

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.

IPR2018-01424 (Patent No. 9,346,881 B2)
IPR2018-01426 (Patent No. 9,890,211 B2)
IPR2018-01427 (Patent No. 8,597,649 B2)¹

Before JENNIFER MEYER CHAGNON, JAMES A. WORTH, and
RICHARD J. SMITH, *Administrative Patent Judges*.

Per Curiam

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

¹ The proceedings have not been consolidated. The parties are not authorized to use a combined caption unless an identical paper is being entered into each proceeding and the paper contains a footnote indicating the same.

IPR2018-01424 (Patent No. 9,346,881 B2); IPR2018-01426 (Patent No. 9,890,211 B2); IPR2018-01427 (Patent No. 8,597,649 B2)

I. INTRODUCTION

This is a Final Written Decision addressing three *inter partes* reviews challenging claims 1–6 and 14–19 of U.S. Patent No. 9,346,881 B2 (“the ’881 patent”) (IPR2018-01424), claims 1–15 of U.S. Patent No. 9,890,211 B2 (“the ’211 patent”) (IPR2018-01426), and claims 1–9 of U.S. Patent No. 8,597,649 B2 (“the ’649 patent”) (IPR2018-01427).² We have jurisdiction under 35 U.S.C. § 6(b). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a). Having reviewed the arguments of the parties and the supporting evidence, we find that Petitioner has demonstrated by a preponderance of the evidence that all of the challenged claims are unpatentable.

A. Procedural History

Eli Lilly and Company (“Petitioner” or “Lilly”) filed three Petitions (Paper 1,³ “Pet.”) requesting an *inter partes* review of the respective challenged claims of the ’881 patent, the ’211 patent, and the ’649 patent. Teva Pharmaceuticals International GmbH (“Patent Owner” or “Teva”) filed a Preliminary Response to each of the Petitions. Paper 8 (“Prelim. Resp.”).

² All of the respective challenged claims are referred to collectively as the “challenged claims,” and the ’881 patent, the ’211 patent, and the ’649 patent are referred to collectively as the “challenged patents.” IPR2018-01424 (“1424 IPR”), IPR2018-01426 (“1426 IPR”), and IPR2018-01427 (“1427 IPR”) are referred to herein as “the three *inter partes* reviews.”

³ Unless this Decision otherwise indicates, all citations are to the Papers and Exhibits in IPR2018-01426. Similar Papers and Exhibits were filed in each of the three *inter partes* reviews.

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We entered our three Decisions on Institution (Paper 14, “Inst. Dec.” or “Institution Decision”)⁴ instituting *inter partes* review of all challenged claims under the only ground asserted in each of the three petitions. In each of the three *inter partes* reviews, Patent Owner filed a substantially similar Response (Paper 24, “PO Resp.”), Petitioner filed a substantially similar Reply (Paper 37, “Reply”), and Patent Owner filed a substantially similar Sur-reply (Paper 49, “Sur-reply”).

In each of the three *inter partes* reviews, Patent Owner filed a substantially similar Motion to Strike (Paper 43, “Mot. Strike”) and Petitioner filed a substantially similar Opposition to the Motion to Strike (Paper 45, “Opp. Strike”). In each of the three *inter partes* reviews, Patent Owner also filed a substantially similar Motion to Exclude (Paper 56, “Mot. Excl.”), Petitioner filed a substantially similar Opposition to the Motion to Exclude (Paper 58, “Opp. Excl.”), and Patent Owner filed a substantially similar Reply to Petitioner’s Opposition to the Motion to Exclude (Paper 59).

Petitioner and Patent Owner requested an oral hearing. Papers 50, 51. A combined⁵ oral hearing was granted, and scheduled for November 22, 2019. Paper 57.

On November 21, 2019, Patent Owner filed the following documents, in each of the three *inter partes* reviews, regarding our denial of its request

⁴ IPR2018-01424 was instituted on February 19, 2019, and IPR2018-01426 and IPR2018-01427 were instituted on February 25, 2019. *See also* 1424 IPR Paper 14; 1427 IPR Paper 14.

⁵ In addition to the three *inter partes* reviews addressed in this Decision, the oral hearing included IPR2018-01422, IPR2018-01423, and IPR2018-01425. Those cases are addressed in a separate decision.

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to file a motion to stay based on the Federal Circuit decision in *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (Fed. Cir. 2019) (“Arthrex”):

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 (Paper 67);⁶

Patent Owner’s Petition to Expedite Under 37 C.F.R. § 1.182 (Paper 65); and

Patent Owner’s Petition Under 37 C.F.R. § 1.181(a)(3) Invoking the Supervisory Authority of the Director (Paper 64).

No decision was reached on Patent Owner’s filings (Papers 64, 65, 67) prior to the hearing scheduled for the following day. Accordingly, we held a combined oral hearing on November 22, 2019, and the transcript of that hearing has been entered into the record. Paper 69 (“Tr.”). Patent Owner’s request for rehearing (Paper 67) was denied on February 18, 2020.

On December 18, 2019, the U.S. Court of Appeals for the Federal Circuit issued an opinion in *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019). In *Fox Factory*, the court “address[ed] the Board’s application of the presumption of nexus” to certain claims as issue. *Id.* at 1374. Because Patent Owner argued a presumption of nexus with respect to its proffered evidence of objective indicia of nonobviousness, we authorized both of the parties to file, in each of the three *inter partes* reviews, a supplemental brief, and a brief responsive to the other party’s supplemental brief, addressing the application, if any, of *Fox Factory* to the three *inter partes* reviews. Paper 70. Petitioner filed a substantially similar supplemental brief and responsive brief (Paper 71, “Pet. Supp. Br.”)

⁶ Patent Owner also requested Precedential Opinion Panel (POP) review of the requests for rehearing. *See* Ex. 3002 (e-mail dated November 21, 2019). That request was denied on February 13, 2020. Paper 75.

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Paper 74, “Pet. Supp. Rep. Br.”), and Patent Owner filed a substantially similar supplemental brief and responsive brief (Paper 72, “PO Supp. Br.,” Paper 73, “PO Supp. Rep. Br.”) in each of the three *inter partes* reviews.

B. Real Parties-in-Interest

Petitioner identifies Eli Lilly and Company as the real party-in-interest. Pet. 64.

Patent Owner identifies Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. as the real parties-in-interest. Paper 4, 1.

C. Related Matters

Petitioner identifies a declaratory judgment action filed by Patent Owner on October 24, 2017, in the District Court for the District of Massachusetts (“the first DJ action”). Pet. 65. According to Petitioner, the first DJ action seeks a declaration that Petitioner’s investigational drug galcanezumab will infringe U.S. Patent Nos. 8,586,045; 9,266,951; 9,340,614; the ’649 patent; and the ’881 patent, and Patent Owner filed an amended complaint in the first DJ action on January 16, 2018. *Id.* Petitioner also identifies a declaratory judgment action filed by Patent Owner on February 6, 2018, seeking a declaration that Petitioner’s product will infringe U.S. Patent Nos. 9,884,907 and 9,884,908 (“the second DJ action”). *Id.* Petitioner states that Patent Owner thereafter filed an amended complaint in the second DJ action to incorporate U.S. Patent No. 9,890,210 and the ’211 patent. *Id.*

According to Petitioner, all of the patents in the first DJ action and the second DJ action purport to claim priority to the same provisional application, and two applications (15/883,218 and 15/956,580) also

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