UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,
Patent Owner.

Case IPR2020-00770
Patent 9,604,901

PATENT OWNER'S MOTION TO EXCLUDE

I. INTRODUCTION

United Therapeutics Corporation ("UT") moves to exclude Petitioner's Exhibits 1002 and 1012 under 37 C.F.R. § 42.64(c) and the Scheduling Order (Paper 8) on the following grounds:

Exhibit	Description	Reason to Exclude
EX1002	Declaration of Jeffrey D. Winkler, Ph.D. (in its entirety)	Not authenticated; hearsay; not reliable
EX1012	Kawakami (JP 56 –122328 A)	Not authenticated; no verified translation

Petitioner relied on these exhibits in its Petition (Paper No. 1) and Petitioner's Reply (Paper No. 15), and thus, Patent Owner also moves to exclude the portions of Petitioner's Petition and Reply that rely on these exhibits.

II. PATENT OWNER TIMELY OBJECTED

A. EX1002: Winkler Declaration

UT timely objected to EX1002 under Federal Rule of Evidence ("FRE") 701, 702, 802, 901, and 902. Paper 10, 2-3. This exhibit should be excluded under each of these rules. No supplemental evidence was timely filed to address these objections.

B. EX1012: Kawakami (JP 56 –122328 A)

UT timely objected to EX1012 under FRE 402, 403, 802, 803-807, 901, 902, 1001-1003, 1012. Paper 10, 2-3. This exhibit should be excluded under each of these rules. No supplemental evidence was timely filed to address these objections.

III. ARGUMENT

A. EX1002 Should Be Excluded

EX1002 purports to be a declaration, but without authentication because it lacks the statutorily-required oath or caveat for a declaration. 35 U.S.C. §25; 37 CFR §42.2. As such, EX1002 falls short of the statutory threshold for a legally-cognizable declaration. This is not mere pedantry. Statements lacking the required oath or caveat "thwart the purpose of our rules regarding affidavits/declarations, and forgo the guarantee of truthfulness imparted by a declarant's acknowledgment of the possible consequences—fine, imprisonment, or penalty of perjury." *Int'l Bus. Machs. Corp. v. Intellectual Ventures II LLC*, IPR2015-01323, Paper 38, 9-11 (2016) (sustaining objection, noting failure to file supplemental evidence).

Similarly, EX1002 constitutes hearsay without exception because it represents an out-of-Board statement not "made under oath or other circumstances that impress the speaker with the solemnity of his statements." *Chambers v.*

Mississippi, 410 U.S. 284, 298 (1973) ("The hearsay rule . . . is based on experience and grounded in the notion that untrustworthy evidence should not be presented to the triers of fact.").

Finally, Dr. Winkler is unqualified to testify on the relevant subject matter and bases his testimony, whether by mistake or design, on materials no expert in pharmaceutical manufacturing would consider probative. FRE 701, 702. Dr. Winkler's self-serving assertions of qualifications in a relevant field are belied by the testimony of experts offered by both Liquidia and UT: Dr. Hall-Ellis and Dr. Pinal, respectively.

Dr. Hall-Ellis explains the education and experience of a person of ordinary skill in the art:

> a person of ordinary skill in this subject matter or art would typically be someone who is a medical physicist with a Ph.D. (or similar advanced degree) in physics, medical physics, or a related field, and two or more years of experience in radiation oncology physics, treatment planning, treatment plan optimization related to radiation oncology applications, and computer programming associated with treatment plan optimization (or equivalent degree or experience).

EX1015, ¶16. Yet, Liquidia provides no evidence that Dr. Winkler has any of these qualifications, and even Dr. Winkler does not claim to possess these qualifications.

Dr. Pinal explained (with corroborating evidence) why Dr. Winkler lacks relevant qualifications to address the issues that faced a person of ordinary skill in the art:

> Organic and medicinal chemists have a particular set of skills to address synthetic or drug design problems. They do not, however, have the requisite skill set for the large-scale manufacture of the same synthetic drugs nor either pharmaceutical compositions or pharmaceutical products. *See* EX2008 (Stahl), *vii* (noting "the majority of medicinal chemists working in the pharmaceutical industry are organic chemists whose main concern is to design and to synthesize novel compounds as future drug entities. While they focus on this challenging primary goal, salt formation is often restricted to a marginal activity with the short term aim of obtaining nicely crystalline material. Moreover, chemists are not explicitly trained in the various aspects of pharmaceutical salts"), 250 ("The preparation of pharmaceutical salts is usually not a matter of university teaching, and most of the organic chemists are not trained to prepare salts.").

EX2002, 92. Dr. Winkler testified he did not know whether manufacturing pharmaceutical products presented problems in the art. EX2026, 72:23-73:9. He was unable to answer accurately even the most basic questions about manufacturing requirements in the United States (*id*., 72:23-74:23) or development considerations (*see*, *e.g.*, EX2032, 171:23-175:5 (acid neutralization), 250:11-252:16 (bioavailability), 252:18-274:22 (counterion selection), 287:6-296:19

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