

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.
Petitioners,

v.

HORIZON THERAPEUTICS, LLC
Patent Owner

Case IPR2017-01159
Patent 9,254,278

**PETITIONERS' REPLY IN SUPPORT OF ITS
MOTION TO EXCLUDE EVIDENCE**

I. Exhibit 2019 Should Be Excluded Because It Is Not Prior Art

Horizon does not dispute that the Häberle reference, Ex. 2019, was published many months after the September 2011 priority date of the '278 patent, and is not itself prior art. (Paper 31 at 2.) It argues, however, that Ex. 2019 is relevant because development of the guidelines referenced in Häberle occurred between October 2008 and August 2011. (*Id.*) While a later publication can be used as evidence of the state of the art existing as of a patent's priority date, the purported fact that these guidelines were *in development* prior to the filing date of the '278 patent does not demonstrate that the guidelines themselves were part of the state of the art as of the priority date. A POSA would not have known about these guidelines until they were published. The testimony of Dr. Enns regarding the relevance of the Häberle reference is conclusory (Ex. 2006 at ¶ 109) and Horizon has provided no other evidence to show that a POSA knew or could have known of these guidelines prior to the priority date of the '278 patent. Therefore, Ex. 2019 is irrelevant under FRE 402/403, as it is neither prior art nor evidence of the "state of the art" available to a POSA at the priority date of the '278 patent.

For this reason and the reasons presented in Lupin's motion, the Board should exclude Ex. 2019.

II. The Board Should Exclude Portions of Dr. Enns's Declaration that Rely on Ex. 2019

The Board should also exclude portions of Dr. Enns's Declaration to the extent they rely on Ex. 2019. Horizon argues that Dr. Enns does not rely on Ex. 2019 to prove the state of the art, but rather as additional support for his opinions. (Paper 31 at 6-7.) This argument is unavailing. Dr. Enns's testimony purportedly relates to the practices of POSAs as of the priority date of the patent, and thus the purpose of his reliance on Ex. 2019 is to demonstrate the alleged state of the art. For example, in ¶¶ 95 and 112 of his declaration, Dr. Enns relies on Ex. 2019 to opine on the state of the art. (Ex. 2006 at ¶¶ 95, 112.) Because Ex. 2019 is post-art and not indicative of the prior art, the portions of Dr. Enns' declaration that rely on Ex. 2019 to address the state of the art should also be excluded under FRE 402/403.

For this reason and the reasons presented in Lupin's motion, the Board should exclude portions of Dr. Enns's Declaration to the extent they rely on Ex. 2019.

III. The Board Should Exclude Ex. 2041

Horizon does not dispute that the RAVICTI label, Ex. 2041, was published years after the September 2011 priority date of the '278 patent, and is not itself prior art. (Paper 31 at 8-9.) To avoid the implications of this fact, Horizon tries to

recast its reliance on this document as merely cumulative of an undisputed fact set forth in the '859 Publication (Ex. 1007). (*Id.*) However, examination of Horizon's reliance on this document reveals that in connection with its arguments about motivation to combine, it in fact seeks to rely on the FDA-approved indications of RAVICTI. (Paper 19 at 43.) But RAVICTI itself was not approved until years after the priority date at issue here, and nothing in Exhibits 2041 or 1007 say differently. Accordingly, Horizon improperly uses this post-art document in an attempt to undercut motivation to combine, but a POSA would not have been aware of the indications of RAVICTI as of the priority date of the '278 patent.

For this reason and the reasons presented in Lupin's motion, the Board should exclude Ex. 2041.

IV. Conclusion

For the reasons herein and the reasons presented in Lupin's motion, Lupin respectfully requests that the Board grant its Motion to Exclude, and exclude Exhibits 2019 and 2041, as well as portions of Ex. 2006, to the extent they rely on Ex. 2019.

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Respectfully submitted,
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