No. 20-1285

In the Supreme Court of the United States

IMMUNEX CORPORATION, PETITIONER

v.

SANOFI-AVENTIS U.S. LLC, ET AL.

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

BRIEF FOR THE FEDERAL RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether petitioner forfeited its Appointments Clause challenge by failing to raise that challenge until its reply brief in the court of appeals.

ADDITIONAL RELATED PROCEEDINGS

United States Court of Appeals (Fed. Cir.):

Immunex Corp. v. *Sanofi-Aventis U.S. LLC*, No. 19-1749 (Oct. 13, 2020)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-24a) is reported at 977 F.3d 1212. The final written decisions of the Patent Trial and Appeal Board (Pet. App. 25a-58a, 59a-93a) are not published in the United States Patents Quarterly but are available at 2019 WL 643024 and 2019 WL 643041.

JURISDICTION

The judgment of the court of appeals was entered on October 13, 2020. On March 19, 2020, the Court extended the time within which to file any petition for a writ of certiorari due on or after that date to 150 days from the date of the lower-court judgment or order denying a timely petition for rehearing. The petition for a writ of certiorari was filed on March 11, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Patent Act of 1952 (Patent Act), 35 U.S.C. 1 *et seq.*, establishes the United States Patent and Trademark Office (USPTO) as an executive agency within the United States Department of Commerce "responsible for the granting and issuing of patents and the registration of trademarks." 35 U.S.C. 2(a)(1); see 35 U.S.C. 1(a). The Patent Trial and Appeal Board (Board) is an administrative tribunal within the USPTO consisting of the Director, the Deputy Director, the Commissioners for Patents and Trademarks, and "administrative patent judges." 35 U.S.C. 6(a). The Board conducts several kinds of patent-related administrative adjudications, including appeals from adverse decisions of patent examiners; derivation proceedings; and inter partes and post-grant reviews. See 35 U.S.C. 6.

Administrative patent judges, of whom there are currently more than 250, are "persons of competent legal knowledge and scientific ability who are appointed by the Secretary [of Commerce], in consultation with the Director." 35 U.S.C. 6(a). Like other "[o]fficers and employees" of the USPTO, most administrative patent judges are "subject to the provisions of title 5, relating to Federal employees." 35 U.S.C. 3(c). Under those provisions, members of the civil service may be removed "only for such cause as will promote the efficiency of the service." 5 U.S.C. 7513(a). Because the Secretary appoints the judges, that removal authority belongs to the Secretary. See *Free Enterprise Fund* v. *Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 509 (2010).[*]

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[*] A small subset of administrative patent judges serve as members of the Senior Executive Service, see 83 Fed. Reg. 29,312, 29,324 (June 22, 2018), and therefore are subject to removal "for misconduct, neglect of duty, malfeasance, or failure to accept a directed

This case arises out of inter partes review proceedings conducted by the Board. Inter partes review allows third parties to "ask the [USPTO] to reexamine the claims in an already-issued patent and to cancel any claim that the agency finds to be unpatentable." *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2136 (2016). When an inter partes review is instituted, the Board determines the patentability of the claims at issue through a proceeding that has "many of the usual trappings of litigation." *SAS Inst. Inc.* v. *Iancu*, 138 S. Ct. 1348, 1354 (2018); see 35 U.S.C. 316; 37 C.F.R. Pt. 42, Subpt. A. At the conclusion of the proceedings, the Board issues a final written decision addressing the patentability of the challenged claims, 35 U.S.C. 318(a), which is subject to rehearing by the Board, 35 U.S.C. 6(c). The Board's final written decisions may be appealed to the Federal Circuit. 35 U.S.C. 319; see 35 U.S.C. 141(c), 144.

2. a. In *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 941 F.3d 1320 (2019), cert. granted, 141 S. Ct. 549, and 141 S. Ct. 551 (2020), the Federal Circuit held that, for purposes of the Appointments Clause, U.S. Const. Art. II, § 2, Cl. 2, administrative patent judges are principal officers who must be appointed by the President with the advice and consent of the Senate. *Arthrex*, 941 F.3d at 1327-1335. The court therefore held that the statutorily prescribed method of appointing administrative patent judges—by the Secretary of Commerce acting alone—violates the Appointments Clause. *Ibid.*; see 35 U.S.C. 6(a).

To cure the putative constitutional defect that it identified, the *Arthrex* court held that the restrictions on removal imposed by Section 7513(a) cannot validly

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reassignment or to accompany a position in a transfer of function," 5 U.S.C. 7543(a); see 5 C.F.R. Pt. 359.

be applied to administrative patent judges, and that the application of those restrictions should be severed so that the judges are removable at will. 941 F.3d at 1335-1338. "Because the Board's decision in [*Arthrex*] was made by a panel of [administrative patent judges] that were not constitutionally appointed at the time the decision was rendered," the court vacated the Board's decision, remanded for "a new hearing" before the Board, and directed "that a new panel of [administrative patent judges] must be designated to hear the [proceeding] anew on remand." *Id.* at 1338, 1340; see *id.* at 1338-1340.

