

Reply Declaration of Sylvia Hall-Ellis, Ph.D.  
Petition for *Inter Partes* Review of  
U.S. Patent No. 10,716,793 B2

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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IPR2021-00406  
U.S. Patent No. 10,716,793 B2

**REPLY DECLARATION OF SYLVIA HALL-ELLIS, PH.D.**

**Table of Contents**

|   | <b>Page</b> |
|---|-------------|
| I. INTRODUCTION .....   | 3           |
| II. MATERIALS CONSIDERED .....  | 4           |
| III. LEGAL PRINCIPLES .....   | 8           |
| A. Public Accessibility of a Printed Publication.....   | 8           |
| B. Persons of Ordinary Skill in the Art .....   | 9           |
| C. Priority Date.....   | 9           |
| D. Summary of Opinions .....  | 10          |
| IV. Library Cataloging Practices.....   | 10          |
| V. Wyman is not qualified to opine on the public accessibility of Voswinckel JAHA and<br>Voswinckel JESC..... | 11          |
| VI. Voswinckel JAHA qualifies as a publicly accessible printed publication.....                               | 14          |
| VII. Voswinckel JESC qualifies as a publicly accessible printed publication .....                             | 39          |

I, Sylvia D. Hall-Ellis, declare as follows:

**I. INTRODUCTION**

1. I am over the age of eighteen and otherwise competent to make this declaration.
2. I have been retained by counsel for Petitioner Liquidia Technologies, Inc. (“Liquidia”) to offer my expert opinion regarding the public availability of certain publications, discussed below.
3. I understand that the Patent Trial and Appeal Board (“the Board”) has instituted inter partes review of U.S. Patent No. 10,716,793 (“793 Patent”) based on the petition submitted by Liquidia. Since institution, I understand that Patent Owner United Therapeutics Corporation (“UTC”) has filed a Patent Owner Response as well as a declaration from Ms. Pilar Wyman in support thereof.
4. I originally submitted a declaration on January 7, 2021 in this proceeding. My background, qualifications, and experience relevant to the issues raised in this proceeding are summarized in Section I.A of my original declaration. Ex. 1036 at ¶¶ 7-10. A full description of my background and qualifications is set forth in my curriculum vitae, attached as Exhibit A to my original 2021 declaration. *Id.*, Exhibit A.
5. This declaration presents my additional opinions in response to the Declaration of Ms. Pilar Wyman (Ex. 2041) (the “Wyman Declaration”), dated November 10, 2021, as it relates to the public availability of the two printed publications referred to in the Wyman Declaration as Voswinckel JAHA and Voswinckel JESC before May 15, 2006.
6. I reserve the right to supplement or amend my opinions, and bases for them, in response to any additional evidence, testimony, discovery, argument, and/or other additional information that may be provided to me after the date of this Declaration.

7. I am being compensated for my time spent working on this matter at my normal consulting rate of \$300 per hour, plus reimbursement for any additional reasonable expenses. My compensation is not in any way tied to the content of this Declaration, the substance of my opinions, or the outcome of this proceeding. I have no other interests in this proceeding or with any of the parties.

## II. MATERIALS CONSIDERED

8. This Declaration is based on information known to me as of the date I signed this Declaration, and I reserve the right to amend or supplement this report in view of any additional discovery, documents, information, reports, and/or testimony that I receive after issuance of this report.

9. The bases for my opinions herein and any testimony that I may be called upon to provide are as follows: (i) the materials identified throughout this Declaration, listed below; (ii) the independent research identified in this Declaration (iii) the materials identified in my 2021 declaration (Ex. 1036); (iv) the materials identified in the Wyman Declaration; (iv) my knowledge, education, research skills and methodology, and experience; and (v) the materials listed in the table below. The foregoing are among the types of information reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case. Throughout this report, I cite portions of these documents. These citations are intended only as examples, and I reserve the right to rely on all portions of these documents in addition to those cited in this report.

| Exhibit No. | Description   |
|-------------|---|
| 1007        | Voswinckel, R., et al., Abstract 218: "Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension," <i>European Heart Journal</i> 25:22 (2004) ("Voswinckel JESC") |



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| 1008 | 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, <i>Circulation</i> , 110(17 Suppl.):III-295 (October 26, 2004) (“Voswinckel JAHA”)  |
| 1036 | Declaration of Sylvia Hall-Ellis, Ph.D. (“Hall-Ellis Decl.”)  |
| 1089 | Voswinckel JESC, UWash  |
| 1090 | Voswinckel JESC, UWisc  |
| 1091 | Voswinckel JESC, British Library  |
| 1092 | Voswinckel JESC, Add’l Pages  |
| 1093 | Voswinckel JAHA, British Library  |
| 1094 | Voswinckel JAHA, Library of Congress  |
| 1095 | Voswinckel JAHA, Stanford   |
| 1096 | Voswinckel JAHA, UC Davis   |
| 1104 | Sulica, R. and Poon, M., “Medical therapeutics for pulmonary arterial hypertension: from basic science and clinical trial design to evidence-based medicine,” <i>Expert Rev. Cardiovasc. Ther.</i> 3(2), (2005) (“Sulica 2005”)   |
| 1106 | Reply Declaration of Nicholas Hill, M.D. (“Hill Reply Declaration”)<br><i>*Note: I only reviewed the excerpts I cite herein, which were provided to me by Liquidia’s counsel</i>  |
| 1110 | Transcript from the December 29, 2021 Deposition of Lyndsey Pilar Wyman, <i>Liquida Technologies, Inc. v. United Therapeutics Corp.</i> , IPR2021-00406   |
| 1113 | JAHA Supplement Author Index  |
| 1114 | American Heart Association 2004 Online Archive, pages <i>available at</i> <a href="https://web.archive.org/web/20041130084648/http://circ.ahajournals.org:80/">https://web.archive.org/web/20041130084648/http://circ.ahajournals.org:80/</a> ; <a href="https://web.archive.org/web/20041206215947/http://aha.agora.com/abstractviewer/">https://web.archive.org/web/20041206215947/http://aha.agora.com/abstractviewer/</a> ; <a href="https://web.archive.org/web/20041128050933/http://circ.ahajournals.org/content/s-by-date.0.shtml">https://web.archive.org/web/20041128050933/http://circ.ahajournals.org/content/s-by-date.0.shtml</a> ; and <a href="https://web.archive.org/web/20041204145419/http://circ.ahajournals.org/content/vol110/issue17/">https://web.archive.org/web/20041204145419/http://circ.ahajournals.org/content/vol110/issue17/</a> |
| 1115 | Affidavit of Duncan Hall, December 7, 2021  |
| 1116 | Voswinckel JAHA British Library Declaration   |
| 1117 | JAHA Supplement PubMed Search Results   |
| 1118 | PubMed.gov search results for Sulica, R. and Poon, M., “Medical therapeutics for pulmonary arterial hypertension: from basic science and clinical trial design to evidence-based medicine,” <i>Expert Rev. Cardiovasc. Ther.</i> 3(2), (2005)   |
| 1119 | Voswinckel JESC British Library Declaration   |
| 1120 | Voswinckel JESC Web of Science Search Results   |
| 1121 | Ghofrani 2005, British Library  |
| 1122 | Ghofrani 2005 Search Results  |
| 1123 | Circulation MARC record, British Library  |

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| 1124 | Circulation MARC record, Library of Congress   |
| 1125 | Circulation MARC record, Stanford  |
| 1126 | Circulation MARC record, UC Davis  |
| 1127 | European Heart Journal bibliographic record, UWash   |
| 1128 | European Heart Journal MARC record, UWisc  |
| 1129 | European Heart Journal MARC record, British Library  |
| 2040 | University of Wisconsin–Madison Library Catalog Search for holdings of <i>Circulation: the journal of the American Heart Association</i> |
| 2041 | Declaration of Ms. Pilar Wyman (“Wyman Declaration”)   |
| 2043 | Deposition Transcript of Sylvia Hall-Ellis, Ph. D.   |
| 2044 | American Heart Association Listing of <i>Circulation</i> Supplements   |
| 2049 | Oxford Academic Listing of <i>European Heart Journal</i> Supplements   |

10. In preparing this report, I used authoritative databases, such as the OCLC bibliographic database (also known as “*WorldCat*”), the Library of Congress Online Catalog, the Internet Archive (also known as the Wayback Machine), and the Web of Science. I also used the databases and sources relied on in the Wyman Declaration, such as *PubMed*, Ovid, Chemical Abstracts, the American Heart Association Online Archive, and the Oxford University Press Medicine Archive.

11. ***Internet Archive.*** The Internet Archive, a 501(c)(3) non-profit, is an online digital archive of Internet web sites and web pages and other cultural artifacts in digital form.<sup>1</sup> Like a paper library, the Internet Archive provides free access to researchers, historians, scholars, the print disabled, and the general public. The organization’s mission is to provide Universal Access to All Knowledge.

12. Established in 1996 by archiving the Internet itself, the Internet Archive features 20+ years of web history accessible through the Wayback Machine and more than 625 library and other partners through our Archive-It program to identify important web pages. As the Internet

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<sup>1</sup> See <https://archive.org/> (last visited Feb. 3, 2022).

Archive grew, so did its commitment to provide digital versions of other published works. Currently, the Internet Archive includes approximately 330 billion web pages, 20 million books and texts, 4.5 million audio recordings (including 180,000 live concerts), 4 million videos (including 1.6 million Television News programs), 3 million images, and 200,000 software programs.

13. The Internet Archive maintains an archive of webpages collected from the Internet using software called a crawler. Crawlers automatically create a snapshot of webpages as they existed at a certain point in time. The Wayback Machine is an application using a crawler created by the Internet Archive to search its archive of web page URLs and to represent, graphically, the date of each crawler capture. The Internet Archive captures data that is openly available to users of the Internet. Some sites are “not archived because they were password protected, blocked by robots.txt, or otherwise inaccessible to our automated systems. Site owners might have also requested that their sites be excluded from the Wayback Machine.”<sup>2</sup>

14. Many Internet Archive captures made by the WayBack Machine have a banner at the top with the capture date prominently displayed. Other dates when captures of the same URL have been made are indicated to the right and left of the date provided in the banner. Some captures may lack this banner. In any case, the URL for the capture begins with the identification of the Internet Archive page (e.g., <http://web.archive.org/web/>) followed by information that dates and time stamps the capture as follows: year in yyyy, month in mm, day in dd, time code in hh:mm:ss (e.g., 20071120082013, or November 20, 2007 at 8:20:13 a.m.). These elements are then followed by the URL of the original capture site. When links are active, the Wayback Machine is

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<sup>2</sup> <https://help.archive.org/hc/en-us/articles/360004651732-Using-The-Wayback-Machine> (last visited Feb. 3, 2022).

programmed to produce the archived file with the closest available date (not the closest available prior date) to the page upon which the link appeared and was clicked. I and other professionals in the field of library and information resources are familiar with the Internet Archive and the Wayback Machine. As previously noted, the Internet Archive and the Wayback Machine are among the types of information reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on matters that are the subject of their work.<sup>3</sup>

### **III. LEGAL PRINCIPLES**

15. I am not an attorney and will not offer opinions on the law. I am, however, rendering my expert opinion on the authenticity of the documents referenced herein and on when and how each of these documents was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the documents before the dates discussed below with respect to the specific documents.

#### **A. Public Accessibility of a Printed Publication**

16. Relevant to my response to the Wyman Declaration, I note below as part of my understanding of the legal standards for public accessibility of a printed publication, in addition to what I already set forth in my 2021 declaration. *See* Ex. 1036, ¶¶ 11-14.

17. I understand that there is a presumption of public accessibility as of the printed publication's publication date if it is published by an established publisher.

18. I am informed by counsel that, even if a printed publication is not cataloged and indexed in a meaningful way, it may still qualify as publicly accessible if it is cited by a "research

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<sup>3</sup> For more information about the Internet Archive see the Wayback Machine FAQ, [https://help.archive.org/hc/en-us#The\\_Wayback\\_Machine](https://help.archive.org/hc/en-us#The_Wayback_Machine) (last visited Feb. 3, 2022).

aid,” a publicly available publication that can reasonably lead a person interested in the relevant subject matter to the non-cataloged and non-indexed printed publication.

19. I am informed by counsel that cataloging and indexing are not the only factors to be considered in determining public accessibility of a printed publication and that a printed publication that has never been cataloged or indexed in any library or database can nevertheless be found publicly accessible. For example, I understand that printed publications presented to an audience of persons interested in the relevant subject matter at an academic conference, without any expectation of confidentiality, may still qualify as publicly accessible.

**B. Persons of Ordinary Skill in the Art**

20. I set forth a definition of a person of ordinary skill in the art (“POSA”) in my 2021 declaration. Ex. 1036, ¶¶ 15-17. I understand from counsel that UTC has since set forth its own definition, reproduced below:

A POSA, with respect to the ’793 patent, 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.

