

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ELI LILLY AND COMPANY,  
Petitioner,

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,  
Patent Owner.

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IPR2018-01422 (Patent 9,340,614 B2)  
IPR2018-01423 (Patent 9,266,951 B2)  
IPR2018-01425 (Patent 9,890,210 B2)<sup>1</sup>

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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)*

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<sup>1</sup> 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.

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## I. INTRODUCTION

This is a Final Written Decision addressing three *inter partes* reviews challenging claims 1–7 and 15–20 of U.S. Patent No. 9,340,614 B2 (“the ’614 patent”) (IPR2018-01422), claims 1–6 and 14–19 of U.S. Patent No. 9,266,951 B2 (“the ’951 patent”) (IPR2018-01423), and claims 1–15 of U.S. Patent No. 9,890,210 B2 (“the ’210 patent”) (IPR2018-01425).<sup>2</sup> 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,<sup>3</sup> “Pet.”) requesting an *inter partes* review of the respective challenged claims of the ’614 patent, the ’951 patent, and the ’210 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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<sup>2</sup> All of the respective challenged claims are referred to collectively as the “challenged claims,” and the ’614 patent, the ’951 patent, and the ’210 patent are referred to collectively as the “challenged patents.” IPR2018-01422 (“1422 IPR”), IPR2018-01423 (“1423 IPR”), and IPR2018-01425 (“1425 IPR”) are referred to herein as “the three *inter partes* reviews.”

<sup>3</sup> Unless this Decision otherwise indicates, all citations are to the Papers and Exhibits in IPR2018-01422. 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”)<sup>4</sup> 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 39, “Reply”), and Patent Owner filed a substantially similar Sur-reply (Paper 51, “Sur-reply”).

In each of the three *inter partes* reviews, Patent Owner filed a substantially similar Motion to Strike (Paper 45, “Mot. Strike”) and Petitioner filed a substantially similar Opposition to the Motion to Strike (Paper 47). In each of the three *inter partes* reviews, Patent Owner also filed a substantially similar Motion to Exclude (Paper 58, “Mot. Excl.”), Petitioner filed a substantially similar Opposition to the Motion to Exclude (Paper 60, “Opp. Excl.”), and Patent Owner filed a substantially similar Reply to Petitioner’s Opposition to the Motion to Exclude (Paper 61).

Petitioner and Patent Owner requested an oral hearing. Papers 52, 53. A combined<sup>5</sup> oral hearing was granted, and scheduled for November 22, 2019. Paper 59.

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

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<sup>4</sup> IPR2018-01422 and IPR2018-01423 were instituted on February 19, 2019, and IPR2018-01425 was instituted on February 25, 2019. *See also* 1423 IPR Paper 14; 1425 IPR Paper 14.

<sup>5</sup> In addition to the three *inter partes* reviews addressed in this Decision, the oral hearing included IPR2018-01424, IPR2018-01426, and IPR2018-01427. 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 69);<sup>6</sup>

Patent Owner’s Petition to Expedite Under 37 C.F.R. § 1.182 (Paper 68); and

Patent Owner’s Petition Under 37 C.F.R. § 1.181(a)(3) Invoking the Supervisory Authority of the Director (Paper 67).

No decision was reached on Patent Owner’s filings (Papers 67, 68, 69) 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 71 (“Tr.”). Patent Owner’s request for rehearing (Paper 69) 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 72. Petitioner filed a substantially similar supplemental brief and responsive brief (Paper 73, “Pet. Supp. Br.”)

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<sup>6</sup> 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 77.

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Paper 76, “Pet. Supp. Rep. Br.”), and Patent Owner filed a substantially similar supplemental brief and responsive brief (Paper 74, “PO Supp. Br.,” Paper 75, “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. 59.

Patent Owner identifies Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. as the real parties-in-interest. Paper 5, 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. 59. 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; 8,597,649; 9,346,881; the ’951 patent; and the ’614 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 the ’210 patent and U.S. Patent No. 9,890,211. *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 that two applications (15/883,218 and 15/956,580) based on

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