The patent owner in *Arthrex* raised its Appointments Clause challenge for the first time in its opening brief in the court of appeals. The court recognized that, as a general rule, "a federal appellate court does not consider an issue not passed upon below." *Arthrex*, 941 F.3d at 1326 (citation omitted). The court concluded, however, that despite "Arthrex's failure to raise its Appointments Clause challenge before the Board," resolving the constitutional issue in that case was "an appropriate use of [the court's] discretion." *Id.* at 1326-1327. The court explained that the issue implicated "important structural interests and [the] separation of powers," and it concluded that "[t]imely resolution [wa]s critical to providing certainty to rights holders and competitors alike." *Ibid.*

b. On October 13, 2020, this Court granted the government's petition for a writ of certiorari seeking review of the Federal Circuit's *Arthrex* decision, as well as two additional petitions filed by the private parties in *Arthrex*. See *United States* v. *Arthrex, Inc.*, No. 19-1434 (argued Mar. 1, 2021); *Smith & Nephew, Inc.* v. *Arthrex, Inc.*, No. 19-1452 (argued Mar. 1, 2021); *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, No. 19-1458 (argued Mar. 1, 2021).

The Court granted certiorari to consider (1) whether administrative patent judges are principal or inferior officers for purposes of the Appointments Clause; and (2) whether, if administrative patent judges are principal officers, the Federal Circuit properly cured any Appointments Clause defect by severing the application of Section 7513(a) to those judges. *United States* v. *Arthrex, Inc.*, 141 S. Ct. 549 (2020). Although the government asked the Court also to consider the Federal Circuit's forfeiture holding in *Arthrex*, the Court did not grant certiorari on that question. See *ibid.*

c. Since resolving *Arthrex*, the Federal Circuit has vacated Board decisions and remanded for new hearings in dozens of other appeals in which final written decisions were issued by the Board and where the litigant presented an Appointments Clause challenge for the first time on appeal. See, *e.g.*, Pet. App. 1a-23a; Pet. App. at 70a-84a, *Iancu* v. *Luoma*, No. 20-74 (filed July 23, 2020).

The Federal Circuit has not, however, invariably excused a litigant's failure to raise an Appointments Clause challenge before the Board. As relevant here, the Federal Circuit has repeatedly refused to apply its Appointments Clause holding in *Arthrex* in cases where the litigant did not raise the Appointments Clause challenge "in its opening briefs or * * * in a motion filed prior to its opening briefs." *Customedia Techs., LLC* v. *Dish Network Corp.*, 941 F.3d 1173, 1174 (2019) (per curiam); see also, *e.g.*, *Huawei Techs. Co.* v. *Iancu*, 813 Fed. Appx. 588, 593 & n.1 (2020) (discussing Federal Circuit "precedent deeming [Appointments Clause] challenge[s] forfeited" when not raised prior to the filing of an "opening brief or in that brief"); *Vivint* v.

Alarm.com Inc., No. 19-2438, 2021 WL 1383259, at *3 (Fed. Cir. Apr. 13, 2021) (similar).

3. a. Petitioner Immunex Corporation owns U.S. Patent No. 8,679,487 (the '487 patent). Private respondents Sanofi-Aventis U.S. LLC, Genzyme Corporation, and Regeneron Pharmaceuticals, Inc. (collectively, Sanofi) filed petitions for inter partes review challenging claims of the '487 patent. See Pet. App. 6a. The Board granted two of Sanofi's petitions and instituted review. *Ibid.* At the conclusion of the administrative proceedings, the Board issued one final written decision, finding that claims 1-17 of the '487 patent were unpatentable as obvious, *id.* at 59a-93a, and a second final written decision, concluding that Sanofi had not shown by a preponderance of the evidence that a subset of those claims were unpatentable because they were anticipated by one of petitioner's own publications, *id.* at 25a-58a.

b. Petitioner appealed to the Federal Circuit the Board's final written decision finding claims 1-17 unpatentable. Pet. App. 6a-7a. Sanofi appealed to the Federal Circuit the Board's other final written decision, and the cases were consolidated as an appeal and a cross-appeal. *Id.* at 7a.

