

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

and

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-01117¹
Patent 8,642,012

**PETITIONERS' OPPOSITION TO
PATENT OWNER'S MOTION TO EXCLUDE EVIDENCE**

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

¹ Case IPR2015-00283, instituted on a petition filed by Lupin Ltd. and Lupin Pharmaceuticals, Inc., has been joined with this proceeding.

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	ARGUMENT.....	1
	A. Patent Owner's Motion to Exclude is an Improper Vehicle to Address the Permissible Scope of Testimony.....	1
	B. Patent Owner's Attempt to Exclude Testimony Regarding Dr. Sondheimer's Background and Experience and Exhibits 1031 and 1033 is Unreasonable.	3
	C. Dr. Sondheimer's Testimony Regarding the Definition of a Person of Ordinary Skill in the Art is Proper.....	5
	D. Patent Owner Should Not be Allowed to Complain about Dr. Sondheimer's Testimony Regarding the Instituted Prior Art.	5
	1. <i>Fernandes</i>	6
	2. <i>Blau</i>	7
	3. <i>Typical gelatin capsule volume, density and dosage of sodium phenylbutyrate in Brusilow '91</i>	8
	E. Patent Owner's Bid to Disqualify Testimony as to the Relevant Time Period for a POSA's Evaluation of Prior Art is Improper.....	8
III.	CONCLUSION.....	9

I. INTRODUCTION

Patent Owner's motion to exclude should be denied because it is both procedurally and substantively flawed. As to the former, the Board has consistently held that a motion to exclude is not the proper mechanism to argue whether new arguments have been raised. Yet Patent Owner seeks to exclude certain testimony of Petitioners' expert, Dr. Neal Sondheimer, and exhibits used during his deposition because such evidence is allegedly beyond the scope of his cross-examination testimony. Notwithstanding Patent Owner's procedural failure that such arguments are improperly raised in a motion to exclude, the disputed evidence should not be excluded because Dr. Sondheimer's deposition testimony and reliance on certain exhibits respond to topics and, in some cases, the exact same questions Patent Owner's counsel raised during cross-examination. Accordingly, the Board should deny Patent Owner's Motion to Exclude.

II. ARGUMENT

A. Patent Owner's Motion to Exclude is an Improper Vehicle to Address the Permissible Scope of Testimony.

The Board has repeatedly and consistently held that a motion to exclude is not the proper vehicle for a party to raise the issue of permissible scope of testimony. *See Vibrant Media Inc. v. General Electric Co.*, No. IPR2013-00170, slip op. at 31, 2014 WL 2965703 at *19 (P.T.A.B. June 26, 2014); *see Lib. Mut.*

IPR2015-01117
Patent No. 8,642,012
Petitioners' Opp. to PO's Motion to Exclude

Ins. Co. v. Progressive Cas. Ins. Co., No. CBM2012-00004, 2014 WL 2213411 at *27 (P.T.A.B. Feb. 11, 2014) (holding that a motion to exclude is not the vehicle to argue whether new arguments have been raised); *see also ABB Inc. v. Roy-G-Biv Corp.*, No. IPR2013-00063, Paper 71 at 13-14 (P.T.A.B. Aug. 1, 2014). Instead, a motion to exclude, for example, must state why the evidence is inadmissible (e.g., based on relevance or hearsay). *See Vibrant Media Inc.*, No. IPR2013-00170, slip op. at 31.

Here, Patent Owner seeks to exclude certain deposition testimony and exhibits used at Dr. Sondheimer's deposition based on the allegation that such evidence exceeded the scope of Dr. Sondheimer's cross-examination testimony. Patent Owner makes no claim of inadmissibility of such evidence under the Federal Rules of Evidence. As noted above, a motion to exclude is not the proper vehicle for a party to raise the issue of permissible scope of testimony.² Patent Owner, therefore, wastes the Board's and Petitioners' resources by improperly raising these issues in a motion to exclude. Patent Owner's motion to exclude should be denied for at least this reason.

² As Patent Owner concedes, Petitioner has not attempted to rely upon the evidence sought to be excluded. (Paper 36 at 2.) As such, Patent Owner's request to exclude such evidence is further improper because it is premature at best.

Notwithstanding the foregoing, the testimony of Dr. Sondheimer and exhibits sought to be excluded do not exceed the scope of evidence permitted by reply. As discussed below, such evidence is directly responsive to Patent Owner's cross-examination questioning.

B. Patent Owner's Attempt to Exclude Testimony Regarding Dr. Sondheimer's Background and Experience and Exhibits 1031 and 1033 is Unreasonable.

Patent Owner seeks to exclude Dr. Sondheimer's testimony about his qualifications and experience treating UCD patients as well as his updated curriculum vitae (Exhibit 1031). (Paper 36 at 4-5, 13.) But Dr. Sondheimer discussed his background and qualifications in his declaration (*See* Exhibit 1002 at ¶¶ 8-14.) And during his cross examination, Patent Owner's counsel questioned Dr. Sondheimer regarding his declaration and his experience treating UCD patients. (*See, e.g.*, Exhibit 2012 at 4:14-5:10, 19:17-25, 20:2-10, 24:7-13, 128:23-129:6.) Indeed, Exhibit 1033, is a prior art publication, cited in Dr. Sondheimer's declaration in support of the petition (Exhibit 1002 at ¶ 12), where he managed and treated patients with urea cycle disorders using ammonia scavenging drugs based on that patient's fasting ammonia level. Exhibit 1033 is background prior art reflecting the state of the art at the time. Therefore, Dr. Sondheimer's testimony

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.