IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC.,	Case No. 1:18-cv-12029-ADB
Plaintiffs,	[redacted]
v.	Leave to File Under Seal Granted on May 6, 2022 (ECF No. 341)
ELI LILLY AND COMPANY,	
Defendant.	

DEFENDANT ELI LILLY AND COMPANY'S RESPONSE TO PLAINTIFFS' LR 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT REGARDING JUDICIAL ESTOPPEL

Pursuant to Local Rule 56.1, Defendant Eli Lilly and Company ("Lilly") submits this Response to Plaintiffs' Statement of Undisputed Material Facts in Support of Plaintiffs' Motion for Summary Judgment Regarding Judicial Estoppel (ECF No. 316). Numerous items within Plaintiffs' Statement of Undisputed Material Facts consist of arguments, characterizations, legal conclusions, statements or characterization of laws or rules, hypothetical scenarios, or otherwise contain little or no factual matter. Lilly disputes any alleged fact unless it is specifically undisputed below. Lilly further disputes the arguments Plaintiffs provide in their headings and sub-headings but have not provided a separate response because Plaintiffs did not provide evidence in support.

I. BACKGROUND

1. Teva owns U.S. Patents 8,586,045 ("the '045 Patent"), 9,884,907 ("the '907 Patent"), and 9,884,908 ("the '908 Patent") (together, the "Method of Treatment Patents"), as well as U.S. Patents 9,346,881 ("the '881 Patent"), 9,890,211 ("the '211 Patent"), 8,597,649 ("the '649 Patent"), 9,340,614 ("the '614 Patent"), 9,266,951 ("the '951 Patent"), and 9,890,210 ("the '210 Patent") (together, the "Composition of Matter Patents," and together with the Method of Treatment Patents, the "Patents-in-Suit"). The Patents-in-Suit share a specification, claim priority to the same original application, and claim the same priority date.

LILLY'S RESPONSE: Disputed. Teva has the burden of proving patent ownership but

cited no evidence that it "owns" the listed patents. Further, this statement provides a legal conclusion as opposed to a factual statement. As such, it cannot be put forth as an "undisputed fact." Moreover, the Composition of Matter Patents are not "Patents-in-Suit." On February 18, 2020, the PTAB held that the Composition of Matter Patents were unpatentable as obvious. *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 2020 WL 806932 (PTAB Feb. 18, 2020); *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 2020 WL 808240 (PTAB Feb. 18, 2020). The Federal Circuit affirmed the PTAB's decisions. *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349 (Fed. Cir. 2021); *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 856 F. App'x 312 (Fed. Cir. 2021). In light of these decisions, the parties stipulated and agreed to dismiss with prejudice "[a]ll claims, counterclaims, and defenses relating to U.S. Patent Nos. 8,597,649; 9,266,951; 9,340,614; 9,346,881; 9,890,210; and 9,890,211" (i.e., the Composition of Matter Patents). ECF No. 164 at 3–4. The Composition of Matter Patents, therefore, are no longer at issue in this lawsuit. *Id.*

2. A person of ordinary skill in the art as of the priority date of the Method of Treatment Patents would have had "(1) a Ph.D. in a relevant field, such as immunology, biochemistry, or pharmacology, with several years of post-doctoral experience in antibody engineering, pharmacokinetics, and pharmacodynamics, or (2) an M.D. with a residency or specialty in neurology, and several years of experience studying CGRP or treating patients with a CGRP-related disease, such as migraine headaches." Ex. 1 (Sept. 16, 2021 Opening Expert Report of Dr. James McDonnell, Ph.D.) ¶ 12.

LILLY'S RESPONSE: Undisputed, and to further clarify: "A person of ordinary skill would also have been able to draw upon the knowledge and experience of a multi-disciplinary antibody development team comprising individuals with expertise outside her primary training. These individuals could include immunologists, biochemists, antibody engineers, pharmacologists, pharmacists, and medical doctors." ECF No. 296, Ex. 48 [Charles Op.] at ¶ 74; *see also* ECF No. 296, Ex. 15 [McDonnell Op.] at ¶ 13; Ex. A[1] [Hale Resp.] at ¶ 20; ECF No. 70

[1] Exhibits A–C referenced herein are exhibits to the Declaration of Emily Gabranski in Support of

at ¶ 24.

3. On August 8, 2018, Eli Lilly and Company ("Lilly") filed six IPR petitions with the Patent Trial and Appeal Board of the United States Patent and Trademark Office (the "Board") alleging that the Composition of Matter Patents—the '649 Patent, '951 Patent, '614 Patent, '881 Patent, '210 Patent, and '211 Patent—were invalid as obvious. ECF No. 43 (Order Staying Case Pending IPR) at 7.

LILLY'S RESPONSE: Disputed. On August 8, 2018, Lilly filed six IPR petitions with the Patent Trial and Appeal Board of the United States Patent and Trademark Office (the "PTAB") alleging that only certain challenged claims in the Composition of Matter Patents were unpatentable as obvious, as follows:

- '614 patent, claims 1–7 and 15–20;
- '951 patent, claims 1–6 and 14–19;
- '881 patent, claims 1–6 and 14–19;
- '210 patent, claims 1–15;
- '211 patent, claims 1–15; and
- '649 patent, claims 1–9.

See ECF No. 43 at 7 nn.7–8. Lilly did not challenge, for example, any patent claims limited to particular antibody amino acid sequences.

