

No. 19-1475

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IN THE  
**Supreme Court of the United States**

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DUKE UNIVERSITY,

*Petitioner,*

*v.*

BIOMARIN PHARMACEUTICAL INC.,

*Respondent.*

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED  
STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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**BRIEF IN OPPOSITION**

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## **QUESTIONS PRESENTED**

1. Whether a party forfeits its right to raise an alleged Appointments Clause violation when the party did not raise the issue until after the Court of Appeals for the Federal Circuit entered a judgment of affirmance under Fed. Cir. R. 36 of a decision of the Patent Trial and Appeal Board.
2. If the answer to Question 1 is “No,” whether the United States Patent and Trademark Office Director’s delegation of authority to institute inter partes reviews to administrative patent judges infringes upon Due Process and violates 35 U.S.C. § 314.
3. Whether a company that owns a patent that allegedly covers a product which enjoys commercial success is entitled to a presumption of nexus and therefore does not need to address issues raised by a patent challenger regarding lack of nexus between the patent and the commercial success.

**RULE 29.6 STATEMENT**

Respondent BioMarin Pharmaceutical Inc. states that it has no parent corporation and that no publicly held company owns 10% or more of its stock.

**TABLE OF CONTENTS**

	<i>Page</i>
QUESTIONS PRESENTED .....	i
RULE 29.6 STATEMENT .....	ii
TABLE OF CONTENTS.....	iii
TABLE OF CITED AUTHORITIES .....	vi
INTRODUCTION.....	1
REASONS FOR DENYING THE WRIT .....	2
I. Duke Forfeited Its Right to Raise a Violation of the Appointments Clause.....	2
A. Appointments Clause Challenges Are Waived If Not Timely Presented .....	2
B. Duke Had Reasonable Knowledge of the Appointments Clause Argument, Such That It Does Not Constitute an “Intervening Change of the Law”.....	3
C. The Forfeiture Issue Raised by Duke is Not Likely to Reoccur .....	5
1. <i>Arthrex</i> Remedied Any Appointments Clause Issue So That APJs Are Now Operating as Inferior Officers .....	5

*Table of Contents*

	<i>Page</i>
2. Patent Owners Having Their Patents Challenged Now Know About Any Appointments Clause Issues. . . . .	7
II. APJs Were Not Unconstitutionally Appointed . . .	7
A. The Director and Secretary of Commerce Exercise a Form of Removal Power Over the APJs . . . . .	7
B. Even if There Were a Finding of Insufficient Removal Power, Severability Remedies the Issue. . . . .	10
C. The Director and Secretary of Commerce Also Have Sufficient Supervision Over APJs. . . . .	10
D. The Director’s Delegation of Institution Authority to APJs Does Not Violate 35 U.S.C. § 314 or Due Process of Law . . . . .	12
III. The Federal Circuit’s Affirmance of the PTAB’s Obviousness Determination Correctly Resolved a Patent-Specific Factual Question That Does Not Warrant This Court’s Review. . . . .	14

*Table of Contents*

	<i>Page</i>
A. Duke Mischaracterizes the Proceedings Below Regarding What Needed to be Proven to Maintain to Maintain the Patent . . . . .	15
B. Duke Waived Its Arguments Regarding Presumption of Nexus at the PTAB and Cited New Evidence at the Federal Circuit Regarding Commercial Success . . . . .	17
C. Duke Failed to Address or Insufficiently Addressed Critical Issues Raised by BioMarin Regarding Commercial Success of the Duke Invention. . . . .	19
IV. Maintaining This Patent Would Give Duke an Undeserved Extension of Its Monopoly on Important Drugs . . . . .	22
CONCLUSION . . . . .	23

**TABLE OF CITED AUTHORITIES**

	<i>Page</i>
<b>Cases</b>	
<i>Arthrex, Inc. v. Smith &amp; Nephew, Inc.</i> , 941 F.3d 1320 (Fed. Cir. 2019), <i>reh'g denied</i> , 953 F.3d 760 (Fed. Cir. 2020) . . . <i>passim</i>	
<i>Ayotte v. Planned Parenthood</i> , 546 U.S. 320 (2006) . . . . .	6
<i>Brown v. Dep't of the Navy</i> , 229 F.3d 1356 (Fed. Cir. 2000) . . . . .	9
<i>Crowell v. Benson</i> , 285 U.S. 22 (1932) . . . . .	9
<i>Curtis Pub. Co. v. Butts</i> , 388 U.S. 130 (1967) . . . . .	3
<i>Customedia Techs., LLC v. Dish Network Corp.</i> , 941 F.3d 1174 (Fed. Cir. 2019) . . . . .	3
<i>Edmond v. United States</i> , 520 U.S. 651 (1997) . . . . .	<i>passim</i>
<i>Ethicon Endo-Surgery, Inc. v. Covidien LP</i> , 812 F.3d 1023 (Fed. Cir. 2016), <i>cert. denied</i> , 137 S. Ct. 625 (2017) . . . . .	12
<i>Free Enter. Fund v.</i> <i>Pub. Co. Accounting Oversight Bd.</i> , 561 U.S. 477 (2010) . . . . .	6, 9, 10

