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 U.S. Court of Appeals for the Federal Circuit*

## REPLY IN SUPPORT OF APPLICATION TO STAY OR RECALL THE FEDERAL CIRCUIT'S MANDATE PENDING THE FILING AND DISPOSITION OF A WRIT OF CERTIORARI


Robert T. Vlasis
WEIL, GOTSHAL & MANGES LLP
2001 M Street N.W., Suite 600
Washington, D.C. 20036
(202) 682-7000

Adam B. Banks
*Counsel of Record*
Elizabeth S. Weiswasser
Anish R. Desai
Sarah M. Sternlieb
Andrew Gesior
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

*Counsel for Appellant Sanofi-Aventis Deutschland GmbH*


February 14, 2020

## CORPORATE DISCLOSURE STATEMENT

Per Supreme Court Rule 29.6, Applicant Sanofi-Aventis Deutschland GmbH's parent corporation is Hoechst GmbH, which in turn is owned by Sanofi Foreign Participations B.V. Sanofi holds a 10% or greater ownership interest in Sanofi Foreign Participations B.V.

Mylan's response to Sanofi's application to stay the Federal Circuit's mandate does little more than confuse the issues and misrepresent the law, including the Federal Circuit's decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019), which undergirds this application and Sanofi's forthcoming petition. As Sanofi demonstrated in its application, a stay would ensure Sanofi's patent rights are not compromised by the *ultra vires* decisions of Administrative Patent Judges, while this Court decides whether to consider the fundamentally important issues Sanofi's petition will present. Those issues include whether the significant change of law announced in *Arthrex* should apply to all pending cases, regardless of waiver, as this Court's precedents have held. This is not merely about the Federal Circuit's misapplication of law in this case; this is a significant issue that affects other parties who are denied the benefit of the *Arthrex* decision, and also more broadly implicates rule-of-law interests that generally ensure that parties' claims are adjudicated according to the law that exists at the time their cases are decided.

For the reasons set forth in Sanofi's application and further discussed in this reply, a stay should be granted.

1. Mylan misapprehends what the Federal Circuit held in *Arthrex*, and therefore the important reasons why, consistent with the long-standing decisions of this Court, the change in law *Arthrex* announced should apply to *all* cases still pending on appeal when the law changed. *Arthrex* held that Administrative Patent Judges (APJs) were unconstitutionally appointed principal officers and, accordingly, all final written decisions (FWDs) they issued while exercising such *ultra vires* authority were invalid. The Federal Circuit held that the proper remedy was to sever removal provisions of the statute (rendering APJs inferior officers), remand the FWDs, and require that "a new panel of APJs must be designated and a new hearing granted." 941 F.3d 1320, 1340 (Fed. Cir. 2019).

Mylan misconstrues this holding in several ways pertinent to this application and Sanofi's anticipated petition for certiorari. First, *Arthrex* did not hold that "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." Resp. at 8. *Arthrex* held exactly the opposite. It held that the APJs were unconstitutionally appointed *at the time they issued their*

*decisions* and thus a remand, *to a different panel of judges*, was necessary to correct the constitutional error. 941 F.3d at 1340. This remedy acknowledged the gravity of the constitutional violation—it could *not* be cured by simply retroactively deeming prior PTAB decisions to be correct or prior APJ appointments proper. And this ruling equally marked a significant change of law that, under this Court's established law, should apply to all cases pending review at the time the change of law was announced. Tellingly, Mylan's opposition nowhere discusses this line of authority or attempts to reconcile the Federal Circuit's holding with it. *See Thorpe v. Hous. Auth. of Durham*, 393 U.S. 268, 281 (1969); *Harper v. Va. Dep't of Taxation*, 509 U.S. 86, 97 (1993); *Griffith v. Kentucky*, 479 U.S. 314, 323 (1987).