My analysis applies equally to either definition of a POSA.

**C. Priority Date**

21. As noted in my 2021 declaration, I am informed by counsel that the priority date for the ’793 Patent at issue is May 15, 2006. Ex. 1036, ¶ 26.

**D. Summary of Opinions**

22. It is my opinion that the Voswinckel JAHA (Ex. 1008) and Voswinckel JESC (Ex. 1007) printed publications discussed in my 2021 declaration were publicly accessible before the May 15, 2006 priority date, and that Wyman's analysis to the contrary is unqualified, flawed, and incorrect.

**IV. LIBRARY CATALOGING PRACTICES**

23. Relevant to my response to the Wyman Declaration, I note the following about library cataloging practices, in addition to what I already set forth in my 2021 declaration. *See* Ex. 1036, ¶¶ 27-46.

24. Cataloging is the transcription of bibliographic data to describe a resource; assignment of subject headings is the assignment of points of access including, but not limited to subjects, genres, and other terms. These two distinct processes take place at the time that a MARC record is prepared for addition to a library's online catalog.

25. Learning to transcribe bibliographic data and classify resources are fundamental skills and competencies that graduate library and information science students choosing a career path in the organization of information must complete as part of the Master of Library and Information Science (MLIS) degree, which I earned before getting my Ph.D. in Library and Information Science.

26. My research has focused on the knowledge, technical skills, and competencies for catalogers and metadata specialists in the library and information profession and provided the foundation for the adoption of core competencies by the American Library Association.<sup>4</sup>

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<sup>4</sup> *See* <https://alair.ala.org/handle/11213/7853> (last visited Feb. 3, 2022).

27. I understand that under the legal principles, the cataloging and indexing of a work in a meaningful way that bears a relationship to the subject of the work at hand provides a key indicator that such work would have been accessible to the public. In almost all libraries, as part of their routine business practice, the assignment of points of access to a work by subject and/or genre, in accordance with the MARC standard, will result in that work being indexed in a way that bears a relationship to the subject of the work, as discussed in my opening declaration (Ex. 1036, ¶¶ 27-43).

**V. WYMAN IS NOT QUALIFIED TO OPINE ON THE PUBLIC ACCESSIBILITY OF VOSWINCKEL JAHA AND VOSWINCKEL JESC**

28. It is my opinion that Wyman is not qualified to opine on the matters of public accessibility of printed publications given her educational background. Wyman has a Bachelor's degree from St. John's College (Santa Fe, New Mexico) in Liberal Arts and two-years-worth of postgraduate education in Mathematics at the University of California at Berkeley and at Mills College (Oakland, California). *See* Wyman Declaration at CV (Pilar Wyman's CV). A general liberal arts degree and graduate work in mathematics do not prepare an individual such as Wyman for graduate studies at a program accredited by the American Library Association<sup>5</sup> in the fields of library services, information science, cataloging practices, and library operations. Ms. Wyman does not hold a graduate degree from an American Library Association accredited program is by her own admission "not a trained librarian." Ex. 1110 (Wyman Dep. Tr.) at 49:13-19 ("Q. And so you don't hold a—a graduate degree from an American Library Association accredited

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<sup>5</sup> *See* <https://www.ala.org/educationcareers/accreditedprograms/directory> (last visited Feb. 3, 2022)

program? A. That's right. I'm not a librarian. I have worked as a librarian, but I am not a trained librarian.").

29. Professional librarians hold a graduate degree from a program accredited by the American Library Association. The Master of Library and Information Science (MLIS) degree prepares students through education, internships, and supervised field experience so that they meet the knowledge, technical skills, and competencies articulated by formal statements from relevant professional organizations.<sup>6</sup> The design, building, and maintenance of databases as part of the graduate education results in highly developed understanding of the information seeking process and searching strategies that surpass those of the clientele they serve. In addition, professional librarians who work in research and academic libraries and information centers typically hold a second graduate degree or doctorate in the discipline or field of study. For example, medical librarians have graduate degrees in biology or nursing; law librarians in academic law libraries have a juris doctor (J.D.). Professional librarians have sophisticated research skills that enable them to conduct formal studies and contribute to the scholarly knowledge of the library, information, and related fields.

30. It is also my opinion that Wyman is not qualified to opine on the matters of public accessibility of printed publications given her professional experience. Outside of serving as an expert in this IPR and the previous IPR2017-01621, Ms. Wyman acknowledges that she's never been asked to assess the public availability of a document. Ex. 1110 (Wyman Dep. Tr.) at 27:15-20. The vast majority of Wyman's career was focused on pursuits outside the realm of library practices. *See* Wyman Declaration at CV (Pilar Wyman's CV). For 19 years, Wyman worked in

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<sup>6</sup> See <https://www.ala.org/educationcareers/node/99/> (last visited Feb. 3, 2022)



various atypical positions such as a research assistant in the Middle East Bureau of the Washington Post, a computer supervisor in the U.S. and abroad, a mathematics teacher, and a computer teacher who provided technical support to students in a private school. *See id.* Wyman does not indicate that any of this experience related to matters of public accessibility of printed publications.

31. Wyman is a member of a professional group that offers workshops and short courses.<sup>7</sup> However, Wyman's experience is not specific to indexing practices in the field of library science (she provided her indexing services to only one library client) nor does she explain the research methodology that she used to arrive at her conclusions. Wyman's CV indicates that she does not have any serious expertise in library or information sciences practices. Wyman has never worked in a research library—her only identifiable work experience as a librarian was at a private K-12 school that did not generate MARC records, the international industry-wide standard for organizing library catalog information. *See* Ex. 1110 (Wyman Dep. Tr.) at 50:22-53:11. Further, Wyman provides some examples of her indexing projects on her professional website<sup>8</sup> but they consist of matching the topics in books or journals to the pages on which they appear, which is not the type of indexing related to the issue of public availability. Ms. Wyman acknowledges that her “own intimate working experience is with closed indexes,” which she defines as “[w]hen you go to the back of the book for these book-style indexes, you see the index entire. You can—you can peruse it. You can read it. You can see all of what's contained in the index. It's called a ‘closed index.’” Ex. 1110 (Wyman Dep. Tr.) at 18:21-19:10, 29:20-30:2.

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<sup>7</sup> *See* <https://www.asindexing.org/become-an-indexer/indexing-courses-and-workshops/> (last visited Feb. 3, 2022).

<sup>8</sup> *See* <https://wymanindexing.wordpress.com/titles-indexed-2020/> (last visited Feb. 3, 2022).

32. All in all, Wyman's CV and deposition testimony show that indexing for libraries was never the focus of her career. Her indexing experience falls substantially short of the rigorous information seeking and indexing practices observed by the colleagues and professional research librarians from which I have obtained copies of the Voswinckel JAHA and Voswinckel JESC abstracts.

#### **VI. VOSWINKCEL JAHA QUALIFIES AS A PUBLICLY ACCESSIBLE PRINTED PUBLICATION**

33. Voswinckel JAHA (Ex. 1008) refers to an abstract titled "Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension" by Robert Voswinckel, Beate Enke, Andre Kreckel, Frank Reichenberger, Stefanie Krick, Henning Gall, Tobias Gessler, Thomas Schmehl, Markus G. Kohstall, Friedrich Grimminger, Hossein A. Ghofrani, Warner Seeger, and Horst Olschewski published in a supplement titled "Abstracts from Scientific Sessions 2004" (the "JAHA Supplement") to Volume 110, No. 17 of the journal "Circulation." Voswinckel JAHA was presented at the 2004 Scientific Sessions of the American Heart Association, which was held on November 7-10, 2004, in New Orleans, Louisiana.<sup>9</sup> I have obtained date-stamped copies of Voswinckel JAHA from the British Library (stamped November 19, 2004), the Library of Congress (stamped October 2004), the Lane Medical Library at the Stanford University Medical Center (stamped November 11, 2004), and the University of California Davis Health Sciences Library (stamped November 17, 2004), which are attached as Exhibits 1093-1096, respectively. Voswinckel JAHA appears on page III-295 of the JAHA Supplement and can be easily found

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*See* [https://www.unboundmedicine.com/medline/citation/16082756/Abstracts\\_from\\_the\\_2004\\_Scientific\\_Sessions\\_of\\_the\\_American\\_Heart\\_Association\\_November\\_7\\_10\\_2004\\_New\\_Orleans\\_Louisiana\\_USA\\_](https://www.unboundmedicine.com/medline/citation/16082756/Abstracts_from_the_2004_Scientific_Sessions_of_the_American_Heart_Association_November_7_10_2004_New_Orleans_Louisiana_USA_) (last visited Feb. 3, 2022).

using the Author Index, beginning on page III-837. *See* Exs. 1093-1096, 1113. The presence of these date stamped copies establishes the public accessibility of Voswinckel JAHA.

34. The Wyman Declaration takes issue about Liquidia not quoting the Voswinckel JAHA abstract title correctly. *See* Wyman Declaration at ¶¶7-8. Specifically, the Wyman Declaration points out that Liquidia cites a section heading in the JAHA Supplement “Pulmonary Arterial Hypertension: New Therapies,” instead of the abstract title “Inhaled Treprostinil Sodium for the Treatment of Pulmonary Hypertension.” *See id.* I am informed by counsel that, in this proceeding, Liquidia cited to the abstract’s proper title in its Petition. Nonetheless, this point in the Wyman Declaration does not change my opinion regarding the public accessibility of Voswinckel JAHA.

35. It is my opinion that Voswinckel JAHA qualifies as a publicly available printed publication that was accessible prior to the May 15, 2006 priority date, based on its availability to the public in at least the British Library, the Library of Congress, the Lane Medical Library at the Stanford University Medical Center, and the University of California Davis Health Sciences Library prior to May 15, 2006. The Wyman Declaration argues that the JAHA Supplement and Voswinckel JAHA are difficult to find and “continue to be difficult to access even today.” *Id.* at ¶¶9-15. In support of its argument, the Wyman Declaration asserts that the Voswinckel JAHA abstract is difficult to find in the JAHA Supplement (*see id.* at ¶10), that the JAHA Supplement is released irregularly and may have been released significantly after the Scientific Sessions 2004 Conference in November 2004 (*see id.* at ¶¶10-12, 14), that the JAHA Supplement does not appear in the American Heart Association online archives (*see id.* at ¶12), and that the JAHA Supplement submitted in the ’793 IPR had no date-stamp evidencing date of receipt by a library (*see id.* at ¶13). Because each prong of the Wyman Declaration’s argument fails, as I explain in detail below, a

person of ordinary skill in the art that was interested in the subject matter would have found Voswinckel JAHA, exercising no more than reasonable diligence.

36. The Voswinckel JAHA abstract is not difficult to find by a person of ordinary skill in the art within the JAHA Supplement. To begin with, the JAHA Supplement was prepared in conjunction with the American Heart Association's 2004 Scientific Sessions. Thus, a person of ordinary skill in the art attending the 2004 Scientific Sessions would have known to review the JAHA supplement prior to the conference and would have found Voswinckel JAHA. Dr. Nicholas Hill, another expert retained by Liquidia, agrees that:

[A] POSA in 2004 would have attended the Scientific Sessions 2004 Conference, as it is one of the principal conferences on the circulatory system and diseases and conditions affecting circulation, including pulmonary hypertension. . . . A person attending the meeting can thus use the meeting program to determine which researchers and clinicians are presenting at the meeting as well as the subject matter on which the clinicians or researchers are presenting. . . . A POSA attending the Scientific Sessions 2004 Conference would have been interested in presentations on treatments for pulmonary hypertension, including pulmonary arterial hypertension, and contrary to Ms. Wyman's opinions, would have been able to identify the abstracts disclosing such treatments, including Voswinckel JAHA. *See* Ex. 2041 (Wyman Decl.) at ¶ 25 (stating without evidence that "a POSA conducting diligent research would not sift through such voluminous results"). The meeting programs and supplements are provided for just this purpose, and I myself use such meeting programs and supplements to identify abstracts on subject matter of interest.

