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

BRIEF IN OPPOSITION TO CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Circuit correctly concluded that Sanofi, by failing to plead or otherwise raise a nonjurisdictional Appointments Clause challenge that was pleaded and briefed by dozens of other parties and was the subject of extensive public commentary, in any brief or at any time until a letter filed two months after oral argument in that court, forfeited such a challenge to the underlying Patent Trial & Appeal Board ruling at issue.

2. Whether the Federal Circuit correctly affirmed the Patent Trial and Appeal Board's fact-bound conclusion that Sanofi's patents were obvious because the purported invention—adding a nonionic surfactant to impede insulin glargine molecules from aggregating during storage—simply applied a known solution to a known insulin problem.

RELATED PROCEEDINGS

The following proceedings are directly related to the case:

Mylan Pharms. Inc. v. *Sanofi-Aventis Deutschland GMBH*, IPR2017-01526 (P.T.A.B.), final written decision entered December 12, 2018.

Mylan Pharms. Inc. v. *Sanofi-Aventis Deutschland GMBH*, IPR2017-01528 (P.T.A.B.), final written decision entered December 12, 2018.

Sanofi-Aventis Deutschland GMBH v. *Mylan Pharms. Inc*., Nos. 2019-1368, 2019-1369 (Fed Cir.), judgment entered on November 19, 2019.

Sanofi-Aventis, U.S. LLC, Sanofi-Aventis Deutschland GmbH, Sanofi Winthrop Industrie v. *Mylan GmbH, Biocon Ltd., BioconResearch, Biocon Sdn. Bhd. and Biocon S.A.*, No. 2-17-cv-09106-SRC-CLW (D.N.J.)

PARTIES TO THE PROCEEDING

Petitioner Sanofi-Aventis Deutschland GmbH was appellant in the court of appeals.

Respondent Mylan Pharmaceuticals Inc. was appellee in the court of appeals.

RULE 29.6 STATEMENT

The parent company of Mylan Pharmaceuticals Inc. is Mylan Inc., which is indirectly wholly-owned by Mylan N.V., a publicly held company.

The parent company of real party-in-interest BGP Products Operations GmbH, which is owned by Mylan Holdings Ltd., which is owned by Mylan N.V.

The parent company of real party-in-interest Biocon Biologics India Ltd. is Biocon Ltd.

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INTRODUCTION

Sanofi's petition for certiorari raises no important and recurring question; the questions it does pose are fact-bound and plagued with vehicle problems; both the Patent Trial and Appeal Board (PTAB) and Federal Circuit correctly held that Sanofi's patent claims were obvious; and the equities support denying review. Certiorari should be denied.

On the first question presented, Sanofi seeks review of a footnote in which the court below concluded that Sanofi's failure to raise its nonjurisdictional Appointments Clause challenge in either "its opening brief" or "reply" forfeited any such challenge. Pet. 22a n.4. According to Sanofi, this ruling threatens to upset forfeiture law by preventing parties from benefitting from "intervening change[s] of law" (Pet. i)—here, the Federal Circuit's decision in *Arthrex, Inc*. v. *Smith & Nephew, Inc*., 941 F.3d 1320 (Fed. Cir. 2019), which invalidated Congress's framework for appointing administrative patent judges (APJs). But the court below did not state any rule on this issue, let alone bar parties from taking advantage of intervening court decisions where appropriate. Rather, it reached the unexceptional, fact-bound conclusion that Sanofi forfeited a nonjurisdictional challenge by failing to raise it at any point, before the PTAB or the Federal Circuit, until months after argument below. And for many reasons, this case is an especially unattractive vehicle to address forfeiture law.

For starters, it did not require "clairvoyance" (Pet. 3) to spot the Appointments Clause issue decided in *Arthrex*. The court there relied not only on the Appointments Clause itself (which is as old as the Constitution), but on four decisions of this Court—the leading decision, *Freytag* v. *Commissioner*, 501 U.S. 868 (1991), and its progeny, *Ryder* v. *United States*, 515 U.S. 177 (1995), *Edmond* v. *United States*, 520 U.S. 651 (1997), and *Lucia* v. *SEC*, 138 S. Ct. 2044 (2018)—plus several circuit decisions involving challenges to similar administrative judges. All these decisions reflected "existing law" (Pet. 12) when Sanofi filed its opening brief below. Indeed, many of the decisions go back decades, and dozens of other parties invoked them far earlier than Sanofi did—often before the PTAB, and certainly after June 2018, when this Court decided *Lucia*. Not so with Sanofi.

Perhaps Sanofi thought it would prevail before the PTAB or Federal Circuit or misjudged its chances of successfully invoking the Appointments Clause. Whatever the reason, six months passed between this Court's decision in *Lucia* and the PTAB's ruling here —a period when extensive commentary addressed the potential application of the Appointments Clause to APJs—yet Sanofi did not bring *Lucia*, *Freytag*, or any other Appointments Clause decision to the PTAB's attention. Similarly, Sanofi failed to raise the Appointments Clause in its notice of appeal (as Federal Rule of Appellate Procedure 44 requires), opening Federal Circuit brief (as settled forfeiture rules require), reply brief (which would have been something, if too late), or oral argument. Rather, Sanofi first raised the Appointments Clause in November 2019, after *Arthrex* issued—when it had lost before the PTAB, two months after argument in the Federal Circuit, and just days before that court ruled. Granting review in these circumstances would only reward Sanofi's sandbagging.

Sanofi does not (and cannot) suggest that a party should be excused from ordinary forfeiture law where it had reasonable notice of the argument that it failed to assert. Nor does the challenged footnote upset the law in this regard. Sanofi says "structural constitutional challenge[s]" warrant a special rule. Pet. 10. But "[n]o 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." *United States* v. *Olano*, 507 U.S. 725, 731 (1993) (internal quotations and citation omitted). Further, the cited decisions that purportedly conflict with the ruling below (Pet. 16–19) are fact-bound, and the reasoning of those that excuse forfeiture supports the result below. Indeed, since forfeiture is "left primarily to the discretion of the courts of appeals, to be exercised on the facts of individual cases," some conflict in the decisions would not be especially troubling. *Singleton* v. *Wulff*, 428 U.S. 106, 121 (1976).

At most, Sanofi quibbles about the application of settled, discretionary forfeiture rules to the particular (unattractive) facts of this case—where the forfeited issue was well-known, the subject of public commentary, and pleaded and briefed by others. But even assuming, *arguendo*, the court below erred in applying the law, certiorari would not be warranted to address any "misapplication of a properly stated rule of law." Sup. Ct. R. 10. Not surprisingly, no Federal Circuit judge called for a vote on Sanofi's rehearing petition, and no amicus supports certiorari.

