

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,

Patent Owner.

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Case IPR2021-00406  
Patent 10,716,793

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**PATENT OWNER'S OBJECTIONS TO PETITIONER'S EVIDENCE  
SUBMITTED WITH PETITION**

Patent Owner United Therapeutics Corporation (“Patent Owner”) hereby objects to the admissibility of certain evidence cited in support of the Petition for *Inter Partes* Review filed on January 7, 2021 (“Petition”). 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 1002**

Exhibit 1002 is described as “Declaration of Dr. Nicholas Hill.” Patent Owner objects to Exhibit 1002, under FRE 702 and 703, because it lacks an appropriate basis—for example, Dr. Hill’s calculations for inhalation dosing contain scientific errors and are based on unfounded assumptions. *See, e.g.*, Ex. 1002, ¶¶ 67, 99. Patent Owner also objects to Exhibit 1002 under FRE 702 and 703 on the basis that the testimony is not based on sufficient facts or data. *See, e.g.*, Ex. 1002, ¶¶ 29-193. 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. Additionally, to the extent Patent Owner’s confidential information is introduced in this proceeding, Patent Owner objects to Dr. Hill being given access to such information. Patent Owner has concerns as to the closeness of his relationship with Petitioner.

**EXHIBIT 1004**

Exhibit 1004 is described as “Declaration of Igor Gonda, Ph.D.” Patent Owner objects to Exhibit 1004 under FRE 702 and 703 on the basis that the testimony is not based on sufficient facts or data. 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.

**EXHIBIT 1007**

Exhibit 1007 is described as “Voswinckel, R., et al., Abstract 218: ‘Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension,’ European Heart Journal 25:22 (2004).” Patent Owner objects to Exhibit 1007 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. Patent Owner further objects to Exhibit 1007 under FRE 106 and 401-403 as incomplete, irrelevant, waste of time, and likely to cause confusion because it contains only an abstract of the article.

**EXHIBIT 1008**

Exhibit 1008 is described as “Robert Voswinckel, Beate Enke, Andre Kreckel, Frank Reichenberger, Stefanie Krick, Henning Gall, Tobias Gessier, Thomas Schmehl, Markus G. Kohstall, Friedrich Grimminger, Hossein A.

Ghofrani, Werner Seeger, and Horst Olschewski, Abstract 1414: 'Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension,' Abstracts from the 2004 Scientific Sessions of the American Heart Association, *Circulation*, 110(17 Suppl.):III-295 (October 26, 2004)." Patent Owner objects to Exhibit 1008 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. Patent Owner further objects to Exhibit 1008 under FRE 106 and 401-403 as incomplete, irrelevant, waste of time, and likely to cause confusion because it contains only an abstract of the article.

### **EXHIBIT 1009**

Exhibit 1009 is described as "Robert Voswinckel, Hossein A. Ghofrani, Friedrich Grimminger, and Werner Seeger, 'Clinical Observations' on 'Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension,' 'Letters' Section of the *Annals of Internal Medicine*, 144(2):149-50 (January 2006)." Patent Owner objects to Exhibit 1009 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. Patent Owner further objects to Exhibit 1009 under FRE 106 and 401-403 as incomplete, irrelevant, waste of time, and likely to cause confusion because it contains only an abstract of the article.

**EXHIBIT 1010**

Exhibit 1010 is described as “Hossein Ardeschir Ghofrani, Robert Voswinckel, et al., Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie, 30(4) HERZ, 30(4):296–302 (June 2005) (‘Ghofrani’) (Foreign article and English translation attached).” Patent Owner objects to Exhibit 1010 under FRE 802, including to the extent Petitioner has asserted that the translation is a true and accurate representation of the original document. 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 further objects to this exhibit under FRE 402 and 403 because an inadequate translation renders the exhibit irrelevant.

**EXHIBIT 1036**

Exhibit 1036 is described as “Declaration of Sylvia Hall-Ellis, Ph.D.” Patent Owner objects to Exhibit 1036, under FRE 701, because the opinion testimony contained in this exhibit reaches legal conclusions for which the declarant has not established that she is capable of providing. Patent Owner also objects to Exhibit 1036 under FRE 702, on the basis that the testimony is not based on sufficient facts and is based on other informal and unpublished documents including its attached exhibits that are hearsay under FRE 802, have not been

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