

No. 20-1285

In the
Supreme Court of the United States

IMMUNEX CORPORATION,

Petitioner,

v.

SANOFI-AVENTIS U.S. LLC, GENZYME CORP., and
REGENERON PHARMACEUTICALS, INC.,

Respondents.

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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

The U.S. Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") determined through inter partes review that 17 claims of one of Petitioner's patents should be canceled as obvious in view of the prior art. Petitioner appealed that decision to the Federal Circuit, arguing that the PTAB misapplied patent law. In its reply brief on appeal, however, Petitioner raised a new argument: that the PTAB's administrative patent judges are principal officers of the United States who must be nominated by the president and confirmed by the Senate. The Federal Circuit affirmed the obviousness determinations and concluded that Petitioner's failure to raise an Appointments Clause objection in its opening brief constitutes forfeiture of that separate challenge.

Accordingly, the questions presented are:

1. Whether Petitioner forfeited its Appointments Clause challenge by not timely raising it in accordance with Federal Circuit precedent.
2. Whether a holding in *United States v. Arthrex, Inc.* (19-1434) that administrative patent judges are unconstitutionally appointed for reasons that cannot be severed from the rest of the statute would vitiate the Federal Circuit's forfeiture jurisprudence such that Petitioner preserved its Appointments Clause challenge below.

CORPORATE DISCLOSURE STATEMENT

Sanofi is the parent company of Sanofi-Aventis U.S. LLC and Genzyme Corp. No publicly owned corporation owns more than 10% of Sanofi. No publicly owned corporation owns more than 10% of Regeneron Pharmaceuticals, Inc.

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INTRODUCTION

In this case, the Federal Circuit affirmed a decision by the Patent Trial and Appeal Board (“PTAB”) to cancel 17 claims of one of Petitioner Immunex Corp.’s patents because those claims are obvious. Rather than challenge that factbound and plainly correct application of patent law, Immunex’s petition instead exclusively raises arguments under the Appointments Clause. In particular, Immunex contends that the PTAB’s administrative patent judges (“APJs”) are principal officers who must be nominated by the President and confirmed by the Senate. Immunex thus urges that its petition be held for the Court’s forthcoming decision in *United States v. Arthrex, Inc.* (19-1434) and then “disposed of as appropriate” in light of that decision. Pet.25.

Immunex’s petition, however, suffers from a fatal flaw: Immunex did not mention the Appointments Clause until its *reply* brief in the Federal Circuit, thus forfeiting the issue under well-established Federal Circuit law. Following its decision in *Arthrex* that APJs are principal officers, the Federal Circuit has consistently held that Appointments Clause challenges are forfeited unless a party raises the challenge in its *opening* brief on appeal. This Court, in turn, has consistently denied petitions raising forfeited Appointments Clause challenges. In fact, since October 2020, the Court has already denied at least six petitions in which the petitioner did not raise the Appointments Clause in its opening brief, including a petition challenging the very decision that the Federal Circuit cited in support of its forfeiture holding in this case. *See Customedia Techs., LLC v.*

Dish Network Corp., 941 F.3d 1173 (Fed. Cir. 2019), *cert. denied*, No. 20-135 (Oct. 13, 2020).

There is no reason to treat this petition differently. To the contrary, in this petition—unlike those the Court has already denied—Immunex does not even challenge the Federal Circuit’s general forfeiture rule nor its specific application of that rule to Immunex in this case. The first two questions presented in the petition—which simply mirror the questions presented in *Arthrex*, without mentioning forfeiture—are thus nonstarters. Accordingly, even more so here than in other cases where petitioners failed to preserve their *Arthrex* arguments below under Federal Circuit law, there is no basis for holding this petition based on the first two questions presented.

Faced with the reality that it forfeited its *Arthrex* arguments below and that this Court has repeatedly denied certiorari in such circumstances, Immunex attempts to manufacture a cumbersome workaround in the form of a third question presented. According to Immunex, *if* the Court holds in *Arthrex* that APJs are unconstitutionally appointed (as the Federal Circuit determined) *and* further holds that the unconstitutional provision of the statute is not severable (a position that the Federal Circuit rejected), *then* those two hypothetical holdings together would “vitate” the Federal Circuit’s “forfeiture rule,” Pet.i, 2, 8, 11, 19, and require a holding “that an Appointments Clause challenge need not have been raised in an opening brief,” *id.* at 13.

This transparent effort to circumvent Immunex’s forfeiture likewise provides no basis for this Court to

intervene. To begin, the Court also has denied petitions presenting this argument. Further, Immunex's third question presented was neither pressed nor passed upon in the Federal Circuit, it is of limited and diminishing importance, and it does not conflict with the decisions of this Court or the courts of appeals. Finally, Immunex's theory fails on the merits.

The inescapable fact is that Immunex forfeited its *Arthrex* arguments below under longstanding Federal Circuit law. That is a dispositive defect that no amount of creative lawyering can cure. Accordingly, like many other similarly situated petitioners, Immunex is not entitled to relief from this Court. The petition should be denied.

STATEMENT OF THE CASE

A. Statutory and Constitutional Background

1. Inter Partes Review

In the Leahy-Smith America Invents Act, Pub. L. No. 112-29, §6(a), 125 Stat. 284, 299, 303 (2011), Congress created the PTAB, “an adjudicatory body within the” U.S. Patent and Trademark Office (“PTO”) with power to review previously issued patent claims. *Oil States Energy Servs., LLC v. Greene’s Energy Grp., LLC*, 138 S.Ct. 1365, 1370-71 (2018). One way that the PTAB reviews patent claims is through inter partes review, which allows third parties to “ask the [PTO] to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2136 (2016).

Inter partes review begins when a party “request[s] cancellation of ‘1 or more claims of a patent’ on the grounds that the claim fails the novelty or nonobviousness standards for patentability.” *Oil States*, 138 S.Ct. at 1371 (quoting 35 U.S.C. §311(b)). Upon receipt of such a petition, the Director of the PTO (or his delegatee¹) determines whether to institute review. This requires finding “that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged.” *Id.* (quoting 35 U.S.C. §314(a)).

