United States Court of Appeals
For the Federal Circuit

DUKE UNIVERSITY,

Appellant,

v.

BIOMARIN PHARMACEUTICAL INC.,

Appellee.

Appeal No. 2018-1696

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, IPR2013-00535

APPELLEE'S RESPONSE TO THE PETITION FOR REHEARING EN BANC

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January 16, 2020

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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)

BioMarin Pharmaceutical Inc.

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
BioMarin Pharmaceutical Inc.	BioMarin Pharmaceutical Inc.	Capital Research Global Investors

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:

Birch, Stewart, Kolasch & Birch, LLP: Eugene T. Perez

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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

1/16/2020
Date

/s/ Gerald M. Murphy, Jr.
Signature of counsel

Please Note: All questions must be answered

Gerald M. Murphy, Jr.
Printed name of counsel

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INTRODUCTION

In response to the letter from the Court dated January 2, 2020, Appellee BioMarin Pharmaceutical Inc. ("BioMarin") herein files a response to the Petition for Rehearing En Banc ("Petition") filed by Appellant Duke University ("Duke"). BioMarin opposes the Petition.

Duke's Petition is based on two basic points: (1) the handling by the Patent Trial and Appeal Board ("PTAB" or "the Board") of secondary indicia of obviousness, and in particular the handling of a presumption of nexus, and (2) issues related to this Court's decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019).

Rehearing en banc review on these issues is unwarranted. Duke brings its petition after the merits panel of this court entered a judgment of affirmance without opinion under FED. CIR. R. 36. *See* Rule 36 J., Oct. 11, 2019. A party seeking en banc consideration must typically show that either the merits panel has (1) failed to follow existing decisions of the U.S. Supreme Court or Federal Circuit precedent or (2) followed Federal Circuit precedent that the petitioning party now seeks to have overruled by the court en banc. *See Information Sheet - Petitions for Rehearing and Petitions for Hearing and Rehearing En Banc* (Fed. Cir. Aug. 21, 2018), http://www.cafc.uscourts.gov/sites/default/files/cmecf/Petitions_Rehearing_En_Banc_-_Information_Sheet.pdf . Duke has not shown either of these to be true.

Duke's Petition does not meet the standards for en banc review under FED. R. APP. P. 35(a)(1) or (2) and therefore this Court does not have an appropriate reason to conduct an en banc hearing.

SUMMARY ARGUMENT

Duke argues that the Board, and the merits panel, refused to properly apply a presumption of nexus and rejected Duke's objective evidence of non-obviousness. The Board never stated, and it cannot be reasonably inferred, that the Board refused to apply a presumption of nexus. This argument is also not supported by merits panel's judgment of affirmance without opinion under FED. CIR. R. 36. This point was fully briefed by both parties before this court. It is submitted that the Board properly evaluated all of the *Graham* factors, including objective evidence of obviousness in rendering the Supplemental Final Written Decision ("SFWD") dated January 17, 2018. The Board found that even considering a presumption of nexus, there was insufficient evidence of nonobviousness to outweigh the evidence of obviousness. Appx19. The merits panel affirmed this finding.

In its Petition, Duke also raises constitutional questions under the Appointments Clause for the very first time in this case. Raising such challenges this late in the appeals process is simply improper. Federal Circuit law is well-established that arguments not raised in the opening brief are waived. *Novosteel SA*

v. United States, 284 F.3d 1261, 1273-74 (Fed. Cir. 2002); *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990).

Duke argues that en banc review is warranted because *Arthrex* significantly changed the law relating to the foundations of *Inter Partes* Review ("IPR"), and thus waiver is inapplicable. However, *Arthrex's* attempt to remedy the constitutional appointment problem of Administrative Patent Judges ("APJs") does not significantly change the law in a way that affects or would have affected Duke's ability to properly and timely raise a constitutional challenge of the APJs who presided over its IPR under the Appointments Clause. *Arthrex* did not change the Appointments Clause itself.

Had it been so inclined, Duke could have raised a constitutional challenge of its APJs prior to the deadline for filing its opening brief in this case. Duke simply chose not to pursue such a challenge even though it was available and has been used in similar instances by other appellants.

