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. IPR2018-01423
Patent No. 9,266,951 B2

PETITIONER'S SUPPLEMENTAL BRIEF

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

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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
'951 patent	U.S. Patent No. 9,266,951
'794 patent	U.S. Patent No. 8,007,794 (Ex. 2024)

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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, 25. Like the patentee in *Fox Factory*, Teva advanced the legally deficient argument that its claims merely "cover[]" Ajovy® and Emgality®. *Id.*; POR, 48; Ex. 2223, ¶106; Paper 68, 63. Teva failed to satisfy the coextensiveness requirement because these products have numerous features that "materially impact" their functionality but are not recited as limitations. *Fox Factory*, 944 F.3d at 1375-76. Indeed, it is undisputed that the specific, optimized sequences of Ajovy® and Emgality® materially impact their function, but the challenged claims do not claim any of the optimized sequences and instead broadly recite antibodies without *any* requirement for amino acid sequence. Thus, *Fox Factory* further confirms that nexus is lacking for Teva's purported secondary considerations.

II. Legal Standard for Presumption of Nexus

Fox Factory reaffirmed that a patentee bears the burden of establishing a

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presumption of nexus. *Fox Factory*, 944 F.3d at 1373, 1378 (citing *WMS Gaming Inc. v. Int'l Game Tech*., 184 F.3d 1339, 1359 (Fed. Cir. 1999)). If the patentee fails to establish the presumption, the petitioner has no burden of rebuttal. *Id.* at 1375. When a product is covered by more than one patent, the patentee has the burden to show that the secondary considerations are due to the challenged claims rather than the other patents. *Id.* (citing *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289, 1299 (Fed. Cir. 2010)).

In *Fox Factory*, the nexus deficiency arose from overbroad genus claims, not the inclusion of a claimed part within a whole product. The patentee established that thirteen bicycle chainring products were "covered" by the claims, and the secondary considerations evidence *pertained to those chainrings* (not larger products like bicycles, cranksets, or drivetrains). *Id.* at 1371. Those chainring products, however, contained multiple features that "materially impact[ed]" their functionality but were not recited as limitations in the challenged claims. *Id.* at 1375-76. Nexus could not be presumed because the claims were not limited to those material features—and thus were not coextensive with the chainring products. *Id*.

Fox Factory's adherence to the coextensiveness requirement parallels other requirements for secondary considerations. For example, when a patentee fails to establish that other embodiments within the scope of the claims would perform "in the same manner" as a cited product, nexus is likewise lacking due to overbroad

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