If review is instituted, proceedings occur before the PTAB, which consists of the Director, the Deputy Director, the Commissioner for Patents, the Commissioner for Trademarks, and “administrative patent judges.” 35 U.S.C. §6(a). The Director is nominated by the President and confirmed by the Senate, *id.* §3(a); the Secretary of Commerce, in turn, appoints a Deputy Director and the Commissioners for Patents and Trademarks, each of whom serves under the Director, *id.* §3(b)(1)-(2). APJs are “persons of competent legal knowledge and scientific ability who are appointed by the Secretary [of Commerce], in consultation with the Director.” *Id.* §6(a). As “[o]fficers and employees” of the PTO, *id.* §3(c), APJs enjoy civil-service protections and thus, generally, may be removed “only for such cause as will promote the efficiency of the service,” 5 U.S.C. §7513(a).

The PTAB ordinarily “sits in three-member panels of administrative patent judges.” *Oil States*,

¹ The Director has delegated authority to the PTAB to determine whether to institute review. See 37 C.F.R. §42.4(a).

138 S.Ct. at 1371. After discovery and motions practice, the PTAB holds an oral hearing to evaluate the challenged claims. *Id.* at 1371. Following that process, if the PTAB concludes in a final decision that claims are not patentable, “the Director must ‘issue and publish a certificate’ ... [that] cancels [those] claims.” *Id.* at 1372 (quoting 35 U.S.C. §318(b)). Dissatisfied parties may appeal to the Federal Circuit. *See* 35 U.S.C. §319.

2. The *Arthrex* Litigation

Inter partes review has been the subject of much constitutional litigation. Three years ago, in *Oil States*, the Court concluded that inter partes review comports with Article III of the Constitution and the Seventh Amendment. *See* 138 S.Ct. 1365. And for the last five years, parties have also challenged inter partes review under the Appointments Clause, on the theory that APJs are principal officers of the United States and thus, under the current statutory scheme, unconstitutionally appointed.

Parties began raising Appointments Clause objections at least as early as 2016, when a party argued to the PTAB that APJs are “principal officers” who “may only be appointed by the President, with the advice and consent of the Senate.” PGR2016-00010, Paper 7 at 32 (P.T.A.B. May 24, 2016); *see also* IPR2015-01836, Response at 65 (P.T.A.B. Jun. 7, 2016) (“The institution and conduct of an IPR by Administrative Patent Judges appointed by a cabinet secretary also violates the Constitution's Appointments Clause.”). Over the years since then, parties have repeatedly raised such objections. *See, e.g.*, IPR2018-00017, Response at 57 (P.T.A.B. Jan. 18,

2018) (“[C]anceling claims in IPR is also unconstitutional if it is carried out by a final order issued by Administrative Patent Judges who have not been nominated by the President and confirmed by the Senate.”); IPR2018-00096, Response at 59-60 (P.T.A.B. Feb. 1, 2018) (same); IPR2018-00107, Response at 57-58 (P.T.A.B. Feb. 6, 2018) (arguing that APJs “are principal officers”).

The volume of Appointments Clause challenges increased following *Lucia v. SEC*, 138 S.Ct. 2044 (2018), where this Court held that the SEC’s administrative law judges are officers of the United States. Just weeks after the Court decided *Lucia*, a party petitioned for certiorari on the ground that APJs are “principal—not inferior—Officers of the United States.” Petition 2, *Smartflash LLC v. Samsung Elecs. Am., Inc.*, No. 18-189 (U.S. Aug. 9, 2018), *cert. denied*, 139 S.Ct. 276 (2018). The Court denied that petition after respondents explained that the petitioner had not preserved an Appointments Clause challenge. *See* Br. in Opp’n 8-11, No. 18-189 (U.S. Aug. 22, 2018). Numerous other parties, however, began properly raising Appointments Clause objections. *See, e.g.*, Opening Br. of Appellant 1-2, *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 18-1768 (Fed. Cir. July 10, 2018) (arguing in opening brief that “[t]he cancellation of Polaris’s claims violated the Appointments Clause”). All the while, the issue of whether APJs’ appointments violate the Appointments Clause was openly discussed by commentators. *See, e.g.*, Ryan Davis, *Are PTAB Appointments Unconstitutional? A Closer Look*, Law360 (Sept. 5, 2018), <https://bit.ly/3hk2g4j> (detailing constitutional litigation); Gary Lawson,

Appointments and Illegal Adjudication: The AIA Through a Constitutional Lens, 26 Geo. Mason L. Rev. 26 (2018) (explaining the argument).

On October 31, 2019, this long-simmering issue finally came to a head when the Federal Circuit decided *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), and held that APJs are principal officers. *Id.* at 1335. The Federal Circuit further held, however, that severing APJs’ “efficiency of the service” tenure protections would render them inferior officers whom the Secretary of Commerce could lawfully appoint. *Id.* at 1338. Finally, the court ordered that the PTAB decision at issue in *Arthrex* be vacated and the matter remanded to a different PTAB panel. *Id.* at 1340. After the Federal Circuit denied rehearing en banc in *Arthrex*, this Court granted certiorari. The Court heard oral argument on March 1, 2021.

Unsurprisingly, in the wake of *Arthrex*, parties to Federal Circuit appeals who had not previously raised an Appointments Clause issue began attempting to do so. In *Customedia*, however—decided shortly after *Arthrex*—the Federal Circuit held that a party that had failed to raise an Appointments Clause challenge in its opening brief had “forfeited” the issue. 941 F.3d at 1175. In so holding, the Federal Circuit applied its “well established” rule that “arguments not raised in the opening brief are waived.” *Id.* (quoting *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006)). The Federal Circuit has since consistently enforced that rule. *See e.g., Pers. Audio, LLC v. CBS Corp.*, 946 F.3d 1348, 1351 n.1 (Fed. Cir. 2020).

