IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY,
Petitioner,

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Patent Owner.

Case IPR2018-01426
Patent 9,890,211 B2

PATENT OWNER'S REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71(D) ON DENIAL OF AUTHORIZATION TO FILE A MOTION TO STAY AND SUPPLEMENTAL BRIEF ADDRESSING *ARTHREX*

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Patent Owner Teva Pharmaceuticals International GmbH ("Teva") respectfully requests rehearing under 37 C.F.R. § 42.71(d) of the Board's November 15, 2019 Decision (Ex. 2274) denying Teva authorization to file a supplemental brief addressing the effects of *Arthrex, Inc. v. Smith & Nephew, Inc.*, — F.3d —, 2019 WL 5616010 (Fed. Cir. Oct. 31, 2019) and a stay to accompany such briefing. Without providing a conference call so that Teva could explain the basis for its motion, the Board denied authorization solely based on the conclusion that "[a]ny Appointments Clause concerns have been addressed by the Federal Circuit in *Arthrex, Inc. v. Smith & Nephew, Inc*., No 2018-2140 (Fed. Cir. Oct. 31, 2019)." Ex. 2274 at 1. Respectfully, the Board's summary refusal to even allow supplemental briefing on the Appointments Clause issues on the basis that *Arthrex* "addressed" those "concerns" reflects a fundamental misunderstanding on the potential impact of *Arthrex* and is itself an APA violation. *Id.*

Arthrex held that Administrative Patent Judges have not been properly appointed and struck down their removal protections to remedy that constitutional violation. But the mandate in *Arthrex* has not issued, and Administrative Patent Judges will not be removable at-will until it does. We are also at a moment of unique uncertainty about the Board's authority to act and whether the Federal Circuit's remedy is enough. Further guidance may be forthcoming from the Government as it decides whether to seek rehearing in *Arthrex*, and from the

Federal Circuit itself as it continues to address the fallout from *Arthrex* in additional opinions and orders. In fact, the Government has already represented that it intends to move for stays in current Federal Circuit appeals pending resolution of any petition for rehearing en banc filed in *Arthrex*. There is no reason IPR proceedings implicating *Arthrex* should move forward, but Federal Circuit appeals should not.

The parties and the Board would all benefit from that additional guidance. A stay until the *Arthrex* mandate issues will give everyone an opportunity to consider that guidance and avoid the considerable risk that pressing forward with an argument and decision in this IPR would repeat the constitutional violation *Arthrex* identified. That would be a tremendous waste of resources by the Board and the parties. Accordingly, Teva requests rehearing of the Board's refusal to allow Teva to file supplemental briefing and a motion to stay addressing these issues.

The Board even denied Teva a conference call to explain the need for supplemental briefing and a stay, despite the fact the Trial Practice Guide "encourages the use of conference calls to raise and resolve issues in an expedited manner." *Trial Practice Guide Update* (July 2019) at 4. The Board's summary denial of Teva's request—particularly when Teva was also denied any opportunity to be heard—is the type of decision the Federal Circuit has repeatedly found violates the APA: the Board (1) "lacked the information necessary to make a

reasoned decision," (2) made a "significant . . . decision without providing an explanation or a reasoned basis," and (3) "the Board's procedures impede meaningful appellate review of the agency decision-making." *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1273-74 (Fed. Cir. 2017); *see also Honeywell Int'l Inc. v. Arkema Inc.*, 939 F.3d 1345, 1350 (Fed. Cir. 2019).

Teva recommends that the Precedential Opinion Panel resolve this rehearing request because it raises two exceptionally important issues of agency policy:

1. The Board's response to, and implementation of, *Arthrex* in pending cases concerns "major policy [and] procedural issues" for which "it is appropriate to create . . . binding agency authority through adjudication before the Board." SOP 2 at 3.

2. Whether the Appointments Clause violation has been fixed prior to the mandate issuing in *Arthrex*, and whether decisions made in pending cases by APJs whose appointments violated the constitution must be vacated, is an important constitutional question. SOP 2 at 4.

I. STATEMENT OF FACTS

This proceeding stems from a petition filed by Eli Lilly, challenging fifteen claims of a Teva patent directed to humanized monoclonal anti-Calcitonin Gene-Related Peptide (CGRP) antagonist antibodies. The Board instituted review (Paper

14), and the oral hearing is scheduled for November 22, 2019 (Paper 57).

In *Arthrex, Inc. v. Smith & Nephew, Inc.*, — F.3d —, 2019 WL 5616010 (Fed. Cir. Oct. 31, 2019), the Federal Circuit held that the Board's Administrative Patent Judges have been functioning as principal officers and that their appointment by the Secretary of Commerce therefore violates the Appointments Clause. *Id.* at *1. Seeking to remedy that constitutional violation, the Federal Circuit severed the portion of the Patent Act that prevents the Director from removing Administrative Patent Judges at-will. *Id.* at *1, *10. Because the panel that decided *Arthrex* consisted of APJs who were not constitutionally appointed, the court held that "a new panel of APJs must be designated and a new hearing granted." *Id.* at *12. The parties in the *Arthrex* appeal have until December 16, 2019 to seek rehearing, and the Federal Circuit will not issue its mandate until after any rehearing petitions are resolved. *See* Fed. R. App. P. 41(b).

Over the past two weeks, a variety of panels of the Federal Circuit have issued approximately a half-dozen orders raising questions about the *Arthrex* remedy, when that remedy takes effect, and whether that remedy goes far enough. *See Uniloc 2017 LLC v. Facebook, Inc.*, 2019 WL 5681316 (Fed. Cir. Oct. 31, 2019); *Customedia Techs., LLC v. Dish Network Corp.*, 2019 WL 5677703 (Fed. Cir. Nov. 1, 2019); *Customedia Techs., LLC v. Dish Network Corp.*, 2019 WL 5677704 (Fed. Cir. Nov. 1, 2019); *Bedgear, LLC v. Fredman Bros. Furniture Co.*,

DOCKET ALARM

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.