In its opening brief, petitioner challenged the Board's determination that claims 1-17 were unpatentable as obvious. See Pet. C.A. Br. 28-30. In its Response and Reply brief, petitioner argued for the first time that the Board's administrative patent judges were unconstitutionally appointed. See Pet. C.A. Response & Reply Br. 33-34. Petitioner requested that the court of appeals vacate and remand to the Board only with respect to the first of the Board's final written decisions, *i.e.*, the decision that was adverse to petitioner. *Id.* at 36.

4. The Federal Circuit affirmed the Board's final written decision finding claims 1-17 unpatentable as obvious. Pet. App. 1a-24a. In light of that holding, the court of appeals found it unnecessary to reach Sanofi's cross-appeal of the Board's other final written decision, which had addressed a subset of those same claims. *Id.* at 23a. At the conclusion of its opinion, the court of appeals noted that, "in its reply brief, [petitioner] raised an Appointments Clause challenge to the Board's authority." *Id.* at 24a n.10. The court of appeals explained that, under its own binding precedent, "failure to raise this challenge in the opening brief constitutes forfeiture" of the issue. *Ibid.* (citing *Customedia Techs., LLC*, *supra*).

ARGUMENT

Petitioner contends (Pet. 6) that the Board's administrative patent judges have been appointed in violation of the Appointments Clause, U.S. Const. Art. II, § 2, Cl. 2. Petitioner urges (Pet. 8, 23-25) this Court to hold the petition pending the Court's disposition of *United States* v. *Arthrex, Inc.*, No. 19-1434 (argued Mar. 1, 2021), in which the Court is considering that question. But petitioner forfeited its Appointments Clause challenge by failing to raise that challenge in its opening brief before the court of appeals. As a result, regardless of this Court's resolution of the Appointments Clause and severability questions presented in *Arthrex*, that decision will provide no basis for disturbing the court of appeals' judgment in this case. See, *e.g.*, *Customedia Techs., LLC* v. *Dish Network Corp.*, 941 F.3d 1173, 1174 (Fed. Cir. 2019) (per curiam) (concluding that, under "'well established'" Federal Circuit precedent, a litigant "forfeited its Appointments Clause challenges" by failing to raise them "in its opening brief" on appeal) (citation

omitted); see also Pet. App. 24a n.10 (citing *Customedia*, 941 F.3d at 1174).

Contrary to petitioner's assertion, a holding by this Court in *Arthrex* that the statutory scheme governing inter partes review is invalid would not "vitiate[]" the court of appeals' forfeiture holding in this case. Pet. 12 (capitalization and emphasis omitted). Appointments Clause challenges can be forfeited, and courts should overlook such forfeitures only in "rare cases" as a matter of "discretion." *Freytag* v. *Commissioner*, 501 U.S. 868, 879 (1991). Petitioner laments (*e.g.*, Pet. 14) the timing of the Federal Circuit's *Arthrex* decision in comparison to its opening brief on appeal. But petitioner could have raised its constitutional arguments before *Arthrex* was decided, as other parties—including Arthrex itself—did. See, *e.g.*, *Polaris Innovations Ltd.* v. *Kingston Tech. Co.*, 792 Fed. Appx. 820, 820 (Fed. Cir. 2020) (per curiam), petition for cert. pending, No. 19-1434 (filed June 29, 2020), and petition for cert. pending, No. 19-1459 (filed July 6, 2020). Even if this Court in *Arthrex* ultimately finds a constitutional violation but rejects the Federal Circuit's remedy for preserved *Arthrex* challenges, Pet. 22, that decision will not call into question the Federal Circuit's application of its usual rule "that arguments not raised in the opening brief" are forfeited. *Customedia*, 941 F.3d at 1174 (citing *SmithKline Beecham Corp.* v. *Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006)).

This Court has repeatedly denied petitions for writs of certiorari asserting similar Appointments Clause challenges where the petitioner had first raised the issue after filing its opening brief in the Federal Circuit. See, *e.g.*, *ThermoLife Int'l LLC* v. *Iancu*, 141 S. Ct. 1049 (2021) (No. 20-150) (Appointments Clause challenge

raised for the first time in a petition for a writ of certiorari); *IYM Techs. LLC* v. *RPX Corp.*, 141 S. Ct. 850 (2020) (No. 20-424) (Appointments Clause challenge initially raised in a petition for rehearing in the Federal Circuit); *Customedia Techs., LLC* v. *Dish Network Corp.*, 141 S. Ct. 555 (2020) (No. 20-135) (Appointments Clause challenge initially raised after the petitioner had filed its opening brief in the Federal Circuit); *Arthrex, Inc.* v. *Smith & Nephew, Inc.*, 141 S. Ct. 236 (2020) (No. 19-1204) (Appointments Clause challenge initially raised after a petition for rehearing was filed in the Federal Circuit). The same result is warranted here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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MAY 2021