B. Factual and Procedural Background

1. Inter Partes Review of the '487 Patent

Since 2017, Immunex and Respondents have been engaged in multi-forum litigation over patents for antibodies that bind to the human interleukin-4 receptor (“IL-4R”). App.3. Interleukin-4 (“IL-4”) and interleukin-13 (“IL-13”) are signaling proteins that help control the human body’s immune system that can harm the body through overactive signaling. App.27-28. Because IL-4 and IL-13 signal by interacting with the cell surface receptor IL-4R, certain antibodies directed against IL-4R can inhibit IL-4 and/or IL-13 signaling. App.28. Thus, antibodies can be made such that, because of their amino acid sequence, they block signaling through IL-4R, and thus help address diseases associated with overactive signaling by IL-4 and IL-13. App.28-29.

Humans who have been injected with non-human antibodies can experience negative immune responses. But “[a]mino acid sequences that are human in origin ... can avoid triggering immune responses.” App.4-5. It therefore is helpful to “humanize” a foreign antibody—*i.e.*, reduce the amount of non-human sequencing—so that the human body is more amenable to the antibody. App.5.

Respondents have developed an IL-4R antibody, Dupixent®, which received FDA approval to treat several inflammatory diseases such as atopic dermatitis (a type of eczema) and asthma. Immunex, by contrast, has not been able to develop its own viable IL-4R antibody. Nevertheless, after Immunex’s antibody failed in clinical trials, Immunex obtained a

patent with broad functional claims seeking to cover IL-4R antibody advances made by others. In particular, on March 25, 2014, Immunex obtained U.S. Patent No. 8,679,487 (the “487 patent”), with claims that purport to cover any “isolated human antibody” that “competes” for binding to IL-4R with an antibody disclosed in the ’487 patent. App.2-4; *see also* App.27-29. After obtaining this patent, Immunex sued Respondents in federal court for infringement. *See Immunex Corp. v. Sanofi*, No. 2:17-cv-2613-SJO (C.D. Cal. filed Apr. 5, 2017).

In response to that lawsuit, Respondents filed three petitions for inter partes review regarding the ’487 patent. On February 15, 2018, the PTO instituted two inter partes reviews. After discovery, briefing, and a hearing, the PTAB issued two decisions on February 14, 2019.

First, the PTAB determined that the ’487 patent’s challenged claims are obvious, and thus unpatentable as a matter of law. The PTAB evaluated, *inter alia*, the claims’ language, specifications, and prosecution history to construe the claim term “human antibody” to encompass “fully human” *and* “partially human” antibodies, rather than just fully human antibodies as Immunex urged. App.10; *see also* App.66-89. So construed, the PTAB concluded, the ’487 patent’s claims are obvious over two references known as Hart and Schering-Plough. *See, e.g.*, App.76-89.

Second, the PTAB addressed Respondents’ argument that even if the ’487 patent claims are not obvious, claims 1-14, 16, and 17 are anticipated by prior art. As Respondents explained, Immunex’s own U.S. Patent Application Publication No. 2002/0002132

(the “132 publication”) predated the asserted priority of the ’487 patent and disclosed an IL-4R antibody known as mAb 6-2 that competes with the antibody in the ’487 patent. *See* App.32-36. On this issue, however, the PTAB sided with Immunex, concluding that the ’132 publication was not “by another”—a requirement for prior art under 35 U.S.C. §102(e) (pre-AIA)—because mAb 6-2 was invented by one of the named inventors of the ’487 patent, even though Immunex had previously identified a different inventor. App.55.

At no point during the yearlong proceedings before the PTAB did Immunex raise a constitutional objection to how the PTAB’s administrative patent judges are appointed. Instead, the parties’ dispute concerned ordinary patent law.

C. The Federal Circuit’s Proceedings

Immunex appealed to the Federal Circuit, challenging the PTAB’s determination that the ’487 patent is obvious; that appeal resulted in case number 19-1749. Respondents cross-appealed, challenging the PTAB’s determination that the ’487 patent is not anticipated; that appeal resulted in case number 19-1777.

On July 25, 2019, Immunex submitted its opening brief in its appeal (No. 19-1749). Although, by that point, parties in numerous other Federal Circuit appeals had argued in their opening briefs that APJs are unconstitutionally appointed—including in *Arthrex* itself—Immunex did not; its opening brief raised only patent-law arguments challenging the PTAB’s decision. Nor did Immunex notify the clerk’s office that its appeal raised a constitutional question,

which the Federal Circuit requires if a party intends to “question[] the constitutionality of an Act of Congress in a proceeding in which the United States or its agency, officer, or employee is not a party.” Fed. R. App. P. 44(a).

Subsequently, Respondents submitted their combined response brief in Immunex’s appeal (No. 19-1749) and principal brief in their cross-appeal (No. 19-1777). Respondents’ brief did not address any constitutional issues but instead exclusively addressed the PTAB’s patent analysis.

On November 6, 2019, one week after the Federal Circuit decided *Arthrex*, Immunex filed its combined reply brief in its appeal and its response brief in Respondents’ cross-appeal. Immunex again largely addressed the patent-law questions that the PTAB had decided. In the reply brief for its appeal, however—under the heading “Reply Brief for 19-1749”—Immunex raised a new issue: the appointment of APJs violates the Appointments Clause. Immunex conceded that it “did not present an appointments clause argument in its opening brief,” and acknowledged that “*Arthrex* indicated that an appointments clause argument is nonjurisdictional and can be waived.” Appellants’ Resp. & Reply Br. 33-34, Nos. 19-1749, 19-1777 (Fed. Cir. Nov. 6, 2019), Dkt.35. Nonetheless, Immunex argued that it could raise an Appointments Clause challenge for the first time on appeal. Immunex contended, among other things, that because of the cross-appeal posture, Respondents would have a “full opportunity to respond in [their] final reply brief,” which would “mitigate any waiver concerns.” *Id.* at 34.

In their reply brief in support of their cross-appeal (No. 19-1777), Respondents argued that Immunex forfeited any Appointments Clause challenge by not raising the issue in its opening brief, citing *Customedia*. See Appellees' Reply Br. 15-17, Nos. 19-1749, 19-1777 (Fed. Cir. Feb. 25, 2020), Dkt.49. Respondents also observed that they could not address the merits of Immunex's Appointments Clause argument because, under the Federal Circuit's rules, a reply brief in support of a cross-appeal "must be limited to the issues presented by the cross-appeal." *Id.* at 17 (quoting Fed. R. App. P. 28.1(c)(4)).

