**No. 19A886**

# In the Supreme Court of the United States

SANOFI-AVENTIS DEUTSCHLAND GMBH,

*Applicant*,

v.

MYLAN PHARMACEUTICALS INC.,

*Respondent*.

*On application to stay or recall the mandate of the United States Court of Appeals for the Federal Circuit*

**RESPONSE TO APPLICATION TO STAY OR RECALL THE FEDERAL CIRCUIT'S MANDATE**


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February 13, 2020

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## CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent Mylan Pharmaceuticals Inc. states:

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 Mylan GmbH is 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 Research Ltd. is Biocon Ltd. Glentec International Co. Ltd. owns more than 10% of Biocon Ltd.

To the HONORABLE JOHN G. ROBERTS, JR., Chief Justice of the United States Supreme Court and Circuit Justice for the United States Court of Appeals for the Federal Circuit ("Federal Circuit"):

## INTRODUCTION

Pursuant to your Honor's Order on February 10, 2020, Respondent Mylan Pharmaceuticals Inc. ("Mylan") opposes the application of Sanofi-Aventis Deutschland GmbH ("Sanofi") for a stay of the Federal Circuit's mandate in *Sanofi-Aventis Deutschland GmbH v. Mylan Pharmaceuticals Inc.*, Nos. 2019-1368 and 2019-1369, pending filing and disposition of Sanofi's petition for a writ of certiorari.

Sanofi's stay application does not begin to show the extraordinary circumstances that are required to satisfy the demanding standards for obtaining a stay pending certiorari. For starters, Sanofi barely acknowledges that it must show irreparable harm, asserting only that its loss below will leave it with less money for research. But Sanofi does not contest that—in the unlikely event this Court were to reverse unpatentability on the merits and Sanofi's claims were ultimately enforced—it "will be able to recover damages from respondents for past patent infringement." *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301, 1301 (2014) (Roberts, C.J., in chambers). That alone warrants denying a stay, especially the indefinite stay Sanofi seeks.

Even setting aside that difficulty, however, Sanofi's application omits critical facts and authority that, once brought into view, foreclose any suggestion that there is either a reasonable probability of a grant of certiorari or a chance of reversal.

According to Sanofi, this case implicates "[its] right to have its case adjudicated according to the law as it exists at the time its case is decided"—and in particular its ability to take advantage of the Federal Circuit's October 31, 2019, decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), which, "significantly changed the law" in holding that administrative patent judges are unconstitutionally appointed. App. 1. In reality, Sanofi raises a fact-bound waiver issue; and for a host of reasons this case is a particularly unattractive candidate for this Court's review.

First, the holding in *Arthrex* was not created out of whole cloth; it relied on this Court's in *Lucia v. S.E.C.*, 585 U.S. __, 138 S. Ct. 2044 (2018) , even earlier decisions such as *Freytag v. Commissioner of Internal Revenue*, 501 U.S. 868 (1991), and *Glidden Co. v. Zdanok*, 370 U.S. 530 (1962), and the Appointments Clause—which is as old as the Constitution itself. *Arthrex*, 941 F.3d at 1325. All of these earlier authorities were part of "the law as it exist[ed] at the time [this] case [was] decided" below (App. 1), and many other parties saw fit to invoke them no later than July 2018, after *Lucia* was decided, while this case remained pending before the Patent Trial & Appeal Board (PTAB). Not so with Sanofi.

Perhaps Sanofi thought it would prevail before the PTAB. Whatever the reason, however, six months passed between this Court's decision in *Lucia* and the PTAB's decision in this case—a period when the press extensively covered the possible application of *Lucia* to patent administrative judges—yet Sanofi never brought *Lucia* to the PTAB's attention. Similarly, even after the PTAB proceedings,

one searches in vain for any reference to *Lucia* or the Appointments Clause in Sanofi's notice of appeal (as is required by Federal Rule of Appellate Procedure 44), its opening brief below (as is required by standard waiver rules), its reply brief below (which would have been something, if too late), or its presentation at oral argument. Rather, Sanofi first raised the possibility of briefing the Appointments Clause question only in November 2019—when it had lost before the PTAB, nearly two months after oral argument in the Federal Circuit, and after two precedential Federal Circuit opinions had already made clear that those who had not previously briefed the issue had waived it.