Regardless of how this Court disposes of the pending petitions for certiorari in *Arthrex*, Sanofi's petition should be denied outright, not held. The Federal Circuit in *Arthrex* stated that others who timely raised the Appointments Clause issue decided there would likewise be entitled to new PTAB hearings. 941 F.3d at 1340. Thus, if this Court denies review in

Arthrex, or takes up that case and affirms, such litigants stand to benefit from the decision. But Sanofi is not similarly situated to those parties: Even if it would have been sufficient to raise the Appointments Clause in its opening Federal Circuit brief, without raising it before the PTAB (precedent suggests otherwise), Sanofi failed to do so. Having made its tactical choices, Sanofi now demands to be treated *better* than other litigants—it asks this Court to "excuse[]" not just "one level of forfeiture" (failing to raise the issue before the PTAB, which the court in *Arthrex* excused), but *two* (failing to raise the issue before either the PTAB *or* the Federal Circuit). Pet. 17. Thus, Sanofi's petition does not implicate "the fundamental rule of law that treats similarly-situated litigants consistently" (Pet. 3) and should be denied regardless of how the Court disposes of *Arthrex*.

On the second question presented, Sanofi misrepresents what the Federal Circuit held. According to Sanofi, that court held its patent claims obvious even though the invention did not solve a known problem. Pet. 4. In reality, the court affirmed the PTAB's finding that a problem known in the field generally is sufficient for obviousness, rejecting Sanofi's view that a skilled artisan must know the *precise* problem that the inventors addressed. Pet. 12a–15a. That is, the claimed invention here—adding a nonionic surfactant to impede insulin glargine molecules from aggregating during storage—simply applied a known solution to a known insulin problem.

The Federal Circuit's actual, fact-bound holding does not merit review. Whether a second PTAB panel relied on "the existing written record" or "reopen[ed]" it (*Arthrex*, 941 F.3d at 1340), a routine application of law to the record would compel that panel (and the

Federal Circuit) to reach the same result as before. Thus, even if the first question presented were otherwise certworthy (it is not), reviewing it (or holding the case) would make little sense, because a ruling would not change the case's ultimate outcome.

Finally, the equities disfavor review. When the shoe has been on the other foot, Sanofi itself has insisted that its litigation opponent forfeited its *Arthrex* claim, stating: "Appointments Clause challenges are forfeited if not raised in an appellant's opening brief." And while insulin glargine was a great invention, Sanofi's obvious reformulation of it was not. For too long, Sanofi has reaped the benefit of market exclusivity at the expense of not only its competitors, but also patients forced to travel abroad or ration their medicine, at risk to their lives. For these reasons too, certiorari should be denied.

STATEMENT

A. Proceedings below

This case began in June 2017, when respondent Mylan filed two inter partes review (IPR) petitions challenging the validity of two Sanofi patents—U.S. Patent Nos. 7,476,652 and 7,713,930. Sanofi's earlier patents on insulin glargine, a successful diabetes drug, had expired. Sanofi extended its exclusivity over insulin glargine with follow-on patents that differ from its original formulation only by adding any of several well-known nonionic surfactants. But simply adding a nonionic surfactant to stabilize insulin in solution was well-known. Indeed, adding nonionic surfactants to improve shelf-life is commonplace in products from shampoo to cosmetics. Handbook of Pharmaceutical Excipients, IPR2017–01526, –01528, Ex. 1019 at 20 (P.T.A.B.).

Mylan demonstrated to the PTAB that Sanofi's reformulation was obvious, and the Federal Circuit affirmed.

1. The PTAB's decision

After reviewing Mylan's petitions and Sanofi's responses, the PTAB found a reasonable likelihood of unpatentability and instituted an IPR. After a trial with over 250 exhibits, including testimony from five witnesses, the PTAB issued comprehensive decisions holding all claims unpatentable. Pet. 81a, 138a. The PTAB credited Mylan's technical experts' testimony, finding that Sanofi's expert testimony was unsupported. Pet. 38a, 58a, 72a, 66a, 92a, 113a, 122a, 128a.

Applying *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398 (2007), the PTAB determined that the level of skill in the art was high, equivalent to a masters or doctorate in the field with significant practical experience. Pet. 47a, 101a. Next, the PTAB determined that all claim elements existed in the prior art (Pet. 49a–53a, 103a–107a) and analyzed whether a skilled artisan would combine those elements with a reasonable expectation of success (Pet. 54a–74a 107a–130a). It found that aggregation would likely be seen as a problem and that nonionic surfactants were used in insulin solutions for precisely this reason. Pet. 69a–71a, 120a–130a. The PTAB also considered indicia of nonobviousness, finding that Sanofi's commercial success was due to the underlying insulin glargine—not Sanofi's reformulation. Pet. 74a–77a, 130a–134a. The PTAB thus held that a preponderance of the evidence established the obviousness of all claims. Pet. 77a–78a, 134a–135a.

At no point before the PTAB did Sanofi mention the Appointments Clause. The closest Sanofi came was a footnote purporting to "reserve[] the right to challenge [the PTAB's institution] decision on Constitutional grounds, including for denying Patent Owner its Seventh Amendment rights and because Petitioner lacked Constitutional standing to challenge patentability at the time it filed the Petition." IPR2017–01526, Paper 8 n.7 (P.T.A.B. Sept. 14, 2017). Even Sanofi's surreplies—filed in July and October of 2018, after this Court's decision in *Lucia*—did not mention the Appointments Clause. *Id.*, Papers 46 (P.T.A.B. July 23, 2018) and 80 (P.T.A.B. Oct. 9, 2018).

2. The Federal Circuit's decision

In January 2019, Sanofi appealed to the Federal Circuit, listing no constitutional issue for review. Pet. 2a; Dkt. 1–2. Nor did Sanofi then notify the Federal Circuit clerk of any constitutional challenge. See Fed. R. App. P. 44(a) (requiring parties raising constitutional challenges in cases with no federal party promptly to notify the clerk, who must notify the Attorney General).

In April 2019, Sanofi filed its opening merits brief, again raising no Appointments Clause question. The same is true of Sanofi's June 2019 reply brief, and of its oral argument, delivered on September 5, 2019.

On October 31, 2019, the Federal Circuit decided *Arthrex*. Sanofi's first mention of the Appointments Clause came on November 5, 2019—two months after oral argument—in a Federal Rule of Appellate Procedure 28(j) letter asking to file a supplemental brief on the issue.

On November 19, 2019—just two weeks later—the court ruled, affirming the PTAB in a nonprecedential opinion. Reviewing the PTAB's legal analysis de novo and its findings for substantial evidence (Pet. 6a–9a), the court held that the PTAB had faithfully applied *KSR*, rejecting Sanofi's contention that the PTAB improperly relied on Sanofi's own patent specification in finding obviousness. Pet. 8a. As the court explained, the PTAB simply pointed to the disclosure as corroborating its findings as to the prior art. Pet. 9a–11a.

The court further held that substantial evidence supported the PTAB's findings concerning reasons to combine the prior art, rejecting the view that insulin glargine is unlike other insulins. Pet. 11a–14a. The court explained that the PTAB reasonably found that skilled artisans would have expected nonionic surfactants to work for insulin glargine without disrupting its mechanism of action, specifically noting Mylan's superior expert testimony. Pet. 16a–19a. Finally, as to objective indicia of nonobviousness, the court held that the PTAB reasonably attributed commercial success to the original insulin glargine product rather than Sanofi's reformulation. Pet. 19a–22a.

