18-1696

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

DUKE UNIVERSITY,

Appellant,

v.

BIOMARIN PHARMACEUTICAL INC.,

Appellee.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00535

APPELLANT'S PETITION FOR REHEARING EN BANC

Steven A. Zalesin
Eugene M. Gelernter
Zhiqiang Liu
PATTERSON BELKNAP WEBB
& TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorney for Appellant Duke University

December 11, 2019

FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

DUKE UNIVERSITY **v.** BIOMARIN PHARMACEUTICAL, INC.

Case No. 18-1696

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ■ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Duke University

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Duke University	Duke University	None
	Synpac Venture Capital, L.P. (indirectly owned	
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4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

Formerly of Patterson Belknap Webb & Tyler LLP: Herman Yue, David Slarskey, Charlene Choi; Cooper & Dunham LLP: John P. White, Gary J. Gershik, Darren Haber, Brittany Internoscia; and Formerly of Cooper & Dunham LLP: Aaron Selikson, Maria Nunez.

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

None

12/11/2019
Date

/s/ Steven A. Zalesin
Signature of counsel

Please Note: All questions must be answered

Steven A. Zalesin
Printed name of counsel

cc: _____

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RULE 35 STATEMENT REGARDING REHEARING EN BANC

Based on my professional judgment, I believe this appeal presents the following precedent-setting questions of exceptional importance:

1. Whether objective evidence of nonobviousness under *Graham v. John Deere Co.*, 383 U.S. 1 (1966), is entitled to a presumption of nexus, where unrebutted evidence establishes that the objective evidence is tied to a specific product or method that is the invention disclosed and claimed in the patent.

2. Whether this Court's decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, No. 2018-2140, 2019 U.S. App. LEXIS 32613 (Fed. Cir. Oct. 31, 2019), holding that the appointment of Administrative Patent Judges ("APJs") to the Patent Trial and Appeal Board ("Board") violated the Appointments Clause, U.S. Const., art. II, § 2, cl. 2, was a significant change in the law governing this appeal.

3. Whether, after *Arthrex*, the Director's delegation of institution authority to APJs acting as principal officers violated 35 U.S.C. § 314 and due process of law.

/s/ Steve A. Zalesin
Attorney for Appellant Duke University

INTRODUCTION

In deciding Duke's first appeal from this *inter partes* review proceeding, the Court expressly noted its misgivings about the Board's rejection of Duke's objective evidence of nonobviousness:

> Notably, 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.

Duke Univ. v. BioMarin Pharm. Inc., 685 F. App'x 967, 977 n.2 (Fed. Cir. 2017) (emphasis added). Yet on remand, the Board missed the message. Duke presented unrebutted evidence that use of the only drugs approved by the U.S. Food and Drug Administration (FDA) for treating patients suffering from Pompe disease—Myozyme® and Lumizyme®—practice method claim 9 of U.S. Patent No. 7,056,712. Under this Court's settled law, Duke's evidence should have triggered a presumption of nexus between claim 9 and the objective indicia, including the long-felt need finally satisfied by Myozyme and Lumizyme. For decades, scientists had tried—but failed—to treat this fatal disease. The "[m]edical [b]reakthrough[]" in claim 9—embodied by Myozyme and Lumizyme—has been hailed as a "[w]onder drug." Appx2222-2225; Appx2212-2213. The Board, however, again refused to apply a presumption of nexus and rejected Duke's objective evidence of nonobviousness. A panel of this Court summarily affirmed the Board under Fed. Cir. R. 36.

The Board's decision—and the panel's summary affirmance—represent a sharp departure from the established rule that presumes a nexus where the objective evidence of nonobviousness is tied to a commercially successful method or product that is the invention disclosed and claimed. If, as the Board held here, a patentee must first prove the negative that commercial success or industry praise is *not* due to all other imaginable contributing factors, then the fourth *Graham* factor is a dead letter. This Court should intervene en banc to reestablish settled law before the Board's new rule takes root.

En banc review is also warranted because *Arthrex* significantly changed the law relating to the foundations of *inter partes* review. Because Duke's patent rights were abrogated by an unconstitutionally appointed panel of APJs, the Court should vacate the Board's decision and remand for a constitutionally compliant proceeding. The Court has held that waiver is inapplicable for similar changes in law affecting core governmental process.

