### UNITED STATES PATENT AND TRADEMARK OFFICE

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## BEFORE THE PATENT TRIAL AND APPEAL BOARD

LIQUIDIA TECHNOLOGIES, INC.,

Petitioner

v.

UNITED THERAPEUTICS CORPORATION.

Patent Owner

Trial No. IPR2021-00406 Patent No. 10,716,793 B2

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**DECLARATION OF Ms. PILAR WYMAN** 



I, Pilar Wyman, hereby declare:

### INTRODUCTION

- 1. I am a paid consultant for United Therapeutics Corporation in connection with this proceeding, IPR2021-00406. My compensation does not depend on the content of this declaration, the substance of any other testimony that I may offer in connection with this proceeding, or the disposition of this proceeding.
- 2. I am a professional freelance medical indexer and indexing consultant. My Curriculum Vitae describing my background and experience is provided as Exhibit 2042. I have personal knowledge of the facts and opinions set forth in this declaration, which I believe to be true, and if called upon to do so, I would testify competently to them. In particular, as shown in my Curriculum Vitae, I have been involved in indexing medical publications for many years, as well as employed as a librarian. I was also lead consultant for the American Medical Association's *AMA Manual of Style, 10<sup>th</sup> edition* chapter 13, "Medical Indexes."
- 3. I understand that a reference is considered "prior art" in these proceedings if it is publicly accessible and can be located prior to a certain date using reasonable diligence by a hypothetical person referred to as the person of ordinary skill in the "art" (which I will refer to as a "POSA" herein) or field to



which the patent pertains. I further understand that the POSA for these proceedings would have an M.D. or a graduate degree (Masters or Ph.D.) in a field relating to drug development and at least two years practical experience in either (i) the investigation or treatment of pulmonary hypertension; or (ii) in the development of potential drug candidates, specifically in the delivery of drugs by inhalation. *See* Patent Owner Response, §3. A POSA may have had a lower level of formal education if such a person had more years of experience in the development of inhalable drugs. *Id*.

- 4. I further believe that the POSA described above would regularly review literature about pharmaceutical sciences and drug delivery and would know how to carry out library research using basic library resources to find out more information about the areas being researched. Such a POSA typically would not, however, spend hundreds of hours scanning supplemental issues of a journal, paging through thousands of abstracts or the like, on the mere chance of finding something relevant to their work. The massive amount of time and effort involved in such searching would be well beyond the typical "diligent" effort I would expect the POSA described above to make.
- 5. I have reviewed the Hall-Ellis Declaration and all of its attachments (Ex. 1036). I have also conducted searches of PubMed (maintained by the



National Library of Medicine, or "NLM"), Ovid, Chemical Abstracts, the American Heart Association Scientific Sessions, the Oxford University Press Medicine Archive, and WorldCat in connection with preparing this Declaration and reviewed certain other exhibits identified below.

- Document 1: Robert Voswinckel, et al., "Inhaled treprostinil sodium for the treatment of pulmonary hypertension," Abstract #1414, Circulation, 110, 17, Supplement (October 2004): III-295 ("Voswinckel JAHA").
- 6. The second reference discussed in the Hall-Ellis Declaration is Voswinckel JAHA, an abstract located in a 1,102-page supplement ("the Supplement") to the journal *Circulation* in 2004 specifically vol. 110, issue 17 (Ex. 1008). The Supplement contains thousands of abstracts, with the Voswinckel abstract appearing on page III-295. Ex. 1008, 3. According to Dr. Hall-Ellis, the abstract stemmed from a meeting of the American Heart Association in New Orleans in November 2004. Ex. 1036, ¶59.
- 7. Dr. Hall-Ellis opines that "the abstract 'Pulmonary Arterial Hypertension: New Therapies' by Voswinckel, et al. published in the Supplement to the journal *Circulation* was available in the Ebling Library for the Health Sciences at the University of Wisconsin Madison ("UWML") on November 26, 2004." *Id.*, ¶61. As an initial matter, I note that Dr. Hall-Ellis does not quote the abstract title correctly (*id.*; *see also id.*, ¶59). The abstract is titled, "Inhaled



treprostinil sodium for the treatment of pulmonary hypertension." By way of contrast, the phrase "Pulmonary Arterial Hypertension: New Therapies" appears as a section heading on page III-295 of Exhibit 1008. When asked in her deposition about using this section heading instead of the actual article title, Dr. Hall-Ellis claimed that she used the section heading on purpose because she knew the researchers would find the article anyway. Ex. 2043, 213:24-214:5.

- 8. I do not agree with Dr. Hall-Ellis' use of the section heading to describe this abstract; the section heading is not the title of the abstract, as Dr. Hall-Ellis seems to suggest, and the section includes other abstracts in addition to the Voswinckel JAHA abstract. Furthermore, I disagree that Dr. Hall-Ellis has shown the public availability of the Voswinckel JAHA abstract as of the priority date, as further discussed below.
  - A. Unlike Normal Journal Issues, Supplements of *Circulation* Are <u>Not</u> Routinely or Predictably Released, and Dr. Hall-Ellis Has Not Provided any Evidence of Receipt by a Library as of the Critical Date
- 9. It is my opinion that Dr. Hall-Ellis has failed to show that either the Supplement or the Voswinckel JAHA abstract was disseminated in any predictable way such as to be accessible more than one year before the May 15, 2006 priority date—as evidenced by the fact that the Supplement and abstract continue to be difficult to access even today.



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