In a footnote, the court acknowledged Sanofi's belated Appointments Clause claim, treating its Rule 28(j) letter as a motion to vacate and remand under *Arthrex*. Pet. 22a n.4. The court denied the motion, explaining that Sanofi could not benefit from an argument not raised in either "its opening brief" or "reply." *Ibid*. (citing *Customedia Techs., LLC* v. *Dish Network Corp*., 941 F.3d 1174 (Fed. Cir. 2019)).

Judge Newman dissented. In her view, the prior art failed to identify a problem or solution specific to insulin glargine and Sanofi should benefit from *Arthrex*. Pet. 23a–29a.

Sanofi sought rehearing or rehearing en banc. No judge requested a vote on Sanofi's petition; it was summarily denied. Pet. 141a–142a.

B. Well before this case began, others were challenging agency appointments before the PTAB and Federal Circuit.

Although Sanofi failed to raise its Appointments Clause challenge until two weeks before the Federal Circuit ruled, that issue has long been known. As discussed below (at 19), at least 30 parties raised the issue before the PTAB during the relevant period.

Mylan first faced the issue after filing a post-grant review ("PGR") petition challenging a patent of Yeda Research & Development Company. PGR2016-00010, Paper 2 (P.T.A.B. Feb. 16, 2016). In May 2016, Yeda responded that conducting "a PGR by Administrative Patent Judges appointed by a cabinet secretary * * * violates the Constitution's Appointments Clause, Art. II, § 2, cl. 2." Paper 7 at 31–32 n.10 (P.T.A.B. May 24, 2016). "The Board exercises significant discretion and issues decisions that are final for the Executive Branch," Yeda argued, making its judges "principal officers" who "may only be appointed by the President, with the advice and consent of the Senate." *Id*. at 32 (citation omitted). The PTAB denied the petition without reaching the Appointments Clause issue. *Id*., Paper 9 (P.T.A.B. Aug. 15, 2016).

In addition, while the IPR petitions here were still pending before the PTAB, this Court decided *Lucia*. Weeks later, other parties began invoking *Lucia* in support of Appointments Clause challenges to APJ appointments. See *Polaris Innovations Ltd*. v. *Kingston Tech. Co., Inc.*, Opening Br. of Appellant 1–2 (Dkt. 22), No. 2018–1768 (Fed. Cir. July 10, 2018)

("The cancellation of Polaris's claims violated the Appointments Clause of the Constitution as a final agency decision requiring the Board to act as 'principal Officers' without having been appointed by the President and confirmed by the Senate."); *id.* at 52–60. Post-*Lucia* challenges to the appointment of APJs received extensive commentary.[1]

REASONS FOR DENYING THE PETITION

I. The Federal Circuit's fact-bound conclusion that Sanofi forfeited its nonjurisdictional Appointments Clause claim does not warrant review, regardless of *Arthrex*'s disposition.

A. The Federal Circuit did not purport to resolve any issue of forfeiture law beyond the issue presented by this record.

Sanofi portrays the footnote it asks the Court to review as a grave departure from settled forfeiture law, and specifically from what it calls "the change-in-law exception" to ordinary preservation rules. Pet. 17. As explained below, this case does not involve an "intervening change in law," but rather a belated attempt to invoke longstanding constitutional principles that reasonably should have been seen—and that others actually raised—far earlier. In this sense, the "question presented" is not really even presented.

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[1] *E.g.*, D. Crouch, *Appointments and Illegal Adjudication: A Second Patent Judge Appointments Crisis*, Patently-O (Jan. 29, 2018); R. Davis, *Are PTAB Appointments Unconstitutional? A Closer Look*, Law360 (Sept. 5, 2018); G. Lawson, *Appointments and Illegal Adjudication: The AIA Through a Constitutional Lens*, 26 Geo. Mason U. L. Rev. 26 (Jan. 2018).

More fundamentally, however, neither the challenged footnote nor the authority that it cites purports to address when a so-called "intervening change in law" might, or might not, justify a departure from black-letter forfeiture law. It neither purports to address what constitutes an "intervening change in law" nor states any broad rule on these (or any other) forfeiture issues, let alone a categorical rule that parties may never invoke intervening precedent.

Instead, the court simply reached the fact-specific conclusion that Sanofi's failure to press the Appointments Clause in its opening brief below effected a forfeiture of the issue: "Sanofi did not raise an Appointments Clause issue in its opening brief in this court (or its reply brief). Our precedent holds that failure to raise the *Arthrex* Appointments Clause issue in the opening brief forfeits the challenge." Pet. 22a n.4. That is a routine application of settled forfeiture law, which recognizes that requiring litigants to raise arguments at the first opportunity "is essential to the orderly administration of civil justice," as it keeps litigants from "letting error go without any comment," and then requesting a do-over when they lose. 9B Wright & Miller, Federal Practice and Procedure § 2472 (3d ed. 2020). Indeed, if anything the Federal Circuit was too generous, as the "general rule" requires raising constitutional objections before the relevant "administrative body" (*United States* v. *L. A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952))—which Sanofi failed to do.

Sanofi does not suggest that Appointments Clause issues are jurisdictional, or that constitutional rights are non-waivable. Nor could it. "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." *Olano*, 507 U.S. at 731 (internal quotations and citation omitted); accord *Stern* v. *Marshall*, 564 U.S. 462, 481–482 (2011). Moreover, the authority cited by the Federal Circuit likewise does not speak to whether "intervening changes in law" warrant excusing forfeiture. It states only the unremarkable proposition that Appointments Clause challenges under *Arthrex* must, like other nonjurisdictional issues, be raised in the appellant's opening brief. *Customedia Techs.*, 941 F.3d at 1174.

Nothing in these statements purports to establish the rule that intervening changes in law may not be applied to pending cases where appropriate. The petition at most raises a dispute over the application of general forfeiture rules, in an area "left primarily to the discretion of the courts of appeals, to be exercised on the facts of individual cases." *Singleton*, 428 U.S. at 121. That does not warrant review under Rule 10.

B. *Arthrex* did not represent an unforseeable "intervening change of law" that excuses Sanofi's failure to plead or press its Appointments Clause challenge.

The Federal Circuit's forfeiture ruling reads as a routine application of settled forfeiture principles because the issue Sanofi belatedly raises was foreseeable. Sanofi asks the Court to indulge the idea that Sanofi's complete failure to mention an Appointments Clause theory until months after oral argument below should be excused because it required "clairvoyance" to anticipate *Arthrex*. Pet. 3. But *Arthrex* was not created out of whole cloth; it relied on earlier Appointments Clause decisions, including many involving similar administrative judges. Numerous parties recognized the issue long before Sanofi did. Even after *Lucia*, however, Sanofi failed to advance the issue, first raising it months after oral argument below—two weeks before the court ruled, when the writing was on the wall.

