Filed: June 7, 2019

Filed on behalf of: Eli Lilly and Company

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY
Petitioner

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH
Patent Owner

Case IPR2018-01422 (Patent No. 9,340,614)
Case IPR2018-01423 (Patent No. 9,266,951)
Case IPR2018-01424 (Patent No. 9,346,881)
Case IPR2018-01425 (Patent No. 9,890,210)
Case IPR2018-01426 (Patent No. 9,890,211)
Case IPR2018-01427 (Patent No. 8,597,649)[1]

PETITIONER'S SECOND OBJECTIONS TO PATENT OWNER'S EVIDENCE

[1] The word-for-word identical paper is filed in each proceeding identified in the caption.

The Federal Rules of Evidence ("FRE") generally apply to proceedings before the Board. 37 C.F.R. § 42.62(a). Pursuant to 37 C.F.R. § 42.64(b)(1) and the FRE, Petitioner Eli Lilly and Company ("Lilly" or "Petitioner") submits the following objections to certain exhibits submitted by Patent Owner Teva Pharmaceuticals International GMBH ("Teva" or "Patent Owner"). These objections apply equally to Patent Owner's reliance on these exhibits in any subsequently filed documents. These objections are timely filed and served within five business days of service. 37 C.F.R. § 42.64(b)(1).

A. Objection Key

A: Lilly objects to the exhibit because it lacks proper foundation or authenticity under FRE 901 and 902.

B: Lilly objects to the exhibit under the Best Evidence Rule (FRE 1001-1003).

H: To the extent Teva relies on the content of the exhibit for the truth of the matter asserted, Lilly objects to the exhibit as inadmissible hearsay (*see* FRE 801 and 802) that does not fall under any exceptions, including FRE 803, 804, 805, and 807.

I: Lilly objects to the exhibit as an incomplete document (FRE 106).

R: To the extent Teva relies upon the exhibit to show the state of the art, Lilly objects to the exhibit as not relevant, confusing, unfairly prejudicial, and wasting time because the exhibit has not been shown to qualify as prior art

(FRE 401-403).

S: Lilly objects to the exhibit as not relevant, confusing, unfairly prejudicial, and wasting time because it has not been cited in one or more of Teva's Patent Owner Responses (FRE 401-403).

T: Lilly objects to the exhibit as not relevant, confusing, unfairly prejudicial, and wasting time because it is not relevant to any issue in these IPR proceedings (FRE 401-403).

X: Lilly objects to the exhibit because it was improperly filed under 37 C.F.R. § 42.6(c).

Z: Lilly objects to the exhibit because it was improperly filed as redacted without any protective order, in violation of the Board's Scheduling Order (Paper 15 at 2).

B. Objections

Teva Exhibit No.	Teva Description	Objections
2052[2]	Inman, S., "Anti-CGRP Monoclonal Antibodies Transforming Migraine Treatment," (Oct. 22, 2018), *NeurologyLive* https://www.neurologylive.com/conferences/ana-2018/anticgrp-mon oclonal-antibodies-transforming-migraine-treatment, (last visited May 20, 2019)	A, H, R, T

[2] Lilly timely objected to these documents during the deposition of Dr. Charles. 37 C.F.R. § 42.64(a); Ex. 2192, 61:4-17, 186:6-11.

