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 OBJECTIONS TO PETITIONER'S EVIDENCE SUBMITTED WITH PETITIONER REPLY



Patent Owner United Therapeutics Corporation ("Patent Owner") hereby objects to the admissibility of certain evidence cited in support of the Reply in Support of Petition for *Inter Partes* Review filed on February 10, 2022 ("Reply"). Patent Owner's objections are based on the Federal Rules of Evidence ("FRE"), relevant case law, federal statute, and the Patent Trial and Appeal Board ("PTAB") Rules. Patent Owner's objections are set forth with particularity below.

EXHIBIT 1087

Exhibit 1087 is described as "Affidavit of Christopher Butler." This Exhibit was served as supplemental evidence in response to Patent Owner's objections to the Petition, so it is improper for Petitioner to cite to this document in its Reply. Patent Owner objects to the extent it includes subject matter that is not permitted pursuant to FRE 602, including without limitation, to the extent that the declaration presents as "facts" information that is outside the personal knowledge of the declarant. Exhibit 1087 is also objected to as irrelevant under FRE 401 and 402 because it does not make any facts at issue in the *inter partes* review more or less probable than it would have been without the evidence. Patent Owner objects to Exhibit 1087, and the exhibits thereto, as unfairly prejudicial, confusing the issues, and a waste of time under FRE 403. Patent Owner also objects to Exhibit 1087 as



it should have been included with the Petition and, thus, does not meet the requirements of Rule 104(b)(5).

EXHIBITS 1089-1096, 1113, 1121

Exhibits 1089-1096 purport to be portions of larger volumes comprising collections of abstracts. Exhibit 1113 is described as "JAHA Supplement Author Index." Exhibit 1121 is described as "Ghofrani 2005, British Library." Patent Owner objects to page 12 of Exhibit 1089 which appears to be different than page 11 and not an accurate representation of the source document. Patent Owner objects to these exhibits under FRE 901-902 as lacking authentication and not selfauthenticating because they lack sufficient indicia that the exhibits are what they purport to be. Patent Owner further objects to these exhibits under FRE 106 and 401-403 as incomplete, irrelevant, waste of time, and likely to cause confusion because they contain only abstracts of the underlying articles. Patent Owner also objects to Exhibits 1089-1099 as they should have been included with the Petition and, thus, do not meet the requirements of Rule 104(b)(5). Patent Owner objects to Exhibit 1121 under FRE 604 as, aside from an abstract, it is presented in German.

EXHIBITS 1088-1105, 1113, 1114, and 1118-1131

Patent Owner objects to these exhibits under FRE 901-902 as lacking authentication and not self-authenticating because they lack sufficient indicia that



the exhibits are what they purport to be. Patent Owner further objects to these exhibits because Petitioner relies on these exhibits to prove the truth of the matter asserted therein, but they fail to meet the requirements of any hearsay exception or exemption under FRE 803-807.

EXHIBIT 1100

Exhibit 1100 is described as "Ventavis EU Summary of Product Characteristics." Patent Owner objects to Exhibit 1100 under FRE 901-902 as lacking authentication and not self-authenticating because it lacks sufficient indicia that the exhibit is what it purports to be. In particular, Exhibit 1100 lacks information as to if, when, where, or how it was published. Patent Owner objects to Exhibit 1100 under FRE 802 as the Petitioner relies on this exhibit to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807. Patent Owner also objects to Exhibit 1100 as it should have been included with the Petition and, thus, does not meet the requirements of Rule 104(b)(5).

EXHIBITS 1104-1105

Exhibits 1104-1105 are described as "Sulica, R. and Poon, M., 'Medical therapeutics for pulmonary arterial hypertension: from basic science and clinical trial design to evidence-based medicine,' Expert Rev. Cardiovasc. Ther. 3(2),



(2005) ("Sulica 2005")" and "European Society of Cardiology Annual Report 2005." Patent Owner objects to these Exhibits under FRE 802 as the Petitioner relies on them to prove the truth of the matter asserted therein, but it fails to meet the requirements of any hearsay exception or exemption under FRE 803-807. Patent Owner objects to these exhibits, which should have been included with the Petition and, thus, do not meet the requirements of Rule 104(b)(5).

EXHIBIT 1106

Exhibit 1106 is described as "Reply Declaration of Nicholas Hill, M.D."

Patent Owner objects to Exhibit 1106 under FRE 702 and 703 on the basis that the testimony is not based on sufficient facts or data or the product of reliable principles and methods reliably applied in this case (pp. 11-76). In addition, Exhibit 1106 contains numerous legal arguments that are proffered as expert opinions (pp. 11-76).

EXHIBIT 1107

Exhibit 1107 is described as "Reply Declaration of Igor Gonda, Ph.D."

Patent Owner objects to Exhibit 1107 under FRE 702 and 703 on the basis that the testimony is not based on sufficient facts or data or the product of reliable principles and methods reliably applied in this case (pp. 5-43). Patent Owner



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