This case is thus a poor vehicle to decide any forfeiture issue involving "intervening changes of law." Pet. 10. *Arthrex* did not involve a novel theory or a claim that "ha[d] not yet been recognized" (Pet. 13); it applied settled precedent. Granting certiorari would encourage parties to raise issues only when doing so appears necessary to avoid an inevitable loss, thus rewarding sandbagging. Indeed, Sanofi itself has elsewhere argued that its opponent forfeited an *Arthrex* challenge by failing to raise the Appointments Clause in its opening Federal Circuit brief. *Infra* at 24–25. Regardless of how *Arthrex* itself is resolved, the same principle warrants denying review here.

1. *Arthrex* simply applied longstanding Appointments Clause precedent, including many decisions involving similar administrative judges.

a. *Arthrex* relied not only on venerable Appointments Clause decisions such as *Buckley* v. *Valeo*, 424 U.S. 1 (1976), but on at least seven other Appointments Clause decisions—four decisions of this Court and three circuit decisions—involving similar administrative judges. For example, the court in *Arthrex* repeatedly invoked *Freytag* v. *Commissioner*, 501 U.S. 868 (1991), which held—three decades ago—that the appointments of special trial judges (STJs) of the Tax Court are subject to the Appointments Clause. 941 F.3d at 1328. Likewise, *Arthrex* relied heavily on

Edmond v. *United States*, 520 U.S. 651 (1997), which held that judges on the Coast Guard Court of Criminal Appeals were properly appointed by the Secretary of Transportation. See 941 F.3d at 1328–1331.

Arthrex also relied on *Ryder* v. *United States*, 515 U.S. 177 (1995), which invalidated the Department of Transportation General Counsel's appointment of judges to the Court of Military Review. 941 F.3d at 1340. And no less than eight times (*e.g.*, 941 F.3d at 1325, 1328, 1340), *Arthrex* cited *Lucia*—which held that the SEC's administrative law judges (ALJs) "qualify as * * * 'Officers [of the United States].'" 138 S. Ct. at 2049. As one illustrative passage of *Arthrex* stated: "Like the special trial judges ('STJs') of the Tax Court in *Freytag*, who 'take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders,' and the SEC Administrative Law Judges in *Lucia*, who have 'equivalent duties and powers as STJs in conducting adversarial inquiries,' the APJs exercise significant authority rendering them Officers of the United States." 941 F.3d at 1328 (citations omitted). In short, *Arthrex* was not a trailblazing decision that parties could not reasonably have anticipated.

Lucia itself was but the latest in a long line of Appointments Clause decisions, some of which involved administrative judges like those at issue in *Arthrex*. In holding that the SEC's ALJs were "Officers of the United States" under the Appointments Clause, this Court relied both on two decisions that "set out this Court's basic framework for distinguishing between officers and employees"—*United States* v. *Germaine*, 99 U.S. 508, 510 (1878), and *Buckley*, 424 U.S. at 126 n.162—and on *Freytag*, which "applied the unadorned 'significant authority' test to adjudicative officials who are near-carbon copies of the Commission's ALJs." 138 S. Ct. at 2051–2052. These decisions had been on the books for decades and, in the case of *Germaine*, for 140 years.

b. *Arthrex* also built on three key circuit-level decisions—two from the Federal Circuit, one from the D.C. Circuit—involving appointments of non-Article III judges. For example, *Arthrex* relied on *Intercollegiate Broadcasting Sys., Inc.* v. *Copyright Royalty Bd.*, 684 F.3d 1332, 1339 (D.C. Cir. 2012), which held that the "nonremovability" of Copyright Royalty Judges and "the finality of their decisions" rendered them principal officers. As the court in *Arthrex* explained: "The lack of any presidentially-appointed officer who can review, vacate, or correct decisions by the APJs combined with the limited removal power lead us to conclude, like our sister circuit in *Intercollegiate*, which dealt with the similarly situated CRJs, that these are principal officers." 941 F.3d at 1335.

Similarly, *Arthrex* distinguished special masters under the Vaccine Act, which *Masias* v. *Secretary of Health and Human Servs.*, 634 F.3d 1283, 1294–1295 (Fed. Cir. 2011), had deemed inferior officers, because their rulings are "supervised by judges of the Court of Federal Claims." 941 F.3d at 1333. And the court cited *Helman* v. *Department of Veterans Affairs*, 856 F.3d 920, 930 (Fed. Cir. 2017), which held that Merit System Protection Board (MSPB) judges exercise significant authority, making it unconstitutional for Congress to prohibit appeal of their decisions to the full Board (a problem the court remedied by severing the appeal prohibition). 941 F.3d at 1335.

This venerable body of precedent, all on the books long before the PTAB ruled here, forecloses any suggestion that it took "clairvoyance to raise an Appointments Clause challenge in [Sanofi's] opening brief" below, or that Sanofi's Appointments Clause claim was "'squarely foreclosed by * * * precedent.'" Pet. 3, 14 (citation omitted). These decisions applied the text of the Appointments Clause, which is as old as the Republic, and longstanding precedent.

That distinguishes *Curtis Publishing Co.* v. *Butts*, 388 U.S. 130 (1967), where this Court allowed the defendant to assert an untimely constitutional defense arising from *New York Times Co.* v. *Sullivan*, 376 U.S. 254 (1964). *Sullivan* was a watershed decision: It marked this Court's first decision imposing First Amendment limits on the common law of defamation, and it repudiated "strong precedent indicating that civil libel actions were immune from general constitutional scrutiny." *Butts*, 388 U.S. at 143–144. The Court thus rejected Butts' argument that, given "the general state of the law at the time of this trial," Curtis Publishing "[should] have seen 'the handwriting on the wall,'" reasoning: "Given the state of the law prior to [*Sullivan*], we do not think it unreasonable for a lawyer trying a case of this kind, where the plaintiff was not even a public official under state law, to have looked solely to the defenses provided by state libel law." *Ibid*. Further, the defendant raised the constitutional defense at the first opportunity in the trial court. 388 U.S. at 138–139.

Here, by contrast, several decisions of this Court and the circuits had recognized Appointments Clause claims involving similar administrative judges before Mylan's IPR petitions were even filed. Yet even after *Lucia*—which issued six months before the PTAB ruled here—Sanofi still did not raise the Appointments Clause before the PTAB. Nor did Sanofi meet its obligation to raise the issue in its docketing statement, opening Federal Circuit brief, reply brief, or oral argument. See Fed. R. App. P. 28(a)(8)(A)–(B) ("The appellant's brief must contain * * * the argument, which must contain: (A) appellant's contentions and the reasons for them, with citations to the authorities and parts of the record on which the appellant relies; and (B) for each issue, a concise statement of the applicable standard of review (which may appear in the discussion of the issue or under a separate heading placed before the discussion of the issues)").[2]

Timely raising issues is especially critical where, as here, they involve constitutional challenges to federal laws. See Fed. R. App. P. 44(a) (requiring notice to the clerk of constitutional challenges); cf. 28 U.S.C. 2403(a) (requiring the courts to give such notice to the Attorney General and granting the United States the rights of a party). Yet Sanofi never pled the Appointments Clause, let alone developed an Appointments Clause argument. Only two months after oral