*Cited Authorities*

	<i>Page</i>
<i>Fresenius USA, Inc. v. Baxter Int'l, Inc.</i> , 582 F.3d 1288 (Fed. Cir. 2009) .....	18
<i>Freytag v. Commissioner</i> , 501 U.S. 868 (1991) .....	2
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1966) .....	15, 19, 21
<i>Hooper v. California</i> , 155 U.S. 648 (1895) .....	9
<i>Hormel v. Helvering</i> , 312 U.S. 552 (1941) .....	3
<i>In re DBC</i> , 545 F.3d 1373 (Fed. Cir. 2008) .....	4
<i>In re Mouttet</i> , 716 F. App'x 984 (Fed. Cir. 2017) .....	11
<i>In re Watts</i> , 354 F.3d 1362 (Fed. Cir. 2004) .....	17, 18
<i>Intercollegiate Broad. Sys. v.</i> <i>Copyright Royalty Bd.</i> , 684 F.3d 1332 (D.C. Cir. 2012) .....	10
<i>James B. Beam Distilling Co. v. Georgia</i> , 501 U.S. 529 (1991) .....	3, 4



*Cited Authorities*

	<i>Page</i>
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007) . . . . .	19, 20, 21, 22
<i>Masias v. Sec’y of HHS</i> , 634 F.3d 1283 (Fed. Cir. 2011) . . . . .	10
<i>Meds. Co. v. Mylan Inc.</i> , No. 11-cv-1285, 2014 U.S. Dist. LEXIS 38714 (N.D. Ill. Mar. 25, 2014) . . . . .	22
<i>Nat’l Fed’n of Indep. Bus. v. Sebelius</i> , 567 U.S. 519 (2012) . . . . .	9
<i>Newell Cos. v. Kenney Mfg. Co.</i> , 864 F.2d 757 (Fed. Cir. 1988) . . . . .	21
<i>Novartis AG v. Torrent Pharms. Ltd.</i> , 853 F.3d 1316 (Fed. Cir. 2017) . . . . .	17
<i>Pers. Audio, LLC v. CBS Corp.</i> , 946 F.3d 1348 (Fed. Cir. 2020) . . . . .	3
<i>Smartdoor Holdings, Inc. v. Edmit Indus., Inc.</i> , 707 F. App’x 705 (Fed. Cir. 2017) . . . . .	19
<i>Spokane Cty. v. Air Base Hous., Inc.</i> , 304 F.2d 494 (9th Cir. 1962) . . . . .	3
<i>Stryker Spine v. Biedermann Motech GmbH</i> , 684 F. Supp. 2d 68 (D.D.C. 2010) . . . . .	4

*Cited Authorities*

	<i>Page</i>
<i>Therasense, Inc. v. Becton, Dickinson and Co.</i> , 593 F.3d 1289 (Fed. Cir. 2010) .....	22
<i>Uniloc 2017 LLC v. Facebook, Inc.</i> , 783 F. App'x 1020 (Fed. Cir. 2019) .....	4, 5
<i>Vandenbark v. Owens-Illinois Glass Co.</i> , 311 U.S. 538 (1941) .....	3

**Statutes**

5 U.S.C. § 7513(a) .....	9
35 U.S.C. § 2(b) .....	11
35 U.S.C. § 3(a) .....	11
35 U.S.C. § 3(a)(2)(A) .....	11
35 U.S.C. § 3(b)(3)(B) .....	14
35 U.S.C. § 3(c) .....	9
35 U.S.C. § 6 .....	9, 11
35 U.S.C. § 6(c) .....	9, 12
35 U.S.C. § 143 .....	11
35 U.S.C. § 314 .....	12, 14

*Cited Authorities*

	<i>Page</i>
35 U.S.C. § 314(a).....	12
35 U.S.C. § 314(b).....	12
35 U.S.C. § 316(a)(4).....	11
35 U.S.C. § 318(b).....	12
 <b>Other Authorities</b>	
John F. Duffy, <i>Are Administrative Patent Judges Unconstitutional?</i> 2007 PATENTLY-O PAT. L.J. 21 (2007) .....	5
Patent Trial and Appeal Board, Standard Operating Procedure 2 (10th rev. Sept. 20, 2018).....	11
 <b>Rules</b>	
37 C.F.R. § 42.4(a) .....	12
Fed. Cir. R. 36 .....	1, 15, 20
Sup. Ct. R. 10 .....	2, 16
Sup. Ct. R. 15.2 .....	15
 <b>Constitutional Provisions</b>	
U.S. CONST. art. II, § 2, cl. 2 .....	4, 8

## INTRODUCTION

Respondent BioMarin Pharmaceutical Inc. (“BioMarin”) submits this Brief in Opposition to the Petition for Writ of Certiorari filed by Petitioner Duke University (“Duke”). This case originated at the Patent Trial and Appeal Board (“PTAB” and/or “Board”) at the United States Patent and Trademark Office (“USPTO”) when a Petition for *Inter Partes* Review (“IPR”) was filed in 2013 against U.S. Patent No. 7,056,712 (the “’712 Patent”). The inventor of the ‘712 Patent is Dr. Yuan-Tsong Chen (“Dr. Chen”). CA-Appx146. The case on appeal involves only claim 9 of the ‘712 Patent. In a Final Written Decision issued in February 2015, the PTAB held that claim 9 was obvious over a combination of several references. Pet. Appx. 130a. In the Final Written Decision, the PTAB also held that other claims of the ‘712 Patent were unpatentable over prior art. Pet. Appx. 132a. Duke appealed the Final Written Decision to the United States Court of Appeals for the Federal Circuit (“Federal Circuit”). The Federal Circuit the decision as to most claims and reversed and remanded as to claim 9, on the basis that claim 9 had been improperly interpreted by the PTAB. The Federal Circuit instructed the PTAB to reconsider the patentability of claim 9 under the proper claim construction. Pet. Appx. 51a, 54a.

