

Nos. 19-1434, -1452, and -1458

IN THE
Supreme Court of the United States

UNITED STATES OF AMERICA, *Petitioner*,

v.

ARTHREX, INC., ET AL.

SMITH & NEPHEW, INC. AND
ARTHROCare CORP., *Petitioners*,

v.

ARTHREX, INC. AND THE
UNITED STATES OF AMERICA.

ARTHREX, INC., *Petitioner*,

v.

SMITH & NEPHEW, INC., ARTHROCare CORP.,
AND THE UNITED STATES OF AMERICA.

ON WRITS OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

**BRIEF OF THE COALITION AGAINST PATENT
ABUSE AS *AMICUS CURIAE* IN SUPPORT OF NO
PARTY**

CHARLES DUAN
Counsel of Record
1801 Columbia Road, Suite 101
Washington DC 20009
(202) 713-5799
supremecourt.gov@cduan.com
Counsel for amicus curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES	ii
INTEREST OF <i>AMICUS CURIAE</i>	1
SUMMARY OF ARGUMENT	1
ARGUMENT	4
I. The Patent Trial and Appeal Board Has Proven Its Merit in Reviewing Patents That Wrongfully Raise Drug Prices and Harm American Consumers	4
A. Alzheimer’s Disease	9
B. Opioid Addiction	11
C. Insulin	13
D. Prostate Cancer	16
E. Ulcerative Colitis	17
F. Heart Disease	19
G. Anemia	20
II. The Appointments Clause Should Not Undermine the Impartiality and Objectivity of the Board	21
A. The Board Is and Ought to Be Structured to Minimize Political Actors’ Influence over Patent Decisions	22
B. What the Federal Circuit Thought the Appointments Clause Requires, This Court’s Justices Have Vigorously Denounced	23
C. Courts, Not Political Officers, Supervise Board Decisions That Are Largely Matters of Pure Law	26
D. To Ensure the Board’s Impartiality, This Court Should Find It Constitutional or Apply a Minimally Disruptive Remedy	30
CONCLUSION	32

TABLE OF AUTHORITIES

CASES AND ADMINISTRATIVE DECISIONS

<i>Accord Healthcare Inc. v. Daiichi Sankyo Co.</i> , No. IPR2015-00864 (P.T.A.B. Sept. 12, 2016) (final written decision)	20
<i>Alappat, In re</i> , 33 F.3d 1526 (Fed. Cir. 1994) (en banc)	24
<i>Arthrex, Inc. v. Smith & Nephew, Inc.</i> , 941 F.3d 1320 (Fed. Cir. 2019)	23, 30
<i>BioDelivery Sciences International, Inc.</i> <i>v. RB Pharmaceuticals Ltd.</i> , 667 F. App'x 997 (Fed. Cir. 2016)	13
<i>BioDelivery Sciences International, Inc.</i> <i>v. RB Pharmaceuticals Ltd.</i> , No. IPR2014-00325 (P.T.A.B. June 30, 2015) (final written decision)	13
<i>BTG International Ltd.</i> <i>v. Amneal Pharmaceuticals LLC</i> , 923 F.3d 1063 (Fed. Cir. 2019)	16–17
<i>Cleveland Clinic Foundation</i> <i>v. True Health Diagnostics LLC</i> , 760 F. App'x 1013 (Fed. Cir. 2019)	27
<i>Consumer Watchdog</i> <i>v. Wisconsin Alumni Research Foundation</i> , 753 F.3d 1258 (Fed. Cir. 2014)	29
<i>Cuozzo Speed Technologies, LLC v. Lee</i> , 136 S. Ct. 2131 (2016)	28
<i>Daiichi Sankyo Co. v. Accord Healthcare Inc.</i> , 706 F. App'x 679 (Fed. Cir. 2017)	20

(iii)

<i>Dr. Falk Pharma GmbH v. GeneriCo, LLC</i> , No. 17-2312 (Fed. Cir. June 12, 2019) (nonpreceden- tial)	18
<i>Edmond v. United States</i> , 520 U.S. 651 (1997)	26, 28
<i>Free Enterprise Fund</i> <i>v. Public Co. Accounting Oversight Board</i> , 561 U.S. 477 (2010)	26
<i>Freytag v. Commissioner</i> , 501 U.S. 868 (1991)	28
<i>General Electric Co. v. United Technologies Corp.</i> , 928 F.3d 1349 (Fed. Cir. 2019)	29
<i>GeneriCo, LLC v. Dr. Falk Pharma GmbH</i> , No. IPR2016-00297 (P.T.A.B. May 19, 2017) (final written decision)	18–19
<i>Graham v. John Deere Co. of Kansas City</i> , 383 U.S. 1 (1966)	26
<i>Great Atlantic & Pacific Tea Co.</i> <i>v. Supermarket Equipment Corp.</i> , 340 U.S. 147 (1950)	26
<i>Hospira, Inc. v. Janssen Pharmaceuticals, Inc.</i> , No. IPR2013-00365 (P.T.A.B. Oct. 24, 2013)	20
<i>Indivior Inc. v. Dr. Reddy’s Laboratories, SA</i> , 930 F.3d 1325 (Fed. Cir. 2019)	13
<i>Lantus Direct Purchaser Antitrust Litigation, In re</i> , 950 F.3d 1 (1st Cir. 2020)	15
<i>Lucia v. SEC</i> , 138 S. Ct. 2044 (2018)	28
<i>Markman v. Westview Instruments, Inc.</i> , 517 U.S. 370 (1996)	27

(iv)

<i>Morrison v. Olson</i> , 487 U.S. 654 (1988)	28
<i>Mylan Pharmaceuticals Inc.</i> <i>v. Sanofi-Aventis Deutschland GmbH</i> , No. IPR2018-01678 (P.T.A.B. May 29, 2020) (final written decision)	14–15
<i>Nidec Motor Corp.</i> <i>v. Zhongshan Broad Ocean Motor Co.</i> , 868 F.3d 1013 (Fed. Cir. 2017)	24
<i>Novartis AG v. Noven Pharmaceuticals Inc.</i> , 853 F.3d 1289 (Fed. Cir. 2017)	9–11
<i>Novartis Pharmaceuticals Corp.</i> <i>v. Par Pharmaceutical, Inc.</i> , 48 F. Supp. 3d 733 (D. Del. 2015)	10–11
<i>Novartis Pharmaceuticals Corp.</i> <i>v. Watson Laboratories, Inc.</i> , 611 F. App'x 988 (Fed. Cir. 2015) (nonpreceden- tial)	10–11
<i>Oil States Energy Services, LLC</i> <i>v. Greene's Energy Group, LLC</i> , 138 S. Ct. 1365 (2018)	24–25
<i>Rivastigmine Patent Litigation, In re</i> , No. 1:05-md-1551 (S.D.N.Y. Sept. 22, 2005)	9
<i>Sanofi-Aventis Deutschland GmbH</i> <i>v. Mylan Pharmaceuticals Inc.</i> , No. 20-1871 (Fed. Cir. June 10, 2020)	14
<i>Sanofi-Aventis Deutschland GmbH</i> <i>v. Mylan Pharmaceuticals Inc.</i> , No. 2012-1368, -1369 (Fed. Cir. Nov. 19, 2019) (nonprecedential)	14

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.