

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

PAR PHARMACEUTICAL, INC.,  
Petitioner,

v.

HORIZON THERAPEUTICS, LLC,  
Patent Owner.

---

Case IPR2017-01767  
Patent 9,254,278

---

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

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

Petitioner Par Pharmaceutical, Inc. (“Par”) hereby objects pursuant to 37 C.F.R. § 42.64(b)(1) to the admissibility of certain exhibits submitted by Patent Owner Horizon Therapeutics, LLC (“Patent Owner”) on November 6, 2017 in connection with Patent Owner’s Preliminary Response (“Preliminary Response,” Paper No. 7) to Par’s Petition for *Inter Partes* Review of U.S. Patent No. 9,254,278 (“the ’278 patent”).

Par’s objections to the admissibility of exhibits submitted with Patent Owner’s Preliminary Response are made in accordance with the Federal Rules of Evidence (“FRE”). Par’s objections are also made pursuant to the Code of Federal Regulations (“C.F.R.”) governing this proceeding, including without limitation 37 C.F.R. §§ 42.61-42.65 and § 42.6(a)(3).

I. THE CHALLENGED EVIDENCE AND GROUNDS FOR OBJECTIONS

A. Exhibit 2002

Par objects to Exhibit 2002 on the grounds of completeness and authenticity to the extent Exhibit 2002 was neither certified nor submitted with an attestation of completeness and accuracy. FRE 106, 901, 902. Par also objects to Exhibit 2002 under FRE 802 as inadmissible hearsay, and is not within a hearsay exception, to the extent it or any of its contents are offered for the truth of the matter asserted. Furthermore, Par 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.

B. Exhibit 2004

Par objects to Exhibit 2004 on the ground that it was not cited in the Preliminary Response, and is therefore irrelevant (FRE 402) and a waste of time (FRE 403), as uncited evidence may not be incorporated by reference.

37 C.F.R. § 42.6(a)(3).

C. Exhibit 2005

Par 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 in a different proceeding regarding different patents, and therefore bears no relevance to the issue of patentability of the '278 patent claims. Par also objects to Exhibit 2005 under FRE 901 and 902 on the basis that it has not been properly authenticated and lacks foundation. Par further objects to Exhibit 2005 as incomplete because it contains only certain portions of Par's Initial Invalidity Contentions and Non-Infringement Contentions, and should therefore be excluded under FRE 106. Moreover, Par objects to Exhibit 2005 under FRE 802 as inadmissible hearsay, and is not within a hearsay exception, to the extent it or any of its contents are offered for the truth of the matter asserted.

D. Exhibit 2006

Par objects to Exhibit 2006 under FRE 402 to the extent it includes or relies on irrelevant or inadmissible information and under FRE 403 to the extent that it includes or relies on information whose probative value of which is substantially outweighed by the danger of unfair prejudice, wasting time, or needlessly presenting cumulative evidence as set forth herein. Par 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. Moreover, Par objects to Exhibit 2006 under FRE 802 as inadmissible hearsay, and is not within a hearsay exception, to the extent it is being offered for the truth of any matter asserted therein.

Exhibit 2006 is also inadmissible expert evidence. FRE 702, 703. The opinions expressed in Exhibit 2006 are not “based on sufficient facts or data” or “the product of reliable principles and methods.” FRE 702. For example, Exhibit 2006 relies on unsupported and conclusory statements relating to plasma ammonia levels. FRE 702, 703. Exhibit 2006 misinterprets the prior art references and provides statements that are unsupported by the prior art. (*See e.g.*, Exhibit 2006, ¶¶ 68, 95.) Moreover, Exhibit 2006 relies on alleged facts that have no support in the record. (*See e.g., id.* at ¶ 104.) In addition, Exhibit 2006 fails to “reliably appl[y] the principles and methods to the facts of the case.” FRE 702,

703. For at least these reasons, Exhibit 2006 is not based on sufficient facts or reliable methods and does not fit the facts presented in this proceeding. Par also objects to Exhibit 2006 for failure to comply with 37 C.F.R. § 42.51 to the extent Patent Owner has not served relevant information that is inconsistent with a position advanced in Exhibit 2006 concurrent with its filing. Par further objects to Exhibit 2006 for failure to comply with 37 C.F.R. § 42.65 to the extent it relies on underlying facts or data that have not been disclosed or that have not been cited in the Preliminary Response.

E. Exhibit 2007

Par objects to Exhibit 2007 under FRE 802 because it is inadmissible hearsay that is not within a hearsay exception. In addition, Par objects to Exhibit 2007 under FRE 402 because it lacks relevance to any issue in this proceeding and does not itself set forth any “evidence” supporting the Preliminary Response.

F. Exhibit 2010

Par objects to Exhibit 2010 on the ground that it was not cited in the Preliminary Response, and is therefore irrelevant (FRE 402) and a waste of time (FRE 403), as uncited evidence may not be incorporated by reference. 37 C.F.R. § 42.6(a)(3).

# 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.