Nor did *Arthrex* hold that the purpose of such a remedy was to "reward[] Arthrex with a remand for raising the issue," as Mylan contends. Resp. at 5, 8. Remedies to cure constitutional errors are not doled out as "rewards" to the first parties to notice their existence, and constitutional principles do not apply only to some similarly-situated litigants who "merit" their protections (Resp. at 8) and not others. The fundamental and unequivocal conclusion of the Federal Circuit here was

that the PTAB judges who issued the FWDs were not constitutionally appointed. 941 F.3d at 1335. The question for this Court is whether that ruling should apply to all cases pending when *Arthrex* was announced, or only some. Indeed, the underlying theme of this Court's waiver doctrine, as well as *stare decisis* and the rule of law, is that "litigants in similar situations should be treated the same." *James B. Beam Distilling Co. v. Georgia*, 501 U.S. 529, 537 (1991). To do as Mylan suggests and "reward" only some parties with the protections afforded by a change in the law undermines *stare decisis* and the rule of law itself.

2. Moreover, for the same reason, Sanofi's forthcoming petition is not "fact-bound," as Mylan claims, Resp. at 3. Again, exactly the opposite is true: the petition presents a pure question of law concerning whether the *Arthrex* decision and the principles it announces apply to all pending cases, *regardless* of the facts of an individual case. This question thus applies to numerous litigants whose patent claims were adjudicated by APJs acting *ultra vires* and carries broader implications for how courts should apply significant changes of law to pending cases.

Equally misplaced is Mylan's contention that the Federal Circuit in fact applied *Arthrex* here. It did not. Rather than apply *Arthrex* and the

Federal Circuit's changed Appointments Clause jurisprudence, the court clearly held that Sanofi forfeited its constitutional challenge. A024 n.4. Indeed, this is a key holding Sanofi challenges in its application and forthcoming petition. Likewise, Mylan's suggestion that *Arthrex* itself precluded relief when an Appointments Clause challenge was not raised in an opening brief is also wrong. *Arthrex* instead held that it applied to "cases where [FWDs] were issued and where litigants present an Appointments Clause challenge on appeal." 941 F.3d at 1340. *Sanofi did present an Appointments Clause challenge while its appeal was pending.*[1]

3. Mylan is further wrong that the significant change in law wrought by *Arthrex* was predictable or otherwise flowed inexorably from *Lucia v. S.E.C.*, 138 S. Ct. 2044 (2018). The central holding of *Arthrex* was that APJs were principal officers, and not inferior officers, and thus subject to certain Appointments Clause restrictions. But *Lucia* did not consider the distinction between principal and inferior officers; it

[1] After *Arthrex*, the Federal Circuit, without the benefit of argument or briefing on the waiver issue, held that Appointments Clause challenges were waived if not briefed in the opening brief. *Customedia Techs., LLC v. Dish Network Corp.*, 941 F.3d 1173, 1174 (Mem.) (Fed. Cir. Nov. 1, 2019).

considered instead whether SEC ALJs were inferior officers or *employees*. 138 S. Ct. at 2053. So, too in *Freytag v. C.I.R.*, 501 U.S. 868 (1991). Indeed, as Judge Hughes' and Judge Wallace's concurrence in *Polaris Innovations Ltd. v. Kingston Technology Co.* makes clear, this Court's precedent has never found that a supposed inferior officer was in fact an unconstitutionally appointed principal officer, unlike the Federal Circuit in *Arthrex*. -- F.3d --, 2020 WL 505974, at *5 (Fed. Cir. Jan. 31, 2020). Moreover, even after *Lucia*, the Federal Circuit and this Court had both summarily *dismissed* these exact Appointments Clause challenges in recent years. *See* Stay Application at 16–17 (citing *Trading Techs. Int'l, Inc. v. IBG LLC*, 771 F. App'x 493 (Fed. Cir. 2019); *Bedgear, LLC v. Fredman Bros. Furniture Co.*, 779 F. App'x 748 (Fed. Cir. 2019); and *Smartflash LLC v. Samsung Elecs. Am., Inc.*, 139 S. Ct. 276 (2018)). What's more, before *Arthrex*, the Federal Circuit had held that APJs were "subordinate officers"—not "principal officers"—in *upholding* the Director's delegation of authority to institute IPR review to APJs. *Ethicon Endo Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1031 (Fed. Cir. 2016), *cert denied*, 137 S. Ct. 625 (2017). In short, even after *Lucia*, claims that the APJs were unconstitutionally appointed faced strong headwinds

in the Federal Circuit's own law and were not seriously considered by prior Federal Circuit panels or this Court.

