IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC.,	)	
Plaintiffs,	)	Case No. 1:18-cv-12029-ADB
v.	)	
ELI LILLY AND COMPANY,	)	
Defendant.	)	

ELI LILLY AND COMPANY'S OPPOSITION TO TEVA'S MOTION TO EXCLUDE LILLY'S EXPERTS FROM TESTIFYING CONCERNING POST-FILING EXPERIMENTATION

I. Introduction

The Court has already denied Teva's Motion in Limine No. 1 seeking to exclude post-filing date evidence relating to enablement. ECF No. 535 at 3 ("[B]ecause evidence that post-dates the filing date is not categorically irrelevant to the issues of written description and enablement, Teva's motion is DENIED."). In seeking to revisit this ruling, Teva raises only factually and legally unsupported arguments that invite legal error and should be rejected.

II. Argument

Teva fails to identify any case law supporting its position that an accused infringer must be aware of an asserted patent for its post-filing date experimentation to have relevance for lack of enablement. In *Abbott*, the Court credited the difficulties of the defendant's inventors in arriving at the accused Stelara® antibody as supporting lack of enablement. *Abbott GmbH & Co. v. Centocor Ortho Biotech, Inc.*, 971 F. Supp. 2d 171, 181 (D. Mass. 2013), *aff'd* 759 F.3d 1285 (Fed. Cir. 2014). The Court nowhere required the defendant's inventors to have known of the asserted patents. Nor did the *Baxalta* court require the defendants' inventors of the accused antibody (emicizumab) to have known of the asserted patents for their difficulties to support lack of enablement. *Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595, 624 (D. Del. 2022) ("Significantly, it took Chugai over ten years of multi-phased experimentation and the screening of tens of thousands of candidate compounds to discover emicizumab."). There is, indeed, no basis in the law for excluding the efforts of Lilly's "large team" of "over 40 people" in making Lilly's antibody, galcanezumab (Emgality®). *See, e.g.*, Trial Tr., Day 9 at 207:13-208:2.

Teva's motion also operates from a factually flawed presumption: that the common specification of the patents-in-suit allegedly discloses how to make and use an antibody similar to Lilly's antibody, which could have shortened Lilly's efforts. *Abbott*, 971 F. Supp. 2d at 181 ("[T]he fact that the patent did not enable any antibodies like [the accused antibody], this conclusion

supports the jury's determination that the patent did not enable the full scope of the claimed invention."). Whether the patents-in-suit contain such a disclosure is precisely the issue currently before the jury—not a basis for excluding evidence. Notably, in its motion, Teva fails to identify any disclosure in its specification directing or enabling a POSA to make Lilly's galcanezumab or any antibody similar to galcanezumab, as required, which distinguishes Teva's reliance on *Allegan*. Mot. at 1; *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015) (holding, unlike here, that the patent specifications "provide *sufficient guidance*" (emphasis added)).

Indeed, nowhere does Teva allege that its patents-in-suit disclose the amino acid sequence of galcanezumab (or any antibody close to galcanezumab's sequence). Teva has admitted no such disclosure exists. ECF No. 400 at SOF 346 (citing Teva Response to RFA No. 3); *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 371-72 (D. Del. 2019) (knowing the sequence of one antibody does not assist with identifying other unique, non-variant antibodies within the scope of the claims). Teva also nowhere alleges that its patents-in-suit disclose how to make any antagonist antibody that binds to CGRP's mid-region, as Lilly's galcanezumab does. TX-0001 at 49:8-51:3 ('045 Patent, Example 1: "all 12 antibodies target a C-terminal epitope"); Trial Tr., Day 3 at 31:24-32:7, 33:2-34:15; TX-3454 at Zeller_FREM_00014559 ("All our mAbs are C-terminal"). Teva further fails to identify any disclosure in the specification purporting that Teva's named inventors actually invented any new or faster methods for making or humanizing antibodies. Dr. Zeller's testimony confirms they did not—the Rinat team relied instead on third-party immunization techniques. Trial Tr., Day 2 at 155:21-156:11. It is also undisputed that the specification does not even describe how Teva's Antibody G1 was made, let alone Lilly's antibody:

> SOF 188: "The specification of the Patents-in-Suit does not expressly disclose how Antibody G1 was made."
>
> Response: "Teva does not dispute that paragraph 188 is factually accurate in that the generation of G1 is not specifically disclosed in the specification."

ECF No. 400 at SOF 188. Teva thus fails to identify any meaningful information in its patents-in-suit that would have guided anyone to make an antibody similar to Lilly's galcanezumab (Emgality®), much less shorten the efforts of Lilly's inventors and antibody development team. *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007) ("Although the knowledge of one skilled in the art is indeed relevant, the novel aspect of an invention must be enabled in the patent.").

Accordingly, Teva incorrectly attempts to create from whole cloth an unsupported exception to *Amgen*'s clear pronouncement that post-priority-date evidence "should not [be] excluded simply because it post-date[s] the claims' priority date." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1374 (Fed. Cir. 2017); ECF No. 535 at 3. Teva courts similar legal error as occurred in *Amgen*, and thus Teva's motion should be denied. 872 F.3d at 1374; *see also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1344 (Fed. Cir. 2003) ("Report of a first success after [the filing date] indicates failure or difficulty [on] or before the [filing date]," supporting lack of enablement); *Monsanto Co. v. Bayer Bioscience N.V.*, No. 4:00-cv-01915, 2005 WL 5989796, at *16 (E.D. Mo. Oct. 28, 2005) (denying motion *in limine* to exclude post-filing date evidence).

III. CONCLUSION

Teva presents no basis for revisiting or modifying the Court's previous decision on Teva's Motion in Limine No. 1. Lilly respectfully requests that Teva's motion be denied.

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CERTIFICATE OF SERVICE

I, Andrea L. Martin, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 1, 2022.

/s/Andrea L. Martin
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