In a Supplemental Final Written Decision (“SFWD”) issued in January 2018, the PTAB again held that claim 9 was unpatentable, this time using the proper claim construction. Pet. Appx. 31a. After a second appeal to the Federal Circuit, including full briefing and oral arguments by the parties, the Federal Circuit affirmed the SFWD in a per curiam decision under Fed. Cir. R. 36. Pet. Appx.

1a. After the per curiam decision, Duke for the first time raised an Appointments Clause challenge in a Petition for Rehearing. The Petition for Rehearing was denied and Duke subsequently filed a Petition for Writ of Certiorari (“Petition”) to this Court.

### **REASONS FOR DENYING THE WRIT**

BioMarin submits that the writ should be denied for the following reasons.

#### **I. Duke Forfeited Its Right to Raise a Violation of the Appointments Clause**

This Court should not accept certiorari as to Question 1 (forfeiture) presented by Duke. Duke has not presented any “compelling reasons,” as required by Sup. Ct. R. 10, as to why this Court should consider this question.

##### **A. Appointments Clause Challenges Are Waived If Not Timely Presented**

According to precedent, Duke forfeited or waived its right to raise an Appointments Clause challenge. The Federal Circuit has held that “Appointments Clause challenges are ‘nonjurisdictional structural constitutional objections’ that can be waived when not presented.” *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320, 1340 (Fed. Cir. 2019), *reh’g denied*, 953 F.3d 760 (Fed. Cir. 2020) (quoting *Freytag v. Commissioner*, 501 U.S. 868, 878-79 (1991)). Several subsequent decisions have echoed this rejection of a patent owner’s attempt to raise Appointments Clause challenges based on *Arthrex*. In a precedential per curiam order, for example, a panel of

the Federal Circuit ruled that an Appointments Clause challenge under *Arthrex* is forfeited if it is not raised in a party's opening brief. See *Customedia Techs., LLC v. Dish Network Corp.*, 941 F.3d 1174, 1175 (Fed. Cir. 2019). This holding was reaffirmed in *Pers. Audio, LLC v. CBS Corp.*, 946 F.3d 1348, 1351 n.1 (Fed. Cir. 2020). Since Duke did not raise the Appointments Clause challenge in its opening brief, Duke forfeited its right to have this constitutional challenge heard.

**B. Duke Had Reasonable Knowledge of the Appointments Clause Argument, Such That It Does Not Constitute an “Intervening Change of the Law”**

Duke bases its opposition to the general idea that Appointments Clause challenges must be raised by a party in their opening brief, citing *Arthrex* which was decided while Duke's appeal was pending. Duke incorrectly argues that application of this forfeiture ruling would prevent parties from benefitting from “intervening change[s] of law” (Pet. 20-21) an exception carved out to the rule of waiver by this Court (see e.g., *Hormel v. Helvering*, 312 U.S. 552, 557-59 (1941); *Vandenbark v. Owens-Illinois Glass Co.*, 311 U.S. 538, 541 (1941); *Spokane Cty. v. Air Base Hous., Inc.*, 304 F.2d 494 (9th Cir. 1962)) and that this Court has held that failure to bring a constitutional defense before a decision is issued that might support the defense “cannot prevent a litigant from later invoking such a ground.” *Curtis Pub. Co. v. Butts*, 388 U.S. 130, 143 (1967). Duke cites *James B. Beam Distilling Co. v. Georgia* to support its proposition that the general forfeiture rule should be foregone here. Pet. 2. However, *James B. Beam Distilling* dealt with the issue of retroactivity,

not forfeiture. The plaintiff in *James B. Beam Distilling* was looking to collect a refund on his taxes because the previous state liquor tax law was found to violate the Commerce Clause. *James B. Beam Distilling Co. v. Georgia*, 501 U.S. 529, 533 (1991). The policy in *James B. Beam Distilling* is for situations in which a party raises a claim for remedies in response to a change of law. Duke is essentially maintaining the holding in *James B. Beam Distilling* should be extended to the present case. See Pet. 21 (“[t]he Court’s rule against applying forfeiture where there is an intervening change of law exists for precisely this scenario—a constitutional decision that upends the legal landscape”). However, the jurisprudence of a party neglecting to timely bring a claim and thereby forfeiting the issue is well-known, subjected to public commentary, and pleaded and briefed by others.