Ex. 1106 (“Reply Declaration of Dr. Hill”) at ¶ 22. Further, Despite the JAHA Supplement being 1,102-pages-long, the abstracts are indexed by author. *See* Ex. 1093 at 5; Ex. 1094 at 6; Ex. 1095 at 9; Ex. 1096 at 4. Specifically, the Voswinckel JAHA abstract, numbered 1414, is indexed under the authors “Voswinckel, Robert” and “Seeger, Werner.” *See* Ex. 1095 at 16; Ex. 1113 at 5. Dr. Hill also “note[s] that at the time, and still today, the number of physicians and researchers working on treatments for pulmonary arterial hypertension was small. A POSA would have thus known the names of the other physicians and researchers in the field and would have sought out research, including abstracts and presentations, by these physicians and researchers. . . . Accordingly, and in direct contradiction to Ms. Wyman’s opinion, a POSA would have found Robert Voswinckel’s name in the Author Index (or the names of other authors from the Giessen Group) and would have further found Voswinckel JAHA.” Reply Declaration of Dr. Hill at ¶ 27; *see also* Ex. 1110 (Wyman Dep. Tr.) at 106:2-5 (“Q. If Voswinckel JAHA, the supplement, had an author index and you knew the name Voswinckel, could you find it? A. Yes.”). Thus, it is my opinion that a POSA would have found Voswinckel JAHA either by diligently searching through the 2004 Scientific Sessions program or by knowing and seeking out Robert Voswinckel’s or Werner Seeger’s name in the Author Index.

37. Ms. Wyman’s “opinion that the Voswinckel JAHA abstract was n[ot] disseminated . . . before May 15, 2006” is directly contradicted by her admission that she has seen the copy of Voswinckel JAHA submitted as Ex. 1003 in IPR2017-01621 prior to this case. Ex. 1110 (Wyman Dep. Tr.) at 83:16-19 (“Q. You mention that you have seen a date stamped copy from the prior case; is that correct? A. I did mention that, yes.”), 85:10-21 (acknowledging that the date-stamped copy was from IPR2017-01621). As I explained in my opening declaration, the copy of Voswinckel JAHA submitted as Ex. 1003 in IPR2017-01621 was pulled from the British Library,

with a receipt date of November 22, 2004. Ex. 1036 at ¶ 59 n.21. Ms. Wyman also agrees that date stamps signify when a periodical is received by a library. Ex. 1110 (Wyman Dep. Tr.) at 58:13-17 (“Q. Okay. But it is your understanding that a date stamp signifies when a—a periodical is received by a library? A. Generally yes, for periodicals, that was my experience.”). Ms. Wyman also agrees that after publications are received, the library then catalogs the publication and begins the process of placing the publication on the shelves for the public. *Id.* at 60:4-9.

38. The assertion that the JAHA Supplement is released irregularly does not support any significant delay between the Scientific Sessions 2004 Conference in November 2004 and the release of the associated abstract supplement. When asked how she defined phrase “significantly delayed” or “well after” the conference, Ms. Wyman stated only months, which would place Voswinckel JAHA’s release well before May 2006. Ex. 1110 (Wyman Dep. Tr.) at 130:22-131:3 (“Months. Like the six months you just mentioned.”); *see also id.* at 126:19-22 (“Q. [S]o I believe you said you had defined ‘well after’ as roughly a few months; is that right? A. Correct.”). The Wyman Declaration’s only support for this notion is Wyman’s single anecdote that she has seen an abstract supplement from a Centre for the Study of Book symposium, which has absolutely no relation or resemblance to the Scientific Sessions 2004 Conference, not be released for a few years. *See* Wyman Declaration at ¶11, n.1. In Ms. Wyman’s own words, there would have been more of an “urgency” to publish abstracts from a medical conference like the American Heart Association than the Centre for the Study of Book symposium she cites. Ex. 1110 (Wyman Dep. Tr) at 125:13-126:15. Furthermore, the American Heart Association online archive,<sup>10</sup> which is Exhibit 2044, that the Wyman Declaration relies on actually undermines Wyman’s argument that the release of the


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<sup>10</sup> *See* <https://www.ahajournals.org/circ/supplements> (last visited Feb. 3, 2022).


JAHA Supplement may have been significantly delayed. A review of the supplement release dates and the conference dates as shown on the American Heart Association online archive reveals that the vast majority of the abstract supplements to *Circulation* were released on the same date as the Scientific Sessions conference date. *See* Ex. 2044. The greatest delay between a Scientific Sessions conference and the release of an abstract supplement was only 18 days, which is nowhere near the approximately 1.5-year gap between the November 7-10, 2004 Scientific Sessions conference date and the priority date. *See id.* at 3. Wyman's argument is also facially incorrect because the date-stamped copies of Voswinckel JAHA from the Library of Congress have a date-stamp in October 2004, prior to the November 7-10, 2004 conference. Thus, there is no support for Wyman's opinion.


39. The Wyman Declaration's assertion that the JAHA Supplement does not appear in the American Heart Association online archives is incorrect and based on Wyman's search of the archives in 2021 that does not exercise ordinary diligence. I am informed by counsel that public accessibility must be assessed from the perspective of a person of ordinary skill in the art exercising reasonable diligence prior to the critical date. Exhibit 1114 shows pages from the *Circulation* journal website from back in November 2004, which I retrieved from Archive.org. A declaration from Archive.org as to the authenticity of the pages in Exhibit 1114 is attached as Exhibit 1115. Prior to May 15, 2006, a person of ordinary skill in the art interested in the subject matter of pulmonary hypertension would have accessed the *Circulation* journal web page and clicked the links "Select an Issue from the Archive" or "Scientific Session Abstracts."

Other AHA Journals

 [Arteriosclerosis, Thrombosis, and Vascular Biology](#)

 [Circulation Research](#)

 [Hypertension](#)

 [Stroke](#)

# Circulation

[Select an Issue from the Archive](#)  
September 1, 1965 - November 30, 2004

[Browse by Special Section](#)

[Browse Articles in Heart Disease & Stroke](#)


[Scientific Statements](#)

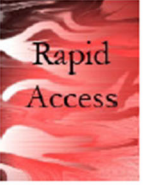
[Circulation Supplements](#)

[Scientific Session Abstracts](#)

[Current Issue](#)

[Publish Ahead of Print](#)

 November 30, 2004  
(Next issue online December 7)

 November 29, 2004

[Editor's Pick \(free\)](#)  
[High-Density Lipoprotein Stimulates Myocardial Perfusion In Vivo](#)  
Bodo Levkau, Sven Hermann, Gregor Theilmeyer, Markus van der Giet, Jerold Chun, Otmar Schober, and Michael Schäfers  
*Circulation* 2004 110: 3355 - 3359

Ex. 1114 at 1. The resulting pages, depicted here, show that, as of November 11, 2004, Volume 110, No. 17 of *Circulation* was uploaded to the American Heart Association online archives and the Scientific Session Abstracts were viewable online.



## Abstract Viewer

Welcome to the American Heart Association's Abstract Viewer. This viewer allows you to search for and read abstracts from certain Scientific Sessions and other American Heart Association scientific conferences. Once you've selected abstracts of interest, click the "Print" icon in your browser display.

To view abstracts, you must have a Netscape Navigator 3.0 compatible browser, or a Microsoft Internet Explorer 4.0 compatible browser. To fully utilize this program, your browser must be configured with "cookies and Java script enabled."

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Abstracts, lectures, and other presentations included in the American Heart Association's Abstract Viewer are embargoed for release at the time of presentation at the American Heart Association's conference and information may not be released before then. Embargo time is the time listed in that conference's Final Program.



## Archive of All Online Issues: 1 Sep 1965 - 23 Nov 2004

### Current Issue:



[November 23, 2004](#)  
Vol. 110, Num. 21

### Recent Issues:



[November 16, 2004](#)  
Vol. 110, Num. 20



[November 9, 2004](#)  
Vol. 110, Num. 19



[November 2, 2004](#)  
Vol. 110, Num. 18

### Full Text and Abstracts: 1 Jan 1995 - 23 Nov 2004

2000s [2000](#) [2001](#) [2002](#) [2003](#) [2004](#) - - - - -  
1990s - - - - - [1995](#) [1996](#) [1997](#) [1998](#) [1999](#)

| October  | November  |  |
|--|---|--|
| <a href="#">October 5</a> ; 110 (14): 1875 - 2071;<br>e333 - e437  | <a href="#">November 2</a> ; 110 (18): 2773 - 2975;<br>e454 - e488  |  |
| <a href="#">October 12</a> ; 110 (15): 2073 - 2275;<br>e438 - e444 | <a href="#">November 9</a> ; 110 (19): 2977 - 3156;<br>e489 - e499  |  |
| <a href="#">October 19</a> ; 110 (16): 2277 - 2549;<br>e445 - e450 | <a href="#">November 16</a> ; 110 (20): 3157 - 3288;<br>e500 - e505 |  |
| <a href="#">October 26</a> ; 110 (17): 2551 - 2771;<br>e451 - e453 | <a href="#">November 23</a> ; 110 (21): 3289 - 3397;<br>e506 - e514 |  |
|  | <a href="#">November 30</a> ; 110 (22): 3399 - 3501;<br>e515 - e516 |  |

Ex. 1114 at 2-5.

40. The Wyman Declaration's assertion that Liquidia submitted a JAHA Supplement with no date-stamp (*see* Wyman Declaration at ¶¶13, 18) is in response to a copy of Voswinckel JAHA pulled from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison attached to my Declaration dated January 7, 2021. *See* Ex. 1036 at ¶59. Attached as Attachment D1 to Exhibit 1036 is a true and correct copy of the MARC record for the journal *Circulation* in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. The library ownership is indicated by the presence of the library's code (uwmadisondb) in the fourth 035 field. The library continues to update this MARC record and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment D1 to Exhibit

1036 occurred on March 13, 2015, as shown in field 005 (“20150313”). I personally identified and retrieved the MARC record that is Attachment D1 to Exhibit 1036 on January 3, 2021.

41. Based on finding a digital copy of Voswinckel JAHA in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and the MARC record in its online library catalog attached as Attachment D1 to Exhibit 1036, it is my opinion that Voswinckel JAHA was available in Ebling Library for the Health Sciences at the University of Wisconsin – Madison on November 26, 2004. The journal *Circulation* has been published 14 times a year since November 1979 (see field 310 in Attachment D1 to Exhibit 1036). Based on the publication frequency, it is reasonable for subscribers to receive new issues within 30 days of the date on the journal cover. Therefore, the Supplement dated October 26, 2004, would have arrived by November 26, 2004. Attachment D1 to Exhibit 1036 also shows that Voswinckel JAHA was cataloged with two descriptor terms reading “Cardiology \$x Societies” (see Attachment D2 to Exhibit 1036, Library of Congress subject heading sh85020214 and Attachment D3 to Exhibit 1036, Library of Congress subject heading sh85124175) and “Heart \$x Diseases \$v Periodicals” (see Attachment D4 to Exhibit 1036, Library of Congress subject heading sh2009126258) in the 650 fields.

42. As noted in the holdings information (362 field of Attachment D1 to Exhibit 1036), the Ebling Library for the Health Sciences at the University of Wisconsin – Madison has received the journal *Circulation* in print since January 1950 and continues to receive the publication in print and digital versions. In view of its MARC record, Voswinckel JAHA was publicly available on November 26, 2004, because the serial title had been received, cataloged, and indexed in the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and made part of its online catalog database.

43. Attached as Attachment D5 to Exhibit 1036 is a true and correct copy of the MARC record for the print version of the journal *Circulation* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment D5 to Exhibit 1036, that library code is “MUL,” which means that the MARC record for this serial was cataloged as part of the Minnesota Union List of Serials at the University of Minnesota Libraries. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the University of Minnesota Libraries created OCLC record number 1554748 on August 17, 1975, as shown in the “Entered” field (“19750817”). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment D5 to Exhibit 1036 occurred on July 31, 2020, as shown in the “Replaced” field (“20200731”). I personally identified and retrieved the MARC record that is Attachment D5 to Exhibit 1036 on January 3, 2021. The “BLvl” entry in Attachment D5 to Exhibit 1036 is “s,” which indicates that the journal *Circulation* is a serial publication. Accordingly, the MARC record corresponds to the journal *Circulation* from the time that the serial title began and includes the date of Voswinckel JAHA.

44. Attachment D5 to Exhibit 1036 further includes an entry in field 050 (“RC681.A1 \$b C5”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment D5 to Exhibit 1036 further includes an entry in field 060 (“W1 CI743”), a subject matter consistent with the National Library of Medicine classification system and an entry in field 082 (“616.105”), a subject matter consistent with the Dewey Decimal classification system. Attachment D5 to Exhibit 1036 further includes three English language descriptor terms reading “Cardiology \$v Periodicals” (*see* Attachment D6 to Exhibit 1036, Library of Congress subject

heading sh2008117649), “Cardiovascular system \$v Periodicals” (*see* Attachment D7 to Exhibit 1036, Library of Congress subject heading sh85020226 and Attachment D8 to Exhibit 1036, Library of Congress subject heading sh85099890), and “Hypertension \$v Periodicals” (*see* Attachment D9 to Exhibit 1036, Library of Congress subject heading sh85063723 and Attachment D8 to Exhibit 1036, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached as Attachment D5 to Exhibit 1036 was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries.

