

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

MERCK SERONO S.A.,
Patent Owner.

Case IPR2023-00481
U.S. Patent No. 8,377,903

**DECLARATION OF NANCY E. ADAMS Ed.D.
IN SUPPORT OF PETITION FOR INTER PARTES REVIEW OF U.S.
PATENT NO. 8,377,903**

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Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Inter Partes Review of U.S. Patent No. 8,377,903
Declaration of Nancy E. Adams Ed.D.

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I. INTRODUCTION

I, Nancy E. Adams Ed.D., do hereby declare as follows:

1. I have been retained as an independent expert witness on behalf of Hopewell Pharma Ventures, Inc. for proceedings before the United States Patent and Trademark Office ("PTO") regarding the authenticity and public availability of certain prior-art references in relation to US Patent No. 8,377,903.

2. I am being compensated for my work in this matter at my customary hourly rate, which is \$250/hour. I am also reimbursed for any reasonable expenses associated with my work on this matter. My compensation is not contingent on the results of my study, the substance of my opinions, or the outcome of this matter.

3. I understand that this Declaration accompanies a petition for an Inter Partes Review (IPR) involving U.S. Patent No. 8,377,903 ("the '903 patent") (EX1001), which resulted from U.S. Patent Application No. 12/766,173 ("the '173 application"), filed on April 23, 2010. I understand that the '903 patent alleges a priority date of December 22, 2004. I refer to this date throughout this declaration.

A. Qualifications and Professional Experience

4. My complete qualifications and professional experience are described in my curriculum vitae (EX1030). The following is a brief summary of my relevant qualifications and professional experience.

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5. I am the Assistant Dean of Foundational Sciences at Penn State College of Medicine and Librarian for Education and Instruction at Harrell Health Sciences Library. I have held this combined position since July of 2017; before that, I held the position Associate Director of the Harrell Health Sciences Library, which began 2010. Before that, I held numerous Librarian positions at the University level, such as Harrisburg University of Science and Technology, The University of Maine, and Wayne State University. I have accumulated a total of 26 years of experience working in an academic library and medical library. I hold an Ed.D. in Adult Education from Pennsylvania State University and a Masters in Library and Information Science from Wayne State University.

6. I am an expert on library cataloging, classification, and searching. I have published contributed chapters to editions on this subject, *Curriculum Mapping: A Match Made for Librarian Skill*, and *Making it better: library and student services collaboration at a new university* (2020 and 2012). I have taught workshops on literature searching to a myriad of college students, physicians, and medical students for decades. I have given presentations, such as “Searching PubMed like an Expert: The Evolution, a PubMed Searching Discussion Forum.” I have served as the search specialist on a systematic review team in which my role was to formulate, execute, and document an exhaustive search of the literature answering a specific research question.

7. I am familiar with metadata schema design and implementation. As a librarian, I routinely use the metadata associated with publications to answer reference questions or track down items that researchers need. I have used online cataloging systems to create new catalog records for items held by libraries.

8. I am personally familiar with many online catalogs, databases, and search engines, including all of the particular catalogs, databases, and search engines that I relied upon in forming my opinions. In preparing for this Declaration, I used the following authoritative information system to search for records:

- Google Scholar (<http://scholar.google.com>)

B. Scope of This Declaration

9. I have been asked to offer an opinion on the authenticity and public-availability date of the following document:

- Stelmasiak, Z., Solski, J., Nowicki, J., Porebska-Piwowarczyk, E., Jakubowksa, B., Ryba, M., and Grieb, P., (1998, Jan 1), "A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis," *Medical Science Monitor*, vol. 4, no. 1, pp. 4-8 (EX1013, "Stelmasiak").

C. Evidence Considered in Forming My Opinions

10. In preparing this Declaration, I have reviewed the documents I reference herein, and each of these is a type of material that experts in my field of library cataloging and reference classification would reasonably rely upon when forming their opinions.