What's more, the *Arthrex* decision undermines the Director's authority to delegate the institution of BioMarin's petition under 35 U.S.C. § 314 to APJs acting not as subordinates, but as independent principal officers outside the Director's review. This Court should also grant en banc review to resolve the implications of *Arthrex* on the Director's unconstitutional delegation of institution authority to ALJs acting as principal officers.

FACTUAL BACKGROUND

A. The Claim 9 Invention Provided Life-Saving Benefits Where Others Had Failed, Achieved Commercial Success, and Won Industry Praise

The '712 patent claims a method of treating glycogen storage disease type II ("GSD-II"), also known as Pompe disease. Appx146(Abstract). The disease is caused by a deficiency of acid α-glucosidase ("GAA")—a critical protein that breaks down glycogen to glucose in the body. Appx153(1:12-20). Without functional GAA, glycogen accumulates in body tissues, especially in skeletal muscles and heart cells. Apx153(1:20-22). This accumulation causes cellular deterioration, leading to muscle failure and, almost always, death. Appx153(1:31-44).

Scientists had recognized a deficiency of the GAA enzyme as the cause of Pompe disease as far back as the early 1960s. Appx627(4:18-20). And for decades after, researchers tried treating patients by administering exogenous human acid α-glucosidase ("hGAA") produced from various sources, including human placenta, the liver, and fungus. Appx1873-1875; Appx1944-1948. But before the '712 patent, "previous attempts at enzyme replacement therapy in Pompe disease had failed." Appx631-632(8:26-9:30). As BioMarin's expert, Dr. Gregory Pastores, conceded, there was "basically 30-plus years of failures by other researchers to . . . treat Pompe's disease in human patients." Appx1258(271:5-11).

The inventor of the '712 patent, Dr. Yuan-Tsong Chen, succeeded where others had failed by administering recombinant hGAA ("rhGAA") produced in Chinese hamster ovary ("CHO") cell cultures. Appx153(2:45-50); Appx154(4:1-8). The '712 patent teaches that, "[i]n a particularly preferred embodiment, the GAA is the precursor form of recombinant human GAA." Appx154(3:66-67).

Claim 1, from which claim 9 depends, is directed to a method of treating Pompe disease using a therapeutically effective amount of hGAA produced in CHO cells. Appx158(12:45-51). Claim 9 covers the "particularly preferred embodiment" in which the hGAA from CHO cells is administered in "precursor form," Appx154(3:66-67):

> 9. The method of claim 1, wherein the human acid α-glucosidase is a precursor of recombinant human acid α-glucosidase that has been produced in chinese hamster ovary cell cultures.

Appx159(13:9-12).

The FDA has approved only two drugs for treating Pompe disease: Myozyme and Lumizyme. The use of both drugs practices the method in claim 9. Appx2009; Appx1888. The FDA-approved prescribing information states that the hGAA in those products is "produced by recombinant DNA technology in a [CHO] cell line," Appx3815, Appx3830, and has a total mass of approximately 110 kDa and 109 kDa respectively, thus reflecting that the hGAA in both drugs is *exclusively in precursor form*. Appx3816; Appx3831; *see also* Appx4.

For many patients, Myozyme and Lumizyme have made the difference between life and death. Appx1868. Even today, these drugs remain the only commercially available treatment for Pompe disease. Appx1914. Because they save lives where others failed, Myozyme and Lumizyme have been a commercial success and won acclaim. While Pompe disease is very rare, Myozyme and Lumizyme sales from 2006 through 2013 totaled approximately $3 billion. Appx2099-2102; *see also* Appx1256(269:10-12) (BioMarin's expert conceding that Myozyme "has been a commercial success [in] the marketplace").

Myozyme has been described in published articles as a "[m]edical [b]reakthrough[]" and a "[w]onder drug." Appx2222-2225; Appx2212-2213. Genzyme received the prestigious James Watson Helix Award for its development of Myozyme as a "life-saving therapy," Appx2217-2218, and the Galien Award, which recognizes the most important new drugs introduced to the market. Appx2219.

