

**Appeal No. 2019-2011**

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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**CONCERT PHARMACEUTICALS, INC.,**

*Appellant*

v.

**INCYTE CORPORATION,**

*Appellee*

**KATHERINE K. VIDAL, Under Secretary of Commerce for Intellectual Property  
and Director of the United States Patent and Trademark Office,**

*Intervenor*

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Appeal from the United States Patent and Trademark Office,  
Patent Trial and Appeal Board in No. IPR2017-01256

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**BRIEF FOR INTERVENOR**

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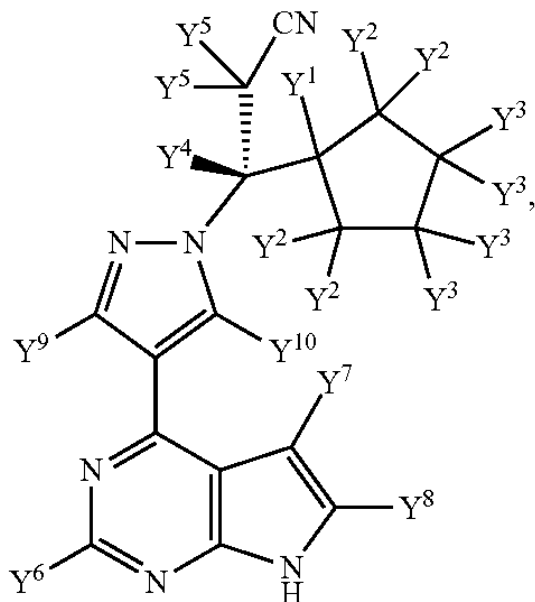
August 1, 2022

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### Claim 1

1. A compound of Formula A:

Formula A



or a pharmaceutically acceptable salt thereof, wherein:

Y1 is a hydrogen;

each Y2 is selected from hydrogen and deuterium, and each Y2 is the same;

each Y3 is selected from hydrogen and deuterium, and each Y3 is the same;

Y4 is selected from hydrogen and deuterium;

each Y5 is the same and is selected from hydrogen and deuterium; and

Y6, Y7, Y8, Y9, and Y10 are each independently selected from hydrogen and deuterium; provided that:

each Y2 is deuterium; or

each Y3 is deuterium; or

each Y2 and each Y3 is deuterium.

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### **Statement of Related Cases**

The Director is not aware of any other appeal from the Patent Trial and Appeal Board (“Board”) of the United States Patent and Trademark Office in connection with U.S. Patent No. 9,249,149 that has previously been before this Court. The Director is not aware of any other case pending in this or any other court that will directly affect, or directly be affected by, the Court’s decision in this appeal.

## Introduction

Appellant Concert Pharmaceuticals, Inc. is a patent owner seeking review of a decision of the Patent Trial and Appeal Board finding claims 1-15 of Concert's U.S. Patent No. 9,249,149 unpatentable as obvious and denying Concert's contingent motion to amend. Appx2-4. Most of Concert's brief is devoted to challenging the merits of the Board's obviousness determinations. Br. at 36-65.

Concert also preserves a constitutional challenge to the authority of Commissioner Hirshfeld, who had been duly delegated the duties and functions of the Director during the former vacancy in that office. Br. at 65-66. The Director has intervened to address this constitutional challenge. Concert argues that, despite the Supreme Court's guidance to the USPTO in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021) (*Arthrex I*), "parties in IPRs are entitled to review by an 'officer properly appointed to a principal office'" (Br. at 65) and, because Commissioner Hirshfeld was neither a properly appointed principal officer nor an "Acting Director" under the Federal Vacancies Reform Act (FVRA), that "he could not issue a final decision under *Arthrex*" without violating the Appointments Clause and the FVRA. Br. at 66.

Concert concedes, however, that "[t]his argument is now foreclosed by Circuit precedent, *see Arthrex, Inc. v. Smith & Nephew, Inc.*, 35 F.4th 1328, 1332-1340 (Fed. Cir. 2022) (*Arthrex II*), but Concert preserves it for purposes of further review." Br. at 66.

Concert is correct that its constitutional and statutory challenges are foreclosed by this Court's decision in *Arthrex II*. This Court should therefore reject Concert's

Appointments Clause and FVRA challenges here.

## **I. STATEMENT OF THE ISSUE**

Whether this Court's decision in *Arthrex II* forecloses Concert's claims that Commissioner Hirshfeld's order denying Concert's request for Director review violates the Appointments Clause or the FVRA.

