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.) Case No. 1.10-CV-12029-ADB
ELI LILLY AND COMPANY,)
Defendant.))

ELI LILLY AND COMPANY'S OBJECTIONS TO FINAL JURY INSTRUCTIONS AND JURY VERDICT FORM



Pursuant to Fed. R. Civ. P. 51(c), and as stated on the record today, Defendant Eli Lilly and Company ("Lilly") objects to the Court's Final Jury Instructions and Jury Verdict Form as follows.

1. "Invalidity – Written Description"

Lilly objects to the instruction insofar as it does not include: (i) "evidence of an accused infringing product (e.g., Lilly's Emgality®) is relevant for showing that a patent does not disclose a representative number of species," and/or (ii) "a patent specification must disclose at least some species (i.e., antibodies) that are structurally similar to the accused infringing product (e.g., Lilly's Emgality®)."

E.g., ECF No. 523-3 at 13-14; AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1295, 1300-01 (Fed. Cir. 2014); Amgen Inc. v. Sanofi, 872 F.3d 1367, 1374-75 (Fed. Cir. 2017); Ariad Pharms. Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

2. "Invalidity – Written Description"

Lilly objects to the instruction insofar as it does not include: "It is not sufficient if the specification discloses only enough to make it obvious for a person of ordinary skill to make or use the claimed invention."

E.g., ECF No. 523-3 at 12; Lockwood v. Am. Airlines, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997); Martin v. Mayer, 823 F.2d 500, 505 (Fed. Cir. 1987); Ariad Pharms. Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc).

3. "Invalidity – Written Description"

Lilly objects to the instruction insofar as it does not include: "An adequate written description of a claimed method of administering a compound (e.g., an antibody) requires an adequate description of the compounds suitable for practicing the claimed method."

E.g., ECF No. 523-3 at 13; Univ. of Rochester v. G.D. Searle & Co., 385 F.3d 916, 926 (Fed. Cir. 2004); Ariad Pharms. Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352-53 (Fed. Cir. 2010) (en banc).



4. "Invalidity – Written Description"

Lilly objects to the instruction insofar as it does not include: "if a patent specification provides nothing more than the mere claim that the claimed invention might work, even though the patent owner has previously persuaded a court that a person of ordinary skill would not have thought it would work, the patent claim is invalid for lack of written description."

E.g., ECF No. 523-3 at 14; Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368, 1381 (Fed. Cir. 2019).

5. "Invalidity - Enablement"

Lilly objects to the instruction insofar as it does not include: (i) "if practicing the full scope of a patent claim would have required excessive experimentation, even if that experimentation was routine, the patent claim is invalid for lack of enablement" and/or (ii) "where the art is unpredictable, and trial and error testing is required to identify methods within the scope of a functionally defined claim for a vast array of possibilities encompassed by the claim, the claim is not enabled even if each individual experiment is routine."

E.g., ECF No. 523-3 at 15; *Idenix Pharm. LLC v. Gilead Scis., Inc.*, 941 F.3d 1149, 1163 (Fed. Cir. 2019); *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013); *Amgen Inc. v. Sanofi*, 987 F.3d 1080, 1088 (Fed. Cir. 2021).

6. "Invalidity – Written Description" and "Invalidity – Enablement"

Lilly objects to the instruction insofar as it states that the filing date for purposes of assessing written description or enablement is November 2, 2006, rather than November 14, 2005.

See, e.g., ECF No. 538; ECF No. 523-3 at 11-12; ECF No. 475; ECF No. 104; ECF No. 353; pre-AIA 35 U.S.C. § 102(a)-(b); MPEP § 2163; Vasudevan Software, Inc. v. MicroStrategy, Inc., 782 F.3d 671, 681-83 (Fed. Cir. 2015); Goeddel v. Sugano, 617 F.3d 1350, 1354 (Fed. Cir. 2010); Ariad Pharms. Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).



7. "Future Lost Profits"

Lilly objects to the instruction insofar as it includes any instruction on future lost profits damages because such damages are too speculative. Lilly also objects to the verdict form insofar as it includes any question on future lost profits damages.

E.g., ECF No. 523-3 at 20; Shockley v. Arcan, Inc., 248 F.3d 1349, 1363-64 (Fed. Cir. 2001); Oiness v. Walgreen Co., 88 F.3d 1025, 1030 (Fed. Cir. 1996); Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1581 (Fed. Cir. 1992).

Dated: November 7, 2022 /s/ Andrea L. Martin

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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 7, 2022.

/s/Andrea L. Martin Andrea L. Martin, Esq.