Duke also argues that, 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 and allegedly conflicts with this Court's decision in *Ethicon. See Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1031-33 (Fed. Cir. 2016). While this argument appears to be a statutory and due process argument, Duke is effectively questioning the constitutionality of the appointments of APJs,

once again invoking the Appointments Clause. Again, Duke waived this argument by not presenting an Appointments Clause challenge in its opening brief.

Duke had an opportunity to timely raise Appointments Clause challenges, but failed to do so. Since Duke did not present Appointments Clause challenges in its opening brief, Duke forfeited these arguments.

For these reasons, Duke's Petition should be denied.

ARGUMENT

I. The Board and the Merits Panel Properly Handled the Secondary Indicia of Obviousness and the Presumption of Nexus

The presumption of nexus issue has been raised by Duke (Duke Br. at 33-35, 40-46), fully briefed and argued (*id.*; BioMarin Br. at 43-54; Duke Reply Br. at 20-32), and summarily dismissed by the panel (Rule 36 J.). By raising this argument again in its Petition, Duke is simply trying to reargue issues previously presented that were not accepted by the merits panel during initial consideration of the appeal.

In a possible attempt to meet the requirements of FED. R. APP. P. 35(a)(1), Duke mischaracterizes the SFWD of the Board as refusing to apply a presumption of nexus. Specifically, Duke makes the allegation that "[t]he Board, however, again refused to apply a presumption of nexus and rejected Duke's objected objective evidence of nonobviousness." Pet. at 2. Although the Board did find that Duke's objective evidence of non-obviousness was insufficient, it is submitted that the

Board properly considered all of the evidence and arguments submitted by both parties.

A. Proper Consideration of Obviousness Requires Consideration of all the *Graham* factors, including any Properly Presented Objective Indicia of Non-Obviousness

Duke oversimplifies how objective indicia of non-obviousness should be handled by the Board. At the PTAB, as in court, the challenger of a patent bears the ultimate burden of proving obviousness. *See Acorda Therapeutics, Inc. v. Roxane Labs., Inc*., 903 F.3d 1310, 1339 (Fed. Cir. 2018) (a case arising in district court) and *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1334 (Fed. Cir. 2016) (a case arising at the PTAB).

In the SFWD, the Board stated that "[w]e have considered anew the record developed during trial and reviewed the parties' positions in light of the Federal Circuit's decision. ... [W]e conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 9 … is unpatentable as obvious … ." Appx2-3. The Board also held that BioMarin submitted sufficient evidence to rebut any presumption of nexus. Appx19. The record reflects, and it seems undisputable, that the Board considered all arguments made by the parties and all evidence cited by the parties that supported their respective positions, including arguments relating to presumption of nexus. The merits panel affirmed the SFWD.

B. Duke Improperly Focuses its Arguments on Commercial Success

Duke's Petition minimizes the importance of the first three *Graham* factors and focuses mainly on objective indicia of non-obviousness, with particular emphasis on commercial success. However, "[a] determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four *Graham* factors, and it is error to reach a conclusion of obviousness until all those factors are considered." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016). In the SFWD, the Board expressly stated that it balanced BioMarin's evidence of obviousness against Duke's asserted objective evidence of non-obviousness and, after considering all the *Graham* factors, determined that a preponderance of the evidence supports BioMarin's position. Appx17-18. Again, the merits panel's judgment of affirmance supports this conclusion.

C. Duke Waived its Arguments Related to Commercial Success and Cited New Evidence Regarding Commercial Success

Duke waived its argument of a presumption of nexus. BioMarin Br. at 43. On appeal, Duke also improperly presented new arguments and relied on new evidence related to nexus. *Id.* at 44-48.

Even though BioMarin (the patent challenger) has the ultimate burden to prove obviousness, Duke (the patent owner) bore the burden of producing evidence of objective indicia of non-obviousness. Duke relied on new arguments and cited new evidence in its appeal that were never argued at or cited to the Board. *Id.* For

example, 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. *Id.* at 53-54. These arguments regarding Duke's failure of proof are alternative grounds upon which the merits panel could have affirmed the Board's decision under FED. CIR. R. 36.

