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 IPR2018-01711
Patent 9,884,907 B2

**PATENT OWNER'S PETITION UNDER 37 C.F.R. § 1.181(A)(3)
INVOKING THE SUPERVISORY AUTHORITY OF THE DIRECTOR**

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Patent Owner Teva Pharmaceuticals International GmbH ("Teva") hereby invokes the supervisory authority of the Director under 37 C.F.R. § 1.181(a)(3) to stay this *inter partes* review proceeding pending issuance of the mandate in *Arthrex, Inc. v. Smith & Nephew, Inc.*, — F.3d —, 2019 WL 5616010 (Fed. Cir. Oct. 31, 2019). That decision 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*. *See, e.g.*, *Hytera Comm'cns Co. Ltd. v. Motorola Solutions, Inc.*, No. 19-2124, Dkt. No. 23 (Nov. 15, 2019). 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 that the Director exercise his supervisory authority to stay this IPR pending issuance of the mandate in *Arthrex*.

This petition is timely filed under 37 C.F.R. § 1.181(f) within two months of the mailing date of the communication notifying Teva that the Board would not give it authorization to move for a stay, or even submit supplemental briefing on this issue. Ex. 2347 (dated Nov. 15, 2019). A petition to expedite consideration of the present petition is being filed concurrently under 37 C.F.R. § 1.182. A petition for rehearing by the Precedential Opinion Panel is also being filed concurrently.

Any additional fees believed to be required for consideration of this petition are hereby authorized to be charged to Deposit Account No. 19-0036.

I. STATEMENT OF FACTS

This proceeding stems from a petition filed by Eli Lilly, challenging eighteen claims of a Teva patent directed to humanized monoclonal anti-Calcitonin Gene-Related Peptide (CGRP) antagonist antibodies. The Board instituted review (Paper 12), and the oral hearing is scheduled for January 8, 2020 (Paper 13).

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.*, 2019 WL 5806893 (Fed. Cir. Nov. 7, 2019); *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 18-1768, Dkt. No. 90 (Fed. Cir. Nov. 8, 2019). Judge Dyk, joined by Judge Newman, filed a concurrence questioning whether the *Arthrex* remedy

can take effect before the Federal Circuit's mandate issues to the Board. *See Bedgear*, 2019 WL 5806893, *4 & n.8. A different panel requested supplemental briefing late last week, asking the parties to address four related questions, including whether severing the removal provisions "sufficiently remedies the unconstitutional appointment at issue." *Polaris Innovations Ltd. v. Kingston Tech. Co.*, No. 18-1768, Dkt. No. 90, at 2 (Fed. Cir. Nov. 8, 2019). The *Polaris* panel will not answer that question until sometime in December at the earliest. *Id.*

II. POINTS TO BE REVIEWED

A brief stay until the *Arthrex* mandate issues will conserve agency resources, and will avoid taking further steps in this proceeding while an Appointments Clause violation still exists. Moving forward with this IPR now virtually guarantees the Board will have to hear and resolve this IPR twice. The *Arthrex* mandate has not issued, so the members of the Board assigned to this proceeding are improperly appointed principal officers who the Director cannot remove at will. And even if they are now inferior officers removable at-will, as a result, they lack authority to preside over this administrative adjudication. Furthermore, it is far from clear that the *Arthrex* remedy will cure the Appointments Clause problem given the authority APJs still exercise. Even if striking down the removal restrictions could cure the constitutional defect going forward, the members of this

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