Trials@uspto.gov
571.272.7822

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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 IPR2018-01423
Patent 9,266,951 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(a)

I. INTRODUCTION

Eli Lilly and Company ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1–6 and 14–19 of U.S. Patent 9,266,951 B2 (the "'951 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. 10–29. Petitioner thereafter requested permission to file a reply to the Preliminary Response to address that issue. We granted Petitioner's request, allowing Petitioner to file a reply and Patent Owner to file a sur-reply. Paper 10. Petitioner thereafter filed its reply (Paper 11, "Pet. Reply") and Patent Owner filed its sur-reply (Paper 12, "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 '951 patent. Therefore, we institute an *inter partes* review for claims 1–6 and 14–19 of the '951 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. 64. 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; 9,340,614; 9,346,881; and the '951 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, all of the patents in the first DJ action and the second DJ action purport to claim priority to the same U.S. provisional application as the '951 patent, and that 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.*

Patent Owner identifies the first DJ action and the second DJ action, as well as eight *inter partes* reviews styled *Eli Lilly and Co. v. Teva Pharmaceuticals International GmbH*, IPR2018-01422, IPR2018-01424, IPR2018-01425, IPR2018-01426, IPR2018-01427, IPR2018-01710, IPR2018-01711, and IPR2018-01712. Papers 5, 7. Patent Owner also identifies U.S. Patent Nos. 9,365,648; 9,328,168; 9,115,194; 8,734,802; 8,007,794, in addition to the patents and patent applications identified by Petitioner. Paper 5. Patent Owner also identifies a litigation styled *Teva Pharmaceuticals International GmbH v. Eli Lilly and Co.*, Civ. No. 1-18-cv-12029 (D. Mass.). Paper 7.

B. The '951 Patent (Ex. 1001)

The '951 patent is titled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide[1] and Methods Using Same," 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], 1:36–39.

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 1:43–45. In humans, two forms of CGRP with similar activities (α-CGRP and β-CGRP) exist and exhibit differential distribution. *Id.* at 1:45–48. At least two CGRP receptor subtypes may also account for differential activities. *Id.* at 1:48–49. 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 1:49–53.

CGRP-mediated vasodilatation is 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 1:53–56. CGRP has been noted for its possible connection to vasomotor symptoms. *Id.* at 1:57–58. Vasomotor symptoms include hot flushes and night sweats. *Id.* at 1:60–61. 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 2:21–24.

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[1] Calcitonin Gene-Related Peptide is abbreviated throughout as CGRP. *See* Ex. 1001, 1:43.

According to the Specification, the precise pathophysiology of migraine is not yet well understood. *Id.* at 3:31–34. Dilation of blood vessels is associated with and exacerbates the pain symptoms of migraine. *Id.* at 3:39–40. 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 3:7–9. 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 3:10–25. 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 2:32–34, 3:25–30, 4:19–21.

The '951 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 3:53–4:3. The '951 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 4:4–4:54. 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 4:55–5:49, 8:24–25. Other embodiments are directed to a polypeptide which may or may not be an antibody. *See id.* at 7:10–8:19. Other embodiments are directed to a polynucleotide encoding a fragment or region of the antibody or its variants, or to expression and cloning vectors and host cells comprising any of the disclosed polynucleotides. *See id.* at 8:26–55.

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