45. Further, as of August 17, 1975, the MARC record attached as Attachment D5 to Exhibit 1036 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, Voswinckel JAHA was publicly accessible by at least November 26, 2004, and in any event at least one year before the May 15, 2006, priority date, because by that time it had been received, cataloged, and indexed at the Ebling Library for the Health Sciences at the University of Wisconsin – Madison and made part of the OCLC bibliographic database. Attachment D5 to Exhibit 1036 indicates that the journal *Circulation* as cataloged at the University of Minnesota Libraries is currently available from 1,168 libraries (“1168 other holdings”).

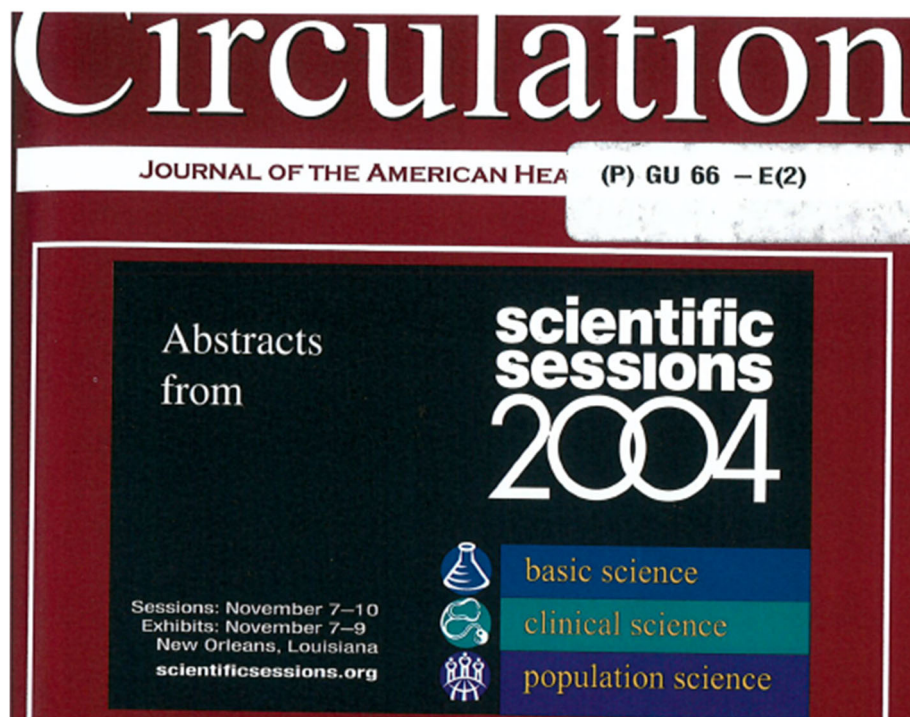
46. Wyman also refers to Ex. 2040 (University of Wisconsin – Madison Libraries Webpage) to argue that the University of Wisconsin – Madison Library online catalog doesn’t show that it has a copy of the JAHA supplement. *See* Wyman Declaration at ¶19. Wyman further

argues that the MARC record provided by me in Attachments D1 through D9 to Exhibit 1036 are for the entire *Circulation* journal and not the JAHA Supplement nor for Voswinckel JAHA. *See* Wyman Declaration at ¶20. However, Wyman ignores my deposition (*see* Ex. 2043 at 104:2 – 113:18, 117:24 – 125:19) where I explain that field 525 of the MARC record for the *Circulation* journal accounts for the fact that *Circulation* has supplements and that fields 362 and 525 of the MARC record show that the libraries which subscribe to the journal hold every supplement to *Circulation*, including the 2004 JAHA Supplement, since 1950. Wyman also ignores her own Exhibit 2040 which shows that the University of Wisconsin – Madison Libraries’ Middleton Shelving Facility, as I explain in my deposition transcript (*see* Ex. 2043 at 117:24 – 125:19), holds more *Circulation* supplements which are available “by request only” but are nevertheless “[a]vailable for checkout.” I explain that the reason why the JAHA Supplement may be missing from the UWML online catalog under the “The Library Has:” section is because it is likely physically housed in the Middleton Shelving Facility. *See id.* It is my opinion that a person of ordinary skill in the art exercising reasonable diligence would have requested the University of Wisconsin – Madison Libraries to retrieve the JAHA Supplement from the Middleton Shelving Facility.

47. In view of the above, this issue of the journal *Circulation* was publicly available on November 26, 2004, and in any event, more than one year before the May 15, 2006 priority date, because by that date it had been received, cataloged, and indexed at the University of Minnesota Libraries, made part of the OCLC bibliographic database, and received at the Ebling Library for the Health Sciences at the University of Wisconsin – Madison. For these reasons, it is my opinion that Voswinckel JAHA was published and accessible to the public at least by November 26, 2004.

48. The above information is sufficient to establish that the Voswinckel JAHA abstract was publicly available well before May 15, 2006. As such, this has proven false the opinion in ¶13 of the Wyman Declaration that my “assumption” was incorrect. Nevertheless, in the past month, I have also located four other date-stamped copies of the Voswinckel JAHA abstract confirming the same.

49. Attached as Exhibit 1093 is a copy of the JAHA Supplement containing Voswinckel JAHA from the British Library, date stamped November 19, 2004.



Supplement to

**Circulation**

Volume 110 Number 17 October 26, 2004

THE BRITISH LIBRARY  
SCIENCE TECHNOLOGY  
19 NOV 2004  
AND INNOVATION

Abstracts From Scientific Sessions 2004  
Morial Convention Center  
New Orleans, Louisiana  
November 7-10, 2004

Ex. 1093 at 2-3.

50. I obtained a research librarian's declaration of Voswinckel JAHA's public availability from The British Library, attached as Exhibit 1116. The declaration states that "[Voswinckel JAHA] was receipted by The British Library on 19th November 2004, and it would have been available for public use from that date. A scan of the cover pages showing the date stamp on page three (referring to Exhibit 1093) indicating the date of availability, title page and contents pages have been attached." Ex. 1116 at 1. Thus, it is my opinion that the declaration confirms that Voswinckel JAHA and the JAHA Supplement were received by and publicly available at the British Library from November 19, 2004.

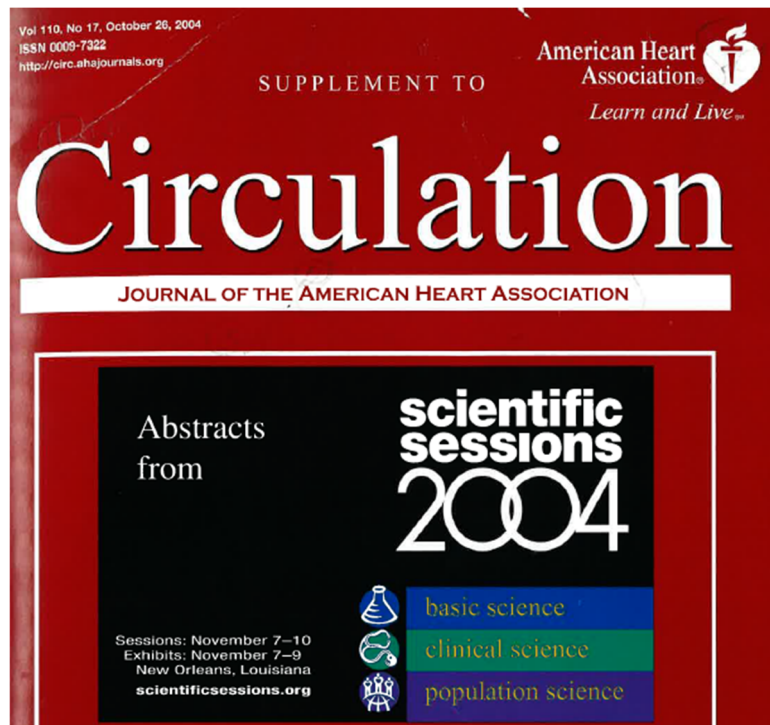
51. I also obtained the MARC record for *Circulation* from the British Library, attached as Exhibit 1123.<sup>11</sup> Fields 362 and 525 of the MARC record show that *Circulation* has an annual supplement with the title "Abstracts" and that the British Library holds every supplement, including the JAHA Supplement, since 1964. *See* Ex. 1123. The 650 fields of the MARC record show that *Circulation* was cataloged with the descriptor terms "Cardiology |v Periodicals" and "Cardiovascular system |v Periodicals." *Id.*

52. Attached as Exhibit 1094 is a copy of the JAHA Supplement containing Voswinckel JAHA from the Library of Congress, date stamped October 2004.

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<sup>11</sup> Available at [http://primocat.bl.uk/F/?func=direct&local\\_base=PRIMO&doc\\_number=009549936&format=001&con\\_lng=eng](http://primocat.bl.uk/F/?func=direct&local_base=PRIMO&doc_number=009549936&format=001&con_lng=eng) (last accessed Feb. 3, 2022).





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- The most frequent adverse events were myalgia (3.3%), constipation (1.4%), asthenia (1.3%), abdominal pain (1.3%), and nausea (1.3%)<sup>3,5</sup>

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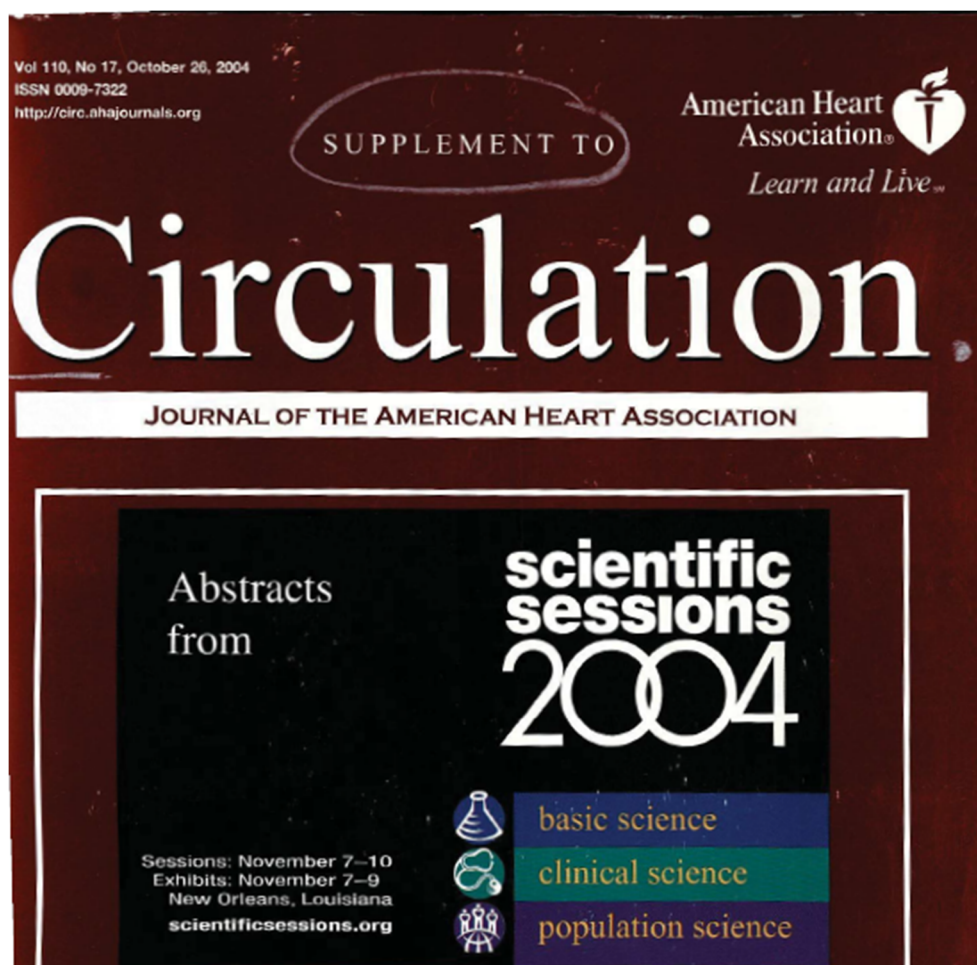
53. I obtained the MARC record for *Circulation* from the Library of Congress, attached as Exhibit 1124.<sup>12</sup> Fields 362 and 525 of the MARC record show that *Circulation* has an annual supplement with the title “Abstracts” and that the Library of Congress holds every supplement, including the JAHA Supplement, since 1964. *See* Ex. 1124. The MARC record further includes English language descriptor terms reading “Cardiology |v Periodicals,” “Cardiovascular system |v Periodicals,” “Hypertension |v Periodicals,” and “Blood Circulation |x Periodicals,” among others, in the 650 field. *Id.* Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Exhibit 1124 was indexed according to its subject matter by virtue of at least two independently sufficient classifications: the field 050 entry and the field 650 entries.