The PTO Director intervened and filed a brief likewise arguing that Immunex "forfeited any Appointments Clause argument by not raising it in or before its opening brief." See PTO Br. 4, Nos. 19-1749, 19-1777 (Fed. Cir. Feb. 25, 2020), Dkt. 48.

In a unanimous decision, the Federal Circuit agreed with the PTAB that Immunex's challenged claims are obvious; accordingly, it did not reach Respondents' cross-appeal. App.3. The Federal Circuit's decision was almost entirely devoted to the parties' patent-law arguments. In a footnote, the panel briefly addressed Immunex's Appointments Clause challenge, citing *Customedia* and explaining that under Federal Circuit precedent, Immunex's "failure to raise this challenge in the opening brief constitutes forfeiture." App.24 n.10. Immunex did not seek panel or en banc rehearing.

REASONS FOR DENYING THE PETITION

I. The First And Second Questions Presented Do Not Warrant The Court's Review.

Immunex's first and second questions presented are copied directly from the *Arthrex* petition, presumably because Immunex wants to enjoy the benefits of any favorable decision in *Arthrex*. See Pet.12 (requesting a hold and then GVR "[i]f the Court affirms in *Arthrex*"). But the Federal Circuit, applying its well-established law, held that Immunex forfeited any *Arthrex* arguments below by failing to raise them in its opening brief. This Court cannot reach Immunex's first two questions unless the Court first concludes that the Federal Circuit's forfeiture determination was erroneous. In its petition to this Court, however, Immunex does not argue that the Federal Circuit's forfeiture determination was incorrect or otherwise warrants this Court's review. Indeed, its first and second questions presented do not even mention forfeiture.

This Court's Rule 14.1 is clear that "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." See, e.g., *Chandris, Inc. v. Latsis*, 515 U.S. 347, 353 n.* (1995) (refusing to consider issue not raised in petition). Furthermore, this Court will not consider issues "only obliquely raised" in a petition. *Stop the Beach Renourishment, Inc. v. Fla. Dep't of Env't Prot.*, 560 U.S. 702, 729 n.11 (2010). Because Immunex's first two questions presented do not "fairly include[]" the question of whether the Federal Circuit erred in finding Immunex's *Arthrex* arguments forfeited—or even challenge (much less "obliquely") the Federal

Circuit’s general requirement that issues not raised in an opening brief are forfeited (or its forfeiture determination in this case)—this Court cannot address Immunex’s forfeiture of its *Arthrex* arguments, and thus Immunex cannot avail itself of any beneficial decision by this Court in the *Arthrex* case. *See Yakus v. United States*, 321 U.S. 414, 444 (1944) (“No procedural principle is more familiar to this Court than that a constitutional right may be forfeited ... by the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it.”).²

It is no secret why Immunex’s petition does not directly challenge the panel’s forfeiture ruling or the Federal Circuit’s forfeiture rule more generally: this Court has repeatedly denied such petitions. In fact, in the wake of *Arthrex*, the Court has denied no fewer than six petitions for certiorari where, as here, the petitioner did not raise an Appointments Clause challenge in its opening brief before the Federal Circuit. *See In re ThermoLife Int’l LLC*, 796 F.App’x 726 (Fed. Cir. 2020), *cert. denied*, 141 S.Ct. 1049 (2021); *IYM Techs. LLC v. RPX Corp.*, 796 F.App’x 752 (Fed. Cir. 2020), *cert. denied*, 141 S.Ct. 850 (2020); *Duke Univ. v. Biomarin Pharm. Inc.*, 779 F.App’x 750 (Fed. Cir. 2019), *cert. denied*, 141 S.Ct. 815 (2020);

² To be sure, Immunex’s third question presented argues that *if* the Court reverses the Federal Circuit’s severance remedy, then the forfeiture rule from *Customedia* must fall. As explained below, that convoluted attempt to avoid forfeiture also does not warrant plenary review. *See* pp.16-31, *infra*. For present purposes, however, Immunex’s failure to challenge the Federal Circuit’s forfeiture holding or even include it in its first two questions presented is fatal to consideration of those questions.

Essity Hygiene & Health AB v. Cascades Canada ULC, 811 F.App'x 638 (Fed. Cir. 2020), *cert. denied*, 141 S.Ct. 555 (2020); *Customedia*, 941 F.3d 1174, *cert. denied*, 141 S.Ct. 555 (2020); *Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc.*, 791 F.App'x 916 (Fed. Cir. 2019), *cert. denied*, 141 S.Ct. 266 (2020). In fact, this Court denied certiorari in *Customedia* on the same day it granted certiorari in *Arthrex*, demonstrating the importance to this Court of properly preserving the Appointments Clause issue according to the Federal Circuit's forfeiture law.

Like the petitioners in the foregoing cases, Immunex did not raise an Appointments Clause challenge in its opening brief on appeal. Like those petitioners, therefore, Immunex forfeited its Appointments Clause argument below and thus cannot avail itself of any beneficial decision in *Arthrex*. Accordingly, for the same reasons the Court denied the other petitions, it should conclude that the first two questions in Immunex's petition do not warrant review or relief for Immunex, regardless of how *Arthrex* is decided. After repeatedly denying petitions that directly challenge the Federal Circuit's forfeiture precedent, it would be passing strange for the Court to grant this petition, which contains no such argument at all.³

³ This Court's recent decision in *Carr v. Saul*, 141 S.Ct. 1352 (2021), does not aid Immunex, and Immunex has never suggested that *Carr* might have any effect on this case. There, the Court held that a party does not forfeit a constitutional challenge to the appointment of Social Security Administration administrative law judges by failing to raise that issue before an ALJ. The Court did not address whether a party forfeits an issue by failing to properly raise it in federal court consistent with that court's own

II. The Third Question Presented Does Not Warrant This Court's Review.

Faced with the reality that this Court has repeatedly denied certiorari when the petitioner failed to raise an *Arthrex* argument in its opening brief—and thus unable and unwilling to directly challenge the Federal Circuit's forfeiture determination below—Immunex manufactures a third question presented that is nothing more than a transparent effort to circumvent those prohibitive obstacles to review. According to Immunex, if the Court in *Arthrex* affirms the Federal Circuit's holding that APJs are principal officers but reverses its holding that the constitutional flaw is severable (such that Congress would have to re-enact inter partes review through new legislation), the Court's decision would "vitate" the Federal Circuit's "forfeiture rule," Pet.i, 2, 8, 11, 19, and require a holding "that an Appointments Clause challenge need not have been raised in an opening brief," *id.* at 13.

