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 No. IPR2018-01711
Patent No. 9,884,907

PETITIONER'S SUPPLEMENTAL BRIEF

(REGARDING *FOX FACTORY, INC. v. SRAM, LLC*)

Table of Contents

GLOSSARY

ADCC	Antibody-dependent cellular cytotoxicity
CDC	Complement-dependent cytotoxicity
CDR	Complementarity-determining region
FDA	U.S. Food and Drug Administration
IPR	*Inter partes* review
Italicized text	Emphasis added unless otherwise indicated
Lilly or Petitioner	Eli Lilly and Company
pM	picomolar
Teva or Patent Owner	Teva Pharmaceuticals International GmbH
'907 patent	U.S. Patent No. 9,884,907
'045 patent	U.S. Patent No. 8,586,045 (Ex. 1001 in IPR2018-01710)
'614 patent	U.S. Patent No. 9,340,614 (Ex. 1001 in IPR2018-01422)
'951 patent	U.S. Patent No. 9,266,951 (Ex. 1001 in IPR2018-01423)
'881 patent	U.S. Patent No. 9,346,881 (Ex. 1001 in IPR2018-01424)
'794 patent	U.S. Patent No. 8,007,794 (Ex. 2024)

I. Introduction

In *Fox Factory, Inc. v. SRAM, LLC*, the Federal Circuit reaffirmed and clarified that a patentee bears the burden of establishing a presumption of nexus, which requires demonstrating that a product cited for secondary considerations is "coextensive" with the challenged claims. 944 F.3d 1366, 1373 (Fed. Cir. 2019). The court rejected the patentee's attempt to broaden the coextensiveness requirement to an inquiry of whether the claims "cover" the cited products. *Id.* at 1377.

For nexus in this case, Teva relied solely on the presumption. Sur-reply, 26-27. Like the patentee in *Fox Factory*, Teva advanced the legally deficient argument that its claims merely "cover[]" Ajovy® and Emgality®. *Id.*; POR, 49; Ex. 2272, ¶110. Teva failed to satisfy the coextensiveness requirement because these products have numerous features that "materially impact" their functionality but are not recited as limitations in the challenged method-of-treatment claims. *Fox Factory*, 944 F.3d at 1375-76. Indeed, the amino acid sequences of Ajovy® and Emgality® drive their therapeutic properties, i.e., efficacy and safety for treating migraine, which are responsible for Teva's alleged secondary considerations evidence. All challenged claims, however, broadly recite using antibodies without *any* requirement for sequence and without *any* requirement for particular levels of safety and efficacy, let alone those observed for Ajovy® and Emgality®. Thus, *Fox Factory* confirms that nexus is lacking.

II. Legal Standard for Presumption of Nexus

Fox Factory reaffirmed that a patentee bears the burden of establishing a presumption of nexus. *Fox Factory*, 944 F.3d at 1373, 1378. If the patentee fails to establish the presumption, the petitioner has no burden of rebuttal. *Id.* at 1375. When a product is covered by multiple patents, the patentee must also show that the secondary considerations are due to the challenged claims, not other patents. *Id.*

Under *Fox Factory*, a patentee relying on the presumption must establish that alleged praise or success is (1) "tied to a specific product" and (2) the product is "coextensive" with the challenged claims. 944 F.3d at 1373. There, the patentee relied on the success of thirteen bicycle chainring products "embody[ing]" the challenged patent. *Id.* at 1370. The court, however, found a lack of coextensiveness because the products' performance (i.e., improved chain retention) was materially impacted by features not recited as limitations, such as an 80% gap-filling feature that had been specifically claimed in a *different* patent. *Id.* at 1375-76, 1378.

In holding the presumption inapplicable, the court did not require the unclaimed features (e.g., 80% gap-filling) to be specifically identified in industry praise or the sole basis for commercial success. Rather, the presumption did not apply because patentee failed to meet its burden of establishing that those unclaimed features were "insignificant" to the chainring products' functionality. *Id.* at 1375-76.

Accordingly, *Fox Factory* demonstrates that no presumption of nexus applies

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