24. APJs—operating as principal officers outside the Director’s ability to review, nullify, or reverse—*continue* to wield the Director’s authority to institute inter partes review in violation of 35 U.S.C. § 314.

Even if this Court determines that the Federal Circuit's fix was sufficient to recast APJs as subordinates to the Director, *Arthrex* did nothing to cure the problem of *ultra vires* institution decisions that had already occurred. In fact, the court in *Arthrex* erroneously saw no "infirmity in the institution decision as the statute clearly bestows such authority on the Director pursuant to 35 U.S.C. § 314." 941 F.3d at 1340. The court did not analyze all the implications of its holding that APJs were "principal officers," including the effect on the Director's delegation of his institution authority under 37 C.F.R. § 42.4(a).

Respondent's assertions notwithstanding, BIO 7, forfeiture is not an impediment to this Court addressing *ultra vires* institution here. *Arthrex* is a fundamental change in the law that is fatal to the Director's delegation of institution authority to the Board, and Duke timely raised the issue at the first available opportunity. *See Hormel*, 312 U.S. at 558-59; Pet. 12.

C. The Director's Delegation of Institution Authority to Principal Officers Should Be Considered Alongside or Held for *Arthrex*

The Federal Circuit's determination in *Arthrex* that APJs operate as principal officers not only implicates the Appointments Clause, but also the propriety of the Director's delegation of his institution authority. This Court should grant Duke's petition for review alongside *Arthrex*.

At the very least, this Court should hold Duke's petition and defer further consideration until *Arthrex*

is decided. The Federal Circuit has incongruously held that APJs operated as “subordinate officers” at institution, *Ethicon*, 812 F.3d at 1031-33, but as “principal officers” during adjudication, *Arthrex*, 941 F.3d at 1325-35. This Court’s consideration of whether APJs are principal officers will directly bear on whether the Director violated 35 U.S.C. § 314 in delegating his institution authority to them.

III. The Federal Circuit’s Retreat from Objective Evidence of Nonobviousness Also Warrants Review

Respondent tries to recast Duke’s petition as asking this Court to engage in fact-bound error correction. BIO 14-22. But Duke is simply asking for a return to the correct legal standard for assessing objective evidence of nonobviousness outlined by this Court in *Graham*. Pet. 28-33. Here, the Board’s entire obviousness analysis—including its consideration of objective indicia—was infected by its erroneous requirement that Duke prove a negative.

In particular, the Board refused to credit compelling objective evidence simply because Duke did not parse “the impact of the ’712 patent, as compared to other relevant patents,” on licensing, commercial success, and industry praise. Pet. App. 24a-25a. But as previous Federal Circuit panels have recognized, objective evidence can be simultaneously linked to commercial products with multiple patents. *See, e.g., Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 730-31 (Fed. Cir. 2017) (“[M]ultiple patents do not necessarily detract from evidence of commercial success of a product or process, which speaks to the *merits of the invention*, not to how many

patents are owned by a patentee.”). The alternative—requiring a patentee to prove that the commercial success of a product is *not* due to a different patent—is unworkable. Indeed, “[a] requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence.” *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1394 (Fed. Cir. 1988).

Respondent has no answer to this settled law. Instead, Respondent alleges that Duke waived its nexus argument. BIO 17-19. But that allegation is belied by the Federal Circuit’s express acknowledgment that “Duke’s objections to the Board’s treatment of its evidence of objective indicia of non-obviousness—including its failure to apply a presumption of nexus—appear well taken.” Pet. App. 54a n.2. Simply put, the nexus issue was squarely before the Board and the Federal Circuit in both appeals. Pet. 8-11.

Duke presented un rebutted evidence showing that the use of Myozyme and Lumizyme practice the method of claim 9. Pet. 7-9, 30. And that should have been enough for the Board to credit Duke’s objective evidence. *See Demaco*, 851 F.2d at 1394 (“It is sufficient to show that the commercial success was of the patented invention itself.”). Respondent’s conjecture that Duke’s objective evidence would not have made a difference anyway, BIO 19-22, disregards the important role that such evidence plays in preventing decision makers from “slipping into use of hindsight.” *Graham*, 383 U.S. at 36 (citation omitted). This Court should grant review to

restore the fourth *Graham* factor to its proper role in the obviousness analysis.

CONCLUSION

For these reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

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