This cumbersome issue also does not merit the Court's review, nor does it warrant holding the petition "pending resolution of *Arthrex*." *Id.* at 23. Indeed, the Court has already denied petitions raising this issue. Further, the issue was neither pressed nor passed upon below, it does not satisfy any of the

law, as here. Although the Court stated at one point that "claimants who raise ... issues for the first time in federal court are not untimely in doing so," *id.* at 1362, the Court was not suggesting that raising an issue at *any point* in federal court—including, for example, only in a reply brief—properly preserves the issue.

traditional requirements for certiorari, and Immunex is wrong on the merits.

A. The Court Has Repeatedly Denied Petitions Raising This Question.

Immunex's theory is that if this Court "reverses the Federal Circuit's severance remedy" in *Arthrex*, that would constitute a "profound change in the law" that would "vitiating the Federal Circuit's forfeiture holding." Pet.19; *see also id.* at 8 ("Arthrex's preferred remedy would effect a profound change in the law so as to vitiate the Federal Circuit's forfeiture rule."); *id.* at 19-20 ("Should this Court agree ... that the Federal Circuit's severance remedy is insufficient, ... the resulting change in law would be so profound and sharp as to have far a greater impact than the Federal Circuit originally envisioned"). But that same theory has already been raised in various forms by other petitioners, and yet the Court still denied certiorari. The same result should follow here.

In the *Duke* petition, for example, Duke argued that forfeiture should not apply when "a constitutional decision ... upends the legal landscape," Petition 21, *Duke*, No. 19-1475 (U.S. July 2, 2020), and then further argued that the Federal Circuit's severability holding "does not cure the problem," *id.* at 23. Thus, Duke urged the Court to "grant review to give Congress 'the opportunity to craft the appropriate fix,' or, "[a]lternatively," to "hold the petition ... for *Arthrex*." *Id.* at 24. By requesting that its petition be held pending this Court's decision in *Arthrex*, Duke indicated that even if the Federal Circuit's decision in *Arthrex* by itself was insufficient to overcome

forfeiture, a decision by this Court rejecting severability would be sufficient.

The *ThermoLife* petition made a similar argument. There, ThermoLife argued that the Federal Circuit’s severability holding in *Arthrex* “did not cure the Appointments Clause violation” and contravened “Congressional intent.” Petition 29-30, *ThermoLife*, No. 20-150 (U.S. Aug. 10, 2020). Like Duke, ThermoLife also asked the Court to either grant its petition or hold the petition for *Arthrex*. *See id.* at 36. Again, the logic of the *ThermoLife* petition—indeed, the only reason to challenge the Federal Circuit’s severability holding—is that a decision from this Court holding that only Congress can cure the constitutional violation would undercut the Federal Circuit’s forfeiture analysis, giving the petitioner relief notwithstanding its failure to raise *Arthrex* arguments in its opening brief below. Similarly, in the *Sanofi* petition, the petitioner observed that the *Arthrex* petition would address “whether the Federal Circuit’s remedy ... successfully rendered APJs inferior officers,” and that the Court’s decision in *Arthrex* “may have significant implications for the question presented here, including as to the proper forfeiture analysis in Appointments Clause cases.” Petition 23-24, *Sanofi*, No. 19-1451 (U.S. June 26, 2020).

Despite these petitioners’ arguments that a decision by this Court reversing the Federal Circuit’s severability holding would have legal significance for assessing forfeiture, thus meriting at least a hold for *Arthrex*, the Court denied each of these petitions outright. Here, Immunex makes the same argument.

Yet the argument has not gotten better with time. Accordingly, the Court should again deny a petition that seeks to leverage a possible decision by this Court reversing the Federal Circuit’s severability analysis as a reason for overriding the Federal Circuit’s forfeiture jurisprudence.⁴

B. This Case Is a Poor Vehicle to Address the Question Presented, Which Does Not Satisfy This Court’s Certiorari Criteria Regardless.

Even if the Court had not already concluded that Immunex’s third question presented is not certworthy, significant vehicle problems independently defeat review. Furthermore, the question does not satisfy any of the Court’s traditional criteria for granting certiorari.

1. Immunex never raised this issue below—not even in its reply brief. Immunex’s reply brief argued that the *Federal Circuit’s* decision in *Arthrex* was such

⁴ Immunex’s third question presented is not even implicated unless the Court in *Arthrex* affirms the Federal Circuit’s constitutional holding but reverses its severability holding such that “the entire inter partes review scheme [is] invalidated.” Pet.21. If the Court does not so rule, Immunex’s third question presented is a nonstarter out of the gate. This Court, of course, holds petitions even when it knows that a forthcoming decision will have no effect on a petition, in order to avoid “tipping its hand” regarding the forthcoming decision. Here, however, there is no basis for holding Immunex’s petition based on the third question presented, for *even if* the Court’s ruling satisfied the conditions that implicate that question, the Court’s intervention still would not be warranted, as explained herein and as confirmed by the Court’s denial of other petitions raising the same theory.

an unexpected change in the law that forfeiture should be excused. *See* Appellants' Resp. & Reply Br. 33-35. Immunex never argued that a decision from *this Court* rejecting the Federal Circuit's severance holding in *Arthrex* would vitiate forfeiture. Nor did it so much as suggest that, if the Federal Circuit heard *Arthrex* en banc, the full court should reject the panel's severability holding and conclude that only Congress could cure the alleged constitutional infirmity, thus warranting a change in its forfeiture jurisprudence. Immunex thus never asked the Federal Circuit to address or resolve the third question it now presents to this Court.

