

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOPEWELL PHARMA VENTURES, INC.,
Petitioner,

v.

ARES TRADING S.A.,
Patent Owner.

Case IPR2023-00482
U.S. Patent No. 10,849,919

**DECLARATION OF NANCY E. ADAMS Ed.D. IN SUPPORT OF
PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO.
10,849,919**

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Inter Partes Review of U.S. Patent No. 10,849,919
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. 10,849,919.

2. I am being compensated for my work in this matter at my customary hourly rate, which is \$250/hour. I am also being reimbursed for any reasonable expenses associated with my work. 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 IPR involving U.S. Patent No. 10,849,919 ("the '919 patent") (EX1001), which resulted from U.S. Patent Application No. 16/199,119 ("the '119 application"), filed on November 23, 2018. I understand that the '919 patent alleges a priority date of November 24, 2017. 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 (EX1064). The following is a brief summary of my relevant qualifications and professional experience.

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 frequently 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 systems to search for records:

- Online catalog of the National Library of Medicine
(https://catalog.nlm.nih.gov/discovery/search?vid=01NLM_INST:01NLM_INST&lang=en);
- Web of Science (<http://clarivate.com/products/webofscience>)
- 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 documents:

- Alvarez-Gonzalez, C., Adams, A., Joela, M., Turner, B.P., Giovannoni, G., Baker, D., and Schmierer, K., (2017, Jul 5), “Cladribine to treat disease exacerbation after fingolimod

discontinuation in progressive multiple sclerosis,” *Annals of Clinical and Translational Neurology*, vol. 4, no. 7, pp. 506-511 (EX1009, “Alvarez-Gonzalez”);

- Giovannoni, G., Comi, G., Cook, S., Rammohan, K., Rieckmann, P., Sørensen, P.S., Vermersch, P., Chang, P., Hamlett, A., Musch, B., and Greenberg, S., (2010, Feb 4), “A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis,” *The New England Journal of Medicine*, vol. 362, pp. 416-426 (EX1007, “Giovannoni”);
- Montalban, X., Cohen, B., Leist, T., Moses, H., Hicking, C., and Dangond F., (2016, Apr 18), “Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study (P3.029),” *Neurology*, vol. 86, suppl. 16, 7 pages (EX1006, “Montalban”); and
- Schreiber, K., and Sorensen, P.S., (2011, Feb), “Cladribine in the treatment of multiple sclerosis,” *Clinical Investigation* vol. 1, no. 2, pp. 317-326 (EX1008, “Schreiber”).

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 *ALVAREZ-GONZALEZ* (EX1009)

A. Authentication

11. **EX1009** is a true and correct copy of “Cladribine to treat disease exacerbation after fingolimod discontinuation in progressive multiple sclerosis” (*Alvarez-Gonzalez*), by Alvarez-Gonzalez et al., *Annals of Clinical and Translational Neurology*, vol. 4, no. 7, pp. 506-511, that I obtained from the publisher. I began my research by searching Google Scholar by the title of *Alvarez-Gonzalez* for records, and a retrieved record led me to the publisher’s webpage for *Alvarez-Gonzalez* at <https://onlinelibrary.wiley.com/doi/full/10.1002/acn3.410> (**EX1048**). Clicking the small, red PDF icon on this webpage led directly to *Alvarez-Gonzalez*. This particular article is available through “open access,” meaning there is no restriction on user access. I then downloaded the full text of *Alvarez-Gonzalez*. This publisher copy is presented as **EX1009** in this Declaration.

12. In **EX1009**, page 1 shows the title, authors, and abstract. A publication history note shows the manuscript was received on February 1, 2017, revised on March 16, 2017, and accepted on March 17, 2017. The top of this page shows *Alvarez-Gonzalez* was published in volume 4, number 7 (2017) of *Annals of Clinical and Translational Neurology* and the “Details” section shows that the

page numbers were 506-511. **EX1009** shows *Alvarez-Gonzalez* has a total of six pages, including 25 references.

13. The publisher's copy of *Alvarez-Gonzalez* (**EX1009**) 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, **EX1009** 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 *Alvarez-Gonzalez* (**EX1009**).