Genzyme, the sole supplier of Myozyme, has taken a license to make and sell products practicing the '712 patent since 2000. Appx2095-2096; Appx1914. Together, the uncommonly high royalty rates of up to 21% for an exclusive license directly establishes industry recognition of the invention's value. Appx2110-2113.

B. Duke's Prior Appeal and the Board's Repeated Failure to Apply a Presumption of Nexus

In its initial Final Written Decision, Appx46-88, the Board found claim 9 was both anticipated and obvious. Appx63-64; Appx74. The Board found that the term "precursor" in claim 9 "encompass[es] administering both precursor and non-precursor forms [of hGAA] at the same time, and [is] not limited to administering exclusively a precursor form and no other form." Appx53.

In Duke's first appeal, the Court disagreed with the Board's construction of "precursor" and held that the correct construction is "*exclusively* a precursor of recombinant hGAA that has been produced in CHO cell cultures." *Duke Univ.*, 685 F. App'x at 975 (emphasis added). Applying the correct construction, the Court found that the allegedly anticipating prior art did not disclose "administering *exclusively* a precursor of rhGAA produced in CHO cell cultures." *Id.* at 976 (emphasis added). The Court then vacated the Board's obviousness finding for claim 9 and remanded for a determination of whether that claim would have been obvious under the correct construction of "precursor." *Id.* at 977.

In addition to correcting the Board's claim construction, this Court directed the Board to consider Duke's "proffered objective indicia." *Id.* In fact, the Court expressly noted its misgivings about the Board's treatment of the objective evidence, "including its failure to apply a presumption of nexus." *Id.* at 977 n.2

Rather than confront this Court's stated concerns on remand, the Board dismissed them and reached the same result. Even though unrebutted evidence showed that the use of Myozyme and Lumizyme practices the method of claim 9, the Board again failed to apply a presumption of nexus between the claimed invention and the objective evidence of nonobviousness. Appx18-19. According to the Board, a presumption of nexus did not apply because the record "does not elucidate adequately the impact of the '712 patent, as compared to other relevant patents." Appx18. And without a presumption of nexus, the Board effectively sidestepped Duke's objective evidence of nonobviousness. *See* Appx18-19.

Duke again appealed the Board's treatment of the objective evidence of nonobviousness. A panel of this Court summarily affirmed the Board's decision under Fed. Cir. R. 36. *Duke Univ. v. BioMarin Pharm. Inc.*, 779 F. App'x 750 (Fed. Cir. Oct. 11, 2019).

ARGUMENT

I. The Panel's Affirmance Is Contrary to Established Law that Presumes a Nexus for Objective Evidence of Nonobviousness

Objective evidence of nonobviousness is part of the overall obviousness analysis, not just an afterthought. *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012). Objective evidence plays a critical role because it is "not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence

of nonobviousness," *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008), and "can be the most probative evidence of non-obviousness in the record, and enables the . . . court to avert the trap of hindsight," *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010) (citation omitted); *see also Graham*, 383 U.S. at 36 (objective evidence "may also serve to 'guard against slipping into use of hindsight,' and to resist the temptation to read into the prior art the teachings of the invention in issue" (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964))).

This Court's settled rule presumes a nexus for objective evidence "when the patentee shows that the asserted objective evidence is tied to a specific product and that 'product is the invention disclosed and claimed in the patent.'" *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1071 (Fed. Cir. 2018) (quoting *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016)); *see also Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988) ("A prima facie case of nexus is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent."). Here, Duke established a nexus by putting forward unrebutted evidence that Myozyme and Lumizyme *are* the invention "disclosed and claimed" in claim 9. *WBIP*, 829 F.3d at 1329; *see also* Appx2009; Appx1888. In fact, the FDA-approved prescribing

information explains that the hGAA in Myozyme and Lumizyme for treating Pompe disease is "produced by recombinant DNA technology in a [CHO] cell line." Appx3815; Appx3830. What's more, the hGAA in Myozyme and Lumizyme has a total mass of approximately 110 kDa and 109 kDa respectively—that is, the hGAA in both drugs is *exclusively in precursor form*. Appx3816; Appx3831; *see also* Appx4.