54. Attached as Exhibit 1095 is a copy of the JAHA Supplement containing Voswinckel JAHA from Lane Medical Library at the Stanford University Medical Center, date stamped November 11, 2004.<sup>13</sup>

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<sup>12</sup> Available at <https://catalog.loc.gov/vwebv/staffView?searchId=23389&recPointer=8&recCount=25&bibId=1145202> (last accessed Feb. 3, 2022).

<sup>13</sup> This copy was obtained through a Stanford medical student’s request, as I was informed that access to offsite materials through the Lane Medical Library is still not open to the public. *See* <https://lane.stanford.edu/using-lib/eligibility.html> (only Stanford Medicine employees and students can access “offsite” materials).





Ex. 1095 at 1, 5.

55. I obtained the MARC record for *Circulation* from the Lane Medical Library at the Stanford University Medical Center, attached as Exhibit 1125.<sup>14</sup> Fields 362 and 525 of the MARC record show that “[s]upplements accompany some volumes” of *Circulation* and that the Lane Medical Library has every supplement, including the JAHA Supplement, since January 1950. Ex. 1125. The MARC record includes an entry in field 050 (“RC681.A1 |b C5”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). *See id.* The MARC

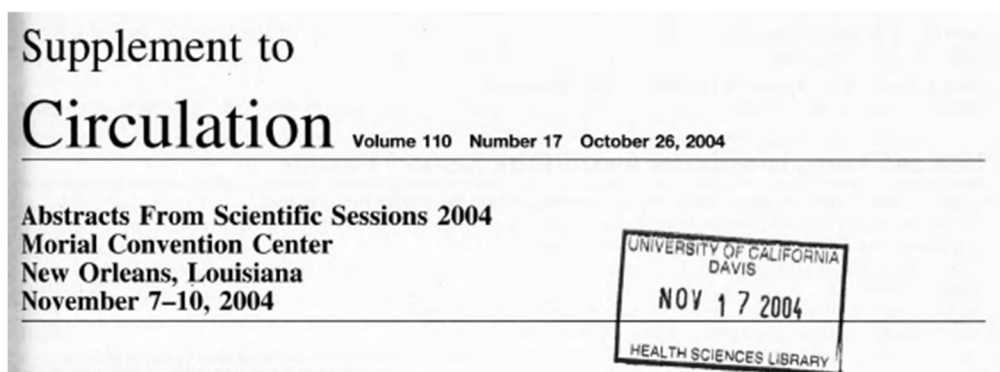
<sup>14</sup> Available at [https://lml.db.stanford.edu/cgi-bin/Pwebrecon.cgi?BBRecID=45&v3=1&SEQ=20211208101647&PID=IKxtlmYFuiY\\_9puqpINTRajPpI](https://lml.db.stanford.edu/cgi-bin/Pwebrecon.cgi?BBRecID=45&v3=1&SEQ=20211208101647&PID=IKxtlmYFuiY_9puqpINTRajPpI) (last accessed Feb. 3, 2022).

record also includes an entry in field 060 (“W1 CI743”), a subject matter consistent with the National Library of Medicine classification system. *See id.* The MARC record further includes English language descriptor terms reading “Blood Circulation,” “Cardiovascular System,” “Cardiology,” and “Vascular Diseases,” among others, in the 650 field. *Id.* Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Exhibit 1125 was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries.

56. Attached as Exhibit 1096 is a copy of the JAHA Supplement containing Voswinckel JAHA from the University of California Davis Health Sciences Library, date stamped November 17, 2004.







Ex. 1096 at 1-2.

57. I obtained the MARC record for *Circulation* from the University of California Davis Health Sciences Library, attached as Exhibit 1126.<sup>15</sup> Fields 362 and 525 of the MARC record show that *Circulation* has an annual supplement with the title “Abstracts” and that the University of California Davis Health Sciences Library holds every supplement, including the JAHA Supplement, since 1964. *See* Ex. 1126. The MARC record includes an entry in field 050 (“RC681.A1 \$bC5”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). *See id.* The MARC record also includes an entry in field 060 (“W1 CI743”), a subject matter consistent with the National Library of Medicine classification system. *See id.* The MARC record further includes English language descriptor terms reading “Cardiology \$vPeriodicals,” “Cardiovascular system \$vPeriodicals,” and “Hypertension \$vPeriodicals,” among others, in the 650 field. *Id.* Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Exhibit 1126 was indexed according to its subject matter by virtue of at

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<sup>15</sup> Available at [https://search.library.ucdavis.edu/discovery/sourceRecord?vid=01UCD\\_INST:UCD&docId=alma990000054810203776&recordOwner=01UCSB\\_INST](https://search.library.ucdavis.edu/discovery/sourceRecord?vid=01UCD_INST:UCD&docId=alma990000054810203776&recordOwner=01UCSB_INST) (last accessed Feb. 3, 2022).

least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries.

58. In sum, four date-stamped exhibits confirm that the Abstract Supplement to Volume 110, No. 17 of *Circulation* dated October 26, 2004, was received and publicly available at least within a month, i.e., by November 26, 2004, and well before the May 15, 2006, priority date.

| Exhibit No. | Location   | Date Stamped      |
|-------------|--|-------------------|
| 1093        | British Library  | November 19, 2004 |
| 1094        | Library of Congress  | October 2004      |
| 1095        | Lane Medical Library at the Stanford University Medical Center | November 11, 2004 |
| 1096        | University of California Davis Health Sciences Library         | November 26, 2004 |

59. The Wyman Declaration also argues that Voswinckel JAHA was not publicly accessible before May 15, 2006, because neither the Supplement nor the abstracts within it were meaningfully indexed. *See* Wyman Declaration at ¶¶16-26. As support, Wyman presented the results of her searches for Voswinckel JAHA on the databases Ovid, CAPlus, and *PubMed*, and noted that they were too voluminous to be helpful to a person of ordinary skill in the art. *See id.* at ¶24; *see also* Exs. 2045-2047. I note, however, that a POSA particularly interested in a subject area would spend the time to find the relevant information. Nonetheless, a closer review of these searches shows that Wyman deliberately cast an extremely wide net. In fact, Ms. Wyman acknowledges that a person interested in pulmonary hypertension would not have used the search methodologies she describes in her declaration. Ex. 1110 (Wyman Dep. Tr.) at 94:15-95:16 (“Q. [I]f you’re interested in treatments with pulmonary hypertension, you would not have searched this way; is that correct? A. Correct. I would have been more — way more specific. Q. How—how would you have been more specific? A. Like I just said, I would have done something

more like using phrases ‘pulmonary hypertension’ and ‘treatment’ or ‘pulmonary hypertension’ and ‘therapy’ for starters.”). Wyman did not use any search terms in conjunction with each other and only elected to use the broadest single search terms such as “Cardiology” or “Heart Disease.” See Wyman Declaration at ¶24. In doing so, Wyman deliberately ignored the narrower search terms highlighted in the MARC records for the journal *Circulation*. See Attachment D5 to Ex. 1036. For example, field 650 in the MARC records for *Circulation* provides descriptive search terms such as, “Cardiology,” “Cardiovascular System,” “Hypertension,” and “Blood Circulation.” *Id.*

60. Wyman’s hypothetical search also ignores several other common-sense ways a POSA would have used to locate this reference, particularly where a POSA is presumed to know the relevant prior art. The MARC record for this reference clearly shows that the reference was classified by subject (e.g., “Cardiology,” “Cardiovascular System,” “Hypertension,” and “Blood Circulation”). This demonstrates that receipted issues would have been indexed according to that subject matter classification upon receipt. The date-stamped copies demonstrate that the articles were in fact received by libraries all over the world. Anytime thereafter, a POSA interested in the subject matter could have gone to any of these libraries and browsed through that library’s selection of “Cardiology,” “Cardiovascular System,” “Hypertension,” and “Blood Circulation” to find this reference. For example, I conducted a search on *PubMed* using the terms “Cardiology,” “Cardiovascular System” and “Cardiovascular diseases” for publications between 1996 and 2006 that yielded 202 results, of which the JAHA Supplement is the 113th result. The results of my search are attached to this report as Exhibit 1117. See also Ex. 1110 (Wyman Dep. Tr.) at 102:6-9 (“Q. Okay. So, to be clear, the supplement containing Voswinckel JAHA can be found on PubMed? A. Yes.”). Thus, it is my opinion that because the JAHA Supplement could be found

by a person of ordinary skill in the art with reasonable diligence on well-known databases prior to May 15, 2006, the JAHA Supplement qualifies as a publicly accessible printed publication.

61. Furthermore, the JAHA Supplement and Voswinckel JAHA were published by the publisher Lippincott Williams & Wilkins, an established publisher of the Wolters Kluwer conglomerate since 1998. See <https://www.wolterskluwer.com/en/solutions/lippincott-journals> (last visited February 3, 2022); <https://www.bioprocessonline.com/doc/lippincott-williams-wilkins-a-wolters-kluwer-0001> (same). The front matter of the JAHA Supplement displays an ISSN number, notes that *Circulation* is published by Lippincott Williams & Wilkins, indicates how to contact Lippincott Williams & Wilkins, and lists subscription rates for receiving periodicals from the American Heart Association.

CIRCULATION (ISSN 0009-7322) is published weekly except combined the first two weeks in January and the last two weeks in December by Lippincott Williams & Wilkins at 16522 Hunters Green Parkway, Hagerstown, MD 21740. Business offices are located at 530 Walnut Street, Philadelphia, PA 19106-3621. Production offices are located at 351 West Camden Street, Baltimore, MD 21201-2436. Individuals may subscribe for their personal use at the following rates: \$206 for members of an American Heart Association scientific council and \$289 for nonmembers; international: \$353 for members of an American Heart Association scientific council and \$495 for nonmembers. Periodicals postage paid at Hagerstown, MD, and additional mailing offices. POSTMASTER: Send address changes to CIRCULATION, American Heart Association, Lippincott Williams & Wilkins, 16522 Hunters Green Parkway, Hagerstown, MD 21740.

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GST Registration Number 89552 4239 RT.

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Ex. 1095 at 7, 14. Thus, it is my opinion that there is a presumption that the JAHA Supplement and Voswinckel JAHA were publicly accessible as of their publication date on October 26, 2004, because they were published by an established publisher.

62. Even if the Voswinckel JAHA abstract were not meaningfully indexed, I am informed by counsel, as discussed *supra* ¶19, that it may still qualify as publicly accessible if cited



by a “research aid,” a publicly available publication that can reasonably lead a person interested in the relevant subject matter to the non-cataloged and non-indexed printed publication. Voswinckel JAHA was cited by a March 2005 article, Roxana Sulica & Michael Poon, *Medical therapeutics for pulmonary arterial hypertension: from basic science and clinical trial design to evidence-based medicine*, 3 EXPERT REV. CARDIOVASCULAR THERAPY 347-360 (2005) (“Sulica 2005”), attached as Exhibit 1104. Because Sulica 2005 generally discusses clinical trial design in treating pulmonary arterial hypertension, a person of ordinary skill in the art interested in the subject matter would be motivated to seek out Sulica 2005 and its cited articles. Ms. Wyman agrees that based on her definition of a POSA (Wyman Declaration at ¶ 3), a POSA would have been interested in Sulica 2005. Ex. 1110 (Wyman Dep. Tr.) at 112:16-113:4. As discussed *supra* ¶20, I am informed by counsel that a person of ordinary skill in the art would have experience treating patients with pulmonary hypertension or experience formulating treatments for pulmonary hypertension. Either way, it is my opinion that a person of ordinary skill in the art would be motivated to search for publications using the keyword “clinical trial” as well as “pulmonary arterial hypertension.” Using such keywords, Sulica 2005 can be easily found on *PubMed* and *WorldCat*. I conducted a *WorldCat* query using the keywords “pulmonary arterial hypertension” AND “clinical trial” for any content between 1971 and 2006 and found 143 results with Sulica 2005 being the ninth result. I also conducted a *PubMed* query using the same keywords between 1970 and 2006 and found 113 results with Sulica 2005 being the first result. I have attached the results of my search as Exhibit 1118. Thus, it is my opinion that even if the Voswinckel JAHA abstract were not meaningfully indexed, it would still qualify as a publicly accessible printed publication because Sulica 2005, an indexed and easy-to-find article, could serve as a “research aid” and direct persons of ordinary skill in the art to Voswinckel JAHA. Ms. Wyman agrees that

Voswinckel JAHA could be found in May 2006 using the citation provided in Sulica 2005 by simply asking a librarian. Ex. 1110 (Wyman Dep. Tr.) at 114:19-116:7. Moreover, the fact that Sulica 2005 cites Voswinckel JAHA further establishes that this reference can be and was found by persons of ordinary skill in the art prior to May 15, 2006. When asked how the authors of Sulica 2005 cited Voswinckel JAHA in an article written at the very least before 2006, Ms. Wyman had no explanation. Ex. 1110 (Wyman Dep. Tr.) at 123:6-9 (“I have no explanation how they knew about it.”).

