

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case IPR2017-01769
Patent 9,326,966

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

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U.S. Patent and Trademark Office
P.O. Box 1450
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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. 9,326,966 (“the ’966 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 2001

Par objects to Exhibit 2001 on the grounds of completeness and authenticity to the extent Exhibit 2001 was neither certified nor submitted with an attestation of completeness and accuracy. FRE 106, 901, 902. Par also objects to Exhibit 2001 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.

B. 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.

C. Exhibit 2003

Par objects to Exhibit 2003 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).

D. 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).

E. 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 '966 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.

F. 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, ¶¶ 67, 94.) Moreover, Exhibit 2006 relies on alleged facts that have no support in the record. (*See e.g., id.* at ¶ 103.) 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.

G. Exhibit 2007

Par objects to Exhibit 2007 under FRE 802 because it is inadmissible

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