

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

NOVARTIS PHARMA AG,
NOVARTIS TECHNOLOGY LLC,
NOVARTIS PHARMACEUTICALS CORPORATION,
Patent Owner.

Case No. IPR2021-00816
U.S. Patent No. 9,220,631

**PETITIONER'S OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE**

TABLE OF CONTENTS

I.	PATENT OWNER’S MOTION TO EXCLUDE IS PROCEDURALLY IMPROPER	2
II.	THE BOARD SHOULD NOT EXCLUDE PARAGRAPHS 28-29 OF KOLLER’S REPLY DECLARATION.....	2
A.	Patent Owner Failed to Satisfy the Procedural Requirements to Seek Exclusion of Mr. Koller’s Testimony	2
B.	Paragraphs 28-29 of Mr. Koller’s Reply Declaration Properly Respond to Arguments Raised in Patent Owner’s Response.....	3
III.	DR. COHEN’S DECLARATION IS PROPER REPLY EVIDENCE TO PATENT OWNER’S RESPONSE.....	6
IV.	THERE IS NO PREJUDICE TO PATENT OWNER	10
V.	CONCLUSION.....	12

Patent Owner requests that the Board strike portions of the reply declaration of Mr. Horst Koller (Ex. 1105 at ¶¶ 28-29) and the entirety of the declaration of Dr. Joel Cohen (Ex. 1108) for allegedly being “outside the scope of proper reply.” Paper 101 at 4. Contrary to Patent Owner’s assertion, however, neither the Koller nor Cohen testimony at issue were necessary for Regeneron’s *prima facie* case of obviousness set forth in the Petition. Instead, the testimony at issue responds directly to argument in the Patent Owner Response (“POR”) that a POSITA would have been deterred from using a Parylene C coating in a PFS for intravitreal injection. Dr. Cohen’s testimony is also proper responsive testimony for the further reason that Patent Owner asserted a different level of ordinary skill in the art – that includes consulting with someone having “specialized skills” in toxicology – in its POR, which Regeneron could not have addressed with Dr. Cohen’s testimony in its earlier filed Petition. Patent Owner has failed to set forth a justification for the extraordinary relief it seeks from the Board because Regeneron was entitled to submit the testimony at issue to reply to the POR arguments. *Anacor Pharm., Inc. v. Iancu*, 889 F.3d 1372, 1380–81 (Fed. Cir. 2018) (“[T]he petitioner in an inter partes review proceeding may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner.”); *see also PTAB’s Consolidated Trial Practice Guide* (November 2019) at 80 (explaining that the exclusion of evidence “is an

exceptional remedy that the Board expects will be granted rarely.”).

I. PATENT OWNER’S MOTION TO EXCLUDE IS PROCEDURALLY IMPROPER

The proper procedure for addressing whether a reply raises new issues is to request authorization to file a motion to strike, not filing a motion to exclude.

Puzhen Life USA, LLC, v. Esip Series 2, LLC, IPR2017-02197, Paper 24 at 48 (PTAB February 27, 2019) (denying patent owner’s motion to exclude and noting that the proper procedure would have been to request authorization to file a motion to strike). Although Patent Owner emailed the Board on May 16, 2022 requesting authorization to submit a sur-reply declaration to respond to Mr. Koller and Dr. Cohen, Patent Owner did not seek authorization from the Board to strike any of Mr. Koller’s or Dr. Cohen’s testimony. Because Patent Owner never requested authorization to file a motion to strike, its belated attempt to do so now should be denied. *See id.* at 49 (declining to treat a motion to exclude as a motion to strike because patent owner did not request authorization).

II. THE BOARD SHOULD NOT EXCLUDE PARAGRAPHS 28-29 OF KOLLER’S REPLY DECLARATION

A. Patent Owner Failed to Satisfy the Procedural Requirements to Seek Exclusion of Mr. Koller’s Testimony

Patent Owner’s assertion that it satisfied the procedural requirements with respect to Mr. Koller’s testimony is incorrect. Pursuant to 37 C.F.R. § 42.64(c), Patent Owner was required to specifically identify the grounds for objecting to Mr.

Koller’s testimony in its objections to evidence served on April 22, 2022. *See* 37 CFR § 42.64(c) (“[A]ny objection *must* be filed within five business days of service of evidence to which the objection is directed. The objection *must identify the grounds for the objection with sufficient particularity.*”) (emphasis added).

Although Patent Owner objected to Dr. Cohen’s declaration as including “Improper New Evidence,” Paper 76 at 26, Patent Owner made no such objection with respect to paragraphs 28-29 of the Reply Declaration of Mr. Horst Koller (Ex. 1105). *See* Paper 76 at 20-22. As such, Patent Owner is foreclosed from moving to exclude any portion of Mr. Koller’s reply declaration on the basis of including improper reply evidence because it failed to make a timely objection as required by 37 C.F.R. § 42.64(c).

B. Paragraphs 28-29 of Mr. Koller’s Reply Declaration Properly Respond to Arguments Raised in Patent Owner’s Response

Even if the Board considers Patent Owner’s belated request, however, paragraphs 28-29 of Mr. Koller’s reply declaration should not be excluded because those paragraphs reply to evidence introduced by Patent Owner. Patent Owner is also incorrect in asserting that Mr. Koller’s testimony in paragraphs 28-29 is necessary for Petitioner’s case-in-chief. Paper 101 at 6.

The Petition set forth all the requisite argument and evidence to demonstrate a *prima facie* case that the claims of U.S. Patent No. 9,220,631 (“the ’631 Patent”) are obvious. This included demonstrating where in the prior art each claim

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.