4. On February 18, 2020 the Board determined that Lilly had established by a preponderance of the evidence that the instituted claims of the Composition of Matter Patents were unpatentable as obvious. *See Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 2020 WL 806932 (PTAB Feb. 18, 2020); *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 2020 WL 808240 (PTAB Feb. 18, 2020).

LILLY'S RESPONSE: Undisputed.

5. The Federal Circuit affirmed the Board's decision, holding that substantial evidence supported the Board's decision that a POSA would have had a motivation to combine the prior art references—including Tan, Queen, and Doods—to achieve the claimed humanized

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Defendant Eli Lilly and Company's Opposition to Plaintiffs' Motion for Partial Summary Judgment Regarding Judicial Estoppel, filed concurrently with this Response.

anti-CGRP antibodies, and a reasonable expectation of success in doing so. *See Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349 (Fed. Cir. 2021); *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 856 F. App'x 312 (Fed. Cir. 2021).

LILLY'S RESPONSE: Disputed. Teva's plural "claimed humanized anti-CGRP antagonist antibodies" is inaccurate. The Federal Circuit affirmed the PTAB's decision, finding that a POSA "would have been motivated to combine the teachings of the references to make ***a*** humanized anti-CGRP antibody." *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349, 1356 (Fed. Cir. 2021) (citing *Lilly*, 2020 WL 806932, at *16–27);[2] *id.*, at 1359 ("We agree with Lilly that substantial evidence supports a motivation to make ***a*** humanized anti-CGRP antibody to study its therapeutic potential for use in treatment of human disease."); *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 856 F. App'x 312, 313 (Fed. Cir. 2021) (affirming the PTAB's unpatentability holding "for the reasons set forth in" *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, 8 F.4th 1349 (Fed. Cir. 2021)).

II. LILLY'S POSITIONS REGARDING ANTI-CGRP ANTAGONIST ANTIBODIES AND METHODS FOR PREPARING THEM

A. Lilly's Positions in the *Inter Partes* Review Proceedings

6. In its petition seeking *inter partes* review of the '210 Patent, Lilly asserted that "[a]nti-CGRP [a]ntagonist [a]ntibodies [w]ere [w]ell [k]nown in the [a]rt." Ex. 2 (*Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, IPR2018-01425, Paper 1, Petition (Aug. 8, 2018)) at 11 (citing "several publications" that "described anti-CGRP antagonist antibodies").

LILLY'S RESPONSE: Disputed to the extent Teva's modified and excerpted quotations mischaracterize Lilly's assertions in its petition seeking *inter partes* review of the '210 patent. Here, Teva generally pulls language from a section header and provides no surrounding context. Lilly did not assert that humanized or human anti-CGRP antagonist antibodies were well known in the art. *See Lilly*, 2020 WL 806932, at *26 ("Although these exhibits (Tan, Tan 1994, Frobert,

[2] Emphases added unless otherwise noted.

Wong, and Andrew) refer to anti-CGRP antibodies that target rat or human CGRP, Petitioner does not assert that these antibodies themselves were humanized."). Lilly also cited only five publications disclosing murine (mouse and rat) anti-CGRP antibodies, which contained no structure or sequence information. ECF No. 317, Ex. 2 at 11 (citing IPR Exs. 1021, 1022, 1032, 1033, 1055); *see also* ECF No. 296, Ex. 13 [Hale Tr.] at 168:3-23. Those publications collectively disclosed, at most, six murine antibodies reported as inhibiting CGRP's biological activity *in vitro* or *in vivo, i.e.*, as measured in assays conducted in rats. Ex. A [Hale Resp.] at ¶¶ 119-122; ECF No. 296, Ex. 45 [McDonnell Reply] at ¶ 21. Moreover, "[a]ll claims, counterclaims, and defenses relating to" the Composition of Matter Patents, including the '210 patent, were dismissed with prejudice from the above-captioned lawsuit and are no longer at issue. ECF No. 164 at 3–4.

7. In its petition seeking *inter partes* review of the '210 Patent, Lilly asserted that "murine monoclonal anti-CGRP antagonist antibod[ies] that bind[] to human CGRP . . . . were extensively described in the prior art." *Id*. at 30–31.

LILLY'S RESPONSE: Disputed. Teva's modified and excerpted quotation mischaracterizes Lilly's assertions in its petition seeking *inter partes* review of the '210 patent. In its petition, Lilly stated the following:

> The first step in making a humanized anti-CGRP antagonist antibody that specifically binds to human αCGRP or βCGRP would have been to make ***a*** murine monoclonal anti-CGRP antagonist antibod***y*** that binds to human CGRP. Such antibodies, and techniques for making them, were extensively described in the prior art. As a result, a POSA would have reasonably expected to succeed in making ***an*** anti-CGRP antagonist antibody that specifically bound human CGRP like those reported in Tan 1995 and elsewhere.

ECF No. 317, Ex. 2 at 30–31 (internal citations omitted). Lilly also cited only five publications disclosing murine (mouse and rat) anti-CGRP antibodies, which contained no structure or sequence information *Id*. at 11 (citing IPR Exs. 1021, 1022, 1032, 1033, 1055); *see also* ECF No. 296, Ex. 13 [Hale Tr.] at 168:3-23. Those publications collectively disclosed, at most, six murine

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