Duke’s position might be somewhat plausible if *Arthrex* was the only case that considered the validity of the appointment of Administrative Patent Judges (“APJs”) in light of the Appointments Clause. The Appointments Clause has been available for constitutional challenges to the appointment of APJs long before the Federal Circuit’s decision in *Arthrex* and has not changed since the drafting of the Constitution. U.S. CONST. art. II, § 2, cl. 2. Challenges under the Appointments Clause have been heard at the Federal Circuit and other courts multiple times, from at least 2008. See, e.g., *In re DBC*, 545 F.3d 1373, 1377-78 (Fed. Cir. 2008); *Stryker Spine v. Biedermann Motech GmbH*, 684 F. Supp. 2d 68, 80-88 (D.D.C. 2010). Additionally, it should be noted that *Uniloc*, which was decided the same day as *Arthrex*, obtained a remedy consistent with *Arthrex* because it had raised the Appointments Clause challenge in its opening brief. See

*Uniloc 2017 LLC v. Facebook, Inc.*, 783 F. App'x 1020 (Fed. Cir. 2019). *Uniloc* independently raised an Appointments Clause challenge without knowing the outcome of *Arthrex*. Duke could have done the same. Further, the issue of using the Appointments Clause to challenge the constitutionality of the appointment of APJs has been discussed among scholars and patent professionals since at least 2007. *See, e.g.*, John F. Duffy, *Are Administrative Patent Judges Unconstitutional?* 2007 PATENTLY-O PAT. L.J. 21 (2007).

Given numerous examples of Appointments Clause challenges filed at the Federal Circuit, Duke had reasonable notice of the issues and failed to timely raise them. By having this knowledge, Duke was free to bring its constitutional challenge of the appointment of APJs who presided over the IPR under the Appointments Clause in its opening brief before the Federal Circuit or in a motion filed prior to its opening brief. Duke chose not to raise the argument and cannot raise the issue now.

### **C. The Forfeiture Issue Raised by Duke is Not Likely to Reoccur**

The forfeiture issue raised by Duke should not be heard by this Court because it is not likely to reoccur in the future.

#### **1. *Arthrex* Remedied Any Appointments Clause Issue So That APJs Are Now Operating as Inferior Officers**

The forfeiture issue raised by Duke is not likely to reoccur and therefore this case does not raise an important issue for currently pending or future cases



such that certiorari should be granted. All patent owners are on notice of the constitutional issues related to the appointment of APJs as identified in *Arthrex* and therefore there should be no future challenges of the type Duke is pressing. In addition, the alleged problem with appointment of APJs has been remedied. *Arthrex*, 941 F.3d at 1336. As such, if there was, in fact, a constitutional issue related to the Appointments Clause, the issue no longer exists.

Duke is correct in asserting that *Arthrex* held 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. Pet. 1; *Arthrex*, 941 F.3d at 1335. Because the response to an Appointments Clause violation is remedial, the Federal Circuit required the Director to appoint a single Board member to hear or rehear any IPR including appeals, derivation proceedings, and post grant review. *Arthrex*, 941 F.3d at 1336.

In citing this Court, the Federal Circuit “tr[ie]d to limit the solution to the problem,’ [by] severing any ‘problematic portions and leaving the remainder intact.’” *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 508 (2010) (quoting *Ayotte v. Planned Parenthood*, 546 U.S. 320, 328-29 (2006)). This new process would effectively fix any Appointments Clause issues because even though the APJs would not be subject to at-will removal, their decisions would not be a “final decision on behalf of the United States unless permitted to do so by other executive officers.” *Edmond v. United States*, 520 U.S. 651, 665 (1997). The Federal Circuit held that this method, in conjunction with the other forms of supervision and control exercised over APJs, to be sufficient to render them inferior officers.

## **2. Patent Owners Having Their Patents Challenged Now Know About Any Appointments Clause Issues**

The forfeiture issue raised by Duke is not likely to reoccur because parties appearing before the PTAB now know, or should know, that the Federal Circuit has held that APJs were previously appointed in violation of the Appointments Clause of the Constitution. Following *Arthrex*, the Appointments Clause problem has also been remedied.

## **II. APJs Were Not Unconstitutionally Appointed**

If the Court does not accept certiorari for Question 1, certiorari should not be accepted for Question 2, since Duke forfeited its right to raise this issue. On the merits of Question 2 of Duke, Question 2 assumes that the Federal Circuit in *Arthrex* correctly decided that APJs at the PTAB were not constitutionally appointed. However, it is submitted by BioMarin that *Arthrex* was not correctly decided and the APJs were constitutionally appointed. It is also submitted that this is not a good case to hear this argument because, as discussed above, if there was a problem, Duke forfeited its right to raise the issue. However, even if Duke were permitted to raise this issue now, the underlying Appointments Clause challenge holds no merit.

### **A. The Director and Secretary of Commerce Exercise a Form of Removal Power Over the APJs**

Under the Appointments Clause, principal officers must be appointed by the President with the consent of

the Senate. *See* U.S. CONST. art. II, § 2, cl. 2. However, this same clause permits Congress to “vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.” *Id.* While there is no exclusive criterion to determine whether one is an inferior or principal officer (*Edmond*, 520 U.S. at 661), the Court has concentrated on not only whether inferior officers have a “superior” who “formally maintain[s] a higher rank,” but on whether the officer is one “whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate.” *Id.* at 662-63. The Court has also noted that exercising a form of removal power is a significant control mechanism for purposes of distinguishing between the two types of officers. *Id.* at 664.