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[2] Citing *Oil States Energy Servs., LLC* v. *Greene's Energy Grp., LLC*, 138 S. Ct. 1365 (2018), Sanofi says "strong precedent" had "upheld the constitutionality of IPR proceedings, including against a challenge that APJs exercised powers beyond their authority as non-Article III judges." Pet. 22. But *Oil States* rejected only Article III and Seventh Amendment challenges; it did not create "strong precedent" on Appointments Clause questions not presented. The Court "emphasize[d] the narrowness of [its] holding," noting, for example, that it was not reaching due process or takings issues. 138 S. Ct. at 1379.

argument, just before the Federal Circuit ruled, did Sanofi ask to brief *Arthrex*.[3]

This is not a case, therefore, where a party raised a previously unforeseeable issue at the first (or second or third) reasonable opportunity. Rather, Sanofi not only waited to see whether it prevailed before the PTAB, but took the opportunity to size up its chances based on oral argument in the Federal Circuit, before saying the entire underlying PTAB regime was illegitimate. It would not be appropriate to reward such gamesmanship by granting certiorari and rewriting settled forfeiture law. Nor would it "promote[] judicial efficiency" or "incentivize the presentation of claims at the proper time and place." Pet. 13–14.

2. Other parties had the "clairvoyance" that Sanofi lacked, frequently raising their Appointments Clause claims even before the PTAB.

a. Dozens of other parties having the same information as Sanofi raised the Appointments Clause far sooner—frequently before the PTAB, and certainly in their Federal Circuit briefs. That is, the "clairvoyance" supposedly needed to foresee the issue was not in short supply. And because Sanofi, unlike other litigants, did not press the Appointments Clause in its opening brief below, this case does not implicate any rule that courts may not "treat similarly situated litigants differently" (*Harper* v. *Va. Dep't of Taxation*, 509 U.S. 86, 97 (1993) (citation omitted)), or that

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[3] Using a Rule 28(j) letter to offer new argument or seek new relief is itself improper. *E.g.*, *Hall* v. *Shinseki*, 717 F.3d 1369, 1373 n.4 (Fed. Cir. 2013).

courts should apply new rules "to all *similar* cases pending on direct review" (*Griffith* v. *Kentucky*, 479 U.S. 314, 323 (1987) (emphasis added)).

Others raised this issue at the PTAB before Mylan filed these IPR petitions. In May 2016, for example, Yeda Research & Development raised such a challenge in an unrelated post-grant review. *Supra* at 9. This challenge came over a year before Mylan filed the petitions here, and over two years before *Lucia*. Because the PTAB denied the petition on patent law grounds, it did not reach the constitutional challenge. But the same challenge was raised in more than 30 PTAB proceedings predating *Arthrex*,[4] and several PTAB decisions addressed the issue.[5]

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[4] *E.g.*, *Coalition for Affordable Drugs VIII, LLC* v. *The Trustees of Univ. of Penn.*, IPR2015-01836, IPR2015-01835; *Mylan Pharms. Inc.* v. *Yeda Res. and Dev. Co.*, PGR2016-00010; *Hulu, LLC* v. *Sound View Innovations, LLC*, IPR2018-00017, IPR2018-00366; *St. Jude Med., LLC* v. *Snyders Heart Valve, LLC*, IPR2018-00105, IPR2018-00106, IPR2018-00107, IPR2018-00109; *ZTE (USA) Inc*. v. *Fundamental Innovation Sys. Int'l LLC*, IPR2018-00425; *Pfizer, Inc*. v. *Biogen, Inc.*, IPR2018-00285; *Investors Exchange LLC* v. *NASDAQ, Inc.*, CBM2018-00041, CBM2018-00042; *Unified Patents, LLC* v. *Bradium Techs. LLC*, IPR2018-00952; *Apple, Inc*. v. *Uniloc 2017 LLC*, IPR2018-00424, IPR2018-00282; *Intel Corp*. v. *VLSI Tech. LLC*, IPR2018-01105, IPR2018-01035, IPR2018-01144, IPR2018-01033, IPR2018-01040, IPR2018-01312, IPR2018-01107; *Samsung Elecs. Am., Inc.* v. *Uniloc 2017 LLC*, IPR2018-01653; *Quest USA Corp*. v. *PopSockets LLC*, IPR2018-00497, IPR2018-01294; *General Elec. Co*. v. *Vestas Wind Sys. A/S*, IPR2018-00928, IPR2018-00895, IPR2018-00896; *Unified Patents, LLC* v. *Uniloc 2017 LLC*,

b. Challenges to APJ appointments only accelerated after *Lucia*. For example, the appellant in *Polaris* raised the Appointments Clause not only before the PTAB, but in an opening brief filed just weeks after *Lucia*, stating: "The cancellation of Polaris's claims violated the Appointments Clause * * * as a final agency decision requiring the Board to act as 'principal Officers' without having been appointed by the President and confirmed by the Senate." Opening Br. of Appellant 1–2 (Dkt. 22), No. 2018–1768 (Fed. Cir. July 10, 2018); *id.* at 52–60. This was sixteen months before Sanofi first mentioned the issue.

As Sanofi notes, "in *Arthrex* itself, the Federal Circuit excused at least one level of forfeiture to reach the Appointments Clause issue, given that Arthrex raised the issue in the Federal Circuit for the first time on appeal." Pet. 17 (citation omitted). Polaris and Arthrex were not alone in raising these issues in their opening Federal Circuit briefs. For example, in one of Sanofi's cases (Pet. 21–22), the court granted rehearing and vacated its earlier decision in light of *Arthrex* where the appellant—unlike Sanofi—raised the issue in its opening brief. See *Bedgear,*

IPR2019-00453; *Starbucks Corp.* v. *Fall Line Patents, LLC*, IPR2019-00610; *Unified Patents Inc.* v. *MOAEC Techs., LLC*, IPR2018-01758; *Flywheel Sports, Inc.* v. *Peloton Interactive, Inc.*, IPR2019-00564, IPR2019-00295, IPR2019-00294.

[5] *E.g.*, *St. Jude Medical, LLC* v. *Snyders Heart Valve, LLC*, IPR2018-00107, Paper 16 at 9 (P.T.A.B. May 3, 2018) ("we are not persuaded that Administrative Patent Judges conducting inter partes reviews is unconstitutional").

LLC v. *Fredman Bros. Furniture Co.*, 779 F. App'x 748 (Fed. Cir. 2019), reh'g granted and judgment vacated, 803 F. App'x 407 (Fed. Cir. 2020); Opening Br. of Bedgear 63–64 (Dkt. 18), No. 2018–2170 (Fed. Cir. Nov. 13, 2018).

c. In our view, the court in *Arthrex* wrongly excused Arthrex's forfeiture before the PTAB. The Executive Branch, no less than the courts, is obligated to abide by the limits of the Appointments Clause. Under this Court's "general rule," moreover, "courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice." *L. A. Tucker*, 344 U.S. at 37; accord *Woodford* v. *Ngo*, 548 U.S. 81, 90 (2006); *McCarthy* v. *Madigan*, 503 U.S. 140, 144–145 (1992); *Unemployment Compensation Comm'n* v. *Aragon*, 329 U.S. 143, 154–155 (1946); *Hormel* v. *Helvering*, 312 U.S. 552, 556–557 (1941).

