IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC., Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	Civil Action No. 1:18-cv-12029-ADB [redacted]

LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS TEVA PHARMACEUTICALS INTERNATIONAL GMBH AND TEVA PHARMACEUTICALS USA, INC.'S MOTION FOR SUMMARY JUDGMENT OF NO INEQUITABLE CONDUCT AND UNCLEAN HANDS

Pursuant to Local Rule 56.1, Plaintiffs Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. ("Teva") submit, in support of their Motion for Summary Judgment of No Inequitable Conduct and Unclean Hands, the following concise statement of the material facts of record as to which Teva contends there are no genuine issues to be tried.

I. BACKGROUND

1. U.S. Patent No. 8,586,045 (the "'045 patent") is titled "Methods of Using Anti-CGRP Antagonist Antibodies." Ex. 1.

2. Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Lee Jones Collier, and Arnon Rosenthal are named inventors of the '045 patent. Ex. 1.

3. U.S. Patent No. 9,884,907 (the "'907 patent") is titled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide." Ex. 2.

4. Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Lee Jones Collier, and Arnon Rosenthal are named inventors of the '907 patent. Ex. 2.

5. U.S. Patent No. 9,884,908 (the "'908 patent") is titled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide." Ex. 3.

6. Joerg Zeller, Kristian T. Poulsen, Yasmina Noubia Abdiche, Jaume Pons, Sierra Lee Jones Collier, and Arnon Rosenthal are named inventors of the '908 patent. Ex. 3.

7. U.S. Patent Nos. 8,586,045, 9,884,907, and 9,884,908 are the patents-in-suit in this litigation. Exs. 1–3.

8. The patent claims at issue in this case are directed to treating migraines by using antibodies that bind to the peptide calcitonin gene-related peptide ("CGRP") and inhibit its function. *See, e.g.*, Ex. 1 at 100:3–7 (claim 17).

9. CGRP has three regions: an N-terminal region, a mid-region, and a C-terminal region. *See* Ex. 9 (Responsive Expert Report of Geoffrey Hale Regarding Validity, dated November 1, 2021) ¶ 112.

10. The specification in the '045 patent shows C-terminal antibodies that bind, but do not antagonize CGRP. Ex. 1 at 26:60–27:2; 51:5–28, 52:1–28.

II. LILLY'S INEQUITABLE CONDUCT THEORIES

11. Lilly's amended counterclaims assert two counts of inequitable conduct. Lilly's Supplemental Second Amended Answer, Dkt No. 275 ("SSAA") ¶¶ 139–84, 187–287.

12. Lilly's first counterclaim for inequitable conduct alleges that an unspecified person committed inequitable conduct relating to the filing of three Petitions to Accept An Unintentionally Delayed Priority Claim Under 35 U.S.C. § 120. SSAA, Count XIX.

13. Lilly's second counterclaim for inequitable conduct alleges that named inventors [redacted] committed inequitable conduct by failing to disclose to the U.S. Patent and Trademark Office ("PTO") prior art literature they were allegedly aware of, *The effect of monoclonal antibodies to calcitonin gene-related peptide (CGRP) on CGRP-induced vasodilatation in pig coronary artery rings*, 106 Br. J. Pharmacol. 196-198 (1992) ("Shaw" or "the Shaw reference"), that allegedly demonstrated that a monoclonal antibody binding to the mid-region of CGRP failed to block CGRP and instead enhanced its effects. *E.g.*, SSAA ¶ 192; Ex. 11 (Shaw).

14. Lilly also alleges that [redacted] committed inequitable conduct by failing to disclose to the PTO [redacted] *E.g.*, SSAA¶ 193.

15. Lilly also alleges that [redacted] committed inequitable conduct by failing to disclose to the PTO [redacted] *E.g.*, SSAA¶ 198.

III. EXPERT OPINION AND FACT TESTIMONY REGARDING LILLY'S FIRST COUNTERCLAIM FOR INEQUITABLE CONDUCT

16. The law firm Wilson Sonsini Goodrich & Rosati, including Drs. Adam Cole and Jeffrey Giering, participated in prosecution of the patents-in-suit. *See, e.g.*, Ex. 19 (deposition transcript of Jeffrey Giering, dated June 4, 2021) at 143:10–144:5; Exs. 20–22 (Giering Dep. Exs. 15, 20, 21).

17. During prosecution, Dr. Cole signed three Petitions Under 37 C.F.R. § 1.78 to Accept An Unintentionally Delayed Priority Claim Under 35 U.S.C. §§ 120, 121 and 365(c)—dated January 15, 2015; April 1, 2015; and June 16, 2015—stating that the "entire delay" in making a priority claim was "unintentional." *See* Exs. 20–22.

18. Dr. Giering's name appeared in the signature block of those Petitions, but he did not sign them. *See* Exs. 20–22.

19. Lilly did not depose Dr. Cole.

20. Dr. Giering testified at his deposition that [redacted]

21. Dr. Giering did not believe that that the statements in the Petitions that the "entire delay" was "unintentional" were false. [redacted]

IV. EXPERT OPINION AND FACT TESTIMONY REGARDING ALLEGEDLY OMITTED DATA AND REFERENCES

22. The '045 Patent includes data on antibodies that bind to CGRP but do not block its effects. *See* Ex. 1 at 51:5–28, 52:1–27 (Tables 2 and 3).

23. Lilly did not serve any expert reports on PTO practice or procedure.

24. Lilly did not serve any expert report that provided an opinion that any of the claims in the patent would not have issued had Shaw, [redacted].

25. Lilly's expert Dr. McDonnell opined in his report [redacted]

[redacted] Ex. 17 (deposition transcript of James McDonnell, dated January 7, 2022) at 151:5–10.

26. Dr. McDonnell testified during his deposition that [redacted]

27. Dr. McDonnell did not consider whether Shaw and [redacted] was cumulative of information disclosed to the PTO. [redacted]

28. Lilly's expert Dr. Charles opined in his report that [redacted].

29. The [redacted] disclosed the Shaw reference during prosecution of the '907 and '908 patents. Ex. 4 (Certified File History of U.S. Patent No. 9,884,907) at TEVA_FREM_000052797; Ex. 5 (Certified File History of U.S. Patent No. 9,884,908) at TEVA_FREM_000025387.

30. During patent prosecution, if an examiner does not strikethrough a reference, it means the reference was considered. MPEP § 609.05(b).

31. The examiner indicated that he considered Shaw in deciding whether to issue the '907 and '908 patents. Ex. 4 at TEVA_FREM_000052797; Ex. 5 at TEVA_FREM_000025387; *see* MPEP § 609.05(b).

32. The Shaw reference included data on an antibody that bound to the mid-region of CGRP and failed to block the effects of CGRP. SSAA ¶ 192.

33. The Shaw reference included data on an antibody that bound to the N-terminal region of CGRP and did block the effects of CGRP. *See* Ex. 11.

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