IN THE 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 IPR2018-01710
Patent 8,586,045

PATENT OWNER'S REPLY BRIEF REGARDING *FOX FACTORY, INC. V. SRAM, LLC*

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The record provides evidence of success and/or praise for *three different* anti-CGRP antibodies, all of which embody the challenged claim elements: Teva's Ajovy®, Lilly's Emgality®, and Alder's eptinezumab. This evidence supports both a presumption of nexus and actual nexus to the challenged claims. POR, 55-56; EX2271, ¶127; EX2262, ¶¶21-26; EX2274, ¶20; EX2257, 5.

Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366 (Fed. Cir. 2019) does not disrupt Teva's presumption. The holding in that case turned on the fact that SRAM only argued that the commercial products were "broadly covered" by the claims, and admitted that the unclaimed features of the product were *both* material to its functionality *and* drove the objective indicia. No such admissions or arguments exist here. Lacking similar facts, Lilly relies on attorney argument that unclaimed features of Ajovy and Emgality are responsible for the objective indicia. Br., 1. The Board should reject these unfounded and late arguments.

Lilly is also wrong that "Teva relied solely on the presumption." Br., 1. Teva demonstrated a direct nexus between objective indicia from a representative number of species and the challenged claims. EX2271, ¶127; EX2262, ¶¶21-26; EX2274, ¶20; EX2257, 5. Thus, Teva independently demonstrated nexus.

I. *Fox Factory* does not require a patentee to prove that all unclaimed features are "insignificant" to obtain a presumption of nexus.

Federal Circuit precedent is clear: while unclaimed features may *rebut* a presumption of nexus, their existence cannot *prevent a finding of* a presumption.

Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1393-94 (Fed. Cir. 1988); *Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1378 (Fed. Cir. 2000); *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 734, 747 (Fed. Cir. 2016). *Fox Factory* confirmed as much: "[t]he mere existence of one or more unclaimed features does not necessarily mean presuming nexus is inappropriate." *Fox Factory*, 944 F.3d at 1376.

Ignoring that the unclaimed features were "critical" in *Fox Factory*, Lilly fashions a new rule to hold that a presumption does not apply where "patentee failed to meet its burden of establishing that those unclaimed features were 'insignificant' to the [] products' functionality." Br., 2. *Fox Factory* includes no such holding. Moreover, it did not overturn decades of Federal Circuit precedent and place that burden on patentees. *Demaco*, 851 F.2d 1394 ("A patentee is not required to prove as part of its prima facie case that the commercial success of the patented invention is *not* due to factors other than the patented invention.").

In *Fox Factory*, the Court unambiguously stated that the "patentee's own assertions about the significance of the unclaimed features" were the basis for its finding of no coextensiveness. *Fox Factory*, 944 F.3d at 1375. Here, Teva has not made any such admissions, and does not have to prove that all unclaimed features of the products are "insignificant" to establish a presumption of nexus.

II. Ajovy and Emgality are coextensive[1] with the claims and Lilly's analysis vis-à-vis unclaimed features does not support finding otherwise.

Under *Fox Factory*, nexus is not presumed where a product's unclaimed features "materially impact[] the product's functionality" *and* are responsible for the objective indicia. *Fox Factory*, 944 F.3d at 1375. Lilly baldly asserts that "numerous [unclaimed] features" of Ajovy and Emgality are "responsible for Teva's alleged secondary considerations evidence."[2] Br., 1, 3-6. But Lilly relies purely on attorney argument, belatedly cobbling together cites from a record without any evidence that the features drive the objective indicia. Br., 1, 3-6. Thus, Lilly's assertion that Ajovy and Emgality are "not coextensive" with the challenged claims is baseless[3].

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[1] Teva did not state otherwise. OA (Nov. 22, 2019), 63:13-15. *Fox Factory* does not overrule the case law that a patentee can demonstrate nexus with a representative number of species. *In re Kao*, 639 F.3d 1057, 1069 (Fed. Cir. 2011).

[2] Lilly waived its opportunity to contest Teva's presumption of nexus because it failed to do so on Reply.

[3] *Celltrion v. Genentech* did not hold that a presumption never applies to a genus. IPR2017-01374, Paper 85 at 46 (PTAB Nov. 29, 2018). There, the claims challenged as obvious were directed "to specific antibodies with specific framework region substitutions" that admittedly "critically affect[ed]" antigen

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