That rule promotes "[s]imple fairness to those who are engaged in the tasks of administration, and to litigants." *L. A. Tucker*, 344 U.S. at 37. The Federal Circuit itself has enforced the rule in this context, holding that a patentee forfeited its Appointments Clause claim that "two of the administrative patent judges on the panel were appointed unconstitutionally" by "failing to raise it * * * before the Board." *In re DBC*, 545 F.3d 1373, 1377 (Fed. Cir. 2008) (footnotes omitted). As noted above (at 19), moreover, even before *Arthrex*, more than 30 parties asked the PTAB to decide the issue resolved there, and parties in other cases have likewise seen fit to press Appointments Clause issues before federal agencies. *E.g.*, *Lucia*, 138 S. Ct. at 2050.

Even assuming that Sanofi was not required to raise the Appointments Clause before the PTAB, however, the issue was certainly foreseeable enough to be raised in its opening Federal Circuit brief. And even assuming that "structural constitutional principles" are important (Pet. 3), they are not jurisdictional and it would be wholly improper "excuse[]" not just "one level of forfeiture" (Pet. 17), but two, when other parties timely raised the issue.

d. According to Sanofi, *Arthrex* was unforeseeable because earlier Federal Circuit decisions "found that APJs were 'subordinate officers'"—"not principal officers, as *Arthrex* later found." Pet. 21. That is false. *Ethicon Endo-Surgery, Inc.* v. *Covidien LP* addressed only "due process"—the court nowhere mentioned the Appointments Clause. 812 F.3d 1023, 1029–1031 (Fed. Cir. 2016). The same is true of *In re Alappat*—which Sanofi misidentifies (Pet. 21) as a "predecessor *inter partes* reexamination regime," rather than an ordinary examination appeal. 33 F.3d 1526 (Fed. Cir. 1994), abrogated on other grounds by *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008). And Sanofi's other authorities—unpublished, one-sentence orders affirming the PTAB under Federal Circuit Rule 36—are not even precedent, let alone conflicting Appointments Clause decisions. See *Trading Techs. Int'l, Inc.* v. *IBG LLC*, 771 F. App'x 493 (Fed. Cir. 2019); *Bedgear,* 779 F. App'x 748. Not surprisingly, the court in *Arthrex* felt no need to mention any of these decisions.

Sanofi also says *DBC* "held that when Congress re-delegated appointment of APJs to the secretary of commerce, it '*eliminate*[*d*] the issue of unconstitutional appointments going forward.'" Pet. 21 (quoting 545 F.3d at 1380) (Sanofi's emphasis)). In truth, *DBC* held that "DBC waived the issue by failing to raise it before the Board." 545 F.3d at 1377. As *Arthrex* explained, the dictum quoted by Sanofi involved "particular APJs who were appointed by the Director, rather than the Secretary," and Congress passed a "new statute" under which the Secretary "reappointed the administrative patent judges involved in DBC's appeal." 941 F.3d at 1339, 1327 (citations omitted). Congress's "remedial action" "weigh[ed] against considering the waived challenge" in *DBC*. 545 F.3d at 1380. But however *DBC* is read, its waiver analysis cannot remotely be read as having foreclosed *Arthrex*. If anything, it simply underscored that, as early as 2008, others were litigating Appointments Clause limitations on APJ appointments.

C. *Freytag* does not support review.

According to Sanofi, that this case involves a "structural constitutional claim[]" itself "overcomes the usual rule of entertaining only preserved issues on appeal." Pet. 15 (citing *Freytag*, 501 U.S. at 878). Not so.

First, the petitioners in *Freytag* raised their Appointments Clause challenge when they first "appeal[ed] to the Fifth Circuit" (which "concluded that petitioners had 'waived this objection' by consenting to the assignment of their case"). 501 U.S. at 893 (quoting *Freytag* v. *Commissioner*, 904 F.2d 1011, 1015 n.9 (1990)). Even then, the Court called for briefing on waiver (*ibid.*) and four Justices "disagree[d] * * * with the Court's decision to reach * * * the Appointments Clause issue" (501 U.S. at 892 (Scalia, J., concurring in part and in the judgment)). Sanofi, by contrast, first mentioned the Appointments Clause months after argument below.

Second, the majority in *Freytag* "d[id] not even mention," much less adopt, the position "that 'structural' constitutional rights as a class simply cannot be forfeited" and may be raised "at any stage." *Id*. at 892. Acknowledging that, "as a general matter, a litigant must raise all issues and objections at trial," the Court simply "exercise[d] [its] discretion to hear petitioners' challenge"—an approach it called "rare." 501 U.S. at 879. Sanofi thus lacks any legal basis to insist that the Court hear its challenge—let alone when others have timely raised the issue, permitting the courts to provide a definitive answer.

Third, the number of parties raising the *Arthrex* issue confirms that the constitutional limitation here is *not* one that "parties cannot be expected to protect." Pet. 15 (quoting *Commodity Futures Trading Comm'n* v. *Schor*, 478 U.S. 833, 851 (1986)). This *is* a case, however, involving a great risk of "sandbagging"—the "strategic" practice of "[permitting] the trial court [to] pursue a certain course, and later—if the outcome is unfavorable—claiming that the course followed was reversible error." *Freytag*, 501 U.S. at 895 (Scalia, J.). Indeed, given Sanofi's strategic decision to raise its claim only months after oral argument—when the writing was on the wall—this is a textbook case of waiting until "the last possible moment to undo the administrative proceeding." *L. A. Tucker*, 344 U.S. at 36. That behavior should not be rewarded.

Finally, that Sanofi is engaged in gamesmanship of the first order is confirmed by a brief that it recently filed. *Immunex Corp*. v. *Sanofi-Aventis U.S. LLC*, No. 2019–1749, Dkt. 49 (Fed. Cir. Feb. 25, 2020). In that case, which involved cross-appeals from a PTAB ruling, Sanofi's opponent (Immunex) first challenged the APJs' appointment in the reply portion of its combined response/reply brief—earlier than Sanofi did so here. But that did not deter Sanofi from objecting that this was "the first time" that Immunex had raised the issue, and that "Appointments Clause challenges are forfeited if not raised in an appellant's opening brief." *Id.* at 15. That reasoning applies with even greater force here, where Sanofi raised the issue only two weeks before the court below ruled.

D. The forfeiture cases on which Sanofi relies are fact-bound and distinguishable.

According to Sanofi, the lower courts "have applied the change-in-law exception to forfeiture inconsistently." Pet. 16–19. But Sanofi does not identify any circuit split on the framework for resolving these issues. Moreover, a review of the cases confirms that they turn on their facts and, if anything, *support* the result below.

