

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.
Petitioner,

v.

HORIZON THERAPEUTICS, INC.
Patent Owner

Case IPR2016-00829
Patent 9,095,559 B2

**PETITIONERS' OBJECTIONS TO EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64**

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

Petitioners Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”) hereby object pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence (“FRE”) to the admissibility of certain purported evidence served by Patent Owner’s Horizon Therapeutics, Inc. on February 10, 2017 in connection with its Response to Lupin’s Petition for *Inter Partes* Review of U.S. Patent No. 9,095,559 (“the ’559 patent”). The exhibits objected to, and grounds for Lupin’s objections, are listed below. Lupin also objects to Patent Owner’s reliance on or citations to any objected evidence in its papers.

Some of the exhibits served by Horizon Therapeutics, Inc. on February 10, 2016 were introduced during the deposition of Keith Vaux in this proceeding, and Lupin objected to those exhibits at the deposition as required by 37 C.F.R. § 42.64(a). Nothing contained herein shall be deemed to withdraw any of Lupin’s objections to deposition evidence or the requirement that evidence to cure those objections must have been provided during the deposition.

I. IDENTIFICATION OF CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS

A. Exhibit 2001

Lupin objects to Exhibit 2001 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2001 is a litigation document which bears no relevance to the issue of patentability of the ’559 patent claims.

Lupin further objects to Exhibit 2001 under FRE 802 because it is inadmissible hearsay, specifically a complaint in a district court litigation, *Horizon Therapeutics, Inc. v. Lupin Ltd.*, 1:15-cv-07624-RBK-JS (D.N.J.). Lupin also objects to Exhibit 2001 under FRE 901 on the basis that it has not been properly authenticated and lacks foundation.

B. Exhibit 2002

Lupin objects to Exhibit 2002 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2002 is a litigation document which bears no relevance to the issue of patentability of the '559 patent claims. Lupin further objects to Exhibit 2002 under FRE 802 because it is inadmissible hearsay, specifically an amended complaint in a district court litigation, *Horizon Therapeutics, Inc. v. Lupin Ltd.*, 1:15-cv-07624-RBK-JS (D.N.J.). Lupin also objects to Exhibit 2002 under FRE 901 on the basis that it has not been properly authenticated and lacks foundation.

C. Exhibit 2003

Lupin objects to Exhibit 2003 as incomplete. It should therefore be excluded under FRE 106 and 403.

D. Exhibit 2004

Lupin objects to Exhibit 2004 as incomplete. It should therefore be excluded under FRE 106 and 403.

E. Exhibit 2005

Lupin objects to Exhibit 2005 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2005 is a litigation document served by Par Pharmaceuticals, Inc. in a different proceeding regarding different patents, and therefore bears no relevance to the issue of patentability of the '559 patent claims. Lupin further objects to Exhibit 2005 under FRE 802 because it is inadmissible hearsay, specifically a non-party's invalidity and non-infringement contentions in an unrelated district court litigation, *Horizon Therapeutics, Inc. v. Par Pharmaceuticals, Inc.*, C.A. No. 2:14-cv-00384-JRG-RSP (E.D. Tex). Lupin also objects to Exhibit 2005 under FRE 901 on the basis that it has not been properly authenticated and lacks foundation. Lupin further objects to Exhibit 2005 as incomplete because it contains only certain portions of Par Pharmaceutical's Invalidity and Non-infringement Contentions, and should therefore be excluded under FRE 106.

F. Exhibit 2006

Lupin objects to Exhibit 2006, the declaration of Dr. Gregory M. Enns, under FRE 402 to the extent that it includes or relies on irrelevant or inadmissible information and under FRE 403 to the extent that it includes or relies on information that probative value of which is substantially outweighed by the danger of unfair prejudice, wasting time, or needlessly presenting cumulative evidence as set forth herein. Lupin further objects to Exhibit 2006 under FRE 901 on the basis that it cites or relies on exhibits that have not been properly authenticated or lack foundation, as set forth herein.

G. Exhibit 2012

Lupin objects to Exhibit 2012 under FRE 402 and 403 because it is irrelevant and its probative value is substantially outweighed by the danger of wasting time in this compressed proceeding. Exhibit 2012 was published in 2012 and, therefore, bears no relevance to what the person of ordinary skill in the art would have known by the relevant date, Sept. 30, 2011. Therefore, Exhibit 2012 should be excluded under FRE 402 and 403. Lupin further objects to Exhibit 2012 under FRE 802 on the basis that it is inadmissible hearsay, not within a hearsay exception.

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.