This Court has never required a patentee "to prove as part of its prima facie case that the commercial success of the patented invention is *not* due to factors other than the patented invention." *Demaco*, 851 F.2d at 1394. Rather, "[i]t is sufficient to show that the commercial success was of the patented invention itself." *Id.* And the Court's rule is sound—"[a] requirement for proof of the negative of all imaginable contributing factors would be unfairly burdensome, and contrary to the ordinary rules of evidence." *Id.*

Yet the panel's summary affirmance endorses precisely what this Court has rejected for decades—a requirement that patentees prove a negative. Appx18-22. Take the Board's statement faulting Duke for not adequately separating "the impact of the '712 patent, as compared to other relevant patents" on licensing, commercial success, and industry praise. Appx18. That misses the entire point of *Demaco* and the presumption of a nexus. Under previously settled law, Duke was not required to prove "the negative of all imaginable contributing factors" before

receiving the benefit of a presumed nexus. *Demaco*, 851 F.2d at 1394. Instead, Duke "was entitled to the presumption of nexus for its objective evidence of non-obviousness because it established that specific products"—Myozyme and Lumizyme—"are embodiments of the invention" in claim 9. *WBIP*, 829 F.3d at 1331.

When a nexus is presumed, "the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus." *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000). "The presumed nexus cannot be rebutted with mere argument; evidence must be put forth." *See id.* BioMarin, however, provided no evidence rebutting the fact that administering Myozyme and Lumizyme to treat Pompe disease practices claim 9 of the '712 patent. *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 734, 747 (Fed. Cir. 2016) ("When the patentee has presented undisputed evidence that its product is the invention disclosed in the challenged claims, it is error for the Board to find to the contrary without further explanation."). By requiring Duke to prove the negative *before* receiving the benefit of a presumed nexus, the Board reduced the presumption to a nullity. And the panel's summary affirmance invites more of the same.

It makes no difference that other patents may also be relevant to Myozyme and Lumizyme. This Court has recognized time and again that 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."); *PPC Broadband*, 815 F.3d at 737 n.1, 746-47 (presumption of nexus applied to three patents covering patentee's commercial product); *Gator Tail, LLC v. Mud Buddy LLC*, 618 F. App'x 992, 995, 999-1000 (Fed. Cir. 2015) (presumption of nexus applied to two patents covering the same commercial product).

The panel's affirmance conflicts with this long line of precedent. Duke was entitled to a presumption of nexus because unrebutted evidence showed that Myozyme and Lumizyme are embodiments of the invention in claim 9. By requiring Duke to additionally prove that its objective evidence is *not* due to some other patent or factor, the Board effectively vitiated this Court's presumption of nexus. Left unchecked, the panel's affirmance will only encourage further disregard for the presumption where commercial products embody the claimed invention. Moreover, the Board's new rule—endorsed by the panel's summary affirmance—invites the very hindsight bias that the Supreme Court sought to ameliorate in *Graham*. This Court should intervene to prevent objective evidence of nonobviousness from being relegated to an afterthought.

II. *Arthrex* Was a Significant Change in the Law Relating to the Foundations of *Inter Partes* Review

The Court held in *Arthrex* that

> APJs are principal officers under Title 35 as currently constituted. As such, they must be appointed by the President and confirmed by the Senate; because they are not, the current structure of the Board violates the Appointments Clause.

2019 U.S. App. LEXIS 32613, at *27. To remedy this constitutional infirmity, this Court partially severed the statutory removal provisions in 35 U.S.C. § 3(c) as applied to APJs. *Id.* at *33-34. But "[b]ecause the Board's decision . . . was made by a panel of APJs that were not constitutionally appointed at the time the decision was rendered," the Court "vacate[d] and remand[ed] the Board's decision without reaching the merits." *Id.* at *36. The Court further held that "a new panel of APJs must be designated to hear the *inter partes* review anew on remand." *Id.* at *40.

So too here, unconstitutionally appointed APJs adjudicated Duke's patent rights. The remedy here should be the same as in *Arthrex*—the Board's decision should be vacated and the case remanded for a constitutionally valid proceeding.