In *Edmond*, military judges were determined to be principal officers. *Id.* at 662-63. The Court reached the conclusion based on the level of supervision that the judges received from its Senate-confirmed officers. *Id.* This was achieved through two methods: directing and reviewing the judges’ work and holding the power to remove the judges from their role. *Id.*

The Court relied on the fact that a higher authority “may also remove a . . . judge **from his judicial assignment without cause**” *Id.* at 664 (emphasis added). Thus, the fact that there was some barrier of removal, despite the fact that it was not absolute, was found to be “a powerful tool of control.” *Id.*

The Director of the USPTO and the Secretary of Commerce are both principal officers that have adequate

removal power of APJs for the purposes of *Edmond*. The Director has authority to designate which members of the Board will compose a panel. *See* 35 U.S.C. § 6(c). Thus, the Director has the power to decide which matters an APJ can handle and may even consistently continue to exclude any APJ from a panel, effectively removing them from their position. This mirrors the authority mandated in *Edmonds*, where absolute removal power was not the requisite, but rather some powerful tool of control was.

The Secretary of Commerce, likewise, is able to remove APJs under civil-service standards applicable to federal employees. In an effort to “promote the efficiency of the service” per 5 U.S.C. § 7513(a), the Secretary of Commerce is able to remove APJs for any legitimate reason provided that there is a “nexus between the misconduct and the work of the agency.” *Arthrex*, 941 F.3d at 1333 (quoting *Brown v. Dep’t of the Navy*, 229 F.3d 1356, 1358 (Fed. Cir. 2000)); *see also Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 509 (2010).

APJs are appointed per 35 U.S.C. § 6 and as USPTO officers and employees, are subject “to the provisions of title 5, relating to the Federal employees.” 35 U.S.C. § 3(c). As a result, this Court can avoid any constitutional issue by interpreting Title 5’s “efficiency of the service” standard to allow removal where the Constitution requires. *See, e.g., Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 563 (2012) (“the question is not whether that is the most natural interpretation of the mandate, but only whether it is a ‘fairly possible’ one” (quoting *Crowell v. Benson*, 285 U.S. 22, 62 (1932))); *see also Hooper v. California*, 155 U.S. 648, 657 (1895) (“every reasonable construction must be resorted to, in order to save a statute from unconstitutionality”).

**B. Even if There Were a Finding of Insufficient Removal Power, Severability Remedies the Issue.**

This Court and the D.C. Circuit have invalidated and severed removal provisions with Constitutional defects instead of broadly invalidating the statute. *See Free Enter. Fund* 561 U.S. at 508-09; *Intercollegiate Broad. Sys. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1336-37 (D.C. Cir. 2012) (invalidating statutory removal protections by providing “a remedy that cures the [Appointments Clause] defect with as little disruption as possible”). Although this remedy is unnecessary for the reasons argued above, it is available if this Court finds that the existing removal protection for APJs is inconsistent with the characteristics of inferior officers.

**C. The Director and Secretary of Commerce Also Have Sufficient Supervision Over APJs**

The Director’s supervision over APJs by other means is powerful, which this Court found relevant to the inferior officer analysis. *See Edmond*, 520 U.S. at 664-65. In *Edmond*, this was met in one way by the Judge Advocate’s ability to create procedures for military judges. *Id.* at 664. It was also met through a finding that Senate-confirmed officers had means of supervising the substance as well as the process of the agency’s final decisions. *Id.* at 664-66 (observing the Court of Appeals for the Armed Forces’ ability to reverse certain decisions made by military judges); *Masias v. Sec’y of HHS*, 634 F.3d 1283, 1294-95 (Fed. Cir. 2011) (noting the Court of Federal Claims’ ability to reverse special masters’ decisions).

Congress vested the powers and duties of the USPTO to the Director who is responsible for “providing policy direction and management supervision for the Office.” 35 U.S.C. § 3(a)(2)(A). The Director is thus permitted to create regulations for APJs concerning *inter partes* review (see 35 U.S.C. §§ 2(b), 316(a)(4)), just as the Judge Advocate was able to create regulations for military judges in *Edmond*. Further, the Director can control the substance of the Board’s decisions through the power to provide policy direction for the USPTO. 35 U.S.C. §§ 3(a), 6.

The Director possesses statutory authority over the composition of a Board to form a standing Precedential Opinion Panel of three Board members that can rehear and reverse any Board decision. See Patent Trial and Appeal Board, Standard Operating Procedure 2 (10th rev. Sept. 20, 2018) (“SOP2”) at 1-2, 15. The rehearing decision of this panel becomes binding only with the Director’s agreement. SOP2 at 8. Through this panel, the Director plays a central position in rehearing Board decisions before they become final agency action eligible for review. *Id.*

The Director also has the right to intervene and become a party to subsequent appeals taken from a decision. See 35 U.S.C. § 143. In invoking this right, the Director can explain the Board’s errors and seek remand to reconsider the case consistent with the Director’s view of the laws and facts. See, e.g., *In re Mouttet*, 716 F. App’x 984, 986 (Fed. Cir. 2017) (“[o]n appeal, the PTO’s Director concedes that the Board erred . . . and is not defending” the Board’s decision). Upon remand, the Director is able to issue regulations governing the issues in the case or

could constitute a panel of his choice to rehear the case. Specifically, the statute states that the Board's decision does not go into effect until after an opportunity to appeal, in which the Director could intervene. *See* 35 U.S.C. § 318(b). There is also no barrier to the Director reassigning an individual judge from a particular panel mid-case if he believes the judge is noncompliant with his policy directions. *See* 35 U.S.C. § 6(c).

