UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM AND ORDER ON MOTIONS IN LIMINE

BURROUGHS, D.J.

Currently before the Court are several motions *in limine* ("MIL") filed by Plaintiffs Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"), [ECF No. 481 (omnibus motion)], and Defendant Eli Lilly and Company ("Lilly"), [ECF Nos. 472, 474, 476, 477, 478, 479, and 480]. Having considered all of the submissions filed in connection with these motions, and having heard oral argument regarding Lilly's MIL No. 2 regarding Bergerot, the Court makes the following determinations with respect to the motions.

I. DISCUSSION

The Court assumes the parties' familiarity with the underlying facts and allegations in this case. In sum, Teva brings this case alleging that Lilly has infringed three patents[1] (the "Patents-in-Suit") that relate to the treatment of headaches. Lilly disputes this and contends that

[1] U.S. Patent Nos. 8,586,045 (the "'045 patent"); 9,884,907 (the "'907 patent"); and 9,884,908 (the "'908 patent").

the Patents-in-Suit are unenforceable because they are invalid and because Teva engaged in inequitable conduct or has unclean hands. The Court ruled on the parties' cross-motions for summary judgment, [ECF No. 513], and the case is now ready for trial.

A. Teva's MIL No. 1: Motion to Preclude Lilly From Arguing and Introducing Post-Filing Date Evidence to Support Its Enablement and Written Description Defenses

Teva moves to preclude Lilly from offering opinions or arguments in support of its invalidity defenses that rely on evidence that post-dates the filing date of the Patents-in-Suit, arguing that such evidence is irrelevant and unfairly prejudicial. [ECF No. 483 at 10]. Teva argues that the evidence is irrelevant because compliance with the written description and enablement requirements is judged based on the state of the art as of the filing date of the patents. [Id. at 11 (citations omitted)].

Although Teva is correct that written description and enablement are judged based on the state of the art as of the filing date, see Ariad Pharms., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) ("[T]he description must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.' In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.") (second alteration in original) (internal citations omitted); Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1345 (Fed. Cir. 2000) ("Enablement is determined from the viewpoint of persons of skill in the field of the invention at the time the patent application was filed."), this does not mean that all evidence that post-dates the filing date is irrelevant. With respect to the written description inquiry, the Federal Circuit has held that in the context of functionally defined genus claims, such as those at issue here, "post-priority-date evidence of a particular species can reasonably bear on whether a patent fails to disclose a representative number of species falling

within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." Amgen Inc. v. Sanofi, 872 F.3d 1367, 1374 (Fed. Cir. 2017) (internal quotation marks and citation omitted). As for enablement, the Federal Circuit has held that "post-priority-date evidence showing that [the patent owner] engaged in lengthy and potentially undue experimentation to enable the full scope of the claims" "could have been relevant to determining if the claims were enabled as of the priority date and should not [be] excluded simply because [the evidence] post-date[s] the claims' priority date." Id. at 1375.

Therefore, because evidence that post-dates the filing date is not categorically irrelevant to the issues of written description and enablement, Teva's motion is DENIED.

B. Teva's MIL No. 2: Motion to Preclude Lilly From Arguing and Introducing Evidence That FDA-Required Studies Are Relevant to Lilly's Written Description and Enablement Arguments

Teva next moves to prevent Lilly from introducing, with respect to the written description and enablement inquiries, three categories of evidence related to testing performed for regulatory purposes in connection with FDA approval. [ECF No. 483 at 16]. The evidence pertains to (1) the timeline relating to Lilly's Phase II and Phase III clinical trials and the amount of effort involved in conducting those trials, (2) the Phase III results for Emgality (Lilly's galcanezumab) and Ajovy (Teva's fremanezumab) for the treatment of episodic cluster headaches, and (3) the assertion by Lilly's experts that testing in "non-human primates" was "required" to comply with the written description and enablement inquiries. [Id.].

35 U.S.C. § 112 states that a patent specification "shall contain a written description of the invention[,]" the test for which is "an objective inquiry into the four corners of the specification from the perspective of a [POSA]." Ariad, 598 F.3d at 1351. "A specification adequately describes an invention when it 'reasonably conveys to those skilled in the art that the

inventor had possession of the claimed subject matter as of the filing date.'" Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1335 (Fed. Cir. 2021) (quoting Ariad, 598 F.3d at 1351). The enablement requirement, for its part, demands that the specification "teach the public how to practice the full scope of the claimed invention." McRO, Inc. v. Bandai Namco Games Am., Inc., 959 F.3d 1091, 1099–100 (Fed. Cir. 2020) (internal quotation marks omitted) (quoting AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003)). Further, "[t]o prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'" Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1084 (Fed. Cir. 2021) (quoting Alcon Rsch. Ltd. v. Barr Lab'ys, Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014)). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

1. The timeline related to Lilly's Phase II and Phase III clinical trials and the effort involved in conducting such trials.

Teva argues that Lilly should not be permitted to introduce evidence related to its Phase II or Phase III clinical trials to support its invalidity defenses because those trials are part of the FDA's process for evaluating the safety and efficacy of new drugs, which, according to Teva, is irrelevant to these defenses. [ECF No. 483 at 17]. Lilly argues in response that Teva has confused what is required for patentability with relevance. [ECF No. 501 at 19]. In Lilly's view, the clinical trials are relevant to both invalidity defenses because they bear on when persons skilled in the art would have believed it was possible to treat headache using an anti-CGRP antagonist antibody. [Id.].

Following the same line of reasoning discussed in the Court's order on Teva's MIL No. 1, the Court finds that evidence of Lilly's clinical trials is relevant to the enablement inquiry because it may offer insight into the extent of experimentation necessary to practice the claimed methods. In contrast, the Court does not see how Lilly's later clinical trials are relevant to the issue of written description. As an en banc panel of the Federal Circuit has held, the test to determine if the written description requirement is met involves "an objective inquiry into the four corners of the specification from the perspective of a [POSA]." Ariad, 598 F.3d at 1351. Evidence of later clinical trials are thus outside of the proper scope of the written description inquiry. Therefore, Lilly may introduce evidence of its Phase II and Phase III clinical trials in the context of enablement but may not use the same evidence with respect to written description unless it can show relevance beyond what is currently before the Court. The Court will give limiting instructions as warranted.

2. Phase III results for Emgality and Ajovy for treating episodic cluster headache.

For the same reasons discussed above, evidence regarding Phase III results for Emgality and Ajovy may be referenced in the context of enablement but not with regard to written description unless there is a showing of relevance at trial.

3. Assertion by Lilly's experts that testing in "non-human primates" is "required" to comply with the written description and enablement inquiries.

The parties appear to agree that Lilly may not suggest to the jury that testing on non-human primates is required to meet Section 112's written description and enablement requirements. The Court concurs. Nevertheless, Lilly may, subject to proper objections, argue that the absence of such data supports its invalidity arguments.

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