

No. 19-1451

IN THE
Supreme Court of the United States

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Petitioner,

v.

MYLAN PHARMACEUTICALS INC.,

Respondent.

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

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

All parties in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed Cir. 2019), have asked this Court to decide whether Administrative Patent Judges (APJs) on the Patent Trial and Appeal Board (PTAB) are unconstitutionally-appointed principal officers. An important corollary is whether a holding that APJs' appointments violate the Appointments Clause applies to all pending PTAB appeals, or only to some. Thus, Sanofi's petition, along with several others, asks this Court to decide whether and when an intervening change of law on a separation-of-powers issue should apply in pending cases, regardless of forfeiture.

Answering that question will help guide courts confronting changes of law arising in pending cases in the Appointments Clause context and elsewhere.

Mylan avoids this important and recurring question. Mylan does not dispute that forfeiture may be excused when there is an intervening change of law, nor can Mylan credibly contend that *Arthrex*—which “invalidated Congress’s framework for appointing” APJs (Br. in Opp. 1)—was not an important change. Instead, Mylan contends (*id.* at 12) that any forfeiture should not be excused because the Appointments Clause argument was supposedly “foreseeable.” But putting aside whether an unforeseeable legal argument would be an *additional* reason to excuse forfeiture, foreseeability is not the test for whether a decision marks a change of law. Indeed, Mylan’s injection of an “unforeseeability” requirement into the change-of-law analysis only underscores the need for this Court’s guidance.

But even were foreseeability relevant, *Arthrex* was not foreseeable. As Mylan observes, several other parties raised Appointments Clause challenges to APJs’ appointments, but they were each unsuccessful—including before the Federal Circuit itself—until *Arthrex*. And while *Arthrex* relied on “existing law” (including the Appointments Clause), none of the controlling cases presaged the decision: none had found an administrative adjudicator to be a *principal* officer, and most—including *Lucia v. SEC*, 138 S. Ct. 2044 (2018)—did not even consider the distinction between principal and inferior officers, the core issue in *Arthrex*.

Nor would applying the change-of-law exception here reward “sandbagging.” See Br. in Opp. 2. Sanofi raised its *Arthrex* claim only days after the Federal

Circuit decided *Arthrex* and before the panel ruled on the merits. Thus, this is not a case where Sanofi supposedly saw “the writing . . . on the wall” (*id.* at 13) and gamed the system; rather, Sanofi raised *Arthrex* “at the first opportunity” (*id.* at 11)—just days after the law changed.

In the end, the Federal Circuit’s approach here trivializes a significant constitutional problem: it deems APJs’ appointments unconstitutional one day, yet enforces their *ultra vires* actions the next. Certiorari is warranted. At a minimum, this Court should hold this petition for *Arthrex*.

The Court should also grant the petition to consider the Federal Circuit’s approach to obviousness as it has evolved since *KSR International, Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Mylan argues that the petition raises only a “patent-specific factual question” (Br. in Opp. 29), but the case in fact illustrates how far the Federal Circuit has deviated from *KSR*’s principles—particularly in the biochemical arts.

I. The Federal Circuit’s Refusal To Apply *Arthrex* Is A Recurring And Important Question

A. The Court Should Answer The Purely-Legal Question Of When The Change-Of-Law Exception Applies

1. Mylan’s first contention, that the Federal Circuit’s decision is “fact-bound” and “fact-specific” (Br. in Opp. 10–11), is demonstrably false. In the decision below, the Federal Circuit relied solely on its precedential decision in *Customedia Techs., LLC v. Dish Network Corp.*, 941 F.3d 1174 (Fed. Cir. 2019), which held that failure to raise an Appointments Clause challenge in an opening brief precludes the court from

applying *Arthrex*. The court did not consider any “fact-specific” circumstances. Rather, the court held that it was bound to follow *Customedia*. App. 22a n.4.

The fact that there are (so far) a half-dozen pending petitions for certiorari presenting exactly the same question further belies Mylan’s suggestion that the question is “fact-bound.” See Petitions for Writs of Certiorari, *Thermolife Int’l LLC v. Iancu* (Aug. 10, 2020) (20-150); *Customedia* (July 31, 2020) (20-135); *Essity Hygiene & Health AB v. Cascades Canada ULC* (July 24, 2020) (20-131); *Duke Univ. v. Biomarin Pharm., Inc.* (July 2, 2020) (19-1475); *Arthrex, Inc. v. Smith & Nephew, Inc.* (Apr. 6, 2020) (19-1204).

