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 IPR2018-01426
Patent 9,890,211

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

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Record evidence shows praise and success 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 demonstrates both a presumption of nexus and actual nexus to the challenged claims. POR, 51-52.

Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366 (Fed. Cir. 2019), does not disturb Teva's presumption. *Fox Factory's* holding of no presumption turned on the fact that unclaimed features were *both* material to a product's functionality *and* responsible for the objective evidence. Lilly provides no evidence that any unclaimed features of Ajovy and Emgality are responsible for the objective indicia. Instead, Lilly asserts that Ajovy and Emgality have different "unclaimed features" and are equally praised and successful. But this argument supports Teva's presumption because, unlike *Fox Factory*, no evidence shows that any one or combination of unclaimed features is responsible for the objective indicia. Thus, Teva is entitled to a presumption of nexus.

Lilly is also wrong that "Teva relied solely on the presumption." Lilly's Brief, 1. The opposite is true: Teva offered evidence, supported by expert testimony, that demonstrates nexus between objective indicia from a representative number of species—Ajovy, Emgality, and eptinezumab—and the challenged claims. EX2226, ¶114; EX2243, ¶20; EX2257, 5. For this additional reason, Lilly's arguments fail and Teva's nexus is sound.

I. Lilly's analysis misapplies the *Fox Factory* holding and actually supports a finding of presumption here.

Lilly wrongly argues that because Ajovy and Emgality have features that "'materially impact' their functionality but are not recited as limitations," Teva failed to satisfy the coextensiveness requirement."[1, 2] Lilly's Brief, 1. But Teva fully met its burden to show the presumption. POR, 51-52. Lilly's analysis under *Fox Factory* is incomplete and actually supports finding a presumption here.

In *Fox Factory*, the prior art chainrings were deficient in that chains were "susceptible to disengaging from the chainring." *Fox Factory*, 944 F.3d at 1369. SRAM's chainring products were successful due to their "ability to 'better retain the chain under many conditions.'" *Id.*, 1374-1375. The improved retention was admittedly due to four features: "forwardly protruding tooth tips," "hook features on the teeth," "mud-clearing recesses," and an "80% gap-filling feature," which was "critical" to the objective indicia. *Id.*, 1375-1376. Thus, not only did these

[1] Lilly does not dispute that the asserted objective evidence is tied to Ajovy, Emgality, and eptinezumab, or that these antibodies embody the claimed features.

[2] By arguing "no presumption" now, Lilly attempts to recast its Reply's "commensurate in scope" argument. Lilly's Brief, 3-6. But *Fox Factory* has not changed the law—it merely "reaffirmed and clarified" it. Lilly's Brief, 1. Lilly waived its opportunity to contest Teva's presumption of nexus.

features (i) materially impact the chainring's functionality, they also indisputably were (ii) responsible for the chainring's success. And the Court held that the chainrings were not co-extensive with claims that did not recite these features. *Id.*

Here, Lilly's argument and evidence stop well short of those in *Fox Factory*. Lilly points to no evidence that the asserted "unclaimed features"—sequences and mutations" and "pm-level binding affinity, antibody format, and antibody class"—are responsible for the praise for and success of Ajovy and Emgality. Lilly's Brief, 3-6. Thus, Lilly's assertion that *Fox Factory* applies here is wrong[3].

Moreover, Lilly's arguments that Ajovy and Emgality each have *different* "unclaimed features" but are both equally praised underscores the fact that differences in sequence, class, affinity, etc., do not drive the objective indicia. This squarely undercuts Lilly's argument and instead supports a presumption here.

Lilly also improperly argues that "[w]hen a product is covered by more than

[3] *Celltrion v. Genentech* did not mandate that a presumption never applies to a genus. IPR2017-01374, Paper 85 at 46 (PTAB Nov. 29, 2018). There, the claims were directed "to specific antibodies with specific framework region substitutions" that admittedly "critically affect[ed]" antigen binding. *Id.*, 6. But the objective indicia was associated with only *one* antibody having *one* claimed substitution. *Id.*, 46. Here, there is no such admission, and the objective indicia is not for only one antibody.

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