This Court has held that Appointments Clause challenges are waivable when not raised in an opening brief or a motion filed prior to an opening brief. *See Customedia Techs., LLC v. Dish Network Corp.*, No. 2019-1001, 2019 U.S. App. LEXIS 32795, at *1-2 (Fed. Cir. Nov. 1, 2019). But constitutional challenges "should not be deemed waived when they relate to the foundations of

governmental process." *Ninestar Tech. Co. v. Int'l Trade Comm'n*, 667 F.3d 1373, 1382 (Fed. Cir. 2012); *see also Glidden Co. v. Zdanok*, 370 U.S. 530, 535-36 (1962) (including Appointments Clause objections in the category of nonjurisdictional structural constitutional objections that could be considered on appeal whether or not they were raised in the district court or the court of appeals).

Allowing unconstitutionally appointed APJs to abrogate property rights and eviscerate a patentee's investment-backed expectations undermines the entire *inter partes* review process. The Supreme Court has recognized "the danger of one branch's aggrandizing its power at the expense of another branch." *Freytag v. Comm'r of Internal Revenue*, 501 U.S. 868, 878-79 (1991). "The Appointments Clause not only guards against this encroachment but also preserves another aspect of the Constitution's structural integrity by preventing the diffusion of the appointment power." *Id.* That Duke did not raise an Appointments Clause challenge in its opening appeal brief does not change the fact that its patent rights were revoked in violation of core constitutional protections.

Not only did the *Arthrex* decision highlight a foundational constitutional flaw in the *inter partes* review regime, but it also represents a significant change in this Court's law. Before the *Arthrex* decision, at least one panel of this Court summarily rejected the same Appointments Clause challenge raised in *Arthrex*. *See Trading Techs. Int'l, Inc. v. IBG LLC*, 771 F. App'x 493 (Fed. Cir. 2019)

(affirming Board under Fed. Cir. R. 36 where appellant raised Appointments Clause challenge in opening brief); *see also Trading Techs. Int'l, Inc. v. IBG LLC*, No. 2018-1489, Dkt. No. 36 at 78-80 (Fed. Cir. Aug. 14, 2018) (appellant's opening brief raising Appointments Clause challenge).

As this Court recognized after *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), "a party does not waive an argument that arises from a significant change in law during the pendency of an appeal." *Polaris Indus. v. Arctic Cat, Inc.*, 724 F. App'x 948, 949-50 (Fed. Cir. 2018). Even now, the ultimate fallout of the Appointments Clause violation remains uncertain as the Government seeks en banc review. Additionally, it remains unclear whether the *Arthrex* panel's decision to sever the statutory removal provisions in 35 U.S.C. § 3(c) as applied to APJs was sufficient to cure the constitutional infirmity. *See Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 2018-1831, Dkt. No. 90 (Fed. Cir. Nov. 8, 2019) (ordering additional briefing on various *Arthrex* issues, including whether severing the statute remedies the constitutional infirmity).

Because *Arthrex* represents a significant—and continuing—change in the law during the pendency of Duke's appeal, waiver should not apply. *See Hormel v. Helvering*, 312 U.S. 552, 558-59 (1941) (holding 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"); *see also Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc.*, Nos. 2019-1368, -1369, 2019 U.S. App. LEXIS 34328, at *34 (Fed. Cir. Nov. 19, 2019) (Newman, J., dissenting) ("[A] change in governing law applies to the pending appeal when the change occurs while the case is on appeal."). Consistent with *Arthrex*, the Board's decision should be vacated and the case remanded for a constitutionally valid proceeding.

III. After *Arthrex*, the Director's Delegation of Institution Authority to APJs Acting as "Principal Officers" Violated 35 U.S.C. § 314 and Due Process of Law

In § 314, Congress expressly assigned institution authority to the Director. 35 U.S.C. § 314(a), (b) ("The Director shall determine whether to institute an inter partes review . . . ."). The Director, however, has delegated institution authority to the Board. 37 C.F.R. § 42.4(a).