Because Immunex's third issue "was not raised below," it is forfeited. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 56 n.4 (2002). By itself, this threshold defect warrants denial of the third question. *See, e.g., Kingdomware Techs., Inc. v. United States*, 136 S.Ct. 1969, 1978 (2016) ("The Department failed to raise this argument ... below, and we normally decline to entertain such forfeited arguments."); *OBB Personenverkehr AG v. Sachs*, 136 S.Ct. 390, 398 (2015) ("Absent unusual circumstances—none of which is present here—we will not entertain arguments not made below."); *Rent-A-Center, W., Inc. v. Jackson*, 561 U.S. 63, 75-76 (2010) (argument "not mentioned below" is "too late, and we will not consider it").

Additionally, the Federal Circuit did not address Immunex's question presented, further militating against review. As the Court has explained many times, because it is "a court of review, not of first view," it does not "generally ... consider arguments" that the

lower courts “did not have occasion to address.” *Byrd v. United States*, 138 S.Ct. 1518, 1527 (2018); *see, e.g., Town of Chester v. Laroe Ests., Inc.*, 137 S.Ct. 1645, 1652 n.4 (2017) (“[I]n light of ... the lack of a reasoned conclusion on this question from the Court of Appeals, we are not inclined to resolve it in the first instance.”); *City & Cnty. of San Francisco v. Sheehan*, 575 U.S. 600, 609 (2015) (“The Court does not ordinarily decide questions that were not passed on below.”); *Zivotofsky ex rel. Zivotofsky v. Clinton*, 566 U.S. 189, 201 (2012) (refusing to resolve issue “without the benefit of thorough lower court opinions”).

Immunex does not acknowledge these flaws, much less explain why the Court should abandon its longstanding practice of denying petitions that advance procedurally improper arguments, including those that were “not pressed or passed upon below.” *United States v. Williams*, 504 U.S. 36, 41 (1992). Even if the third question presented did not suffer from all manner of other problems, “[p]rudence” would dictate “awaiting ... the benefit of” a lower-court opinion “squarely addressing” the merits of that issue. *Yee v. City of Escondido*, 503 U.S. 519, 538 (1992). The Court should not resolve that unaddressed question in the first instance or grant relief to Immunex based on an argument that was neither pressed nor passed upon in the Federal Circuit.⁵

⁵ It is no answer for Immunex to say that the Court should grant, vacate, and remand in light of *Arthrex* in order for the Federal Circuit to decide the question in the first instance. That gets matters backward: an issue must be “pressed or passed upon below” *before* this Court can grant relief, including a GVR.

2. Immunex also does not argue that its third question presented satisfies this Court's customary requirements for certiorari. Other petitions arising in this posture—petitions the Court denied—at least tried to demonstrate that the lower courts were divided about how to apply forfeiture. *See* Petition 13-19, *Essity*, No. 20-131 (U.S. July 24, 2020). Immunex identifies no purported conflicts of any kind; instead, it simply seeks factbound error correction of the Federal Circuit's decision, which is not a valid basis for certiorari.

Immunex also does not show that its third question is sufficiently important and recurring to warrant this Court's intervention. Nor could it. By repeatedly denying petitions arising in the same posture as this one, the Court has indicated that such petitions are not certworthy. Yet the passage of time has made such petitions even less certworthy. When Duke petitioned, for example, it could credibly say that the Federal Circuit's forfeiture rule would affect numerous parties. *See Duke.Pet.18-19*. Likewise, Customedia stressed that its *own* case prompted the Federal Circuit's precedential holding on forfeiture, and it identified other parties who were affected by that precedential holding and would seek certiorari from this Court. *See* Petition 22-25, *Customedia*, No. 20-135 (U.S. Aug. 1, 2020).

Now, however, it is implausible that *any* similarly situated party other than Immunex even could benefit from certiorari in this case. The Court has already denied the petitions of every other petitioner who is similarly situated. And there is no reason to think that more petitions presenting Immunex's third

question will be filed. Parties first started raising Appointments Clause objections to inter partes review as early as 2016. And the Federal Circuit decided *Arthrex* on October 31, 2019—more than 18 months ago. At present, every lawyer who wishes to raise an Appointments Clause challenge knows to do so in its opening brief in the Federal Circuit, consistent with that court’s longstanding forfeiture rule. There is no need for any other party to resort to Immunex’s convoluted theory for avoiding forfeiture that it presents here. Because Immunex’s third question is of insufficient and (if it were even possible) diminishing importance, denial is appropriate.

C. Immunex’s Argument Is Meritless.

Finally, review of the third question presented is unwarranted because Immunex’s argument lacks merit. Immunex contends that if this Court “reverses the Federal Circuit’s severance remedy” in *Arthrex*, that would “effect a profound change in the law so as to vitiate the Federal Circuit’s forfeiture rule” requiring a party to raise an issue in its opening brief on appeal. Pet.8, 19. Immunex is wrong.

1. Forfeiture “is essential to the orderly administration of civil justice.” 9B Wright & Miller, *Federal Practice & Procedure* §2472 (3d ed. 2021). Accordingly, only a party “who makes a timely challenge to the constitutional validity of the appointment of an officer who adjudicates his case’ is entitled to relief.” *Lucia*, 138 S.Ct. at 2055 (quoting *Ryder v. United States*, 515 U.S. 177, 182-83 (1995)).

The Federal Circuit’s longstanding forfeiture rule requiring an issue to be raised in an opening brief is consistent with these principles. And it is consistent

with the forfeiture rules of other courts of appeals. *See, e.g., Island Creek Coal Co. v. Wilkerson*, 910 F.3d 254, 256 (6th Cir. 2018) (party “forfeited its Appointments Clause challenge” by “not rais[ing] the issue ... in its opening brief”); *NLRB v. RELCO Locomotives, Inc.*, 734 F.3d 764, 795 (8th Cir. 2013) (party forfeited “appointments clause challenge” that “was not made in [its] opening briefs”); *Turner Bros., Inc. v. Conley*, 757 F.App’x 697, 700 (10th Cir. 2018) (party forfeited Appointments Clause challenge by “not rais[ing] the issue until after it filed its brief with th[e] court”). Whatever this Court holds in *Arthrex*, there is no reason to believe that it will modify, much less repudiate, basic principles of forfeiture.

