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

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

SMITH, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Eli Lilly and Company ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–18 of U.S. Patent 9,884,907 B2 (the "'907 patent"). Paper 1 ("Pet."). Teva Pharmaceuticals International GmbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp.").

In its Preliminary Response, Patent Owner argued that we should exercise our authority to deny the Petition based on 35 U.S.C. § 325(d) because the same or substantially the same prior art or arguments previously were presented to the Patent and Trademark Office. Prelim. Resp. 11–27. Petitioner thereafter requested permission to file a reply to the Preliminary Response to address that issue, which we granted, allowing Petitioner to file a reply and Patent Owner to file a sur-reply. Petitioner thereafter filed its reply (Paper 10, "Pet. Reply") and Patent Owner filed its sur-reply (Paper 11, "PO Surreply").

We have authority under 35 U.S.C. § 314 to determine whether to institute an *inter partes* review. To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we conclude that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim of the '907 patent. Therefore, we institute an *inter partes* review for claims 1–18 of the '907 patent.

A. Related Proceedings

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. 61–62. 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; 9,266,951; 9,340,614; and 9,346,881. *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 No. 9,884,908 and the '907 patent ("the second DJ action"). *Id.* at 62. 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.* Those patents purport to claim priority to the same provisional application as the '907 patent, and two applications (15/883,218 and 15/956,580) based on the same provisional application are pending before the United States Patent and Trademark Office. *Id.* Petitioner also identifies six *inter partes* review proceedings that it filed naming Patent Owner, and that have been now been instituted. *Id.*; *see* IPR2018-01422, IPR2018-01423, IPR2018-01424, IPR2018-01425, IPR2018-01426, and IPR2018-01427. Petitioner further identifies petitions for *inter partes* review against U.S. Patent No. 8,586,045 (IPR2018-01710) and U.S. Patent No. 9,884,908 (IPR2018-01712). *Id.*

Patent Owner identifies the first DJ action and the second DJ action, as well as a litigation styled *Teva Pharmaceuticals International GmbH v. Eli Lilly & Co.*, Civ. No. 1-18-cv-12029 (D. Mass.). Paper 6. Patent Owner also identifies the above-referenced *inter partes* reviews identified by Petitioner, styled *Eli Lilly & Co. v. Teva Pharmaceuticals International*

GmbH. *Id.* Patent Owner also identifies U.S. Patent Nos. 9,365,648; 9,328,168; 9,115,194; 8,734,802; and 8,007,794, in addition to the patents and patent applications identified by Petitioner. *Id.*

B. The '907 Patent (Ex. 1001)

The '907 patent is titled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide[1]" and "relates to the use of anti-CGRP antagonist antibodies for the prevention, amelioration, or treatment of vasomotor symptoms, such as CGRP related headaches (e.g., migraine) and hot flushes." Ex. 1001, [54], 1:34–37.

According to the Specification, CGRP is a 37 amino acid neuropeptide, which belongs to a family of peptides that includes calcitonin, adrenomedullin and amylin. *Id.* at 1:41–43. In humans, two forms of CGRP with similar activities (α-CGRP and β-CGRP) exist and exhibit differential distribution. *Id.* at 1:43–46. At least two CGRP receptor subtypes may also account for differential activities. *Id.* at 1:46–47. CGRP is a neurotransmitter in the central nervous system, and has been shown to be a potent vasodilator in the periphery, where CGRP-containing neurons are closely associated with blood vessels. *Id.* at 1:47–51.

CGRP-mediated vasodilatation is also associated with neurogenic inflammation, as part of a cascade of events that results in extravasation of plasma and vasodilation of the microvasculature and is present in migraine. *Id.* at 1:51–54. CGRP has been noted for its possible connection to vasomotor symptoms. *Id.* at 1:55–56. Vasomotor symptoms include hot

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[1] Calcitonin Gene-Related Peptide is abbreviated throughout as CGRP. *See* Ex. 1001, 1:41.

flushes and night sweats. *Id.* at 1:58–59. CGRP is a potent vasodilator that has been implicated in the pathology of other vasomotor symptoms, such as all forms of vascular headache, including migraines (with or without aura) and cluster headache. *Id.* at 2:20–23.

According to the Specification, the precise pathophysiology of migraine is not yet well understood. *Id.* at 3:35–36. Dilation of blood vessels is associated with and exacerbates the pain symptoms of migraine. *Id.* at 3:41–42. The variety of pharmacologic interventions that have been used to treat migraine and the variability in responses among patients indicate that migraine is a diverse disorder. *Id.* at 3:8–10. Different classes of drugs have been used in treatment (and some patients, usually those with milder symptoms, are able to control their symptoms with non-prescription remedies). *See id.* at 3:11–27. Some patients respond well to sumatriptan, which is a 5HT1 receptor agonist, which also inhibits release of CGRP; others are relatively resistant to its effects. *See id.* at 2:32–35, 3:27–32, 4:22–24.

The '907 patent is directed, *inter alia*, to methods of treating or preventing a vasomotor symptom, migraine headache, or cluster headache in an individual using an effective amount of an anti-CGRP antagonist antibody. *See id.* at 3:55–4:5. The '907 patent is also directed to methods of ameliorating, controlling, reducing incidence of, or delaying the development or progression of a migraine headache or cluster headache, using an effective amount of an anti-CGRP antagonist antibody with or without additional agents. *See id.* at 4:6–54. In various embodiments, the antibody is a human antibody or humanized antibody, the antibody recognizes a human CGRP, or the antibody comprises modified regions. *See id.* at 4:58–5:55, 8:20–22. Other embodiments are directed to a polypeptide,

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