In *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1031-33 (Fed. Cir. 2016), this Court held that the Director was permitted to delegate institution authority to "subordinate officers"—APJs—under 35 U.S.C. § 314(a). *Arthrex*, however, is clear that APJs were not subordinate after all—rather, they were "principal officers." 2019 U.S. App. LEXIS 32613, at *6-27. Indeed, the Director's "control and supervision of the APJs is not sufficient to render them inferior officers." *Id.* at *26.

As Judge Newman noted in her *Ethicon* dissent, "[t]he statute requires that these proceedings be separated, the first decision required to be made by the Director, and the second decision made by the Board." 812 F.3d at 1035 (Newman, J., dissenting). In fact, bifurcation between the Director and the Board was critical to protecting due process guarantees of "a fair trial in a fair tribunal." *Id.* at 1038 (citation omitted); *see also Ethicon Endo-Surgery, Inc. v. Covidien LP*, 826 F.3d 1366, 1367-69 (Fed. Cir. 2016) (Newman, J., dissenting from denial of reh'g en banc) (Congress expressly vesting the Director with the authority to institute review ensures that "constitutionally mandated patent rights were not abrogated without due process of law"). Nevertheless, the majority in *Ethicon* justified the Director's delegation of institutional decisions based, at least in part, on the APJs' status as "subordinate officers." 812 F.3d at 1031-33.

This Court's decision in *Arthrex* is a fundamental change in the law that undermines the core of the *Ethicon* majority's rationale. *See Polaris*, 724 F. App'x at 949-50 (holding waiver inapplicable). APJs did not institute trials as "subordinate officers" as contemplated in *Ethicon*, 812 F.3d at 1031-33, but as independent principal officers that the Director could not "review, vacate, or correct." *Arthrex*, 2019 U.S. App. LEXIS 32613, at *26. The Director's delegation under 37 C.F.R. § 42.4(a) of institution authority to APJs acting as principal

officers cannot be squared with 35 U.S.C. § 314, which requires the Director—not a panel of unreviewable APJs—to authorize institution.[1]

This Court should grant en banc review to resolve the apparent conflict between *Arthrex* and *Ethicon*, and make clear that the Director's delegation of institution authority to APJs acting as principal officers violated 35 U.S.C. § 314 and due process of law.

CONCLUSION

The Court should grant rehearing en banc.

Date: December 11, 2019

Respectfully submitted,

/s/ Steven A. Zalesin
Steven A. Zalesin
Eugene M. Gelernter
Zhiqiang Liu
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036
(212) 336-2000

Attorney for Appellant Duke University

[1] In *Arthrex*, this Court saw "no constitutional infirmity" with institutions. 2019 U.S. App. LEXIS 32613, at *40-41. But the Court did not analyze the implications of its holding that APJs were "principal officers" on the Director's delegation of his institution authority to the Board under 37 C.F.R. § 42.4(a).

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rule 32(a) or Federal Circuit Rule 28.1:

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Date: December 11, 2019

/s/ Steven A. Zalesin
Steven A. Zalesin
Eugene M. Gelernter
Zhiqiang Liu
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, NY 10036

Attorney for Appellant Duke University

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

DUKE UNIVERSITY,
Appellant

v.

BIOMARIN PHARMACEUTICAL INC.,
Appellee

2018-1696

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2013-00535.

JUDGMENT

STEVEN A. ZALESIN, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for appellant. Also represented by GEORGE B. FLEMING, EUGENE M. GELERNTER, ZHIQIANG LIU; IRENA ROYZMAN, Kramer Levin Naftalis & Frankel LLP, New York, NY.

GERALD MYERS MURPHY, JR., Birch Stewart Kolasch & Birch, LLP, Falls Church, VA, argued for appellee. Also represented by MARYANNE ARMSTRONG.

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (NEWMAN, LOURIE, and TARANTO, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

October 11, 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

FORM 30. Certificate of Service

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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Steven A. Zalesin	/s/ Steven A. Zalesin
Name of Counsel	Signature of Counsel

Law Firm	PATTERSON BELKNAP WEBB & TYLER LLP
Address	1133 Avenue of the Americas
City, State, Zip	New York, NY 10036
Telephone Number	212-336-2110
Fax Number	212-336-2222
E-Mail Address	sazalesin@pbwt.com

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