2. Immunex’s first argument is that the Federal Circuit’s forfeiture rule “appears predicated in part on its choice of a surgical severance remedy” in *Arthrex*, where the court purportedly “sought to further limit the impact of its unconstitutionality decision with its forfeiture rule.” Pet.13. Immunex thus insinuates that if this Court were to reject the severance remedy, then the Federal Circuit’s forfeiture rule must fall as well. The problem, though—signaled by Immunex’s telling use of the word “appears”—is that nothing in *Arthrex* remotely supports this argument. Indeed, Immunex does not offer a single statement from *Arthrex* that backs up its claim or in any way demonstrates that the court adopted its severability holding to achieve a “surgical” result or applied straightforward principles of forfeiture law as part of that same surgery.

On the contrary, the Federal Circuit’s forfeiture rule is a longstanding general principle that is

analytically separate from the severability holding in *Arthrex*. See *Customedia*, 941 F.3d at 1174 (“Our law is well established that arguments not raised in the opening brief are waived.’ That rule applies with equal force to Appointments Clause challenges.” (quoting *SmithKline*, 439 F.3d at 1319)). Accordingly, even if this Court in *Arthrex* were to reverse the Federal Circuit’s severability holding, there is no reason to conclude that the Federal Circuit’s forfeiture analysis would collapse. The questions are independent. And because they are independent, there is no basis in law or fact to hold this petition pending the Court’s *Arthrex* decision, much less to grant relief based on that decision.

Immunex also argues that the Federal Circuit’s forfeiture analysis is “arbitrary and unfair” and that *Customedia* arbitrarily distinguishes between appeals “that—by sheer fortuity—involve a Final Written Decision issued before the *Arthrex* decision” and those appeals that involve “an opening brief filed after the *Arthrex* decision.” Pet.13-14 (emphases omitted). As a threshold matter, this contention has nothing to do with *Arthrex*’s severability holding and thus Immunex’s third question presented; it challenges the Federal Circuit’s forfeiture rule completely apart from the potential effects of *Arthrex*. But such an assertion is not within the scope of any of the questions presented, none of which challenges the Federal Circuit’s forfeiture rule as a general matter. Regardless, the premise of this argument is false. Parties have been raising Appointments Clause challenges to APJs since as early as 2016, which was years before the Federal Circuit decided *Arthrex*. See pp.5-7, *supra*. This argument is also not new—it is the

same argument advanced in all six of the petitions that this Court has already denied.⁶

Next, Immunex states that it promptly raised *Arthrex* to the Federal Circuit and that Respondents “responded to the Appointments Clause arguments,” thus “generating a complete record of the parties’ positions” and ensuring that the Respondents suffered no “prejudice.” Pet.14. This is another backdoor attack on the Federal Circuit’s general forfeiture rule (or, more precisely, a factbound argument as to why that rule should not apply in the circumstances here), rather than an argument that has anything to do with *Arthrex*’s severability holding. Regardless, Immunex’s attempt to leverage the cross-appeal posture of the case below is unavailing. Immunex raised the Appointments Clause in the reply brief to its appeal, and Respondents’ final brief—the reply brief to its cross-appeal—was necessarily “limited to the issues presented by [Respondents’] cross-appeal.” Fed. R. App. P. 28.1(c)(4); that is, Respondents were prohibited from addressing the Appointments Clause issue in their cross-appeal reply brief. *See also* Practice Note to Fed. Cir. R. 28.1 (warning counsel “that the fourth brief must be limited to the issues presented on cross-appeal”). Moreover, the Court has already rejected a similar argument. *Arthrex* was decided after *Essity* filed its opening brief.

⁶ *See, e.g., Customedia.Pet.22* (“The fact that the Federal Circuit applied its *Arthrex* cure to some cases and not to Customedia is unjust, and further shows that the ultimate factor was simply being fortunate enough to have an opening brief due after *Arthrex*.”); *Essity.Pet.13* (condemning “the unsparing harshness and unnecessary rigidity of the Federal Circuit’s reasoning”).

Afterwards, Essity moved to vacate and remand, and stressed that the appellee could file its own brief and “respond to Essity’s argument.” *Essity*.Pet.13. Nonetheless, this Court denied certiorari.

Immunex next contends that *Customedia* conflicts with Federal Circuit jurisprudence holding that a “sufficiently sharp change of law sometimes is a ground for permitting a party to advance a position that it did not advance earlier in the proceeding.” Pet.15 (quoting *In re Micron Tech., Inc.*, 875 F.3d 1091, 1097 (Fed. Cir. 2017)). This is yet another argument that has no connection with *Arthrex*’s severability holding and is just an attack on the Federal Circuit’s general forfeiture rule that lies beyond the scope of the questions presented. And, again, it is wrong, not only because many parties raised Appointments Clause challenges well before *Arthrex*, but because the Federal Circuit has already distinguished *Micron* and rejected the argument “that *Arthrex* was such a substantial change in the law that any forfeiture should be forgiven.” *Vivint v. Alarm.com Inc.*, ___ F.App’x ___, 2021 WL 1383259, at *4 (Fed. Cir. Apr. 13, 2021). Regardless, even if Federal Circuit cases were at loggerheads (and they are not), intra-circuit disagreement does not warrant certiorari. *See, e.g., Taylor v. United States*, 493 U.S. 906 (1989) (Stevens, J., respecting the denial of certiorari).⁷

⁷ Immunex devotes several pages to arguing that this Court “should reverse the Federal Circuit’s severance remedy.” Pet.15-19. Immunex’s arguments simply mirror those advanced by *Arthrex*. Respondents will not here respond to those forfeited

3. After devoting numerous pages to arguments unconnected to its third question presented, *see* Pet.13-19, Immunex finally gets to the merits of that question, contending that if the Court concludes that “the Federal Circuit’s severance remedy is insufficient,” that holding “would vitiate the Federal Circuit’s forfeiture rule” and trigger a purported “intervening change in law” exception to forfeiture. Pet.19-20, 22. That is so, Immunex argues, because “clairvoyance is not the standard—a party cannot forfeit an argument or a constitutional claim that has not yet been recognized.” *Id.* at 22.