2. Mylan’s argument that this case involves only “routine application of settled forfeiture law” (Br. in Opp. 11) is also wrong. As Mylan acknowledges, neither in this case nor in *Customedia* did the Federal Circuit even *consider* whether the change-of-law exception applies. *Id.* at 12. Indeed, the Federal Circuit rejected briefing on the question. And contrary to Mylan’s assertions (*id.*), the Federal Circuit left no room for “discretion” to consider the change-of-law exception, instead holding that it “*must* treat that argument as forfeited.” *Customedia*, 941 F.3d at 1175 (emphasis added).

This approach did not reflect “settled” law (Br. in Opp. 10, 11), but rather added to the disarray of standards lower courts have applied. Indeed, Mylan’s opposition highlights the variation. Some courts have excused forfeiture when an intervening decision was “directly contrary to controlling precedent.” *Id.* at 28 (citing *Gucci Am., Inc. v. Weixing Li*, 768 F.3d 122, 135–36 (2d Cir. 2014)). Others have excused forfeiture where a “significant legal development” arose. *Id.* (citing *Wang v. Chinese Daily News, Inc.*, 737 F.3d 538,

543 (9th Cir. 2013)). Still others applied intervening decisions reflecting merely an “important clarification of” law. *Id.* (citing *DSC Commc’ns Corp. v. Next Level Commc’ns*, 107 F.3d 323, 326 n.2 (5th Cir. 1997)). These results do not reflect distinguishable facts, as Mylan claims (*id.* at 25); they reflect the lack of a coherent standard. This Court should clarify that standard.

B. *Arthrex* Reflected An Intervening Change-Of-Law That Was Unforeseeable

The force of Mylan’s opposition is not really about the applicable standard for the change-of-law exception at all. Rather, Mylan argues something else: forfeiture may not be excused when the *argument* was “foreseeable,” “foreseeable enough,” or in another formulation, a party had “reasonable notice of the argument.” *Id.* at 3, 12, 22. It is far from clear that the *foreseeability* of an argument determines whether an intervening decision adopting it reflects a change-of-law—certainly, this Court has applied the change-of-law exception without regard for foreseeability. *E.g.*, *Harper v. Dep’t of Taxation*, 509 U.S. 86 (1993); *Hormel v. Helvering*, 312 U.S. 552 (1941).¹ And, to the extent Mylan suggests foreseeability *should* be

¹ Contrary to Mylan’s suggestion (Br. in Opp. 25–26), the Eighth Circuit in *NLRB v. RELCO Locomotives, Inc.* did not reject the change-of-law exception because the argument was foreseeable, but because the intervening decision—the *D.C. Circuit’s* decision in *Noel Canning*—was “not binding on us and did not change the state of the law in this circuit.” 734 F.3d 764, 796 (8th Cir. 2013). But once this Court decided *Noel Canning*, a decision that was binding, courts *did* invoke the change-of-law exception because parties “could not have known with any certainty . . . until the Supreme Court handed down its decision.” *UC Health v. NLRB*, 803 F.3d 669, 673 (D.C. Cir. 2015).

pertinent, that is yet another reason this Court should clarify the appropriate standard.

Nonetheless, *Arthrex* was undeniably a significant change of law and a result that was unforeseeable, including because the Appointments Clause argument had been serially rejected—at least twice by the Federal Circuit itself.

1. *Arthrex* literally changed the law. As Mylan put it, *Arthrex* “invalidated Congress’s framework for appointing administrative patent judges.” Br. in Opp. 1. For nearly a decade, APJs have presided over more than 11,000 IPR proceedings, invalidating some or all of the challenged patent claims in more than 80% of final written decisions. Patent Trial and Appeal Board, *Trial Statistics* 3, 11 (July 2020). *Arthrex* held that *every time* APJs did so—taking away valuable property rights from myriad patent owners—they were acting *ultra vires*. Mylan does not and cannot credibly explain how this result was not a drastic change in the law.

2. The Federal Circuit understood that *Arthrex* changed the law. At least twice before *Arthrex*, the Federal Circuit summarily rejected exactly the same Appointments Clause challenge. *Trading Techs. Int’l, Inc. v. IBG LLC*, 771 F. App’x 493 (Fed. Cir. 2019); *Bedgear, LLC v. Fredman Bros. Furniture Co., Inc.*, 779 F. App’x 748 (Fed. Cir. 2019), *rehearing granted & judgment vacated*, 803 F. App’x 407 (Fed. Cir. 2020). Indeed, *Bedgear* illustrates the point: it came out one way before *Arthrex* (summarily denying the Appointments Clause claim), and the other way after *Arthrex* (granting rehearing, vacating and remanding). That is the definition of a change of law.