1. Take Sanofi's circuit decisions involving belated Appointments Clause claims. Pet. 16 n.6, 17. In *NLRB* v. *RELCO Locomotives, Inc.*, for example, the Eighth Circuit refused to consider an Appointments Clause claim that was not pressed "before the NLRB or in [the appellant's] initial briefs on appeal," but only "in a Rule 28(j) letter" filed after an intervening decision (*Noel Canning*). 734 F.3d 764, 795 (8th Cir. 2013). That is precisely the situation here. Yet the court rejected the notion that the intervening decision excused the forfeiture because the appellant "had no way of anticipating 'the relatively arcane constitutional grounds' that led to the decision" and "cannot be asked to "raise (or risk waiving) every potential legal argument, no matter how novel and lacking in legal support" (*id.* at 795–796)—precisely Sanofi's argument here. Pet. 14. As the court explained:

> All of the facts and legal arguments necessary to make an appointments clause challenge were available to RELCO when its case was heard by the Board. RELCO was aware that the NLRB's quorum included recess appointees, and it was aware of when and by what means those members were appointed. Indeed, according to RELCO the legal argument has been available since the 1789 ratification of the Constitution. The fact that RELCO initially decided not to pursue this argument because it viewed it as "arcane," "novel," and "lacking in legal support" is a strategic decision whose consequences it must accept.

Id. at 796. So too here.

Similarly, in *David Stanley Consultants* v. *Dir., Office of Workers' Compensation Programs* (*DSC*), the Third Circuit declined to address an appointments challenge raised earlier than Sanofi's—in "a motion to remand before the [Benefits Review] Board," *and* in its opening circuit brief. 800 F. App'x 123, 127 (3d Cir. 2020). As the court stated, "[o]ur sister circuits have repeatedly held, including in post-*Lucia* cases, that a petitioner forfeits an Appointments Clause challenge if it fails to properly raise the challenge before the Board." *Ibid*. The court disagreed that *Lucia* excused the forfeiture, as the Court there was simply "applying its prior decision in *Freytag*," not "creating new law." *Id*. at 128. So too here.

As *DSC* recognized, *Jones Brothers, Inc*. v. *Secretary of Labor*, 898 F.3d 669 (6th Cir. 2018)—one of the cases that Sanofi likes (Pet. 17)—declined to find a forfeiture only because of "the absence of legal authority addressing whether the Mine Commission could entertain the challenge." 800 F. App'x at 128. Indeed, "the Sixth Circuit has since held that, in a Black Lung Benefits Act case, an employer forfeits its Appointments Clause claim under 20 C.F.R. § 802.211(b) if it fails to properly raise the claim before the Board." *Ibid.* (citing *Island Creek Coal Co.* v. *Bryan*, 937 F.3d 738, 754 (6th Cir. 2019)). Sanofi waited much longer here.

In *Samuels, Kramer & Co.* v. *Commissioner*—another of Sanofi's favored authorities (Pet. 17)—the court rejected the contention that a taxpayer forfeited the right to challenge the appointment of Tax Court judges by "litigat[ing] its tax deficiencies in the Tax Court, rather than * * * pay[ing] the tax assessed and then seek[ing] a refund in federal district court." 930 F.2d 975, 983 (2d Cir. 1991). But the appellant there "challenged the assignment of its cases to a special trial judge from the outset"—not in a letter filed weeks before the circuit court ruled. *Ibid.*

2. As to Sanofi's non-Appointments Clause cases, the Fifth Circuit in *Martinez* v. *Tex. Dep't of Criminal Justice* (Pet. 19) refused to consider a new issue because existing precedent "was not so settled" against the forfeiting party "that raising [the issue] in district court would have been pointless." 300 F.3d 567, 574–575 (5th Cir. 2002). That approach tracks *Butts*, which the court cited: Any intervening-change-in-law exception applies only where "there was strong precedent' prior to the change," "such that the failure to raise the issue was not unreasonable." *Id.* at 574 (quoting *Butts*, 388 U.S. at 143).

In *Gucci Am., Inc.* v. *Weixing Li*, by contrast, the Second Circuit held that a personal jurisdiction argument considered "for the first time" in *Daimler AG*

v. *Bauman*, 571 U.S. 117 (2014), understandably was "not known" before then and in fact was "directly contrary to controlling precedent." 768 F.3d 122, 134, 135–136 (2d Cir. 2014). Similarly, in *Wang* v. *Chinese Daily News, Inc.*, 737 F.3d 538, 543 (9th Cir. 2013), the Ninth Circuit held that *Wal-Mart* v. *Dukes*, 564 U.S. 338 (2011), was such a "significant legal development" that it excused the failure to raise a class-action defense based on that decision. See also *DSC Commc'ns Corp*. v. *Next Level Commc'ns*, 107 F.3d 322, 326 n.2 (5th Cir. 1997) (allowing a party that had already challenged application of "corporate opportunity" doctrine to invoke an "important clarification of" that doctrine—one limiting it to "officers, directors, and major shareholders").

These cases turn on a fact-bound question: whether, in the court's judgment, the issue was foreseeable or rather clearly foreclosed by precedent. Here, Sanofi's belated Appointments Clause challenge was not so contrary to "strong precedent" (*Butts*) that it could not reasonably be asserted. Rather, the issue remained open until *Arthrex* resolved it, and others raised the issue long before Sanofi did. *Supra* at 18–21. As evidenced by the many similar decisions on which *Arthrex* relied, the underlying theories were long recognized. Thus, the ruling below is consistent with the above decisions, and with Sanofi's other cases too. *E.g.*, *United States* v. *Nealy*, 232 F.3d 825, 830 (11th Cir. 2000) (parties may "submit supplemental authority on '*intervening* decisions or *new* developments,'" but may not "raise totally new issues" not raised "in [their] initial brief" (citations omitted)).

In sum, Sanofi's lower court decisions confirm that the court below properly enforced the forfeiture rules here. Any variations among the results in those decisions are fact-driven—reflecting the fact that forfeiture law is "left primarily to the discretion of the courts of appeals, to be exercised on the facts of individual cases." *Singleton*, 428 U.S. at 120.

II. The Federal Circuit's affirmance of the PTAB's obviousness determination correctly resolved a patent-specific factual question that does not warrant this Court's review.

Sanofi's request for review of the Federal Circuit's obviousness holding likewise lacks merit. The court correctly applied *KSR*; its decision turns on the facts and credibility determinations; and Sanofi's second question presented mischaracterizes both the Federal Circuit's and the PTAB's holdings. Further, that the factual record so strongly supports the obviousness holding below confirms that, even if the first question presented were otherwise certworthy (it is not), there would be no point in deciding it, as reversal would not affect the ultimate outcome.

A. Sanofi's assertion that the Federal Circuit departed from *KSR*'s obviousness analysis mischaracterizes the decision below and the PTAB findings that it affirmed.

In Sanofi's view, the court below broke from *KSR* in two ways: (1) by ignoring the need to find a "known problem that the claimed invention solved" (Pet. 27), and (2) by relying on Sanofi's patent specification in concluding that insulin glargine was prone to aggregation (Pet. 27–28). These claims mischaracterize the PTAB's finding and the Federal Circuit's affirmance. Once that becomes clear, moreover, it is evident that the petition raises only a fact-bound appeal involving an alleged misapplication of settled law.