63. Even if both the Voswinckel JAHA abstract and Sulica 2005 were not meaningfully indexed, I am informed by counsel, as discussed *supra* ¶20, that a printed publication that has never been cataloged or indexed in any library or database can nevertheless be found publicly accessible if it is publicly presented to an audience at an academic conference. Voswinckel JAHA was presented at the 2004 Scientific Sessions of the American Heart Association meeting held on November 7-10, 2004, in New Orleans, Louisiana. More specifically, Voswinckel JAHA was presented at the Ernest N. Morial Convention Center, Hall I2 on Wednesday November 10, 2004. For example:

**Pulmonary Arterial Hypertension: New  
Therapies**

Subspecialty: Integrative Biology  
Wednesday  
Ernest N Morial Convention Center, Hall I2  
Abstracts 1414–1418

**Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary  
Hypertension**

1414

Robert Voswinckel, Beate Enke, Andre Kreckel, Frank Reichenberger, Stefanie Krick,  
Henning Gall, Tobias Gessler, Thomas Schmehl, Markus G Kohstall, Friedrich Grimminger,  
Hossein A Ghofrani, Werner Seeger, Horst Olschewski; Univ Hosp Giessen, Giessen,  
Germany

Ex. 1093 at 6. As explained *supra* ¶36, other experts retained by Liquidia agree that the American

Heart Association Scientific Sessions are well-attended by persons of ordinary skill in the art and that they would have sought out abstracts specific to pulmonary arterial hypertension. Thus, it is my opinion that even if Voswinckel JAHA and Sulica 2005 were not meaningfully indexed, Voswinckel JAHA would still qualify as a publicly accessible printed publication because it was publicly presented at an academic conference well attended by persons of ordinary skill in the art.

64. In conclusion, contrary to the Wyman Declaration's assertion, Voswinckel JAHA was publicly available well before the priority date of May 15, 2006. By then, it had been received in multiple libraries worldwide, cataloged and indexed, cited by another publication that can serve as a "research aid" and presented at a well-attended academic conference.

#### **VII. VOSWINCKEL JESC QUALIFIES AS A PUBLICLY ACCESSIBLE PRINTED PUBLICATION**

65. Voswinckel JESC refers to an abstract titled "Inhaled Treprostinil is a Potent Pulmonary Vasodilator In Severe Pulmonary Hypertension" by R. Voswinckel, M.G. Kohstall, B. Enke, T. Gessler, F. Reichenberger, H.A. Ghofrani, W. Seeger, and H. Olschewski, which was published in Volume 25, Abstract Supplement (the "JESC Supplement") of the *European Heart Journal*. Voswinckel JESC was presented at the 2004 European Society of Cardiology Congress held on August 28 – September 1, 2004, in Munich, Germany. I have obtained a date-stamped copy of Voswinckel JESC from the University of Washington Health Sciences Libraries, dated November 16, 2004, from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison, dated October 15, 2004, and from the British Library, dated September 27, 2004. The date-stamped copies are attached as Exhibits 1089-1091, respectively. The Voswinckel JESC abstract appears on page 22 of the JESC Supplement and can be easily found using the table

of contents under the subject “Epidemiology and treatment of pulmonary arterial hypertension.”

*See* Ex. 1089 at 5; Ex. 1091 at 2.

66. It is my opinion that Voswinckel JESC qualifies as a publicly available printed publication that was accessible prior to the May 15, 2006, priority date. The Wyman Declaration argues that the JESC Supplement and Voswinckel JESC are difficult to find and “continue to be difficult to access even today.” Wyman Declaration at ¶¶29-33. In support of its argument, the Wyman Declaration asserts that Voswinckel JESC is difficult to find in the JESC Supplement (*see id.* at ¶30), that the JESC Supplement is released irregularly and may have been released significantly after the 2004 European Society of Cardiology Congress in August/September 2004 (*see id.* at ¶¶30-32), that the JESC Supplement does not appear in the European Heart Journal online archives (*see id.* at ¶32), and that I have not provided any evidence that the JESC Supplement was actually received by a library before the May 15, 2006, priority date (*see id.* at ¶33). Because each prong of the Wyman Declaration’s argument fails, as I explain in detail below, a person of ordinary skill in the art that was interested in the subject matter could have found Voswinckel JESC with reasonable diligence.

67. The Voswinckel JESC abstract is not difficult to find within the JESC Supplement. Despite the JESC Supplement being more than 700 pages and Voswinckel JESC being one of 3,850 abstracts, the abstracts are organized by subject in a table of contents that spans a mere 5 pages. *See* Ex. 1089 at 5-9. Specifically, abstract number 218, which corresponds to Voswinckel JESC, is listed under the subject “Epidemiology and treatment of pulmonary arterial hypertension.”

## Contents

| Programme number (P = poster)   | Page |
|---|------|
| Abstract Selection .....  | iii  |
| Abstract Review Committee .....   | vii  |
| Abstracts .....   | 1    |
| <b>Day 2 — Sunday 29 August 2004</b>  |      |
| 117–122 Trends and risk factors in cardiovascular disease .....                                 | 3    |
| 123–128 Risk factors management in prevention .....   | 4    |
| 129–134 Predictive factors in dilated cardiomyopathy .....                                      | 6    |
| 135–140 New applications of strain and strain rate imaging .....                                | 7    |
| 149–154 From mice to men: lessons in myocardial protection and hypertrophy .....                | 9    |
| 155–160 Impact of non surgical treatment and physiological stress on the GUCH-heart .....       | 10   |
| 161–166 Vascular growth and collateral vessels: opportunities and drawbacks .....               | 12   |
| 176–181 Drug eluting stent in complex lesion subsets .....                                      | 13   |
| 182–187 Gene variants in hypertension, coronary artery disease and dilated cardiomyopathy ..... | 15   |
| 188–193 Markers of severity in hypertrophic cardiomyopathy .....                                | 16   |
| 199–204 How to perfect coronary artery bypass grafting? .....                                   | 18   |
| 209–214 Intravascular ultrasound and plaque characterisation .....                              | 19   |
| 215–220 Epidemiology and treatment of pulmonary arterial hypertension .....                     | 21   |

### 218 Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension



R. Voswinckel, M.G. Kohstall, B. Enke, T. Gessler, F. Reichenberger, H.A. Ghofrani, W. Seeger, H. Olschewski. Medical Clinic 2, Department of Internal Medicine, Giessen, Germany

**Background:** Treprostinil has been approved for therapy of PAH (US and Canada) as continuous subcutaneous infusion. However, local pain at the infusion site is a major drawback. Inhaled therapy with another stable prostacyclin analogue (iloprost) has been approved for PPH (EMEA). In this study we investigated the acute hemodynamic response to inhaled treprostinil.

**Methods:** Open-label, single blind placebo-controlled clinical study. After placement of a Swan-Ganz catheter and a femoral artery line, patients inhaled solvent solution (placebo) (n=8) or treprostinil for 6 min (OptiNeb ultrasound nebulizer, Nebu-tec, Germany) in concentrations of 16, 32, 48, and 64 µg/ml (n=6, 6, 6, and 3 patients). Measurement was performed before and after 0, 15, 30, 60, 90, 120, 150 and 180 min. The mean area between the placebo and the treprostinil curves (ABC186) was calculated (baseline=100%).

**Results:** We investigated idiopathic PAH (n=10), collagen vascular disease (n=5), chronic thromboembolic disease (n=9), and pulmonary fibrosis (n=5), f/m = 19/10, age 56 ± 3 years, PAP, PAWP, and CVP 51.3 ± 2.2, 9.2 ± 0.8, and 6.6 ± 0.6 mmHg, CO 4.4 ± 0.3 l/min, SvO<sub>2</sub> 62.3 ± 1.2%, PVR 895 ± 72 dyn s cm<sup>-5</sup>. At 16 µg/ml there were no significant adverse events. Headache, cough or bronchoconstriction were observed in 2, 1, and 2 patients at 32, 48, and 64 µg/ml. These were mild and transient in all patients but one (64 µg/ml) who complained of major headache for 1 hour. Placebo inhalation was followed by slowly increasing PVR. Compared to this, the maximum treprostinil effect was reached after about 50 min and half-maximal effects at about 110 min. The ABC186 for PVR was -24.7 ± 4.4, -28.7 ± 4.9, and -29.0 ± 4.7%; PAP -14.4 ± 3.3, -13.5 ± 5.2, -13.1 ± 2.6%; SAP -5.1 ± 3.0, -6.0 ± 3.1, -3.8 ± 2.1% at 16, 32 and 48 µg/ml.

**Conclusion:** Treprostinil inhalation results in a significant long-lasting pulmonary vasodilatation. With the applied technology, at a concentration of 16 µg/ml, near maximal pulmonary vasodilatation is achieved without adverse effects. At higher doses, local and systemic side effects may occur, whereas pulmonary selectivity is preserved.

This study was supported by Lung Rx.

Ex. 1089 at 5, 12. Furthermore, the JESC Supplement indexes Voswinckel JESC by topic in the Index of Topics that spans a mere 9 pages. Specifically, abstract number 218 is indexed under the topic “Therapy (Pulmonary circulation)”.

Therapy (Pulmonary circulation)

155, 157, 217, 218, 219, 220, P541, P546, P547, P549, P553, P558, P1133,  
P1142, P1861, P2370, 2725, 2726, 2727, 2728, 2729, P2831, P3399

Ex. 1092 at 10. As stated *supra* ¶23, I am informed by counsel that that a person of ordinary skill in the art would have a medical education with a specialty in pulmonology or cardiology or experience in treating pulmonary hypertension. Thus, it is my opinion that a person of ordinary skill in the art interested in the subject matter would have looked for and found the Voswinckel JESC abstract under the subject “Epidemiology and treatment of pulmonary arterial hypertension” in the JESC Supplement table of contents and under the topic “Therapy (Pulmonary circulation)” in the JESC Supplement Index of Topics.

68. The assertion that the JESC Supplement is released irregularly does not support any significant delay between the 2004 European Society of Cardiology Congress in August/September 2004 and the release of the associated abstract supplement. When asked how she defined phrase “significantly delayed” or “well after” the conference, Ms. Wyman stated only months, which would place Voswinckel JESC’s release well before May 2006. Ex. 1110 (Wyman Dep. Tr.) at 130:22-131:3 (“Months. Like the six months you just mentioned.”); *see also id.* at 126:19-22 (“Q. [S]o I believe you said you had defined ‘well after’ as roughly a few months; is that right? A. Correct.”). The Wyman Declaration’s only support for this notion is Wyman’s single anecdote that she has seen an abstract supplement from a librarian’s conference, which has absolutely no relation or resemblance to the 2004 European Society of Cardiology Congress, not be released for a few years. *See* Wyman Declaration at ¶31, n.9. In Ms. Wyman’s own words, there would have been more of an “urgency” to publish abstracts from a medical conference like the European Society of Cardiology Congress than the Centre for the Study of Book symposium

she cites. Ex. 1110 (Wyman Dep. Tr) at 125:13-126:15. Furthermore, the *European Heart Journal* online archive,<sup>16</sup> which is Exhibit 2049, that the Wyman Declaration relies on actually defeats Wyman's argument that the release of the JESC Supplement may have been significantly delayed. A review of the supplement release dates and the conference dates as shown on the *European Heart Journal* online archive reveals that the vast majority of the abstract supplements were released before their associated conference ended. See Ex. 2049. The greatest delay between a European Society of Cardiology Congress and the release of an abstract supplement was 62 days, which is much shorter than the approximately 1.5-year gap between the August 28 - September 1, 2004 European Society of Cardiology Congress conference date and the priority date. See *id.* at 1.

69. A quick look through the *European Heart Journal* online archive tells us that the Wyman Declaration's assertion that the JESC Supplement does not appear in the *European Heart Journal* online archive is plainly false. Wyman's own exhibit shows that the JESC Supplement containing Voswinckel JESC is listed on the *European Heart Journal* online archive as the entry "Volume 25, Issue suppl\_1, September 2004." See *id.* at 3. This is a telling example, among several others highlighted in this Report, of Wyman's lack of ordinary diligence in performing her searches.

70. The Wyman Declaration's assertion that I have not provided any evidence that the JESC Supplement was actually received by a library before the May 15, 2006, is based on a copy of Voswinckel JESC pulled from the University of Iowa Libraries, which was not date-stamped, attached to my Declaration in the '793 IPR. See Ex. 1036 at ¶68. The copy of Voswinckel JESC

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<sup>16</sup> See <https://academic.oup.com/eurheartj/supplements> (last visited Nov. 29, 2021).

from the University of Iowa Libraries is attached as Exhibit E to Exhibit 1036. I also obtained the MARC record for the journal in which the abstract appeared, the *European Heart Journal*, in the University of Iowa Libraries. See Attachment E1 to Exhibit 1036.