B. PubMed Records

14. Because *Alvarez-Gonzalez* was published in an online open-access journal, the publication date is the public availability date. To determine whether *Alvarez-Gonzalez* was indexed before November 24, 2017, I searched PubMed by the article title for records and located a record at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5497536/>. This PubMed record is presented as **EX1049** in this Declaration. PubMed is an authoritative system that contains "more than 34 million citations for biomedical literature from MEDLINE, life science journals, and online books" and PubMed records may include links to "full text content from PubMed Central and publisher web sites." **EX1049**, Page 1. I personally located, identified, and obtained the PubMed metadata record for

Alvarez-Gonzalez (EX1049). I saved the metadata record as a PDF and also in PubMed format to show the record details in data fields.

15. **EX1049** is a true and correct copy of the PubMed metadata record for *Alvarez-Gonzalez*. The top of page 1 shows a full text link to “Wiley Free Full Text Article” that takes users to the publisher’s webpage for *Alvarez-Gonzalez*. Page 1 also shows the title, authors, and an abstract. The area above the title shows a note of “Ann Clin Transl Neurol. 2017 Jul; 4(7): 506–511. doi: 10.1002/acn3.410. eCollection 2017 Jul.” **EX1049**, Page 1. The journal title, issue number, and pagination match the information presented in the publisher’s copy of *Alvarez-Gonzalez (EX1009)* and confirm this record represents *Alvarez-Gonzalez*. This page also shows the PubMed record identifier is 28695150, discussed below, and the PubMed Central identifier for *Alvarez-Gonzalez* is PMC5497536. **EX1049**, Page 1. The “Full Text Sources” field shows that users can find the full text of *Alvarez-Gonzalez* in Europe PubMed Central, PubMed Central, and Wiley, and each source is presented as a live link for easy access to this article. **EX1049**, Page 2.

16. Page 3 of **EX1049** is the PubMed record in PubMed format which shows data in specific fields. I used the “MEDLINE/PubMed Data Element (Field) Descriptions” (**EX1049**) to interpret the record. The “PMID” field shows “28695150” as the PubMed identifier for the record for *Alvarez-Gonzalez*. The

“STAT” field shows the status of the record is “PubMed-not-MEDLINE”

(meaning the record is in PubMed but not medical subject headings are assigned to this record and it is not elevated into the MEDLINE database). The IS fields show the ISSN (International Standard Serial Number) of the print version is “2328-9503” and the ISSN of the electronic version of this journal is also “2328-9503.”

Id. Fields VI (volume), IP (issue), DP (date of publication), TI (title), and JT (journal title) show *Alvarez-Gonzalez* was published in vol. 4, issue 7 (2017 Jul) of *Annals of Clinical and Translational Neurology* as “506-511.” **EX1049**, Page 3.

The first FAU (full author) field shows “Alvarez-Gonzalez, Cesar” as the first author. **EX1049**, Page 3. Field CRDT (creation date) and field EDAT (entrez date) show the metadata record was added to PubMed on “2017/07/12” (i.e., July 12, 2017). **EX1049**, Page 4. Field “AID” (Article identifier) shows the doi of *Alvarez-Gonzalez*. **EX1049**, Page 4.

17. This PubMed metadata record (**EX1049**) made *Alvarez-Gonzalez* discoverable in PubMed on July 12, 2017, before November 24, 2017. **EX1049**, Page 4. Interested users would have been able to search for and locate *Alvarez-Gonzalez* in PubMed by the authors, title, journal title, ISSN, and abstract as of July 12, 2017.

C. Summary of My Opinion on *Alvarez-Gonzalez*

18. The publisher's copy of *Alvarez-Gonzalez* (**EX1009**), the PubMed records for *Alvarez-Gonzalez* (**EX1049**), and my knowledge of digital archives in particular inform my opinion that *Alvarez-Gonzalez* was published on July 5, 2017, as an open access article. Because *Annals of Clinical and Translational Neurology* has been available as a journal, *Alvarez-Gonzalez* would have become publicly accessible when it was published online on July 5, 2017 (**EX1009**). The PubMed records show that *Alvarez-Gonzalez* was indexed and became searchable in PubMed on July 12, 2017 (**EX1049**), making it possible for interested users to search for *Alvarez-Gonzalez* in PubMed by title, authors, journal title, ISSN, and abstract.