D. Duke's Arguments Fail Even If the Belated Arguments and Improper Reliance on New Evidence Are Considered

Regarding the merits of the nexus argument, BioMarin argued that the presumption of nexus should not apply where several patents cover the marketed products. BioMarin Br. at 44. In the alternative, BioMarin argued that even if a presumption applies, Duke's arguments and evidence fail on the merits. *Id.* at 44-54. This point was fully briefed by both parties. In the SFWD, the Board considered the arguments and evidence on both sides of the issue and concluded that the evidence and arguments of both parties were not sufficient to establish the non-obviousness of claim 9. Appx2-3.

E. The Board Did Not Create a New Rule

Duke mischaracterizes the SFWD as creating 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. at 3. However, no such new rule was stated by the Board or can be reasonably implied from the decision or the subsequent merits panel's judgment

of affirmance without opinion. In addition, BioMarin never urged the creation of such a new rule to the Board or to this Court. To the contrary, the Board 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. Appx2-3. The merits panel agreed.

In its petition, Duke is actually the party asking for this Court to create a new rule. *See* Pet. at 1. Even if this new rule proposed by Duke is accepted, the Court should not overturn the Board's and merits panel's decision because (1) Duke did not establish the facts necessary to be entitled to the presumption and (2) a proper balancing of all of the *Graham* factors still would result in a finding of obviousness.

F. This Case Does Not Involve a Case of Exceptional Importance

Finally, regarding FED. R. APP. P. 35(a)(2), the proceeding does not involve one or more questions of exceptional importance. If it is determined that the Board did not fail to properly apply the presumption of nexus, or that Duke failed to establish nexus, then there is no need to consider whether the requirements of FED. R. APP. P. 35(a)(2) are met. The only time Duke mentions "exceptional importance" or FED. R. APP. P. 35(a)(2), as it relates to the nexus argument, is in the Rule 35 Statement Regarding Rehearing En Banc. *See* Pet. at 1. But, this point is not further developed in the Petition.

II. The *Arthrex* Decision

Contrary to Duke's arguments in its Petition, *Arthrex* does not constitute a significant change in the law during the pendency of Duke's appeal to make waiver inapplicable. Therefore, Duke has waived its Appointment Clause challenge without exception. By questioning *Arthrex's* alleged conflict with *Ethicon* regarding the Director's delegation of constitutional authority to APJs, Duke tries to make a further Appointments Clause argument. But, this challenge has also been waived since Duke did not bring an Appointments Clause challenge in its opening brief. Even so, *Arthrex* presents no conflict with *Ethicon* that creates statutory or due process issues.

A. There Is No Exception to Waiver Since *Arthrex* Does Not Constitute a Significant Change in the Law During Pendency of Duke's Appeal

As the Supreme Court held in *Freytag*, "Appointment Clause challenges are 'nonjurisdictional structural constitutional objections' that can be waived when not presented." *Arthrex*, 941 F.3d at 1340 (quoting *Freytag v. Comm'r*, 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 (Fed. Cir. 2019). This holding was reaffirmed in *Pers. Audio, LLC v. CBS Corp.*, No. 2018-2256, 2020 U.S. App. LEXIS 729, at *6 n.1 (Fed. Cir. Jan. 10, 2020). Since Duke did not raise the Appointments Clause challenge in its opening brief, Duke forfeited its right to have this constitutional challenge heard.

Even so, Duke now argues that the Court's decision in *Arthrex* was a significant change in the law relating to the foundations of *Inter Partes* Review and therefore waiver should not apply. Pet. at 14-15.

However, Duke is fundamentally mistaken. The Appointments Clause has been available for constitutional challenges to APJs long before the Court's decision in *Arthrex*. The Appointments Clause has not changed since the drafting of the Constitution. U.S. CONST. art. II, § 2, cl. 2. Further, the issue of using the Appointments Clause to challenge the constitutionality of APJs has been discussed among scholars and patent professionals since at least 2007. *See* John F. Duffy, *Are Administrative Patent Judges Unconstitutional?*, 2007 Patently-O Pat. L.J. 21. Appointments Clause challenges of APJs have also been heard at the Federal Circuit 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). And, in 2019, besides the *Arthrex* Appointments Clause challenge, there was at least another challenge in *Polaris Innovations* at the Federal Circuit, which was filed prior to the deadline for Duke's opening brief in this case.

