United States Court of Appeals for the Federal Circuit

ELI LILLY AND COMPANY,
Appellant

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH,
Appellee

2020-1876, 2020-1877, 2020-1878

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2018-01710, IPR2018-01711, IPR2018-01712.

Decided: August 16, 2021

WILLIAM BARRETT RAICH, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellant. Also represented by PIER DEROO, ERIN SOMMERS, YIEYIE YANG; SANJAY M. JIVRAJ, MARK STEWART, Eli Lilly and Company, Indianapolis, IN.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for appellee. Also represented by ELAINE BLAIS, EDWINA CLARKE, ALEXANDRA LU, Boston, MA; NATASHA ELISE DAUGHTREY, Los Angeles, CA; WILLIAM

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MILLIKEN, DEBORAH STERLING, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC.

Before LOURIE, BRYSON, and O'MALLEY, *Circuit Judges*.

LOURIE, *Circuit Judge*.

Eli Lilly and Company ("Lilly") appeals from a combined final written decision of the U.S. Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("Board") holding that the claims of U.S. Patents 8,586,045 ("'045 patent"), 9,884,907 ("'907 patent"), and 9,884,908 ("'908 patent") are not unpatentable as obvious. *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, Nos. IPR2018-01710, IPR2018-01711, IPR2018-01712, 2020 WL 1540364 (P.T.A.B. Mar. 31, 2020) ("*Board Decision*"). For the reasons provided below, we affirm.

BACKGROUND

I. Patents

Teva Pharmaceuticals International GmbH ("Teva") owns the '045, '907, and '908 patents (collectively, the "challenged patents") directed to methods of using humanized antagonist antibodies that target calcitonin gene-related peptide ("CGRP"). CGRP is a 37-amino acid peptide that 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." '045 patent, col. 1 ll. 31–35.

The challenged patents explain that "CGRP has been noted for its possible connection to vasomotor symptoms," *id.* at col. 1 ll. 39–40, such as "all forms of vascular headache, including migraines," *id.* at col 2 ll. 3–6. Although at the time of the challenged patents the pathophysiology of migraine was not well understood, dilation of blood vessels was associated with and thought to exacerbate the pain symptoms of migraine. *Id.* at col. 3 ll. 14–26. Thus, even

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before the challenged patents, the possible connection between CGRP as a vasodilator and the pathology of migraine informed the development of treatments for migraine that sought to restrict the activity of CGRP in the body. For example:

> Possible CGRP involvement in migraine has been the basis for the development and testing of a number of compounds that inhibit release of CGRP (e.g., sumatriptan), antagonize at the CGRP receptor (e.g., dipeptide derivative BIBN4096BS (Boe[]hringer Ingelheim); CGRP (8-37)), or interact with one or more of receptor-associated proteins, such as, receptor activity membrane protein (RAMP) or receptor component protein (RCP), both of which affect binding of CGRP to its receptors.

Id. at col. 2 ll. 14–22.

The challenged patents are directed to methods of treatment using humanized antibodies that antagonize CGRP and thus inhibit its activity in the body by targeting and binding to the CGRP ligand (as opposed to CGRP receptors). The challenged patents' written description describes "anti-CGRP antagonist antibodies and methods of using anti-CGRP antagonist antibodies for treating or preventing vasomotor symptoms, such as headaches, such as migraine." *Id.* at col. 3 ll. 37–45. The claims at issue are directed to methods of treatment comprising the step of administering a humanized anti-CGRP antagonist antibody.[1] Claim 1 in each patent is representative:

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[1] In contrast with the claims at issue in this case, which are directed to methods of using anti-CGRP antibodies in treatment, Teva also owns related patents with claims directed to the antibodies themselves. Those claims are at issue in Appeal Nos. 2020-1747, 2020-1748, 2020-1749, 2020-1750, 2020-1751, and 2020-1752.

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> 1. A method for reducing incidence of or treating at least one vasomotor symptom in an individual, comprising administering to the individual an effective amount of an anti-CGRP antagonist antibody, wherein said anti-CGRP antagonist antibody is a human monoclonal antibody or a humanized monoclonal antibody.

'045 patent, col. 99 ll. 2–7.

> 1. A method for treating headache in an individual, comprising:
>
> > administering to the individual an effective amount of a humanized monoclonal anti-Calcitonin Gene-Related Peptide (CGRP) antagonist antibody, comprising:
> >
> > two human IgG heavy chains, each heavy chain comprising three complementarity determining regions (CDRs) and four framework regions, wherein portions of the two heavy chains together form an Fc region; and
> >
> > two light chains, each light chain comprising three CDRs and four framework regions;
> >
> > wherein the CDRs impart to the antibody specific binding to a CGRP consisting of amino acid residues 1 to 37 of SEQ ID NO:15 or SEQ ID NO:43.

'907 patent, col. 103 ll. 21–35.

> 1. A method for treating headache in an individual, comprising:
>
> > administering to the individual an effective amount of a humanized monoclonal anti-

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> Calcitonin Gene-Related Peptide (CGRP) antagonist antibody, comprising:
>
> two human IgG heavy chains, each heavy chain comprising three complementarity determining regions (CDRs) and four framework regions, wherein portions of the two heavy chains together form an Fc region; and
>
> two light chains, each light chain comprising three CDRs and four framework regions;
>
> wherein the CDRs impart to the antibody specific binding to a CGRP consisting of amino acid residues 1 to 37 of SEQ ID NO:15 or SEQ ID NO: 43, and wherein the antibody binds to the CGRP with a binding affinity (K_D) of about 10 nM or less as measured by surface plasmon resonance at 37° C.

'908 patent, col. 99 l. 55–col. 100 l. 57. The differences between these claims have not been argued as significant to these appeals.

II. IPR Petitions and Prior Art

Lilly filed petitions for *inter partes* review of claims 1, 3, 4, 8–17, 19, 20, and 24–31 of the '045 patent, claims 1–18 of the '907 patent, and claims 1–18 of the '908 patent. Lilly asserted that each of the challenged claims would

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