Mylan argues that neither *Bedgear* nor *Trading Technologies* is relevant because the decisions were

“unpublished, one-sentence orders.” Br. in Opp. 22. But that fact, too, underscores that *Arthrex* changed the law. Federal Circuit Rule 36(a), which governs such orders, is reserved for opinions that “would have no precedential value.” The fact that before *Arthrex* the court had treated the Appointments Clause issue as so settled that it did not require an opinion with “precedential value” only demonstrates how groundbreaking *Arthrex* was.

3. For much the same reason, the result in *Arthrex* was unforeseeable *precisely because* other parties who brought prior Appointments Clause challenges were repeatedly rebuffed. In addition to the parties who were unsuccessful before the Federal Circuit, parties were also uniformly unsuccessful before the PTAB. *See, e.g., St. Jude Med., LLC v. Snyders Heart Valve, LLC*, IPR2018-00105, IPR2018-00106, IPR2018-00107, IPR2018-00109 (P.T.A.B. May 2, 2019) (noting the PTAB was aware of no authority holding that APJs are principal officers).

4. Nor did any of the controlling cases cited in *Arthrex* “foresee,” much less dictate, the result. Mylan argues that *Arthrex* “simply applied longstanding Appointments Clause precedent . . . involving similar administrative judges.” *Id.* at 13. But none of the controlling cases found that those judges were *principal* officers, as the Federal Circuit did in *Arthrex*. Indeed, most of the cases—including *Lucia* and *Freytag*—did not even *consider* the question whether the judges were principal or inferior officers; instead the cases concerned the distinction between inferior officers and employees. *See Lucia*, 138 S. Ct.

at 2051 n.3 (“[A] distinction . . . between ‘principal’ and ‘inferior’ officers” was “not at issue” (citation omitted)); *Freytag v. C.I.R.*, 501 U.S. 868, 880 (1991) (considering whether special trial judges are inferior officers or employees); *Buckley v. Valeo*, 424 U.S. 1, 140–41 (1976) (holding that Federal Election Commissioners are officers not employees); *Helman v. Dep’t of Veteran Affairs*, 856 F.3d 920, 929 (Fed. Cir. 2017) (considering whether MSPB ALJs are inferior officers or employees); *cf. Ryder v. United States*, 515 U.S. 177 (1995) (considering actions of inferior officers).

Likewise, of the three cases that *did* contemplate the inferior versus principal officer distinction, the only two cases binding on the Federal Circuit found that the judges were inferior officers. *Edmond v. United States*, 520 U.S. 651, 666 (1997); *Masias v. Sec’y of Health & Human Servs.*, 634 F.3d 1283, 1294 (Fed. Cir. 2011). The final case, *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Board*, 684 F.3d 1332 (D.C. Cir. 2012), was certainly not part of a “venerable body of precedent” (Br. in Opp. 15), as it was not binding on the Federal Circuit.

5. Finally, applying the change-of-law exception here does not promote sandbagging, as Mylan suggests. *Id.* at 2. Instead, it promotes the principle that courts should apply the law as it stands when it renders its decision. *See Harper*, 509 U.S. at 86; App. 29a (Newman, J., dissenting).

Nor did Sanofi engage in gamesmanship. Sanofi timely raised the change of law at the earliest opportunity—just days after *Arthrex*. Even Mylan’s own definition of sandbagging—claiming error “if the

outcome is unfavorable” (Br. in Opp. 24 (quoting *Freytag*, 501 U.S. at 895 (Scalia, J., concurring)))—does not support its argument. The panel issued its merits decision *after* Sanofi raised the *Arthrex* issue.

Nor is there anything improper in Sanofi’s request that the Federal Circuit apply its currently-governing law in another appeal, *Immunex Corp. v. Sanofi-Aventis U.S. LLC*, No. 2019-1749 (Fed. Cir.). When Sanofi filed its *Immunex* brief, the Federal Circuit (having denied Sanofi’s en banc petition in this case) had already made clear that under its binding law, courts “must” deem an argument forfeited if not raised in an opening brief. Sanofi’s *Immunex* brief simply restated that law.

C. This Petition Should Be Considered Alongside Or Held For *Arthrex*

All parties in *Arthrex* have asked the Court to decide the underlying Appointments Clause challenge and related issues. Petitions for Writs of Certiorari, *Arthrex, Inc. v. Smith & Nephew, Inc.* (June 30, 2020) (19-1458); *Smith & Nephew, Inc. v. Arthrex, Inc.* (June 29, 2020) (19-1452); *United States v. Arthrex, Inc.* (June 25, 2020) (19-1434). If the Court grants any of these petitions, it should grant this one and likewise decide whether the decision should apply to all parties in pending cases, regardless of when they raised the Appointments Clause challenge.