71. Based on the copy of Voswinckel JESC pulled from the University of Iowa Libraries and the MARC record in its online library catalog attached as Attachment E1 to Exhibit 1036, it is my opinion that Voswinckel JESC was available in the University of Iowa Libraries on October 15, 2004. Attachment E1 to Exhibit 1036 also shows that Voswinckel JESC was cataloged with two descriptor terms reading “Cardiology \$v Periodicals” and “Heart \$x Diseases \$v Periodicals” in the 650 fields.

72. As noted in the holdings information (362 field of Attachment E1 to Exhibit 1036), the University of Iowa Libraries has received the *European Heart Journal* in print since February 1980 and continues to receive the publication. In view of the MARC record for Attachment E1 to Exhibit 1036, Voswinckel JESC was publicly available on October 15, 2004, because the serial title had been received, cataloged, and indexed in the University of Iowa Libraries and made part of its online catalog database.

73. Attached as Attachment E2 to Exhibit 1036 is a true and correct copy of the MARC record for the print version of the *European Heart Journal* obtained from the OCLC bibliographic database. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment E2 to Exhibit 1036, that library code is “NSD,” which means that the MARC record for this serial was cataloged as part of the National Serials Data Program at the Library of Congress. As can be seen in the “Entered” field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 5585193 on October 25, 1979, as shown in the “Entered” field (“19791025”). The library continues to update this MARC record



and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment E2 to Exhibit 1036 occurred on February 18, 2020, as shown in the “Replaced” field (“20200218”). I personally identified and retrieved the MARC record that is Attachment E2 to Exhibit 1036 on January 3, 2021. The “BLvl” entry in Attachment E2 to Exhibit 1036 is “s,” which indicates that the *European Heart Journal* is a serial publication. Accordingly, the MARC record corresponds to the *European Heart Journal* from the time that the serial title began and includes the date of the Voswinckel JESC abstract.

74. Attachment E2 to Exhibit 1036 further includes an entry in field 050 (“RC681.A1 \$b E94”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment E2 to Exhibit 1036 further includes an entry in field 060 (“W1 \$b EU636”), a subject matter consistent with the National Library of Medicine classification system. Attachment E2 to Exhibit 1036 further includes an English language descriptor term reading “Cardiology \$v Periodicals” (*see* Attachment D6 to Exhibit 1036, Library of Congress subject heading sh2008117649) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached as Attachment E2 to Exhibit 1036 was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entry.

75. Further, as of October 25, 1979, the MARC record attached as Attachment E2 to Exhibit 1036 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before that same date through any library with access to the OCLC bibliographic database or through an individual library. Therefore, in view of

Attachment E2 to Exhibit 1036, Voswinckel JESC was publicly accessible by at least October 15, 2004, and in any event at least one year before the May 15, 2006, priority date, because by that time it had been received, cataloged, and indexed at the University of Iowa Libraries and made part of the OCLC bibliographic database. Attachment E2 to Exhibit 1036 indicates that the *European Heart Journal* as cataloged at the Library of Congress is currently available from 282 libraries (“282 other holdings”).

76. Wyman also argues that the MARC record for the *European Heart Journal* from the University of Iowa Libraries is for the entire *European Heart Journal* and not specific to the JESC Supplement nor to Voswinckel JESC. See Wyman Declaration at ¶35. However, as explained *supra* ¶54, Wyman ignores my deposition (see Ex. 2043 at 104:2 – 113:18, 117:24 – 125:19) where I explain that field 525 of the MARC record for a journal accounts for the fact that the journal has supplements and that fields 362 and 525 of the MARC record indicate whether a library holds every supplement to the journal. Indeed, fields 362 and 525 of the MARC record for the *European Heart Journal* from the University of Iowa Libraries show that the *European Heart Journal* had an irregular supplement and that the libraries which subscribe to the journal held every supplement, including the 2004 JESC Supplement, since February 1980. See Attachment E2 to Exhibit 1036.

77. In view of the above, this issue of the *European Heart Journal* was publicly available on October 15, 2004, and in any event, more than one year before the May 15, 2006, priority date, because by that date it had been received, cataloged, and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the University of Iowa Libraries. For these reasons, it is my opinion that Voswinckel JESC was published and accessible to the public on October 15, 2004.

78. The above information is sufficient to establish that Voswinckel JESC was publicly available well before May 15, 2006. Nevertheless, in the past month, I have also located three other date-stamped copies of Voswinckel JESC confirming the same.

79. Attached as Exhibit 1089 is a copy of the JESC Supplement containing Voswinckel JESC from the University of Washington Health Sciences Libraries, date stamped November 16, 2004.



Ex. 1089 at 1.

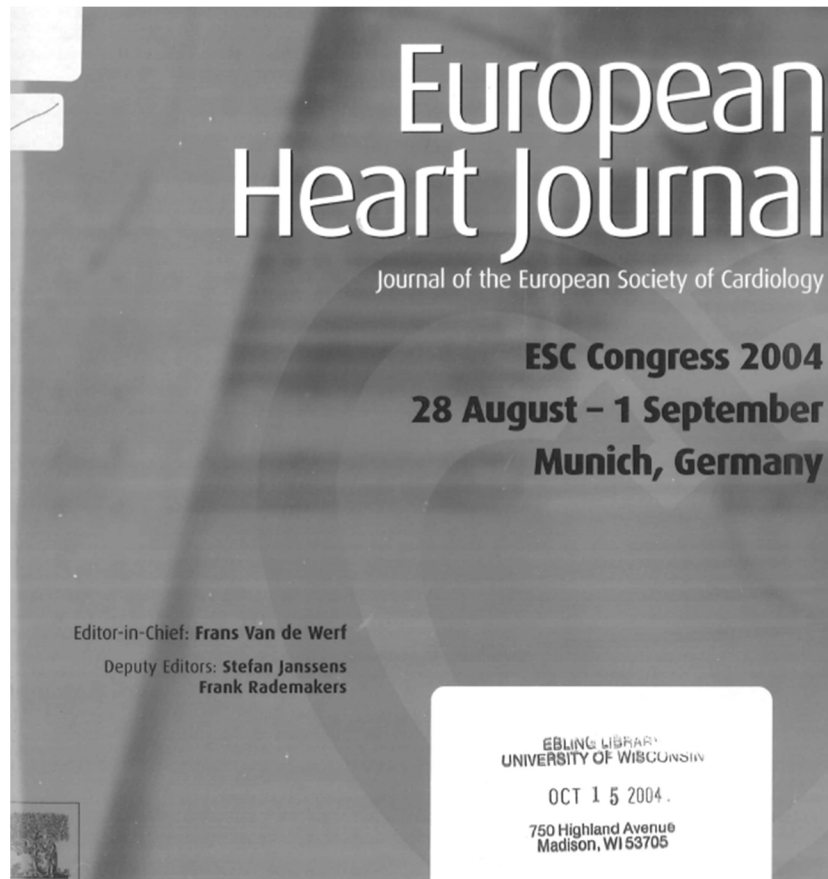
80. The University of Washington Health Sciences Libraries do not make their MARC records visible to the public. I obtained a detailed record for the *European Heart Journal* from the University of Washington Health Sciences Libraries, attached as Exhibit 1127, which I believe is

based on the publication's MARC record.<sup>17</sup> The record shows that the *European Heart Journal* has irregularly issued supplements and that the University of Washington Health Sciences Library holds every supplement, including the JESC Supplement, since 1980. *See* Ex. 1127. The record also indicates a MeSH Subject of "Cardiology". Thus, as of its cataloging, the publication corresponding to Exhibit 1127 was indexed according to its subject matter by virtue of its MeSH Subject.

81. Attached as Exhibit 1090 is a copy of the JESC Supplement containing Voswinckel JESC from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison, date stamped October 15, 2004. It was provided in a separate *Inter Partes Review*, IPR2017-01621.

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<sup>17</sup> Available at <https://alliance-primo.hosted.exlibrisgroup.com/permalink/f/kjtuig/CP71118869740001451> (last accessed Dec. 8, 2021).



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**ESC Congress 2004, Munich**

*28 August - 1 September 2004*

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EBLING LIBRARY  
UNIVERSITY OF WISCONSIN

OCT 15 2004

750 Highland Avenue  
Madison, WI 53705

Ex. 1090 at 1-2.

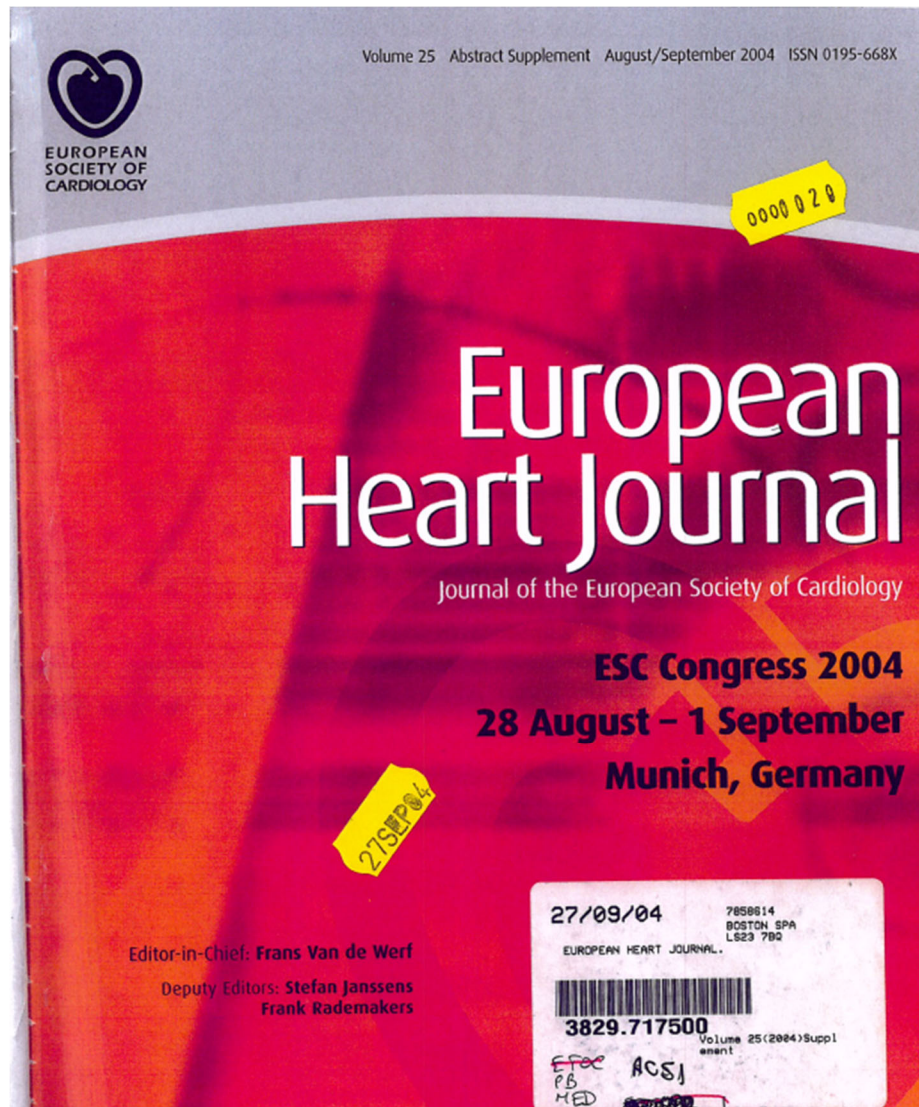
82. I obtained the MARC record for the *European Heart Journal* from the Ebling Library for the Health Sciences at the University of Wisconsin – Madison, attached as Exhibit

1128.<sup>18</sup> Field 362 of the MARC record shows that the Ebling Library holds every issue of the *European Heart Journal* since 1980. *See* Ex. 1128. The MARC record includes an entry in field 050 (“RC681.A1\$bE87C”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). *See id.* The MARC record further includes English language descriptor terms reading “Cardiology\$zEurope\$vPeriodicals” and “Cardiology” among others, in the 650 field. *Id.* Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Exhibit 1126 was indexed according to its subject matter by virtue of at least two independently sufficient classifications: the field 050 entry and the field 650 entries.

83. Attached as Exhibit 1091 is a copy of the JESC Supplement containing Voswinckel JESC from the British Library, date stamped September 27, 2004.

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<sup>18</sup> Available at <https://search.library.wisc.edu/catalog/9911025127902121> (last accessed Dec. 8, 2021).