Compare Polaris Innovations Ltd. v. Kingston Tech. Co., No. 2018-1768, Polaris Br. at 52-59 (Fed. Cir. July 12, 2018), ECF No. 22, *with* Duke Br. (filed Sept. 24, 2018). Additionally, *Uniloc*, which was decided the same day as *Arthrex*, was able to obtain a remedy consistent with *Arthrex* since 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). Obviously, *Uniloc* raised its Appointments Clause challenge without knowing the outcome of *Arthrex*.

Given numerous examples of Appointments Clause challenges filed at the Federal Circuit, Duke should have been aware of the possibility of making such an argument and was free to bring a constitutional challenge of the APJs who presided over its IPR under the Appointments Clause in its opening brief or a motion filed prior to its opening brief. Yet, Duke chose not to raise the argument.

Only now that Arthrex was successful with its Appointments Clause challenge does Duke argue that "allowing unconstitutionally appointed APJs to abrogate property rights and eviscerate a patentee's investment-backed expectations undermines the entire *inter partes* review process." Pet. at 14. However, given the opportunity to brief the Court on these issues earlier during the appeal, Duke never challenged the constitutionality of its APJs.

To defend its argument for an exception to waiver, Duke cites to cases that Duke alleges hold that waiver is inapplicable for similar changes in law affecting

core governmental process. Pet. at 13-14 (citing *Ninestar Tech. Co. v. ITC*, 667 F.3d 1373, 1382 (Fed. Cir. 2012) and *Glidden Co. v. Zdanok*, 370 U.S. 530, 535-36 (1962)). However, each of these cases only addresses waiver when the issue was timely filed at the time of appeal, but not presented below. These cases do not address waiver when an issue was not timely presented on appeal, which is the issue here. As discussed above, this Court's well-established law is that if an issue is not brought in opening brief it is waived.

Glidden does suggest that a court can treat an alleged defect as jurisdictional and agree to consider it on direct review even though the issue was not raised at the earliest practicable opportunity. *Glidden*, 370 U.S. at 535-36. Even so, this Court has held that Appointments Clause challenges are "nonjurisdictional" and may be waived when not presented. *Arthrex*, 941 F.3d at 1340.

Duke further relies on *Hormel* to suggest that waiver is not applicable when judicial interpretations might have materially altered the result. Pet. at 15-16 (citing *Hormel v. Helvering*, 312 U.S. 552, 558-59 (1941)). However, *Hormel* cites to *Vandenbark,* which holds that a judgment rendered under law that correctly applied the law as interpreted at the time, must be reversed on appeal if, in the meantime, a contrary interpretation has been adopted. *See Hormel*, 312 U.S. at 558-59, n.8 (citing *Vandenbark v. Owens-Illinois Glass Co.*, 311 U.S. 538 (1941)).

In this case, neither the decision of the Board nor the subsequent decisions of the Federal Circuit were predicated on an interpretation of the Appointments Clause as it applies to the constitutionality of APJs. *See* Appx46-88; Appx25-45; Appx1-24; Rule 36 J.

In contrast to Duke's argument, this is not a matter of significant change in the law that resulted in, as Duke characterizes in the Petition, "its patent rights revoked in violation of core constitutional protections." Pet. at 14. Instead, this issue shows Duke's "lack of diligence to present an issue of which it was, or should have been aware." *In re DBC*, 545 F.3d at 1380.

Therefore, the panel should hold that there is no exception to waiver and Duke waived its right to bring an Appointment Clause challenge in this case.

B. Duke Waived Its Right to Present Additional Constitutional Challenges Under the Appointments Clause

Duke further argues that, after *Arthrex*, the Director's delegation of institution authority to APJs acting as principal officers allegedly violated 35 U.S.C. § 314 and due process of law and is allegedly in conflict with this Court's decision in *Ethicon*.