## **II. STATEMENT OF THE CASE**

Concert was the respondent in an IPR proceeding that culminated in a Board decision finding that the challenged claims of Concert's patent were unpatentable and denying Concert's contingent motion to amend. Appx1-53. Concert appealed to this Court. Before Concert filed its opening brief, this Court granted Concert's motion for remand to the USPTO per this Court's decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019). Dkt. No. 39 at 2. After the Supreme Court granted a petition for a writ of certiorari (Dkt. No. 49) and following the Supreme Court's decision in *Arthrex*, this Court recalled its mandate (Dkt. 51) and issued a limited remanded to the USPTO to allow Concert to request Director review of the Board's decision. Dkt. No. 56 at 2. Commissioner Andrew Hirshfeld issued an order denying Concert's Director review request. Appx54-55. Concert notified this Court of that order. Dkt. No. 57. On March 16, 2022, this Court set a deadline for Concert's opening brief. Dkt. No. 60.

On May 27, 2022, this Court decided *Arthrex II*, holding that Andrew Hirshfeld performing the functions and duties of the Director did not violate the Appointments

Clause or the FVRA. On June 27, 2022, Concert filed its opening brief (Dkt. No. 64 (“Br.”)), arguing that Board’s decision was wrong (Br. at 36-65) and that Commissioner Hirshfeld’s order denying Concert’s request for Director review violated the Appointments Clause and the FVRA. Br. at 65-66. Concert acknowledges that its Director review challenge is foreclosed by this Court’s *Arthrex II* decision, but “preserves it for purposes of further review.” Br. at 66.

### **III. SUMMARY OF THE ARGUMENT**

Concert recognizes that this Court has already rejected its Appointments Clause and FVRA challenges to Andrew Hirshfeld’s authority in *Arthrex II* and the outcome should be the same here. *See Arthrex*, 35 F.4th 1328 (Fed. Cir. May 27, 2022).

### **IV. ARGUMENT**

#### **A. Standard of review**

This Court reviews de novo the constitutional and statutory interpretations questions addressed in this brief. *MCM Portfolio LLC v. Hewlett-Packard Co.*, 812 F.3d 1284, 1287 (Fed. Cir. 2015).

#### **B. This Court’s *Arthrex* decision denied the same constitutional challenge that Concert raises here**

In *Arthrex II*, this Court held that Commissioner Hirshfeld did not “violate[] the Appointments Clause, the FVRA, or the Constitution’s separation of powers in denying [a] rehearing request.” *Arthrex II*, 35 F.4th at 1345. In challenging the constitutionality of the IPR process under Andrew Hirshfeld’s authority, Concert



raises the same Appointments Clause and FVRA arguments that *Arthrex* did, which are foreclosed by *Arthrex II*.

Specifically, Concert argues, as did *Arthrex*, that the Supreme Court's decision in *Arthrex* requires, under the Appointments Clause, that there be the possibility for review by a Presidentially appointed and Senate confirmed official. Br. at 65. This Court rejected that very argument in *Arthrex II*, holding that “the Commissioner’s exercise of the Director’s authority while that office was vacant did not violate the Appointments Clause.” *Arthrex*, 35 F.4th at 1335.

Concert also argues that that the Federal Vacancies Reform Act precludes the USPTO from having the Commissioner of Patents temporarily perform the functions and duties of the Director. Br. at 65-66. That argument was also made by *Arthrex* and rejected by this Court. As this Court explained, “the FVRA applies only to non-delegable duties,” and, since “deciding rehearing requests is a delegable duty,” “the FVRA does not apply here.” *Arthrex II*, 35 F.4th at 1335.

The USPTO takes no position on the other arguments raised by Concert.

## **V. CONCLUSION**

For the foregoing reasons, this Court should reject Concert’s Appointments Clause and FVRA challenges.

August 1, 2022

Respectfully submitted,

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**RULE 32(a)(7)(C) CERTIFICATE OF COMPLIANCE**

I certify pursuant to Fed. R. App. Proc. 32(a)(7) that the foregoing brief complies with the type-volume limitation required by the Court's rule. The total number of words in the foregoing brief, excluding the table of contents and the table of authorities, is 1,066 words as calculated using the Word<sup>®</sup> software program.

/s/ Robert E. McBride  
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