At the very least, this Court should hold Sanofi’s petition and defer further consideration until *Arthrex* is decided. As Mylan points out, one of the questions presented in *Arthrex* concerns the nature of any forfeiture of Appointments Clause claims. *E.g., id.* at 26. The Federal Circuit (incongruously) held that the Appointments Clause challenge was so important that

it can be decided over claims of forfeiture, yet declined to do so here. If this Court entertains that question, its answer could bear on the application of those forfeiture principles here.

II. The Federal Circuit’s Obviousness Analysis Improperly Strayed From *KSR* And Core Obviousness Principles

This Court’s review is also warranted to recalibrate the Federal Circuit’s obviousness analysis as it has developed in the years since *KSR* and incorrectly applied here.

Mylan argues that Sanofi’s question presented “mischaracterizes both the Federal Circuit’s and the PTAB’s holdings.” Br. in Opp. 29. Not so. As Mylan acknowledges (at least by omission), nothing in the prior art disclosed a glargine aggregation problem—and neither the Federal Circuit nor the PTAB identified any such known problem in the prior art. *See* App. 25a (Newman, J., dissenting) (glargine aggregation “was not reported in the prior art”). Mylan’s response, like the Federal Circuit majority’s, is that the absence of a known glargine aggregation problem does not matter: the gap could be filled by art relating to different compounds, with different characteristics, and different mechanisms of action. Br. in Opp. 31–32; App. 9a; *id.* 64a.

But this is precisely the distortion of *KSR* that warrants this Court’s review. It is not merely a question of the “level of generality” (Br. in Opp. 32) or the “level of specificity” (App. 9a) a court uses to *define* the problem solved. There must be some prior art recognition of the problem (however defined) related to the *actual invention* claimed by the challenged patents. Insisting on this rigor in the analysis does not transform the person of ordinary skill in the art into

an “automaton,” as Mylan charges. Br. in Opp. 31. Instead, it protects against hindsight bias by focusing the analysis on the real-world facts regarding the specific claimed subject matter.

Indeed, the Federal Circuit’s (and the PTAB’s) reliance on the patents’ specification illustrates how hindsight impermissibly seeped into the analysis. The specification “acknowledge[d] what other prior art sources taught,” but this was not a “damaging admission” or regrettable “candor” about *glargine*. *Id.* at 31. The cited prior art said *nothing* about glargine. Nor did the specification “corroborate” any prior art teachings about *glargine*. *Id.* at 32. Only the Federal Circuit’s hindsight-driven analysis led it to read the specification as confirming a *prior-art* link between glargine and aggregation properties in insulins. To the extent the specification made that link, it could only have been the contributions of the inventors—not a “teaching[] about prior-art knowledge.” App. 10a.

Mylan further claims (Br. in Opp. 33), incorrectly, that Sanofi (i) advocates for an “inflexible” obviousness standard that limits *KSR* to cases “not involving the biochemical arts” and (ii) has forfeited those arguments. As Sanofi’s petition acknowledges, *KSR* properly discussed the “flexible” approach this Court’s obviousness cases have applied, and nowhere limited its reach to one field or another. Pet. 25–26, 30. Nor did Sanofi forfeit Mylan’s strawman argument. Still, as Judge Newman recognized, there are additional considerations of experimentation and unpredictability at play in the biochemical arts, for which *KSR* does not provide a license to ignore. App. 24a–25a. This Court should take this opportunity to explain how the obviousness considerations outlined in *KSR* apply in these contexts.

III. Equitable Principles Support Certiorari

Finally, Mylan contends that the “equities” support denying certiorari. Mylan has it backwards. The Patent Office duly granted Sanofi two patents covering the reformulation of glargine. The APJs who invalidated those patents had no constitutional authority to do so. The Federal Circuit declined to apply this governing law, without even *considering* that the law changed while Sanofi’s case was pending on appeal. The equities—including rule-of-law principles—support reviewing that decision. *See* App. 29a (Newman, J., dissenting).

Mylan’s additional suggestion that Sanofi’s patents have “burden[ed] U.S. diabetes patients” (Br. in Opp. 34) likewise has the facts turned around. Mylan acknowledges that “[i]nsulin glargine was a useful invention,” but suggests that “Sanofi’s reformulation thereof was not.” *Id.* If that were in fact true, the parties would not be engaged in this litigation—the patents on the original glargine molecule have expired. Nor have Sanofi’s patents improperly excluded competition, forcing patients to “travel abroad” or “dangerously ration their insulin supply.” *Id.* Since 2016, Eli Lilly has marketed a competing glargine product, and Mylan itself recently launched its own glargine products. Ujjval Jauhari, *Pick-up in biosimilar launches drives Biocon’s prospects*, *Bus. Standard*, Sept. 2, 2020, at 12.

CONCLUSION

The petition for a writ of certiorari should be granted.

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