

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. IPR2018-01426
Patent No. 9,890,211 B2

**PETITIONER'S RESPONSE TO TEVA'S SUPPLEMENTAL BRIEF
REGARDING *FOX FACTORY, INC. v. SRAM, LLC***

Table of Contents

I. Teva Failed to Meet Its Burden of Establishing Coextensiveness..... 1

II. Teva Failed to Meet Its Burden of Showing Insignificance of
Unclaimed Features and Other Patents..... 1

III. Teva Failed to Establish Nexus 4

I. Teva Failed to Meet Its Burden of Establishing Coextensiveness

Fox Factory rejected changing the coextensiveness requirement to an analysis of whether a claim “cover[s]” products cited for secondary considerations. *Fox Factory v. SRAM, LLC*, 744 F.3d 1373, 1377 (Fed. Cir. 2019). Yet in its substantive briefing, Teva merely alleged that the claims “cover one or both of Ajovy[®] and Emgality[®]” without addressing coextensiveness, the broad scope of the claims, or the materiality of unclaimed features. POR, 51-52; Sur-reply, 25-26; Ex. 2226, ¶114.

Although Teva reaffirmed at the oral hearing that its position was that the claims “cover” the products and that the claims are *not coextensive*, Teva now contends that coextensiveness exists because Ajovy[®] and Emgality[®] “are humanized anti-CGRP antagonist antibodies” within the broad scope of the claims. Br., 1-2, 5; Paper 69, 63 (“Your Honor, I’m not saying they’re co-extensive”). This is a distinction without a difference, as Teva fails to address the incredible breadth of the claims or its many admissions that unclaimed features materially impact function.

II. Teva Failed to Meet Its Burden of Showing Insignificance of Unclaimed Features and Other Patents

Lilly identified multiple features encompassed by the claims but not recited as limitations that materially affect function—such as amino acid sequence, pM-level binding affinity, and antibody class. Reply, 21-24. Despite bearing the burden of establishing that unclaimed features are “insignificant,” *Fox Factory*, 944 F.3d at 1374-75, Teva offered *no response*. Sur-reply, 25-26.

Indeed, Teva fails to offer *any* evidence contradicting the universally understood principle that sequence is critical and dictates antibody function. Teva represented to the FDA that it introduced multiple specific mutations into Ajoovy[®]—out of more than 20²²⁰ possible mutations—to achieve pM-level binding affinity and eliminate ADCC and CDC. Ex. 1320, 8-9; Ex. 1142, 392 (mutating sequence to achieve “picomolar range” affinity can have “*profound effects* on the utility of antibodies as therapeutic and prophylactic agents”); Ex. 1301, 91:25-92:22. This is highly analogous to *Fox Factory*, where a patentee’s representations in its marketing materials confirmed lack of nexus due to unclaimed features. 944 F.3d at 1375-76. Emgality[®]’s specific sequence and resulting properties, with mutations to eliminate ADCC and CDC, were likewise highlighted to the FDA. Ex. 2216, 17, 21-22, 41.

Teva concedes that Ajoovy[®] and Emgality[®] have different sequences, but fails to support its baseless (and belated) assertion that sequence is insignificant to its secondary considerations evidence. Br., 4-5. Sequence matters: depending on their specific sequence, anti-CGRP antibodies within the broad scope of all challenged claims would have (1) binding affinity *orders of magnitude worse* than Ajoovy[®] and Emgality[®], (2) strong effector functions having the *undesired side effect of killing cells* (cytotoxicity), and/or (3) an antibody class *never successfully used before* in any FDA-approved antibody. Reply, 21-24; Ex. 1301, 34:9-35:1, 102:1-104:19; Ex. 1012, ¶¶167, 178-179. These unclaimed features would lead to materially different

properties (e.g., no efficacy or significant adverse events) as compared to Ajovy[®] and Emgality[®]. Reply, 21-24. Notably, even these antibodies have fundamentally different properties: Lilly's Emgality[®] is FDA-approved to treat cluster headache while Teva's Ajovy[®] failed clinically. Ex. 2153, 1.

Teva newly argues that antibodies with different sequences are “associated with the same praise.” Br., 4. But this alleged praise is directed to *only two* high-affinity, sequence-optimized antibodies (Ajovy[®] and Emgality[®]) and is not representative of the broad challenged claims.¹ See *AbbVie Deutschland GmbH v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1291-92, 1301 (Fed. Cir. 2014) (concluding that even *300 antibodies* do not represent a functionally defined genus). Moreover, the alleged praise extends to compounds *outside* the scope of the claims such as anti-CGRP *receptor* antibodies and small molecule inhibitors. Reply, 24-25. As Dr. Rapoport admitted, the *only* property he considered for nexus is the ability of antibodies to “block the CGRP pathway,” which is legally insufficient because this mechanism of action was already disclosed to treat migraine. Reply, 23-24; Ex. 1304, 142:1-8.

¹ Teva argued Alder only in the context of a license agreement. POR, 60-61. Teva's new arguments alleging praise and success for Alder's antibody should be rejected. *Cablz, Inc. v. Chums, Inc.*, 708 F. App'x 1006, 1011-12 (Fed. Cir. 2017).

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.