Sanofi does not (and cannot) suggest that a party should be excused from ordinary waiver principles where it had reasonable notice of an argument and nevertheless failed to assert it on a timely basis. At most, therefore, Sanofi is quibbling about the application of settled and essentially undisputed waiver principles to the particular (unattractive) facts of this case—where the issue was already well-known, covered in the press, and briefed by others. But "certiorari is rarely granted when the asserted error consists of . . . the misapplication of a properly stated rule of law." Sup. Ct. R. 10; see also App. 6 (acknowledging that the Federal Circuit has been consistent in applying waiver to similarly situated appellants).

Second, Sanofi does not seek application of *Arthrex* to its case; rather, Sanofi seeks to be an *exception* to what *Arthrex* and the following Federal Circuit cases have held. In *Arthrex*, the Federal Circuit solved the Appointments Clause problem

by severing an employment provision that impeded agency-head oversight. 941 F.3d at 1338. The Federal Circuit nevertheless rewarded Arthrex with a remand for raising the issue and indicated that others that had properly raised the issue would also be entitled to a remand. *Id*. at 1340-41. Because Sanofi does not fall within the class of appellants who timely briefed the issue, under *Arthrex*, Sanofi is not entitled to a remand. Sanofi's theory for relief is actually inconsistent with *Arthrex*.

Third, for this Court's intervention to make a practical difference, Sanofi would need not only to obtain both a grant of certiorari and a favorable decision from this Court on its fact-bound waiver argument, but then to prevail on the merits on remand, before a different PTAB panel and the Federal Circuit. (Sanofi says it will raise a substantive patent question before this Court (App. 4), but never explains either why the question is certworthy or why the holding below is likely to be reversed.) This is exceedingly unlikely. Even if the decisions below were vacated solely on Appointments Clause grounds, there is no reason to believe that a different panel of PTAB judges, or the Federal Circuit, would reach a different result the second time around. *Arthrex* leaves to the PTAB's discretion whether to "proceed[] on the existing written record [or] allow additional briefing or reopen the record in any individual case." 941 F.3d at 1341. The purported invention here—adding a surfactant to impede insulin molecules from aggregating during storage—simply applied a known solution to a known insulin problem, as the PTAB held after a trial and the Federal Circuit confirmed on appeal. For that reason too, this case is a poor vehicle to review Sanofi's waiver question.

Finally, although the Court need not reach the issue (because Sanofi cannot satisfy the other requirements for a stay), the public interest is best served by encouraging parties to raise legal issues early in litigation—not for the first time before this Court—and the patent system is not designed to allow invalid patents to continue blocking competition. Citing an out-of-context snippet from *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313, 343 (1971), Sanofi asserts that "[t]his Court recognizes the 'patent system's desirable stimulus to invention.'" App. 25. But that snippet looks quite different in context: "Although recognizing *the patent system's desirable stimulus to invention*, we have also viewed the patent as a monopoly which, although sanctioned by law, has the economic consequences attending other monopolies. A patent yielding returns for a device that fails to meet the congressionally imposed criteria of patentability is anomalous." 402 U.S. at 343 (emphasis on Sanofi's quotation) (footnotes omitted).

Sanofi's patents are just that sort of patent. They have rightly been held unpatentable, and they are neither poster-children for the benefits of the patent system nor a basis for any appeal to equity. If a stay were granted, moreover, it would harm diabetes patients in the United States by delaying their access to affordable generic alternatives to Sanofi's insulin products—alternatives that Mylan already sells elsewhere in the world.

## ARGUMENT

"Denial of such in-chambers stay applications is the norm; relief is granted only in 'extraordinary cases.'" *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009)

(Ginsburg, J., in chambers) (quoting *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers)). To warrant such relief, Sanofi must demonstrate (1) a reasonable probability that this Court will grant certiorari, (2) a fair prospect that the Court will then reverse the decision below, and (3) a likelihood that irreparable harm will result from the denial of a stay. *Teva*, 572 U.S. at 1301. In a close case, balancing the equities—exploring the relative harms to applicant and respondent, as well as the interests of the public at large—may be appropriate. *Conkright*, 556 U.S. at 1402. On every element of this test, Sanofi's stay application comes up short.[1]

## I. Sanofi's Challenge to the Federal Circuit's Application of Unchallenged Waiver Law Makes Certiorari Very Unlikely in this Fact-Bound Case

Sanofi spends much of its brief on this factor addressing the importance of the Federal Circuit's *Arthrex* decision. *Arthrex* does indeed raise many enticing issues. They are not, however, Sanofi's issues because Sanofi never briefed them, making this case an extremely poor vehicle for certiorari to consider these issues. The case for considering the *Arthrex* issues is *Arthrex* itself.

