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 SUPPLEMENTAL BRIEF REGARDING *FOX FACTORY, INC. V. SRAM, LLC*

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. Teva's presumption of nexus is sound. 2
II. Teva also has demonstrated nexus between the objective indicia and the challenged claims.. 6
III. Conclusion 7

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Teva has presented strong evidence of objective indicia of nonobviousness of the challenged claims in the form of widespread praise, long-felt need, unexpected results, and commercial acquiescence. All challenged claims recite humanized anti-CGRP antagonist antibodies. POR, 51-61; Surreply, 25-27. And Teva's evidence of objective indicia is tied to the humanized anti-CGRP antagonist antibody products Ajovy® (fremanezumab; Teva), Emgality® (galcanezumab; Lilly), and Alder's eptinezumab (as yet unbranded). The present record does not identify any critical, unclaimed features of these products that are responsible for any objective indicia that Teva has provided evidence of in this case. Rather, these products embody the claimed features (they are humanized anti-CGRP antagonist antibodies) and are coextensive with them. Thus, Teva is entitled to a presumption of nexus. The Federal Circuit's recent opinion in *Fox Factory* does not change that and in fact supports such a determination. *Fox Factory, Inc. v. SRAM, LLC*, 2019 WL 6884530, Case Nos. 2018-2024, -2025 (Fed. Cir. 2019).

As the Federal Circuit stated in *Fox Factory*, a presumption of nexus applies "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory*, *5. This is not new law. In *Fox Factory*, the Board erred by presuming nexus simply because the product at issue was "broadly covered" by the claims at issue. *Fox Factory*, *6-7. But, in *Fox* Factory, the commercial product

DOCKET
ALARM
Find authenticated court documents without watermarks at docketalarm.com.

included an unclaimed feature that the patentee had admitted was "critical," i.e., it "materially impact[ed] the product's functionality" and was responsible for the praise and success relied on as evidence of objective indicia: "the product's ability to 'better retain the chain under many conditions.'" *Id*. Thus, the commercial products were not coextensive with the challenged claims. *Id*. Here, in contrast, the record lacks any evidence of such an unclaimed, yet "critical" feature responsible for the objective indicia of nonobviousness. Thus, the products embodying Teva's claimed invention—humanized anti-CGRP antagonist antibodies—are coextensive with the claims, meaning that the presumption applies here.

Teva also offered evidence, supported by expert testimony, demonstrating nexus between the challenged claims and objective indicia from a representative number of species: Ajovy, Emgality, and Alder's eptinezumab. EX2226, ¶114; EX2243, ¶20; EX2257, 5. For this additional reason, *Fox Factory*—where patentee relied solely on the presumption—is inapposite.

I. Teva's presumption of nexus is sound.

Teva is entitled to a presumption of nexus. POR, 51-52. "[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016). Consistent with the law, Teva's objective

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

evidence is tied to three humanized anti-CGRP antagonist antibody products, which are "the invention disclosed and claimed." POR, 51-52; EX2226, ¶114; EX2237, ¶¶21-24; EX2243, ¶¶19-22, 25; EX2257, 5. Thus, the presumption applies.

To the extent that *Fox Factory* has further clarified the law of presumption, that clarification does not apply here because the facts on which *Fox Factory* was decided are entirely distinguishable. In *Fox Factory*, the product in question was a bicycle chainring. *Fox Factory*, *2. That chainring had four unclaimed features that the patentee admitted materially impacted the chainring's functionality—an "80% gap-filling feature," "forwardly protruding tooth tips," "hook features on the teeth," and "mud-clearing recesses." *Id.*, *6, 7. Of these, patentee admitted the "80%" feature was "critical" to the functionality that drove the objective indicia. *Id.* Not surprisingly, the Court thus found that the chainring was not coextensive with the independent claims. *Id.* Where the objective indicia evidence is that people praise and pay for a chainring with improved chain retention that is admittedly due to an "80% gap-filling feature," it would be incongruous for the praise and success of the chainring to be presumed to support nonobviousness of a patent that does not claim the touted "80% gap-filling feature." In other words, where a Patent Owner concedes that objective indicia are due to something other than the claimed invention, it is common sense that a nexus cannot be presumed.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | sales@docketalarm.com | 1-866-77-FASTCASE

fastcase®
Smarter legal research.