

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MARINUS PHARMACEUTICALS, INC.,
Petitioner,

v.

OVID THERAPEUTICS INC.,
Patent Owner.

Case PGR2023-00020
Patent 11,395,817 B2

**PATENT OWNER'S REPLY
IN SUPPORT OF ITS MOTION TO EXCLUDE**

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I. INTRODUCTION

The Board should exclude Marinus Exhibits 1013, 1014, 1015, 1033, 1058, and 1060.

II. EXHIBITS 1013 AND 1014 SHOULD BE EXCLUDED

Petitioner argues that Exhibits 1013 and 1014 are highly relevant because they are 35 U.S.C. § 102(a) prior art. Opp. at 1. Petitioner misconstrues Patent Owner’s arguments. *Because* Petitioner has failed to show that Exhibits 1013 and 1014 are prior art (as Patent Owner argues in its brief, *see* Response at 61-65), they are irrelevant, highly prejudicial, and should be excluded.

Petitioner further argues that Exhibits 1013 and 1014 have been properly authenticated by the Saporito Declarations, Exhibits 1015 and 1033. Opp. at 2-4. For the reasons explained in Patent Owner’s Motion to Exclude (MtE at 4-5), and further explained below, the Saporito Declarations are themselves inadmissible and therefore insufficient to authenticate Exhibits 1013 and 1014. And, even if the Saporito Declarations are admissible, they cannot properly authenticate Exhibits 1013 and 1014 because there is insufficient support for the conclusory statements relied upon for authentication. Petitioner has not “produce[d] evidence sufficient to support a finding that the item is what the [Petitioner] claims it is.” FRE 901(b)(1).

Finally, Petitioner again argues that Patent Owner challenges the sufficiency of the evidence rather than admissibility under FRE 801/802. Opp. at 4-5. This is

false. Petitioner does, in fact, attempt to rely on Exhibits 1013 and 1014 for the truth of statements contained therein. *See* Petition at 50-57. Because of this, and as further explained in Patent Owner’s motion (MtE at 5), Exhibits 1013 and 1014 should be excluded.

III. EXHIBITS 1015 AND 1033 SHOULD BE EXCLUDED

Petitioner asserts that Patent Owner’s motion to exclude Exhibits 1015 and 1033 “is simply an attempt to keep the Board from considering highly relevant evidence as to the status of the Saporito Posters as prior art.” Opp. at 5. But Patent Owner’s arguments are that the deficiencies in Exhibits 1015 and 1033, including as explained below, render them irrelevant and prejudicial (and fatal to the status of Saporito Posters as prior art, as explained above). *See* MtE at 6-8.

Petitioner asserts without support that the details and facts presented in Exhibits 1015 and 1033 are sufficient to satisfy FRE 602. Opp. at 6. But as explained in Patent Owner’s motion, the evidence demonstrates that there is *not* sufficient support to find that Dr. Michael Saporito has personal knowledge of the subject matter to which he is testifying. *See* MtE at 7. Petitioner discounts Dr. Saporito’s deficiencies as “relate[d] to recollection of very specific details seven years [after the relevant events],” but those events seven years ago are the events critical to determining whether Exhibits 1013 and 1014 are prior art. Based on the record, as

described in Patent Owner's motion to exclude, Exhibits 1015 and 1033 fail to satisfy FRE 602.

In arguing that Exhibits 1015 and 1033 are admissible under FRE 801/802, Petitioner ignores the deficiencies in Dr. Saporito's declarations and testimony, including where he relied on documents to supplement his own recollection. *See* MtE at 7-8 (citing Dr. Saporito's deposition transcript). These deficiencies in Dr. Saporito's testimony make them hearsay subject to exclusion under FRE 801/802.

IV. EXHIBITS 1058 AND 1060 SHOULD BE EXCLUDED

Petitioner asserts that because Patent Owner's objections are to the content of Exhibits 1058 and 1060, those exhibits satisfy FRE 702(a). *Opp.* at 8. But again, Petitioner misconstrues Patent Owner's arguments. *Because* the contents of Exhibits 1058 and 1060 are deficient and irrelevant they are therefore unhelpful to the trier of fact and do not satisfy FRE 702(a). Dr. Baughman's models are irrelevant to the claims at issue and it is unclear based on the declarations themselves how they even support Petitioner's arguments for which they are relied upon. *See* MtE at 9-10; Sur-reply at 15-17. Therefore, they should be excluded under FRE 702(a).

For the same reasons, Exhibits 1058 and 1060 are irrelevant, prejudicial, confusion, *and* a waste of time and should be excluded under FRE 401, 402, and 403. Petitioner again asserts that this is a sufficiency argument rather than an

admissibility argument. But the insufficiency of the exhibits makes them inadmissible because they are irrelevant, confusing, and a waste of time.

Petitioner argues that because Dr. Baughman included “some” of the pharmacokinetic information in her declarations, Exhibits 1058 and 1060 satisfy FRE 702(b), (c), and (d). But Dr. Baughman’s declarations fail to disclose *all* of the data, meaning that her models and testimony cannot be replicated, confirmed, or otherwise tested. Without this data, neither Patent Owner nor the Board are able to determine if Dr. Baughman’s declarations are based on sufficient facts or data, are the product of reliable principles and methods, or reflect a reliable application of the principles and methods to the facts of the case. Therefore, Exhibits 1058 and 1060 should be excluded under FRE 702(b), (c), and (d).

Petitioner also argues that Exhibits 1058 and 1060 cannot be hearsay because Patent Owner has not challenged the admissibility of the data underlying Dr. Baughman’s models. But Petitioner’s argument is nonsensical. The data underlying Dr. Baughman’s models has not been provided and only a fraction of the parameters used by Dr. Baughman have been provided in her declarations, which are being challenged as inadmissible. Thus, Patent Owner is challenging the admissibility of some of the data but cannot challenge the admissibility of other data because it has not been provided. Additionally, Petitioner asserts without support that the data Dr. Baughman relies upon is “data upon which experts in the field would reasonably

rely.” Opp. at 13. But neither Petitioner nor Dr. Baughman has established such a showing. Therefore, Exhibits 1058 and 1060, and the data upon which they rely, should be excluded under FRE 801/802. *See Wi-LAN Inc. v. Sharp Elecs. Corp.*, 992 F.3d 1366, 1374-76 (Fed. Cir. 2021).

Finally, Petitioner argues that Dr. Baughman disclosed the underlying facts and data on which her models are based. As explained above, this is false and therefore cannot support Petitioner’s argument. Exhibits 1058 and 1060 should therefore be excluded under 37 C.F.R. § 42.65(a).

V. CONCLUSION

Patent Owner respectfully requests that the Board exclude the entirety of Exhibits 1013, 1014, 1015, 1033, 1058, and 1060.

Respectfully submitted,

Dated: May 13, 2024

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Reply in Support of Its Motion to Exclude** was served electronically via email on May 13, 2024, to counsel of record for the petitioner at the following:

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Petitioner has consented to electronic service by email.

Dated: May 13, 2024

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