As a result, the Director's supervisory power is in some ways even greater than the ones the Supreme Court has relied on in previous cases. The Director has authority to issue binding guidance to all of the USPTO on how to interpret the law.

**D. The Director's Delegation of Institution Authority to APJs Does Not Violate 35 U.S.C. § 314 or Due Process of Law**

Duke argues that Congress's express assignment of institution authority to the Director under 35 U.S.C. § 314(a), (b), is inconsistent with the requirement that the Director delegate institution authority to the Board under 37 C.F.R. § 42.4(a). Pet. 25. The Director was previously found permitted to delegate institution authority to subordinate officers (APJs). *See Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1031-33 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017). But now that the Federal Circuit has recognized that they are "principal officers" in *Arthrex*, the delegation of the Director's institution authority to APJs that he could not review, vacate, or correct violates Due Process and 35 U.S.C. § 314. Pet. 26. However, the Federal Circuit has remedied the situation by requiring the Director to appoint a Board

member to rehear or reverse any IPR. *Arthrex*, 941 F.3d at 1336.

For Duke to properly assert this argument, it must be assumed that both (1) *Arthrex* was correctly decided; and (2) the remedy provided by the Federal Circuit was insufficient to cure the problem. Pet. 23. To support this second proposition, Duke mistakenly argues that APJs still retain authority to issue unreviewable decisions in violation of *Edmond* and that Congress would not have chosen to divest APJs removal protections to correct any constitutional infirmity, attempting to support these arguments with the conclusory statement that APJs “continue to adjudicate patent rights in violation of the Appointments Clause.” Pet. 23.

This argument is without merit because, as noted above, APJs act as inferior officers, even prior to the decision in *Arthrex*. But assuming *arguendo* that *Arthrex* was correctly decided and APJs previously acted as principal officers, the Federal Circuit remedied that issue by requiring the Director to appoint a Board member to rehear or reverse any IPR. Duke cites nothing to support the notion that this remedy was not consistent with the Appointments Clause. APJs’ decisions are reviewable. The rehearing decision of the Precedential Opinion Panel becomes binding only with the Director’s agreement. *See* SOP2 at 8. Through this panel, the Director rehears Board decisions before they become final agency action eligible for review. *Id.* If this level of review is not sufficient, the appointment of a Board member of the Director’s choice to rehear cases in conjunction with the panel power is surely sufficient.



Further, there is no indication that the Federal Circuit's remedy is inconsistent with Congressional intent. Congress explicitly granted the Director the power to delegate his duties to other officers and employees as is necessary and may "delegate to them such of the powers vested in the Office as the Director may determine." *See* 35 U.S.C. § 3(b)(3)(B). There is nothing else to infer from this guidance except that Congress trusted the Director with both the ability to act and delegate his statutory powers. The remedy to the Constitutional infirmity requires the Director to do just that: delegate his power to a Board member for reviewing IPRs.

Thus, the Director's delegation to APJs, as inferior officers, is consistent with the Constitution and 35 U.S.C. § 314.

### **III. The Federal Circuit's Affirmance of the PTAB's Obviousness Determination Correctly Resolved a Patent-Specific Factual Question That Does Not Warrant This Court's Review.**

Regarding Question 3 of Duke's Petition, Duke's request for review of the Federal Circuit's obviousness holding does not warrant this Court's review. The Federal Circuit correctly affirmed the PTAB's decision that relied on the specific facts of the case. Duke also failed to sufficiently address the nexus argument raised by BioMarin at both the PTAB and the Federal Circuit. Thus, a nexus between alleged commercial success and the patented invention was not established. Even if nexus was established, commercial success is only one factor in reaching an ultimate conclusion on the issue of obviousness. The Board correctly analyzed all evidence

when making the obviousness determination and this Court does not need to reestablish the role of objective evidence of non-obviousness.

**A. Duke Mischaracterizes the Proceedings Below Regarding What Needed to be Proven to Maintain to Maintain the Patent**

In Question 3, Duke improperly suggests that the PTAB created a “new rule” where “a patentee must first prove the negative that commercial success or industry praise is *not* due to all other imaginable contributing factors,” rendering the fourth *Graham* factor a “dead letter.” Pet. ii, 4.; *see also Graham v. John Deere Co.*, 383 U.S. 1 (1966). Pursuant to Sup. Ct. R. 15.2, BioMarin challenges this assertion of Duke as not being supported by the record. No new rule was stated by the Board nor can one be reasonably inferred from the PTAB decision. Nor can a new rule be reasonably inferred from the subsequent merits panel’s judgment of affirmance without opinion by the Federal Circuit under Fed. Cir. R. 36.

***BioMarin never urged the creation of a new rule to the PTAB or the Federal Circuit.***

***The PTAB never stated that it applied such a rule.*** The PTAB clearly considered all of the *Graham* factors and stated that it considered all of the evidence and arguments by both parties in rendering its decision. The PTAB properly evaluated all of the *Graham* factors, including objective evidence of obviousness in the SFWD issued in January 2018. Pet. Appx. 22a-23a. The PTAB specifically found that “Petitioner [BioMarin] has presented sufficient evidence to rebut any presumption of nexus between the

commercial success, licensing, and praise of Myozyme and Lumizyme and the claimed invention.” Pet. Appx. 26a. In other words, there was insufficient evidence of non-obviousness to outweigh the evidence of obviousness presented by BioMarin.