1. As to Sanofi's first objection to the decision below, the court only affirmed the PTAB's finding that the prior art demonstrated both the problem (that insulins generally were known to aggregate) and the solution (that non-ionic surfactants were known to reduce aggregation). Pet. 12a. As this Court stated in *KSR*, "a patent's subject matter can be proved obvious" by showing "that there existed at the time of invention a known problem for which there was an obvious solution encompassed by the patent's claims." 550 U.S. at 419–420. This is exactly what the Federal Circuit held in affirming the Board's findings here:

> The Board's findings with respect to the motivation to combine are detailed and well supported. The Board found that insulins "had a known tendency to aggregate in the presence of hydrophobic surfaces" and at air-water interfaces and that a relevant artisan would have expected glargine to behave similarly to other insulins when in contact with hydrophobic surfaces and at air-water interfaces. The Board also found that nonionic surfactants, including the claimed ones, were well known and had been used successfully to stabilize insulin formulations, and so would have been looked to by a relevant artisan concerned about aggregation in glargine. The record contains substantial evidence to support those findings.

Pet. 12a (citations omitted). The PTAB's findings, moreover, rested largely on credibility determinations. Pet. 38a, 58a, 72a, 66a, 92a, 113a, 122a, 128a.

Sanofi nevertheless insists that the PTAB and Federal Circuit identified the *wrong* problem by considering the scope and content of the insulin art *generally* rather than limiting the analysis to what was publicly known about insulin glargine *specifically*. Pet. 4, 7, 8-9. Even if that were true, the error would not raise an issue of national importance—it would at most reflect "the misapplication of a properly stated rule of law." S. Ct. R. 10. But Sanofi's conception of obviousness does precisely what *KSR* rejects: it reduces a person of ordinary skill in the art to an automaton. 550 U.S. at 421.

2. As to Sanofi's second objection to the decision below, the court simply affirmed that the PTAB appropriately cited disclosures in the patent specification to corroborate its understanding of the prior art. Pet. 10a–11a. Sanofi now regrets its damaging admissions. C.A. App. 105–106, 114–115. But neither the PTAB nor the court below treated Sanofi's candor as *representing* or *modifying* the prior art—only as acknowledging what other prior art sources taught.

In fact, the court below reaffirmed its "longstanding recognition that a tribunal should not look[] to knowledge taught by the inventor * * * and then use[] that knowledge against its teacher." Pet. 10a (internal quotation and citation omitted). But as the court explained, "the Board did not violate that principle, because it did not use the specification for its teachings about the inventor's discovery. Rather, it used the specification for its teachings about prior-art knowledge," which "is not just common, given patent drafters' standard practice of reciting prior art in setting out the background of the invention, but permissible." Pet. 10a. The court then explained that the PTAB "used the cited material not as the sole support for any finding but in conjunction with support from other sources." Pet. 11a. And when patent applicants seek to benefit their applications by discussing the prior art, they cannot reasonably be dismayed when their statements are taken as true—especially when those statements simply corroborate what the cited references themselves teach.

In sum, each of Sanofi's objections to the decision below rests on a mischaracterization of what the Federal Circuit actually held. The court did not decline to identify a known problem that the claimed invention solved; it simply defined that problem at a slightly higher level of generality than did Sanofi. And the court did not improperly rely on Sanofi's patent specification in concluding that insulin glargine was prone to aggregation; it simply concluded that Sanofi's specification corroborated what the prior art itself taught. In both respects, the court's analysis was unremarkable and correct. But even if the court had erred, the petition would at most raise fact-bound questions involving the application of settled law.

B. Sanofi's authorities do not raise concerns about the Federal Circuit's interpretation of *KSR*.

Sanofi's discussion of other Federal Circuit precedents does not bolster its case for review. Citing dissents from two nonprecedential decisions, Sanofi says the court has tended to "stretch[] the criteria *KSR* set forth" by finding claimed inventions obvious even absent any showing that the problems they solved were previously known. Pet. 28–29. But Sanofi does not explain how these rulings depart from *KSR*; and even accepting Sanofi's questionable characterizations of the decisions, three obviousness decisions in thirteen years do not reflect a disturbing trend.

That is especially clear in that the other two unpublished cases, like this one, turned on their facts—not on any unsupportable theory of obviousness or failure to account for hindsight bias. In *I/P Engine, Inc.* v. *AOL Inc.*, the court simply concluded that the jury's findings were incomplete, self-contradictory, and unsupported; the dissent broke from the majority based on concern that it over-relied on common sense. 576 F. App'x 982, 989–991, 996 (Fed. Cir. 2014). And in *Chapman* v. *Casner*, the court simply affirmed the PTAB's finding that the inventor's problem was known in the prior art. 315 F. App'x 294, 297–298 (Fed. Cir. 2009).

C. Sanofi forfeited its chance to advocate for a new, inflexible standard of obviousness.

Finally, while accusing the Federal Circuit of departing from *KSR*'s "expansive and flexible" analysis (Pet. 24–25), Sanofi asks this Court to limit *KSR* to cases not involving "the biochemical arts," which are supposedly "unpredictable." Pet. 29. That argument is telling confirmation that the court below faithfully applied *KSR*. But the argument is forfeited, as Sanofi failed to advance it below, much less in any developed way. *Nautilus Inc.* v. *Biosig Instruments Inc.*, 572 U.S. 898, 913 (2014) (this Court is "a court of review, not of first view" (citation omitted)).

Regardless, this case would be a particularly poor vehicle to consider that question. As the PTAB found and the Federal Circuit affirmed, the problem that Sanofi's claimed invention purported to solve was "a well-established problem" and the effectiveness of the solution—using known nonionic surfactants to stabilize insulin glargine—was "well known" and expected.

Pet. 12a. Thus, this case does not involve an "unpredictable" art.

III. The equities support denying certiorari.

Beyond the foregoing, the equities powerfully support denying certiorari. Insulin glargine was a useful invention. But as both the PTAB and the Federal Circuit recognized, Sanofi's reformulation thereof was not, and Sanofi's patents never should have issued.

Sanofi has nonetheless reaped the benefits of monopoly pricing for 18 years—excluding competition and burdening U.S. diabetes patients needing affordable insulin. Many such patients must travel abroad or dangerously ration their insulin supply. *E.g.*, C.A. App. 7527 (U.S. News & World Report, *Insulin Costs Are Skyrocketing. This Is Why.* (June 29, 2018) ("'Self-rationing' of insulin by patients can result in serious and potentially life-threatening complications such as blindness, loss of limbs, kidney failure and even death. Many patients are going to pharmacies only to find out that they must pay hundreds—if not thousands—of dollars for insulin."). If Sanofi had valid patents covering insulin glargine, that state of affairs might pose a difficult policy question. But Sanofi's patents are invalid, and Sanofi's forfeited Appointments Clause claim should not be allowed to extend this litigation.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted.

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