This argument suffers from several serious flaws. First, it is simply untrue that “a party cannot forfeit an argument or a constitutional claim that has not yet been recognized.” Putting aside what it means to “recognize” an argument or claim (as opposed to a right), Immunex’s assertion contradicts the basic rule that a party must properly raise an argument or claim in a lower court in order to preserve it for appellate review, even if the right that party seeks to have recognized through that argument or claim has not yet been accepted by the federal courts. *See, e.g., Island Creek Coal*, 910 F.3d at 257. Unsurprisingly, Immunex cites no support for its curious proposition except a footnote from *Freytag v. Commissioner*, 501 U.S. 868 (1991). But that footnote is from a non-controlling opinion concurring in part and concurring in the judgment—not a majority opinion. Furthermore, in that footnote, Justice Scalia was simply explaining the difference between “waiver” and

arguments except to incorporate by reference the opposing arguments advanced in the *Arthrex* case.

“forfeiture.” And even that explanation does not help Immunex, because what occurred in the Federal Circuit here was not waiver—the “intentional relinquishment or abandonment of a known right or privilege”—but forfeiture—the “failure to make timely assertion of the right before a tribunal having jurisdiction to determine it.” *Id.* at 894 & n.2 (Scalia, J., concurring in part and concurring in the judgment). In short, nothing in that footnote supports Immunex’s anomalous conception of forfeiture.

Second, there was no need for “clairvoyance” here, because many parties *did* seek the exact change in law that Arthrex seeks from this Court (and sought in the Federal Circuit), and nothing stopped Immunex from doing the same in its opening brief below. For years before *Arthrex*, and particularly following *Lucia*, parties raised the argument that appointment of APJs violates the Constitution and that severance does not cure the problem. *See* pp.5-7, *supra*. It is implausible that Immunex was unaware of this common argument. Indeed, Immunex’s *own law firm* flagged the issue in *July 2018*—a year before Immunex filed its opening brief. *See* Rebecca Lindhorst & Jason D. Eisenberg, *Do You Want an Inferior Judge?: Why PTAB Judges May Be Unconstitutional*, Sterne Kessler Goldstein & Fox (July 2018), <https://bit.ly/3tKNDe1>. What is more, Immunex’s law firm explicitly recognized that parties must “*timely challenge* the constitutional validity of the PTAB APJs who adjudicated their case.” *Id.* (emphasis added). Yet Immunex did not timely raise this issue in its own case.

In an effort to escape that conclusion, Immunex relies on *Hormel v. Helvering*, 312 U.S. 552 (1941). Five of the six petitions that this Court has denied did the same. See *Customedia*.Pet.18; *Sanofi*.Pet.12; *Essity*.Pet.17; *Duke*.Pet.20-21, 26 n.6; Petition 15, *IYM* No. 20-424 (U.S. Sept. 30, 2020). *Hormel* did not address a situation like this one, where it was obvious what a party had to do to avoid forfeiture (and numerous parties, in fact, did so). *Curtis Publishing Co. v. Butts*, 388 U.S. 130 (1967), is also inapposite. *Butts* stands for the unremarkable proposition that “a party cannot be said to waive a right that was judicially created after the supposed waiver.” *Oyster Optics, LLC v. Coriant Am. Inc.*, No. 2:16-CV-1302, 2017 WL 4225202, at *3 (E.D. Tex. Sept. 22, 2017). That is not this case at all. This case involves forfeiture of a long-available legal challenge, not waiver of some newly created substantive right.

Finally, Immunex points to a number of Federal Circuit decisions that purportedly rejected Appointments Clause challenges prior to *Arthrex*, in an effort to suggest that Immunex could not have foreseen the need to raise the issue in its opening brief. See Pet.22-23 (citing *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1032 (Fed. Cir. 2016), *Trading Techs. Int’l, Inc. v. IBG LLC*, 771 F. App’x 493 (Fed. Cir. 2019), *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 779 F.App’x 748 (Fed. Cir. 2019), and *In re DBC*, 545 F.3d 1373, 1380 (Fed. Cir. 2008)). But these cases are distinguishable, are unpublished, or undermine Immunex’s argument. *Ethicon* does not even mention the Appointments Clause. *Trading Technologies* is a non-precedential, one-line order. In *Bedgear*, the panel subsequently *granted rehearing*

after the appellant pointed out that it “raised an Appointments Clause challenge in its opening brief,” 803 F.App’x 407, 407 (Fed. Cir. 2020)—*i.e.*, precisely what Immunex did not do here. Similarly, in *In re DBC*, the Federal Circuit *declined* to address an Appointments Clause challenge because—like here—that issue was not timely raised. *See* 545 F.3d at 1377.⁸

None of these decisions, therefore, settled the Appointments Clause issue such that it would not “have been appropriate, much less fruitful, for Immunex to raise an Appointments Clause challenge in its opening brief.” Pet.23. Indeed, the absence of settled law explains why many other parties, in their opening briefs, pressed the Appointments Clause arguments that the Federal Circuit ultimately addressed in *Arthrex*. But Immunex did not. And that incontrovertible fact of forfeiture is dispositive here, no matter how creative Immunex’s efforts to evade its consequences.

⁸ Immunex also asserts that “[e]ven this Court has denied *certiorari* in a case presenting the same Appointments Clause question.” Pet.23 (citing *Smartflash LLC v. Samsung Elecs. Am., Inc.*, 139 S.Ct. 276 (2018), *cert. denied*, 139 S.Ct. 276 (2018)). But “denial of a writ of *certiorari* imports no expression of opinion upon the merits of the case,” *Teague v. Lane*, 489 U.S. 288, 296 (1989), and the Court’s denial of *certiorari* in *Smartflash* was likely predicated on the fact that—as here—the petitioner’s Appointments Clause challenge was not preserved below. *See* Br. in Opp’n 8-11, *Smartflash*, No. 18-189 (U.S. Aug. 22, 2018).

CONCLUSION

The Court should deny the petition.

Respectfully submitted,

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