To the extent Mylan suggests that Sanofi slept on its rights after *Arthrex* issued, they are decidedly wrong. *Arthrex* was issued on October 31, 2019. 941 F.3d at 1320. Sanofi filed its Rule 28(j) letter five days later, on November 5, 2019. ECF 52. As Judge Newman recognized in her dissent in this case, Sanofi "promptly . . . moved to brief the application of this ruling to the PTAB decisions here on appeal." A030.

4. Mylan's attempt to disprove irreparable harm exposes its fundamental failure to understand the issues at hand. Sanofi does not seek an "indefinite" stay, Resp. at 5; Sanofi merely asks that the Court stay the Federal Circuit's mandate until it decides its cert petition. A stay of the mandate will not prevent access to long-lasting insulin. Indeed, there has been a follow on biologic product available since Eli Lilly entered the market in December 2016. When the 30-month stay of FDA approval expires on March 18, 2020, Mylan, presuming it obtains FDA approval, would be able to come to market with its own follow on biologic. Mylan has issued public statements declaring that it intends to do just that: launch its biologic in mid-2020. *Biocon-Mylan's Plans For*

*Broader US Fulphila Access, Glargine on Track*, Anju Ghangurde, Scrip, Infora Pharma Intelligence (Jan. 27, 2020), https://tinyurl.com/refhy7t.

5. Finally, Mylan's response that Sanofi's patents "have rightly been held unpatentable" and thus are unworthy of protection by the patent system, Resp. at 6, ignores the fundamentally important question this application presents: whether the rule in *Arthrex* should apply to *all* cases currently pending. Under *Arthrex*, there is no question that Sanofi's patents have *not* been "rightly" held unpatentable because they were adjudicated by APJs the Federal Circuit has held were acting *ultra vires*. Only upon a remand to a new panel of APJs will Sanofi's patents be able to be determined as properly valid or invalid.

## CONCLUSION

For the foregoing reasons, Sanofi respectfully requests that the Court stay the issuance of the Federal Circuit's mandate pending the disposition of Sanofi's petition for a writ of certiorari.

Dated: February 14, 2020

Respectfully submitted,

*/s/ Adam B. Banks*
Adam B. Banks
*Counsel of Record*
Elizabeth S. Weiswasser
Anish R. Desai
Sarah M. Sternlieb

Andrew Gesior
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
(212) 310-8000

Robert T. Vlasis
WEIL, GOTSHAL & MANGES LLP
2001 M Street N.W., Suite 600
Washington, D.C. 20036
(202) 682-7000

*Counsel for Appellant Sanofi-Aventis Deutschland GmbH*

## CERTIFICATE OF SERVICE

I, Adam B. Banks, hereby certify that on February 14, 2020, I caused a true and correct copy of the **APPLICATION FOR STAY OF PROCEEDINGS PENDING THE FILING AND DISPOSITION OF A WRIT OF CERTIORARI** to be served on Respondent's counsel via FedEx listed below.

Adam Burrowbridge
Lora M. Green
Richard Torczon
WILSON SONSINI GOODRICH & ROSATI
1700 K Street NW, 5th Floor
Washington, D.C. 20006
aburrowbridge@wsgr.com
lgreen@wsgr.com
rtorczon@wsgr.com

Douglas H. Carsten
Elham F. Steiner
Jeffrey W. Guise
Alina Litoshyk
WILSON SONSINI GOODRICH & ROSATI
12235 El Camino Real
San Diego, CA 92130
dcarsten@wsgr.com
esteiner@wsgr.com
jguise@wsgr.com
alitoshyk@wsgr.com

Lorelei Westin
WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304
lwestin@wsgr.com

Nicole W. Stafford
WILSON SONSINI GOODRICH & ROSATI
900 South Capital of Texas Highway
Las Cimas IV, Fifth Floor
Austin, TX 78746
nstafford@wsgr.com

February 14, 2020

Respectfully submitted,

*/s/ Adam B. Banks*

Adam B. Banks
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, NY 10153
adam.banks@weil.com
(212) 310-8000

*Counsel for Applicant*