

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 IPR2018-01710
Patent 8,586,045 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, 3, 4, 8–17, 19, 20, and 24–31 of U.S. Patent 8,586,045 B2 (the “’045 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. 12–28. 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 ’045 patent. Therefore, we institute an *inter partes* review for claims 1, 3, 4, 8–17, 19, 20, and 24–31 of the ’045 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

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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 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 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 ’045 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.* at 67; *see* IPR2018-01422, IPR2018-01423, IPR2018-01424, IPR2018-01425, IPR2018-01426, and IPR2018-01427.

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, and further identifies petitions for *inter partes* review against U.S.

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Patent No. 9,884,907 (IPR2018-01711) and U.S. Patent No. 9,884,908 (IPR2018-01712), 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 '045 Patent (Ex. 1001)

The '045 patent is titled “Methods of Using Anti-CGRP^[1] Antagonist Antibodies” 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], 1:18–21.

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 1:25–27. In humans, two forms of CGRP with similar activities (α -CGRP and β -CGRP) exist and exhibit differential distribution. *Id.* at 1:27–30. At least two CGRP receptor subtypes may also account for differential activities. *Id.* at 1:30–31. 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 1:31–35.

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 1:35–38. CGRP has been noted for its possible connection to

¹ Calcitonin Gene-Related Peptide is abbreviated throughout as CGRP. *See* Ex. 1001, 1:25.

vasomotor symptoms. *Id.* at 1:39–40. Vasomotor symptoms include hot flushes and night sweats. *Id.* at 1:42–43. 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 2:3–6.

According to the Specification, the precise pathophysiology of migraine is not yet well understood. *Id.* at 3:17–18. Dilation of blood vessels is associated with and exacerbates the pain symptoms of migraine. *Id.* at 3:23–24. 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 2:57–59. 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 2:60–3:8. 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 2:14–16, 3:8–13, 4:4–6.

The '045 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 3:37–54. The '045 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 3:55–4:36. 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*

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