Sanofi's response to the poor-vehicle argument is that "Sanofi is not challenging—and is not asking the Supreme Court to review—this Court's underlying decision in *Arthrex*." Sanofi Stay Reply at 1, No. 2019-1368 (Fed. Cir.)

[1] Sanofi indicates that it will also challenge the merits of the Federal Circuit's decision, but provides no explanation at all. App. 5. Hence, that hypothetical challenge can play no role in deciding Sanofi's application.

(Paper 74, filed Jan. 31, 2020). Instead, Sanofi argues that *Arthrex* should be applied in its case, without acknowledging that the Federal Circuit has already done just that. The Federal Circuit used severability to restore the constitutionality of administrative patent judges (the only reason a remand to the PTAB even makes sense absent a legislative fix). 941 F.3d at 1335-40. The effect is necessarily retroactive. *Harper v. Virginia Department of Taxation*, 509 U.S. 86, 94, 96-97 (1995). Under the very terms of *Arthrex* itself, the PTAB panel that issued the decisions in this case retroactively became proper when the Federal Circuit in *Arthrex* severed an employment provision deemed to impede proper agency-head supervision.

Sanofi nevertheless cites *Arthrex* for the need to incentivize constitutional challenges. App. 5. Yet, in recognizing that policy, *Arthrex* sensibly limited it to the parties that actually made the argument. 941 F.3d at 1340. The decision rewarded all appellants that merited the incentive without singling out Arthrex alone, but excluded those who did not merit the incentive. Sanofi wishes to reap where it did not sow. Having never made the argument, Sanofi is not entitled to the *Arthrex* exception to the general retroactivity of its severance solution because Sanofi did not earn the exception. *Cf. In re DBC*, 545 F.3d 1373, 1380-81 (Fed. Cir. 2008) (declining to excuse waiver of challenge to an earlier administrative patent judge appointments issue because Congress had already solved the problem, eliminating the need to incentivize appellant). Sanofi's disagreement with how the Federal

Circuit consistently applied its discretion to the facts of each appeal merits neither certiorari nor reversal. Sup. Ct. R. 10.

## II. Sanofi's Utter Failure to Brief a Known Issue Makes Reversal Very Unlikely in this Case

This case presents no basis for reversal. The Federal Circuit has already provided Sanofi with the outcome it seeks: the court applied *Arthrex* to Sanofi's appeal. What Sanofi really seeks is to modify *Arthrex* to create a windfall for appellants that did nothing to earn the windfall and that no longer face a constitutional infirmity because the infirmity was repaired retroactively. In any case, Sanofi is a particularly undeserving appellant for such a windfall.

Sanofi failed to raise the issue at the PTAB, which might have allowed the government to respond with compelling counter-arguments or to implement measures to avoid the numerous remands now flooding the PTAB. Sanofi failed to advise the Federal Circuit of any constitutional problem, even though it was required to do so. Fed. R. App. P. 44(a) (notice to the court triggers notice to the Attorney General); cf. 28 U.S.C. § 2403(a). Sanofi failed to move promptly for a remand in light of *Lucia*, thus wasting court and respondent resources. Sanofi failed to raise the issue in its opening or reply briefs, or at oral argument. Only two months after oral argument, right before the merits panel issued its decision, did Sanofi file a Fed. R. App. P. 28(j) letter[2] asking for an opportunity to brief *Arthrex*.

[2] Use of 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 (Fed. Cir. 2013).

Yet as Sanofi acknowledges (App. 6), by that time both *Arthrex* itself and a precedential order in another case made clear that parties that had not raised the issue in opening briefs had waived the issue. *Arthrex*, 941 F.3d at 1340 ("Thus, we see the impact of this case as limited to those cases where final written decisions were issued and where litigants present an Appointments Clause challenge on appeal."); *Customedia Technologies, LLC v. Dish Network Corporation*, 941 F.3d 1173, 1174 (Fed. Cir. 2019) ("Customedia did not raise any semblance of an Appointments Clause challenge in its opening briefs or raise this challenge in a motion filed prior to its opening briefs. Consequently, we must treat that argument as forfeited in these appeals.").