II. AUTHENTICITY AND PUBLIC AVAILABILITY OF *STELMASIAK* (EX1013)

A. Authentication

11. **EX1013** is a true and correct copy of "A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis," (*"Stelmasiak"*), *Medical Science Monitor*, vol. 4, no. 1, pp. 4-8, that I obtained from the publisher of the journal. I began my research by searching Google Scholar by the title of *Stelmasiak* for records, and a retrieved record led me to the publisher's webpage for *Stelmasiak* at <https://medscimonit.com/abstract/index/idArt/502798> (**EX**) that shows the publisher provides "open access" to *Stelmasiak*, meaning there is no restriction on user access. I then followed the PDF link to download the full text of *Stelmasiak*. This publisher copy is presented as **EX1013** in this Declaration.

12. In **EX1013**, page 1 shows the title, authors, abstract, key words, and a note at the bottom of page 1 title showing *Stelmasiak* was received "97.08.30"

(1997, August 30), and accepted "98.01.03" (1998, January 3). **EX1013** shows *Stelmasiak* has a total of 5 pages, including 21 references.

13. The publisher's copy of *Stelmasiak* (**EX1013**) is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text on each page appears to flow seamlessly from one page to the next, and there are no visible alterations to the document. Moreover, **EX1013** is in the custody of the publisher, a place where, if authentic, it would likely be found. Accordingly, I see no reason to question the authenticity of this copy of *Stelmasiak* (**EX1013**).

B. Usage Record

14. Actual usage of an article is reflected by other articles that make reference to it. Langtry, H.D., and Lamb, H.M., "Cladribine, A Review of its Use in Multiple Sclerosis," *Biodrugs* 9(5):419-433, vol. 9, no. 5, pp. 419-433 "*Langtry*" (**EX1016**) cites *Stelmasiak*, which shows that as of *Langtry*'s publication date, *Stelmasiak* would have been publically available, which was before December 22, 2004. *Stelmasiak* was cited in the '173 application specification when it was originally filed (**EX1004**, page 28, lines 13-14). I understand that the '173 application later issued as the '903 patent, which also cites *Stelmasiak* (**EX1001**, col. 3, lines 20-21).

C. Summary of My Opinion on *Stelmasiak*

15. The publisher's copy of *Stelmasiak* (**EX1013**) and my knowledge of digital archives in particular inform my opinion that *Stelmasiak* was published on January 3, 1998. Because *Medical Science Monitor* has been available as a journal, *Stelmasiak* would have become publicly accessible when it was published on January 3, 1998 (**EX1013**), before December 22, 2004.

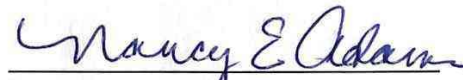
III. LIST OF DOCUMENTS CONSIDERED

<i>Exhibit #</i>	<i>Description</i>
1001	De Luca, G., "Cladribine Regimen for Treating Multiple Sclerosis," U.S. Patent No. 8,377,903 B2 (filed Apr. 23, 2010; issued Feb. 19, 2013)
1004	File History for U.S. Patent No. 8,377,903, pages 25-49
1013	Stelmasiak, Z., et al., "A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis," <i>Med Sci Monit</i> 4(1):4-8 (1998)
1016	Langtry, H.D. and Lamb, H.M., "Cladribine, A Review of its Use in Multiple Sclerosis" <i>BioDrugs</i> 9(5):419-433 (1998)
1030	Curriculum Vitae of Nancy E. Adams, Ed.D.
1039	Stelmasiak, Z., et al., "A pilot trial of cladribine (2-chlorodeoxyadenosine) in remitting-relapsing multiple sclerosis," <i>Med Sci Monit</i> 4(1):4-8 (1998), available at https://medscimonit.com/abstract/index/idArt/502798

IV. CONCLUSION

16. I 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 Section 1001 of Title 18 of United States Code.

Respectfully submitted,


Nancy E. Adams, Ed.D.

Date: 1/22/23