***The Federal Circuit never stated a new rule, nor can it be reasonably inferred that the Federal Circuit held Duke to the new rule that Duke alleges.*** The issue of a presumption of nexus was fully briefed by both parties before the Federal Circuit. The merits panel affirmed the PTAB decision. Duke is asking this Court to overturn a rule that was never expressly stated nor implicitly relied upon by the PTAB or the Federal Circuit.

In actuality, Duke is the party asking for the creation of a new rule. Essentially, Duke is urging that claim 9 cannot be found to be obvious because Duke allegedly proved that claim 9 of the patent at issue covers two commercially successful products for treating Pompe disease and that the invention solved a long-felt need. Pet. 3. However, the underlying facts asserted by Duke before this Court were vigorously challenged by BioMarin and were fully addressed by the Board, and fully briefed at the Federal Circuit. “A petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law.” Sup. Ct. R. 10. Question 3 in Duke’s Petition rests on an assertion of erroneous factual findings by the PTAB. There was no misapplication of a properly stated rule of law to the facts of the case. To the contrary, the factual findings and all statements of the law by the PTAB were correct. As detailed below, there were numerous failings in Duke’s case, and thus there were numerous

reasons for affirming the PTAB decision other than the alleged errors asserted by Duke.

**B. Duke Waived Its Arguments Regarding Presumption of Nexus at the PTAB and Cited New Evidence at the Federal Circuit Regarding Commercial Success**

Duke waived its argument of a presumption of nexus before the Board. Duke never argued to the Board that a presumption of nexus should apply. CA-Appx352-355; *see also* BioMarin Br. 43. The Federal Circuit has held that “a party waives an argument that it ‘failed to present to the Board’ because it deprives the court of ‘the benefit of the Board’s informed judgment.’” *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1329 (Fed. Cir. 2017) (quoting *In re Watts*, 354 F.3d 1362, 1367-68 (Fed. Cir. 2004)). Duke waived the “presumption” argument when it failed to present it to the Board. *Id.* Duke does not point to any pleadings before the PTAB where this issue was raised. ***On appeal, Duke also improperly presented new arguments and relied on new evidence to support their nexus argument.*** *See* BioMarin Br. 44-48. The PTAB properly addressed the arguments that were actually presented by the parties.

In its brief before the Federal Circuit, Duke raised new arguments and relied on evidence that was not cited before the Board. Duke argued an alleged nexus and cited to paragraphs in expert declarations that were not previously cited in their Patent Owner Response (“POR”) (*See* CA-Appx292-355) and which were not previously argued at the oral hearing before the PTAB (*See* CA-Appx377-439). Duke also relied on the Myozyme

and Lumizyme prescribing information, which was not presented before the Board with regard to nexus or objective indicia of non-obviousness. *See* CA-Appx352-355. Arguments made for the first time on appeal are waived, including arguments that differ from those raised before the Board. *See Watts*, 354 F.3d at 1367-68. Waiver also applies where a party failed to develop an argument sufficiently for the fact-finder to consider it. *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1296 (Fed. Cir. 2009).

Duke attempted to remedy deficiencies in its proofs and arguments by arguing for the first time before the Federal Circuit that the use of Myozyme and Lumizyme allegedly practices the method described in claim 9. However, Duke's POR before the PTAB did not even include the words, "Myozyme" or "Lumizyme." *Compare* Duke Br. 6 to CA-Appx352-355. Further, ***Duke did not cite to any expert support or analysis of the '712 Patent's claims as compared to the commercial products.*** *See* Duke Br. 6-8. Duke did not offer persuasive evidence before the Board demonstrating that the commercial products relied on to establish commercial success actually practiced the invention of dependent claim 9. *See* BioMarin Br. 53-54. Duke's failure to prove this critical fact is another alternative ground upon which the merits panel could have affirmed the Board's decision under Fed. Cir. R. 36.

On appeal to the Federal Circuit, Duke cited an expert declaration for the first time as support for any of its arguments regarding objective indicia of non-obviousness. *See* BioMarin Br. 45-46. Therefore, another alternative reason for affirming the decision of the Board is that

Duke cannot be allowed to rely on evidence in an appeal that was never cited to or considered by the Board. *See Smartdoor Holdings, Inc. v. Edmit Indus., Inc.*, 707 F. App'x 705, 708 (Fed. Cir. 2017). Reliance on such evidence was waived by Duke's failure to cite it. *Id.*

**C. Duke Failed to Address or Insufficiently Addressed Critical Issues Raised by BioMarin Regarding Commercial Success of the Duke Invention**

Not only is Duke mischaracterizing the proceedings below, but Duke is also oversimplifying how objective indicia of non-obviousness should be handled. Duke infers that evidence of secondary considerations, such as commercial success, is sufficient to rebut strong evidence of obviousness, and thus Duke does not need to address BioMarin's evidence of obviousness. *See* Pet. 28-32. This is an attempt to minimize the importance of the first three *Graham* factors and improperly elevate the importance of objective indicia of non-obviousness, with particular emphasis on commercial success and long-felt need. However, to the contrary, a proper consideration of obviousness requires consideration of all the *Graham* factors, including any properly presented secondary considerations based on evaluating and crediting objective indicia of non-obviousness. *See Graham*, 383 U.S. at 17.

