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 IPR2018-01712
Patent 9,884,908 B2

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

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Teva has presented strong objective evidence of nonobviousness of the challenged claims in multiple forms: widespread praise, long-felt need, unexpected results, and commercial acquiescence. POR, 55-63; Surreply, 27-29. And Teva's objective evidence is tied to the claimed methods of using humanized anti-CGRP antagonist antibodies, such as Ajovy® (fremanezumab; Teva), Emgality® (galcanezumab; Lilly), and Alder's eptinezumab (as yet unbranded), to treat migraine. "This showing—that the specific products are embodiments of the claimed invention and that the proffered objective evidence relates to these products—is sufficient to establish the presumption of nexus for the objective considerations." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1330 (Fed. Cir. 2016). Thus, Teva has met its burden in demonstrating a presumption of nexus.

Fox Factory does not change that. *Fox Factory, Inc. v. SRAM, LLC, 944* F.3d 1366 (Fed. Cir. 2019). *Fox Factory* did not create new law; it merely applied the long-standing law on presumption to a unique set of facts. *Id.* at 1373-1374. There, the commercial product included an unclaimed feature *that the patentee had admitted* was "critical:" it "materially impact[ed] the product's functionality" *and* was responsible for the objective indicia. *Id*. at 1375. Under those facts, the Court found that the commercial product was not coextensive with the challenged claims, even though it was "broadly cover[ed]" by the claims. *Id.* at 1376. Here, the record lacks any evidence of such an unclaimed, yet "critical," feature responsible for the

objective indicia, admitted or otherwise. Thus, *Fox Factory* does not apply.

Not solely relying on a presumption, Teva also offered evidence demonstrating nexus between the challenged claims and objective indicia from a representative number of species. EX2273, ¶123; EX2264, ¶¶21-26; EX2276, ¶20; EX2257, 5. For this additional reason, *Fox Factory*—where patentee relied solely on the presumption—is inapposite.

I. Teva is entitled to a presumption of nexus.

Teva met its burden and demonstrated that nexus should be presumed. POR, 54-55. Teva's objective evidence is tied to treating migraine with a humanized anti-CGRP antagonist antibody, and this *is* "the invention disclosed and claimed:" "The present invention relates to the use of anti-CGRP antagonist antibodies for the prevention, amelioration, or treatment of … migraine." *WBIP, LLC,* 829 F.3d at 1329; EX1001, 1:34-37; POR, 54-55; EX2264, ¶¶21-26; EX2273, ¶123; EX2276, ¶¶19-20, 23-24, 26; EX2257, 5. Thus, the methods that are the subject of the objective indicia here embody the claimed features and are coextensive[1] with

[1] Teva did not state otherwise during Oral Argument in IPRs 2018-01422, -01423, -01424, -01425, -01426, and -01427 when it answered the Board's claim scope question by describing Ajovy and Emgality as "a representative number of species within the [genus] claims." OA (Nov. 22, 2019), 63:13-15. *Fox Factory* did

them, and the presumption applies. *Fox Factory*, 944 F.3d at 1373.

Fox Factory does not control here because its finding that there was a lack of coextensiveness turned on the fact—absent here—that unclaimed features were *both* material to a product's functionality *and* responsible for the objective evidence. The commercial chainring that embodied the claims there was successful due to its "ability to 'better retain the chain under many conditions.'" *Id.* at 1373-1375. The improved retention was admittedly due to four unclaimed features: "forwardly protruding tooth tips," "hook features on the teeth," "mud-clearing recesses," and an "80% gap-filling feature," which was "critical." *Id.* at 1375-1376. Thus, not only did these unclaimed features materially impact the chainring's functionality, they also indisputably were responsible for the chainring's success.

In stark contrast, the record here is devoid of evidence that the success of the claimed methods derives from any critical, non-recited feature. The challenged claims are directed to methods of treating migraine with humanized anti-CGRP antagonist antibodies. And all of the objective indicia evidence here relates to the methods of treating migraine with humanized anti-CGRP antagonist antibodies

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not concern genus/species claims and 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).

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