In *Arthrex*, the Court limited the application of *Arthrex* "to those cases where final written decisions were issued and where litigants present an Appointments Clause challenge on appeal." *Arthrex*, 941 F.3d at 1340. Therefore, for *Arthrex* to be applicable in this case, Duke was required to bring a timely Appointments Clause challenge in this appeal. In order to question the Director's delegation authority,

Duke is asking the Court to hear the issue of the constitutionality of APJs much too late.

In *Ethicon*, the court held that neither the statute nor the Constitution "precludes the same panel of the Board that made the decision to institute inter partes review from making the final determination" in the same IPR. *Ethicon*, 812 F.3d at 1640. Even though the court's rationale for this holding relied at least in part on the assumption that APJs are subordinate officers, the issue of whether APJs are "principal" or "inferior" officers was not part of the overall discussion or holding. Therefore, there is no actual conflict between *Arthrex* holding that APJs are principal officers and *Ethicon*'s finding that the same panel of the Board that made the decision to institute an IPR can make the final determination in the case.

While Duke's argument alleging conflict between this court's decision in *Arthrex* and its rationale in *Ethicon* appears to be a statutory and due process argument, Duke is effectively questioning the constitutionality of APJs and APJs' status as either "inferior" or "principal" officers, under the Appointments Clause. *See* Pet. at 13-18. *But see Arthrex*, 941 F.3d at 1335; *see also* U.S. CONST. art. II, § 2, cl. 2.

Duke had an opportunity to timely raise Appointments Clause challenges, but failed to do so. As discussed above, since Duke did not present Appointments Clause challenges in its opening brief, Duke forfeited these arguments.

Even if this argument had not been waived, this Court's decision in *Arthrex* does not raise due process or statutory issues and does not conflict with *Ethicon*'s decision regarding the Director's delegation of institution authority. The Director's delegation of institution authority to APJs does not violate 35 U.S.C. § 314 or due process since, after *Arthrex*, APJs are inferior officers who are constitutionally appointed. Further, *Arthrex* holds that where there are decisions on appeal from APJs acting as principal officers, any party properly raising an Appointments Clause challenge is entitled to hearing in front of a new panel of constitutionally appointed APJs, rendering these statutory and due process issues moot. *See Arthrex*, 941 F.3d at 1339-40.

Therefore, the panel should hold that Duke waived its right to bring an additional Appointment Clause challenge in this case and deny Duke's Petition.

C. Consideration of Appointments Clause Challenges for the First Time on Appeal is Discretionary with this Court

Consideration of Appointments Clause challenges for the first time on appeal is discretionary with this Court. *See Arthrex*, 941 F.3d at 1327; *In re DBC*, 545 F.3d at 1379. The Supreme Court has never indicated that such challenges must be heard regardless of waiver. *In re DBC*, 545 F.3d at 1380 (citing *Freytag*, 501 U.S. at 893). It is submitted that the following factors considered in *In re DBC* weigh against the court exercising discretion in this appeal to consider the Appointments Clause challenge: (1) the challenge is not based on any legal proposition that was not

previously knowable to Duke, (2) the challenge was not based on any change in law or facts that were not previously knowable to Duke; (3) exercising the courts discretion would encourage "sandbagging," (4) Duke has not made any allegation of incompetence or other impropriety regarding the APJs that heard this case and (5) the problem has already been fixed and therefore exercising discretion in this case to hear the appointments clause challenge will not affect cases decided by future panels. *See In re DBC*, 545 F.3d at 1379-1380 (the discussion of these five factors).

CONCLUSION

For the foregoing reasons, Duke's Petition should be denied.

Dated: January 16, 2020

Respectfully submitted,

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FORM 30. Certificate of Service

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

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I certify that this response complies with the type-volume limitation of FED. CIR. R. 35(e)(4). The response contains 3,653 words, excluding the parts of the response exempted by FED. CIR. R. 35(c)(2). This response complies with the typeface requirements of FED. R. APP. P. 32(a)(5) and the type style requirements of FED. R. APP. P. 32(a)(6). The response has been prepared in proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman.

Dated: January 16, 2020

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