Teva Exhibit No.	Teva Description	Objections
2053[2]	"Pain Like No Other," *UCLA Health David Geffen School of Medicine* 38(2): 18-25 (2018)	A, H, R, T
2056	Hay, D.L., *et al*., *"*A comparison of the actions of BIBN4096BS and $CGRP_{8-37}$ on CGRP and adrenomedullin receptors expressed on SK-N-MC, L6, Col 29 and Rat 2 cells,*" British Journal of Pharmacology* 137(1): 80 - 86 (2002)	H, S
2057	Hay, D.L., *et al.,* "CL/RAMP2 and CL/RAMP3 produce pharmacologically distinct adrenomedullin receptors: a comparison of effects of $adrenomedullin_{22–52}$, $CGRP_{8–37}$ and BIBN4096BS," *British Journal of Pharmacology* 140(3): 477–486 (2003)	H, S
2058	Uren, N.G., *et al*., "Effect of intravenous calcitonin gene related peptide on ischaemia threshold and coronary stenosis severity in humans," *Cardiovascular Research* 27: 1477- 1481 (1993)	H, T
2059	Geppetti, P., *et al*., "CGRP and migraine: neurogenic inflammation revisited," *Journal of Headache & Pain* 6(2):61–70 (2005)	H
2060	Hay, D., *et al*., "Pharmacological discrimination of calcitonin receptor: receptor Activity-modifying protein complexes," *Molecular Pharmacology* 67(5): 1655–1665 (2005)	H, T
2061	Franco-Cereceda, A. and Liska, J., "Potential of Calcitonin Gene-Related Peptide in Coronary Heart Disease," *Pharmacology* 60:1–8 (2000)	H, T
2062	*The Biochemical Basis of Neuropharmacology, Chapter 4: Receptors*, 65-84, (Jack R. Cooper *et al*. eds., 8th ed. 2003)	H, I, T
2063	Excerpt from Rang, H., *et al*., *Pharmacology*, p. 15, 5th ed., Elsevier Science Limited, (2003)	H, I, T
2064	*Molecular Cell Biology, Chapter 13: Signaling molecules and cell-surface receptors*, 537-538, (Harvey Lodish *et al.* eds., 5th ed. 2003)	H, I, T
2065	Sheykhzade, M., *et al*., "Noncompetitive antagonism of BIBN4096BS on CGRP-induced responses in human subcutaneous arteries," *British Journal of Pharmacology*	H, T

Teva Exhibit No.	Teva Description	Objections
	143(8): 1066–1073 (2004)	
2066	Gallai, V., *et al*., "Vasoactive peptide levels in the plasma of young migraine patients with and without aura assessed both interictally and ictally," *Cephalalgia* 15(1):384-390 (1995)	H, S, T, X
2067	Sarchielli, P., *et al*., "Nitric oxide metabolites, prostaglandins and trigeminal vasoactive peptides in internal jugular vein blood during spontaneous migraine attacks," *Cephalalgia,* 20(10): 907-918 (2000)	H, S, T, X
2068	Hay, D.L. and Poyner, D. "The Preclinical Pharmacology of BIBN4096BS, a CGRP Antagonist," *Cardiovascular Drug Reviews* 23(1): 31-42 (2005)	H
2070	Wimalawansa, S.J., "Circadian variation of plasma calcitonin gene-related peptide in man," *Journal of Neuroendocrinology* 3(3): 319-322 (1991)	H, S, T
2073	Hendrikse, E.R., *et al*., "Molecular studies of CGRP and the CGRP family of peptides in the central nervous system," *Cephalalgia* 39(3):403–419 (2019)	H, R, S, T
2075	*Concise Dictionary of Biomedicine and Molecular Biology*, pp. 40, 80 (Juo, P-S., ed.)	H, R, S, T
2077	Jain, R., "Physiological barriers to delivery of monoclonal antibodies and other macromolecules in tumors," *Cancer Research (Suppl.)* 50: 814s-819s (1990)	H, S, T
2078	Juul, R., *et al*., "Calcitonin gene-related peptide-LI in subarachnoid haemorrhage in man. Signs of activation of the trigemino-cerebrovascular system?," *Br. J. Neurosurgery* 4: 171-180 (1990)	H, S, T
2079	Gennari, C., *et al*., "Improved cardiac performance with human calcitonin gene related peptide in patients with congestive heart failure," *Cardiovascular Research* 24: 239-241 (1990)	H, T
2082	Humbert, M., *et al*., "Treatment of pulmonary arterial hypertension," *N. Engl. J. Med.* 351:1425-1436 (2004)	H, S, T
2084	Tjen-A-Looi, S., *et al*., "CGRP and somatostatin modulate chronic hypoxic pulmonary hypertension," *Am. J. Physiol.* 263(3): H681-H690 (1992)	H, T

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