

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Case IPR2021-00406
Patent 10,716,793

PATENT OWNER'S MOTION TO EXCLUDE

I. INTRODUCTION

Under 37 CFR § 42.64(c), United Therapeutics Corporation (“UT”) moves to exclude all or parts of the following exhibits:

Exhibit	Description	Reason to Exclude
EX1037	English translation of OptiNeb® User Manual 2005	Hearsay; Lack of authentication; Lack of relevance; Lacks original writing
EX1087	Butler Affidavit	Lack of personal knowledge & relevance
EX1112 (partial)	Reply Declaration of Sylvia Hall-Ellis, Ph.D.	Testimony not based on sufficient facts or analysis
EX1114	American Heart Association 2004 Online Archive	Hearsay
EX1117	Voswinckel JAHA Supplement PubMed Search Results	Hearsay
EX1120	Voswinckel JESC Web of Science Search Results	Hearsay
EX1029	Ventavis® Label 2004	Lack of authentication
EX1050	Pulmozyme® Label	Lack of authentication
EX1066	AccuNeb® Label	Lack of authentication
EX1074	Orenitram® Label	Lack of authentication
EX1078	Azmacort® Label 2003	Lack of authentication

Petitioner relied on these exhibits in its Petition and/or Reply. The Petition cites EX1037 (Paper 2 at 23) and the Reply cites EX1037 (Paper 44 at 12, 15) and EX1087 (*id.*, 14). EX1029 was cited throughout the Petition and Reply. *E.g.*, Paper 2 at 17; Paper 44 at 22, 24. The Reply also cites EX1050 (Paper 44 at 12) and heavily relies on EX1112, which in turn cites to EX1114, EX1117, and EX1120 (*id.* at 1-9, 8n.5, 14). UT moves to exclude these portions of the Petition and Reply.

Petitioner's experts, Drs. Nicholas Hill and Igor Gonda, also rely on EX1037

(EX1002 at ¶¶34, 67, FN3, 161, 172), EX1029 (EX1002 at ¶¶36, 41, 42; EX1004 at ¶¶33, 56, 59, 51, 92, 104, 108, 131), EX1050 (EX1004 at ¶56), EX 1066 (EX1004 at ¶56), EX1074 (EX1004 at ¶136), and EX1078 (EX1002 at ¶119). UT moves to exclude these portions of EX1002 and EX1004.

II. PATENT OWNER TIMELY OBJECTED

A. EX1037: English translation of OptiNeb® User Manual 2005

UT timely objected to EX1037 under Federal Rule of Evidence (“FRE”) 802, 402, 403, 901, and 902. Paper 20 at 6-7.

B. EX1087: Butler Affidavit

EX1087 was served as supplemental evidence in an attempt to address UT's objections to EX1037, but it fails to remedy them. UT timely objected to EX1087 under FRE 602, 401, 402, and 403. Paper 46 at 2-3. Petitioner did not serve any supplemental evidence in response.

C. EX1112: Reply Declaration of Sylvia Hall-Ellis, Ph.D. and Supporting Exhibits 1114, 1117, 1120

UT timely objected to EX1112 under FRE 702 and to supporting Exhibits EX1114, EX1117, and EX1120 under FRE 802. Paper 46 at 6-11. Petitioner did not serve any supplemental evidence in response.

D. EX1029: Ventavis® Label 2004

UT timely objected to EX1029 under FRE 901 and 902. Paper 20 at 8.

Petitioner served supplemental evidence in an attempt to address the objections, but it fails to address the deficiencies.

E. EX1050, 1066, 1074, 1078: Various Labels

UT timely objected to EX1050, EX1066, EX1074, and EX1078 under FRE 402, 403, 901 and 902. Paper 20 at 7-8. Petitioner did not serve any supplemental evidence in response.

III. ARGUMENT

A. EX1037 Should Be Excluded

EX1037, which purports to be an English translation of an undated¹ German-language user manual for an OptiNeb® device, should be excluded as falling woefully short of evidentiary standards. Petitioner has offered a translation without the underlying German language document or competent testimony to authenticate it. FRE 901-902. Even if Petitioner had properly authenticated EX1037, it is being offered for the truth of the matter asserted—how specific devices operated in a specific time period and what would have been known to a

¹ Petitioner identifies it as a “2005” document in its exhibit list, but no such date is present on the document, nor does the accompanying translator declaration indicate any date or source for the document.

person of ordinary skill in the art—and Patent Owner has not proven that it falls into any hearsay exception. FRE 802-807. Additionally, even if EX1037 was authenticated and not hearsay (or excepted from the rule), EX1037 is irrelevant and unfairly prejudicial because it is being used to show the state of the prior art while lacking any verifiable publication date. FRE 402-403. Finally, EX1037 is not an original writing and genuine questions regarding its authenticity and the circumstances of its production make it unfair to admit. FRE 1001-1003.

In response to UT's objection, Petitioner submitted EX1087 as supplemental evidence, but as discussed below, EX1087 does not cure the deficiencies or address the objections to EX1037.

1. EX1037 Constitutes Hearsay under FRE 802

The Petition relies on EX1037 for the truth of the matter asserted directly (Paper 2 at 23) and indirectly through the Hill declaration as alleged evidence that a nebulizing rate of 0.6 mL/min and “pulsed ultrasonic nebulizer[s]” were known in the prior art (Paper 2 at 23-24, 59). The Reply similarly relies on EX1037 (Paper 44 at 12, 14-15, n.10). Each of these assertions is hearsay.

Petitioner could have provided a translator declaration to identify which German document was translated, but it failed to do so. Rather, the declaration appended to EX1037 states it is a translation of “a user manual for OPTINEB®-ir,”

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