

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

STEADYMED LTD.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION

Patent Owner.

Case IPR2016-00006

Patent No. 8,497,393

---

**PETITIONER'S REPLY IN SUPPORT OF  
PETITIONER'S MOTION TO EXCLUDE**

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

# TABLE OF CONTENTS

Page

I.	INTRODUCTION .....	1
II.	ARGUMENT .....	2
A.	Dr. Ruffolo must understand enough of the long-felt-need legal standard to have a reliable methodology.....	2
B.	Dr. Ruffolo's testimony showed that he did not understand what a long-felt but unsolved need was. ....	3
C.	All of Dr. Ruffolo's testimony concerned long-felt need.....	5

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>CASES</b>	
<i>DSU Med. Corp. v. JMS Co.</i> , 471 F. 3d 1293 (Fed. Cir. 2006).....	2
<i>Meds. Co. v. Mylan Inc.</i> , No. 11-CV-1285, 2014 WL 1227214 (N.D. Ill. Mar. 25, 2014).....	2
<b>OTHER AUTHORITIES</b>	
37 C.F.R. § 42.64(c).....	1

Petitioner, SteadyMed Ltd. ("Petitioner"), respectfully submits this reply in support of its Motion to Exclude Patent Owner's Evidence Pursuant to 37 C.F.R. § 42.64(c) ("Motion" or "Mot."), Paper No. 62.

## **I. INTRODUCTION**

Expert testimony must be excluded when an expert ignores the relevant legal standard in reaching his or her conclusion. Patent Owner does not dispute that Dr. Ruffolo was entirely unaware of the correct standard supporting his opinion on long-felt need. Rather, Patent Owner premises its Opposition on false grounds, arguing that Petitioner's Motion should be denied because "Petitioner does not attack Dr. Ruffolo's qualifications, the factual basis of his opinions, or the methodology employed, including its reliability." (Opp. at 1, 4). Patent Owner is wrong: because Dr. Ruffolo was unaware of the correct legal standard required to form his opinion, the factual basis of his opinion, his methodology, and his opinion are all unreliable, and should be excluded. Dr. Ruffolo was specifically asked by Patent Owner to opine whether there was a "long-felt, unmet need" that the '393 Patent satisfied; yet, Dr. Ruffolo had no understanding of the legal requirements to establish a long-felt, unmet need, and used the wrong facts and methodology. Accordingly, Dr. Ruffolo's opinions should be excluded.

## II. ARGUMENT

### A. **Dr. Ruffolo must understand enough of the long-felt-need legal standard to have a reliable methodology.**

Patent Owner premises its Opposition ("Opp." [Paper No. 66]) on its contention that there is no requirement that experts need to know the legal standard that inform their opinions because experts are not "required to be fluent in the law ...prior to making [their] opinions." (Opp. at 8). Numerous courts, however, have excluded expert testimony where, as here, an expert completely ignores the legal standard in reaching his or her conclusion. *See, e.g., Meds. Co. v. Mylan Inc.*, No. 11-CV-1285, 2014 WL 1227214, at \*5 (N.D. Ill. Mar. 25, 2014) ("Because Mr. Flammia applies the wrong legal standard regarding commercial success ... his methodology fails to comply with the law on commercial success. Accordingly, the Court strikes his opinions on commercial success because they are legally flawed and will not be helpful to the trier of fact."); *see also DSU Med. Corp. v. JMS Co.*, 471 F. 3d 1293, 1308 (Fed. Cir. 2006) (affirming exclusion of expert's "proffered methodology ... [because it] is not grounded on established legal principle and is far too remote factually to be within the line drawn for legally compensable patent injuries."). Any assertions to the contrary are wrong.

### B. **Dr. Ruffolo's testimony showed that he did not understand what a long-felt but unsolved need was.**

Patent Owner argues Petitioner "mischaracterizes" Dr. Ruffolo's testimony on the legal standards relating to secondary considerations, a "topic outside his

# 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.