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

TEVA'S RESPONSE TO ELI LILLY AND COMPANY'S SUPPLEMENTAL BRIEF REGARDING THE JURY CHARGE

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I. INTRODUCTION

Teva respectfully submits this response to Lilly's supplemental brief regarding the draft jury charge. ECF No. 583.

II. ARGUMENT

Lilly is badly confusing two very different concepts. The standard for written description requires that the claimed invention be described in the specification, not just be obvious in light of some different invention described in the specification. Therefore, if the specification nowhere described the invention of a method of treatment using humanized anti-CGRP antagonist antibodies—for example, if the specification only described the invention as the use of murine antibodies—then whether it would be obvious to use humanized antibodies could be insufficient for written description purposes. That is the point of the *Lockwood* and *Ariad* decisions Lilly cites. *See* ECF No. 583 at 3 (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010)); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

But of course here, the specification *does* describe *the invention* as a method of using humanized anti-CGRP antagonist antibodies, so the "obviousness" case law on which Lilly relies is entirely inapplicable. What Lilly is mistakenly trying to do is take that body of inapplicable law, and use it argue that a POSA in reading the written description would not combine the teachings of the prior art in support of the invention that is described—in this case, for example, that a POSA could not—as a matter of law—combine knowledge of numerous murine anti-CGRP antagonist antibodies, and knowledge of routine humanization techniques, to understand what tools could be used to perform the described and claimed method of using humanized anti-CGRP antagonist antibodies. None of the cases Lilly cites stand for that very different proposition, and the law is to the contrary. As the Court knows, "[a] patent need not teach, and preferably omits,

what is well known in the art." *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 982 (Fed. Cir. 2021); *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988) ("A patent need not disclose what is well known in the art."); *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004). Therefore, having described the invention as a method of using humanized anti-CGRP antagonist antibodies, the applicants did not need to further describe all the details concerning murine antibodies and humanization that already would have been known to a POSA.

Lilly might try to argue as a *factual* matter that a POSA would not have viewed the murine antibodies as particularly relevant to humanized antibodies—Teva, and the PTO in issuing the patents and the PTAB in finding that a POSA would have been motivated to create the humanized antibodies used in the claims, obviously disagreed—but Lilly's factual position does not impact the applicable law. In that regard, the *Pernix* case that Lilly attaches to its email is easily distinguishable. *See* ECF No. 583 at 5 (citing *Pernix Ireland Pain DAC v. Alvogen Malta Operations Ltd.*, 323 F. Supp. 3d 566, 626–27 (D. Del. 2018)). There, the court, sitting as fact finder in a bench trial, concluded as a *factual* matter that "the identity of the hydrocodone formulations that would have a similar effect on subjects with and without hepatic impairment was not known." *Pernix*, 323 F. Supp. at 626. Here, of course, the PTAB previously found that a POSA would have known of anti-CGRP antagonist antibodies that could be used in the invention, and been motivated to humanize them. The jury is entitled to draw the same conclusion. Nowhere does *Pernix* state that, in a method of use claim, where a POSA would have been motivated to take a prior art composition and modify it in the manner required by the claimed invention, nonetheless, as a matter of law, the prior art composition should be ignored, which seems to be the position Lilly's "obviousness" argument asserts.

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