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Paper 69
Date: March 31, 2020

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.

IPR2018-01710 (Patent 8,586,045 B2)
IPR2018-01711 (Patent 9,884,907 B2)
IPR2018-01712 (Patent 9,884,908 B2)[1]

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

Per Curiam

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

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[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.

I. INTRODUCTION

This is a Final Written Decision addressing three *inter partes* reviews challenging claims 1, 3, 4, 8–17, 19, 20, and 24–31 of U.S. Patent No. 8,586,045 B2 ("the '045 patent") (IPR2018-01710), claims 1–18 of U.S. Patent No. 9,884,907 B2 ("the '907 patent") (IPR2018-01711), and claims 1–18 of U.S. Patent No. 9,884,908 B2 ("the '908 patent") (IPR2018-01712).[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 failed to demonstrate by a preponderance of the evidence that any 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 '045 patent, the '907 patent, and the '908 patent. Teva Pharmaceuticals International GmbH ("Patent Owner" or "Teva") filed a Preliminary Response to each of the Petitions. Paper 8 ("Prelim. Resp.").

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[2] All of the respective challenged claims are referred to collectively as the "challenged claims," and the '045 patent, the '907 patent, and the '908 patent are referred to collectively as the "challenged patents." IPR2018-01710 ("1710 IPR"), IPR2018-01711 ("1711 IPR"), and IPR2018-01712 ("1712 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 IPR2018-01710. Similar Papers and Exhibits were filed in each of the three *inter partes* reviews.

We entered our three Decisions on Institution (Paper 12, "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 21, "PO Resp."), Petitioner filed a substantially similar Reply (Paper 32, "Reply"), and Patent Owner filed a substantially similar Sur-reply (Paper 43, "Sur-reply").

In each of the three *inter partes* reviews, Patent Owner filed a substantially similar Motion to Strike (Paper 38, "Mot. Strike") and Petitioner filed a substantially similar Opposition to the Motion to Strike (Paper 40, "Opp. Strike"). In each of the three *inter partes* reviews, Patent Owner also filed a substantially similar Motion to Exclude (Paper 51, "Mot. Excl."), Petitioner filed a substantially similar Opposition to the Motion to Exclude (Paper 52, "Opp. Excl."), and Patent Owner filed a substantially similar Reply to Petitioner's Opposition to the Motion to Exclude (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 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 49);[5]

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[4] The three *inter partes* reviews were instituted on April 3, 2019. *See also* 1711 IPR Paper 12; 1712 IPR Paper 11.

[5] 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 65.

Patent Owner's Petition to Expedite Under 37 C.F.R. § 1.182 (Paper 48); and

Patent Owner's Petition Under 37 C.F.R. § 1.181(a)(3) Invoking the Supervisory Authority of the Director (Paper 47).

Patent Owner's Petition invoking the supervisory authority of the Director (Paper 47) was denied on February 18, 2020. Paper 66. Patent Owner's request for rehearing (Paper 49) also was denied on February 18, 2020. Paper 67.

We held a combined[6] oral hearing on January 8, 2020, and the transcript of that hearing has been entered into the record. Paper 68 ("Tr.").

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 at issue. *Id.* at 1374. Because Patent Owner argued a presumption of nexus with respect to its proffered evidence of objective indicia of nonobviousness,[7] 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 60. Petitioner filed a substantially similar supplemental brief and responsive brief (Paper 62, Paper 63), and Patent

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[6] The hearing included the three *inter partes* reviews addressed in this Decision.

[7] Because we determine that Petitioner has failed to establish by a preponderance of the evidence that a person of ordinary skill in the art would have had a reasonable expectation of success in achieving the invention of the independent claims of the challenged patents (*see infra* Section II.D.4.b)), we need not rely on Patent Owner's evidence of objective indicia of nonobviousness for purposes of this Final Written Decision.

Owner filed a substantially similar supplemental brief and responsive brief (Paper 61, Paper 64) 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. 66.

Patent Owner identifies Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. as the real parties-in-interest. Paper 6, 2.

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. 66. According to Petitioner, the first DJ action seeks a declaration that Petitioner's investigational drug galcanezumab will infringe U.S. Patent Nos. 8,597,649; 9,266,951; 9,340,614; 9,346,881; and the '045 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 the '907 patent and '908 patent ("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 Nos. 9,890,210 and 9,890,211. *Id.*

According to Petitioner, the court dismissed Patent Owner's amended complaints in the first DJ action and the second DJ action, and Patent Owner filed a third action for infringement of the same patents on September 27, 2018. *Id.* Petitioner asserts that those patents purport to claim priority to the

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