Sanofi cannot argue surprise. Appellants from PTAB decisions started challenging administrative patent judge appointments immediately after *Lucia*. *E.g.*, Appellant's Brief at 1-2, *Polaris Innovations Ltd. v. Kingston Technology Co., Inc.*, No. 2018-1768 (Fed. Cir.) (Paper 22, filed 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."). By contrast, in July 2018, Sanofi was still before the PTAB, but failed to raise the question at any time before the PTAB issued its final written decision in December 2018. Similarly, Sanofi filed its opening brief at the Federal Circuit in April 2019, but failed to raise the question. Sanofi did not raise the question in its reply brief in June or at oral argument in September. Instead, Sanofi first indicated that it might want to brief

the issue in November 2019, nearly two months after oral argument, and well over a year after others had fully briefed the issue.

## III. Damages are Ample Remedy to Any Harm Sanofi Could Conceivably Suffer

The possibility of damages is sufficient remedy for any harm Sanofi might suffer without a stay. *Teva*, 572 U.S. at 1302.[3] Although Sanofi implies that its patent claims will be canceled without a stay, it does not support this assertion with any authority or logic. In fact, the Director of the United States Patent and Trademark Office, the officer designated by statute to issue the certificate canceling claims held unpatentable, does not do so while claims are still under judicial review. 35 U.S.C. § 318(b). If the Director cancels Sanofi's claims while certiorari is pending, it is because Sanofi neglected to tell the Director it is seeking certiorari. Any irreparable harm will arise from Sanofi's failure to pursue the normal administrative remedy.

Sanofi urges that it needs its invalid patents to exclude competitors other than Mylan from the market. App. 23-24. Sanofi suggests Mylan itself would not be harmed because it can launch a competing product once a 30-month stay expires on March 18, 2020.[4] Significantly, absent a covenant not to sue Mylan over these patents, Sanofi's assurances ring hollow. Moreover, Sanofi asks the Court to hold

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[3] Sanofi mentions damages once in the abstract. App. 23. Sanofi never discusses *Teva* even though it was briefed below.

[4] Mylan will also need FDA approval, but presently expects approval in less than 90 days.

this case until *Arthrex* is resolved, but the Federal Circuit is still weighing whether to grant rehearing, meaning Sanofi effectively seeks a stay until well into 2021. Any stay beyond March 18, 2020 necessarily harms Mylan. Any stay that prevents market entry by any Sanofi competitor directly harms a public very much in need of more affordable long-lasting insulin.

## IV. The Equities Overwhelmingly Favor the Public and the Respondent

Insulin glargine was a great invention. The modest reformulation of a prior-art insulin at issue here was not, as ***both*** the PTAB and the Federal Circuit held after careful consideration. Despite the finding that Sanofi's patents are unpatentable and never should have issued, Sanofi has already reaped the benefit of market exclusivity at the expense of its competitors and to the detriment of more affordable insulin options to patients throughout America.

We live in a country where diabetic patients must travel to foreign countries or dangerously ration their insulin supply at risk to their lives because they cannot afford the insulins currently prescribed.[5] If Sanofi had valid patents covering insulin glargine, these facts might pose a difficult policy question. But Sanofi's patents are not valid, and an already-resolved question about appointments does

[5] E.g., U.S. News & World Report, *Insulin Costs Are Skyrocketing. This Is Why.* (June 29, 2018) (Appx7527 in the joint appendix at the Federal Circuit) ("'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."), also available at https://health.usnews.com/health-care/for-better/articles/2018-06-29/whats-behind-the-rising-costs-of-insulin.

not revive them. The relief Sanofi seeks is extraordinary, not just because this Court rarely grants such stays, but in this case also because Sanofi must know that the greatest burden will fall on suffering patients.

## CONCLUSION

Because Sanofi has little chance of the Court granting a writ of certiorari, much less reversal, on the question of whether it is entitled to an exception to the waiver rule on its unique circumstances, because damages and the PTAB's hold on certifying cancellation provide Sanofi with a complete remedy, and because American diabetic patients have already waited too long for access to affordable, long-lasting insulin, Mylan respectfully urges denial of Sanofi's stay application.

Respectfully submitted,

Date: February 13, 2020

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