Properly applying a more recent Supreme Court decision in *KSR* to the facts of this case, the Board determined that a person of ordinary skill in the art would have had reason to administer exclusively a precursor of recombinant hGAA from CHO cells to treat GSD-II as required by claim 9. Pet. Appx. 18a-22a; *see also KSR*

*Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Moving to secondary considerations, the Board evaluated Duke's arguments of the long-felt need and failure by others, unexpected results, licensing, commercial success, and praise and industry acceptance, and determined that regarding **each of the secondary considerations**, Duke failed to establish a nexus between the recited methods and asserted objective evidence of non-obviousness. *See* Pet. Appx. 22a-30a. Finding that Duke failed to establish a nexus, the Board turned to BioMarin's evidence of obviousness and evaluated all of the evidence together to make a final determination of obviousness. *Id.* at 30a-31a. The Board held that a preponderance of evidence established the obviousness of Duke's claims. *Id.* at 24a. There was no legal error in this approach.

The Board also determined that Duke did not offer persuasive evidence demonstrating that the commercial products relied on to establish commercial success actually practiced the invention of dependent claim 9. *Id.* at 24a-26a; *see also* BioMarin Br. 53-54. Without establishing this foundational fact, Duke's case cannot succeed. Duke's failure to prove that the products on which commercial success are based actually practice claim 9 is a failure to establish a fact that is essential to Duke's case. This failure to establish a critical underlying fact is an alternative ground upon which the merits panel could have affirmed the Board's decision under Fed. Cir. R. 36.

Duke relies on evidence of unsuccessful research that occurred decades prior to the critical date in an attempt to show long-felt need and failure of others. *See* Pet. 7. But Duke fails to acknowledge the importance of the critical breakthroughs, that were described in the prior art, that

occurred prior to the critical date of the '712 Patent. The Board correctly realized that Duke ignored intervening innovations (***which were part of the prior art before Duke filed its patent application***) that made claim 9 obvious. See Pet. Appx. 26a-30a; see also *Graham*, 383 U.S. at 36:

The [1956] Scoggin invention . . . rests upon exceedingly small and quite nontechnical mechanical differences in a device which was old in the art. At the latest, those differences were rendered apparent in 1953 by the appearance of the Livingstone patent [invalidating prior art], and unsuccessful attempts to reach a solution to the problems confronting Scoggin made before that time became wholly irrelevant.

Here, the relevant state of the art was far more advanced than the state of the art that is reflected by Duke's citations to irrelevant and decades-old problems.

It is well established that even when a long-felt need exists, if technological developments before the invention allow one of ordinary skill in the art to accomplish the invention, solving a long-felt need and other secondary considerations do not overcome a strong case of obviousness. See *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768-69 (Fed. Cir. 1988). This approach is also mandated by this Court. As explained in *KSR*:

We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared



knowledge, define a new threshold from which innovation starts once more.

*KSR*, 550 U.S. at 427. Since obviousness of the invention claimed in the '712 Patent is measured from July 17, 1999, and since the invention could be accomplished by "a design step well within the grasp of a person of ordinary skill in the relevant art," the invention is obvious, despite any evidence of secondary considerations the patent owner might present. *Id.*

#### **IV. Maintaining This Patent Would Give Duke an Undeserved Extension of Its Monopoly on Important Drugs**

It is undisputed that multiple patents were identified as covering Sanofi Genzyme's Myozyme and Lumizyme, including U.S. Patent No. 7,351,410 to van Bree; U.S. Patent No. 7,655,226 to van Bree; and U.S. Patent No. 6,118,045 to Reuser. *See* CA-Appx3953-3954; *see also* CA-Appx4100-4101 (Patent Term Extension approval for U.S. Patent No. 6,118,045 to Reuser based on Myozyme). BioMarin raised the issue of the fact that multiple patents allegedly covered Myozyme and Lumizyme. Despite the fact that BioMarin raised this issue, Duke never distinguished the contributions of each patent with regard to Myozyme and Lumizyme. *See* CA-Appx352-355. Duke is not entitled to presumed nexus where several patents cover the marketed products. *See Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1289, 1299 (Fed. Cir. 2010); *see also Meds. Co. v. Mylan Inc.*, No. 11-cv-1285, 2014 U.S. Dist. LEXIS 38714, at \*18-19 (N.D. Ill. Mar. 25, 2014). Even if Duke was entitled to a presumption of nexus, this does not excuse that fact that Duke did not respond

to the arguments that were timely and effectively raised by BioMarin regarding nexus. Accepting the argument that Duke urges would result in a situation where a patent could be granted on a product covered by multiple patents which expire at different times, whereby the later filed and last to expire patent, even though obvious over the prior art when all factors are considered, would be improperly entitled to a presumption of nexus. And, to emphasize, even if Duke is entitled to a presumption of nexus, Duke did not effectively rebut the contrary evidence and arguments submitted by BioMarin.

### CONCLUSION

For the foregoing reasons, Duke's Petition for Writ of Certiorari should be denied.

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