Ex. 1091 at 1. “Boston SPA” is a reading room that provides access to material that is part of the “British Library” in Europe, which is equivalent to the Library of Congress in the United States.<sup>19</sup>

<sup>19</sup> The Library of Congress and its sister institutions in the Washington, DC area, the National Library of Medicine and the National Agricultural Library, serve as cornerstone libraries with the largest collections of resources in the United States. Each country has a large library and archives institution that serves a parallel role for its citizens. In the United Kingdom, the British Library (BL) is the pre-eminent institution. In addition to its role as an organizational leader for the libraries throughout the country, the British Library provides access to its collections for users around the world seeking research, inspiration, and enjoyment through the Document Supply Centre (DSC) and its physical Boston Spa location. <https://www.bl.uk/>; <https://www.york.ac.uk/library/other-libraries/british-library/>.

84. I obtained the MARC record for the *European Heart Journal* from the University of California Davis Health Sciences Library, attached as Exhibit 1129.<sup>20</sup> Fields 362 and 525 of the MARC record show that the *European Heart Journal* has irregularly issued supplements and that the British Library holds every supplement, including the JESC Supplement, since February 1980. *See* Ex. 1129. The MARC record includes an entry in Field 050 (“RC681.A1”)—as described above, this includes a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). *See id.* The MARC record further includes English language descriptor terms reading “Cardiology |v Periodicals” and “Heart |x Diseases |x Periodicals,” among others, in the 650 field. *Id.* Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Exhibit 1129 was indexed according to its subject matter by virtue of at least two independently sufficient classifications: the field 05000 entry and the field 650 entries.

85. I also obtained a research librarian’s declaration of public availability from The British Library, attached as Exhibit 1119. The declaration states that “[Voswinckel JESC] was receipted by The British Library on 27th September 2004, and it would have been available for public use from that date. A scan of the cover pages showing the date stamp on page one (referring to Exhibit 1091) indicating the date of availability, title page and contents pages have been attached.” Ex. 1119 at 1. Thus, it is my opinion that the declaration confirms that Voswinckel JESC and the JESC Supplement were publicly available at the British Library from September 27, 2004.

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<sup>20</sup> Available at [http://primocat.bl.uk/F/?func=direct&local\\_base=PRIMO&doc\\_number=007858614&format=001&con\\_lng=eng](http://primocat.bl.uk/F/?func=direct&local_base=PRIMO&doc_number=007858614&format=001&con_lng=eng) (last accessed Dec. 8, 2021).



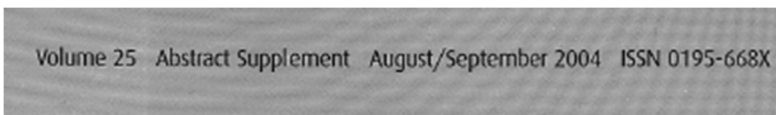
86. In sum, three date-stamped exhibits confirm that the Abstract Supplement to Volume 25 of the *European Heart Journal* dated August/September, 2004, was received and publicly available within two months, i.e., by November 16, 2004.

| Exhibit No. | Location  | Date Stamped       |
|-------------|---|--------------------|
| 1089        | University of Washington Health Sciences Libraries                              | November 16, 2004  |
| 1090        | Ebling Library for the Health Sciences at the University of Wisconsin – Madison | October 15, 2004   |
| 1091        | British Library, Boston SPA   | September 27, 2004 |

87. The Wyman Declaration also argues that Voswinckel JESC was not publicly accessible before May 15, 2006, because neither the Supplement nor the abstracts within it were meaningfully indexed. *See* Wyman Declaration at ¶¶34-37. However, the Wyman Declaration does not even present any search results for Voswinckel JESC on any database, nor does it disclose any search terms, to support its argument. Indeed, the Wyman Declaration states in ¶38 that based on Wyman’s “own research,” Voswinckel JESC was not meaningfully indexed, but neglects to describe any such “research” she conducted with respect to Voswinckel JESC. As discussed *supra* ¶23, I am informed by counsel that a person of ordinary skill in the art would have experience treating patients with pulmonary hypertension. Thus, it is my opinion that a person of ordinary skill in the art would be motivated to search for publications using the keywords “pulmonary hypertension” and “treprostinil.” Using such keywords, the JESC Supplement can be easily found on the Web of Science. I conducted a Web of Science query using the keywords “pulmonary hypertension” AND “treprostinil” for publications between 2001 and 2006 and found 55 results with the JESC Supplement being the 34th result. My search results on Web of Science are attached as Exhibit 1120. Thus, it is my opinion that because the JESC Supplement could be found by a

person of ordinary skill in the art with reasonable diligence on well-known databases prior to May 15, 2006, the JESC Supplement qualifies as a publicly accessible printed publication.

88. Furthermore, the JESC Supplement and Voswinckel JESC were published by the publisher Elsevier which, in my opinion, is an established publisher. The cover page and front matter of the JESC Supplement displays an ISSN number, publication date, and identification of the publisher.



Volume 25 Abstract Supplement August/September 2004 ISSN 0195-668X

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Ex. 1089 at 1, 4. Thus, it is my opinion that there is a presumption that the JESC Supplement and Voswinckel JESC were publicly accessible as of their publication date on September 1, 2004, because they were published by an established publisher.

89. Even if Voswinckel JESC were not meaningfully indexed, I am informed by counsel, as discussed *supra* ¶19, that it may still qualify as publicly accessible if cited by a “research aid,” a publicly available publication that can reasonably lead a person interested in the relevant subject matter to the non-cataloged and non-indexed printed publication. Voswinckel JESC was cited by a June 2005 article, Hossein A. Ghofrani et al., *Neue Therapieoptionen in der Behandlung der pulmonalarteriellen Hypertonie*, 30(4) HERZ 296-302 (June 2005) (“Ghofrani 2005”). A copy of Ghofrani 2005, date-stamped July 7, 2005, from the British Library is attached as Exhibit 1121. Because the English abstract of Ghofrani 2005 discusses inhaled treprostinil as a promising new therapy in treating pulmonary arterial hypertension, a person of ordinary skill in

the art interested in the subject matter would be motivated to seek out Ghofrani 2005 and its cited articles. Ms. Wyman acknowledged during her deposition that a POSA as defined in Paragraph 3 of her declaration would be interested in Ghofrani 2005. Ex. 1110 (Wyman Dep. Tr.) at 162:11-163:14. As discussed *supra* ¶23, I am informed by counsel that a person of ordinary skill in the art would have experience treating patients with pulmonary hypertension and would be interested in searching for new therapies. Thus, it is my opinion that a person of ordinary skill in the art would be motivated to search for publications using the keywords “pulmonary arterial hypertension” and “therapies.” Using such keywords, Ghofrani 2005 can be easily found on *PubMed* and *WorldCat*. I conducted a *WorldCat* query using the keywords “pulmonary arterial hypertension” AND “therapies” for any content between 1971 and 2006 and found 204 results with Ghofrani 2005 being the 34th result. I also conducted a *PubMed* query using the same keywords between 1999 and 2006 and found 103 results with Ghofrani 2005 being the 11th result. My search results for Ghofrani 2005 on PubMed and WorldCat are attached as Exhibit 1122. Thus, it is my opinion that even if Voswinckel JESC were not meaningfully indexed, it would still qualify as a publicly accessible printed publication because Ghofrani 2005, an indexed and easy-to-find article, could serve as a “research aid” and direct persons of ordinary skill in the art to Voswinckel JESC. Moreover, the fact that Ghofrani 2005 cites Voswinckel JESC further establishes that this reference can be and was found by persons of ordinary skill in the art prior to May 15, 2006.

90. The Wyman Declaration also makes the unsupported assertion that the table of contents in the JESC Supplement “lacks a *meaningful* topic index.” Wyman Declaration at ¶36. The Wyman Declaration does not provide any explanation as to why the JESC Supplement table of contents, which provides a detailed list of topics and only spans 5 pages, would not be sufficient to guide a person of ordinary skill to Voswinckel JESC. And, as discussed above, within this table

of contents there is a specific section titled “Epidemiology and treatment of pulmonary arterial hypertension.” *See* Ex. 1089 at 5; Ex. 1091 at 2. In my opinion, “treatment of pulmonary hypertension” within the short table of contents provides a more-than-meaningful index. During her deposition, Ms. Wyman agreed that the topic “Treatment of Pulmonary Arterial Hypertension” is only 12 lines down on the first page of the table of contents, that a POSA as she defines it would be interested in treatments for PAH, and that Voswinckel JESC is only the fourth abstract listed under that topic. Ex. 1110 (Wyman Dep. Tr.) at 160:19-161:7. Thus, it is my opinion, that a person of ordinary skill in the art interested in the subject matter would have looked for and found the Voswinckel JESC abstract under the subject “Epidemiology and treatment of pulmonary arterial hypertension” in the JESC Supplement table of contents with ordinary diligence.

91. Finally, the Wyman Declaration mischaracterizes my deposition. *See* Wyman Declaration at ¶37. I was not able to locate the Voswinckel JESC abstract because I was not able to access *Ovid*, *PubMed*, or *CAPLus* due to the COVID-19 pandemic shutting down medical libraries across the country. *See* Ex. 2043 at 197:7 – 198:17, 241:12-243:21. It appears that Wyman did not carefully review my deposition transcript.

92. Even if Voswinckel JESC were not meaningfully indexed, I am informed by counsel, as discussed *supra* ¶20, that a printed publication that has never been cataloged or indexed in any library or database can nevertheless be found publicly accessible if it is publicly presented to an audience at an academic conference. Voswinckel JESC was presented at the 2004 European Society of Cardiology Congress held on August 28-September 1, 2004, in Munich, Germany. More specifically, Voswinckel JESC was presented on Day 2 of the conference, Sunday August 29, 2004. For example:

Reply Declaration of Sylvia Hall-Ellis, Ph.D.  
Petition for *Inter Partes* Review of  
U.S. Patent No. 10,716,793 B2

| Day 2 — Sunday 29 August 2004 |   |    |
|-------------------------------|---|----|
| 117–122                       | Trends and risk factors in cardiovascular disease .....                                 | 3  |
| 123–128                       | Risk factors management in prevention .....   | 4  |
| 129–134                       | Predictive factors in dilated cardiomyopathy .....                                      | 6  |
| 135–140                       | New applications of strain and strain rate imaging .....                                | 7  |
| 149–154                       | From mice to men: lessons in myocardial protection and hypertrophy .....                | 9  |
| 155–160                       | Impact of non surgical treatment and physiological stress on the GUCH-heart .....       | 10 |
| 161–166                       | Vascular growth and collateral vessels: opportunities and drawbacks .....               | 12 |
| 176–181                       | Drug eluting stent in complex lesion subsets .....                                      | 13 |
| 182–187                       | Gene variants in hypertension, coronary artery disease and dilated cardiomyopathy ..... | 15 |
| 188–193                       | Markers of severity in hypertrophic cardiomyopathy .....                                | 16 |
| 199–204                       | How to perfect coronary artery bypass grafting? .....                                   | 18 |
| 209–214                       | Intravascular ultrasound and plaque characterisation .....                              | 19 |
| 215–220                       | Epidemiology and treatment of pulmonary arterial hypertension .....                     | 21 |


Ex. 1089 at 5; Ex. 1091 at 2. Other experts retained by Liquidia agree that the European Society of Cardiology Congress was well-attended by persons of ordinary skill in the art and that they would have sought out abstracts specific to pulmonary arterial hypertension. Dr. Hill opines that “[I]like the AHA Scientific Sessions Conference, the ESC Conference is a leading meeting on the cardiovascular system and diseases and conditions of the circulatory system, which a POSA in 2004 would have attended. . . . In my experience, a POSA would have been highly interested in treatments for pulmonary hypertension, including pulmonary arterial hypertension, and thus would have been interested in abstracts and presentations included in this session. . . . Accordingly, a POSA would have been interested in the abstracts listed and identified Voswinckel JESC within the EHJ Supplement and abstract book.” Ex. 1106, Reply Declaration of Dr. Hill, at ¶¶28-29. Thus, it is my opinion that even if Voswinckel JESC were not meaningfully indexed, it would still qualify as a publicly accessible printed publication because it was publicly presented at an academic conference well attended by persons of ordinary skill in the art.

93. In conclusion, contrary to the Wyman Declaration’s assertion, Voswinckel JESC was publicly available well before the priority date of May 15, 2006. By then, it had been received in multiple libraries worldwide, cataloged and indexed, cited by another publication that can serve as a “research aid,” and presented at a well-attended academic conference.

Reply Declaration of Sylvia Hall-Ellis, Ph.D.  
Petition for *Inter Partes* Review of  
U.S. Patent No. 10,716,793 B2

94. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001.

Executed on February 10, 2022.

  
Sylvia D. Hall-Ellis, Ph.D.