III. AUTHENTICITY AND PUBLIC AVAILABILITY OF *GIOVANNONI* (EX1007**)**

A. Authentication

19. **EX1007** is a true and correct copy of "A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis" ("*Giovannoni*"), by Giovannoni et al., *The New England Journal of Medicine* vol. 362, pp. 416-426, that I obtained from the publisher. I began my research by searching Google Scholar by the title of *Giovannoni* for records, and a retrieved record led me to the publisher's webpage for *Giovannoni* at <https://www.nejm.org/doi/full/10.1056/nejmoa0902533> (**EX1050**). I clicked the "download PDF" icon on this webpage which linked me to

the PDF full text of *Giovannoni*, which the publisher provides as “open access,” meaning there is no restriction on user access. I then downloaded the full text of *Giovannoni*. This publisher copy is presented as **EX1007**.

20. In **EX1007**, page 1 shows the title, authors, and abstract. A publication history notes the article was published on January 20, 2010. The first page shows *Giovannoni* was published in volume 362, (2010) of *N Engl J Med* as 416-26 and has a copyright date of 2010, from the Massachusetts Medical Society. **EX1007** shows *Giovannoni* has a total of eleven pages, including 19 references. *Giovannoni*, as originally published on January 20, 2010, includes numerous references to its supplementary appendix. **EX1007**, Pages 1-4, and 7.

21. The publisher’s copy of *Giovannoni* and its supplementary appendix (**EX1007**) 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, **EX1007**, 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 *Giovannoni* (**EX1007**).

B. PubMed Records

22. To determine whether *Giovannoni* was indexed before November 24, 2017, I searched PubMed by the article title for records and located a record at

<https://pubmed.ncbi.nlm.nih.gov/20089960/>. **EX1051**, Page 1. I personally located, identified, and obtained the PubMed metadata record for *Giovannoni* (**EX1051**). I saved the metadata record as a PDF and also in PubMed format to show the record details in data fields.

23. **EX1051** is a true and correct copy of the PubMed metadata record for *Giovannoni*. The left side of page 1 shows a full text link to “NEJM Free Full Text” that takes users to the publisher’s webpage for *Giovannoni*. Page 1 also shows the title, authors, and an abstract. The area above the title shows a note of “N Engl J Med. 2010 Feb 4;362(5):416-26. doi: 10.1056/NEJMoa0902533. Epub 2010 Jan 20.” **EX1051**, Page 1. The journal title, issue number, and pagination match the information presented in the publisher’s copy of *Giovannoni* (**EX1007**) and confirm this record represents *Giovannoni*. This page also shows the PubMed record identifier is 20089960. **EX1051**, Page 1. The “Full Text Sources” field shows that users can find the full text of *Giovannoni* in Atypon and Ovid Technologies, Inc., and each source is presented as a live link for easy access to this article. **EX1051**, Page 2.

24. Page 3 of **EX1051** is the PubMed record in PubMed format to show data in specific fields. I used the “MEDLINE/PubMed Data Element (Field) Descriptions” (**EX1051**) to interpret the record. The “PMID” field shows “20089960” as the PubMed identifier for the record for *Giovannoni*. The “STAT”

field shows the status of the record is “MEDLINE” (meaning the record is in Pubmed. MEDLINE is the primary component of PubMed, a literature database developed and maintained by the NLM National Center for Biotechnology Information (NCBI)). The IS fields show the ISSN (International Standard Serial Number) of the print version is “1533-4406.” *Id.*, Page 3. Fields VI (volume), IP (issue), DP (date of publication), TI (title), and JT (journal title) show *Giovannoni* was published in vol. 362, issue 5 (2010, Feb 4) of *The New England Journal of Medicine* as “416-26.” **EX1051**, Page 3. The first FAU (full author) field shows “Giovannoni, Gavin” as the first author. **EX1051**, Page 11. Field CRDT (creation date) and field EDAT (entrez date) show the metadata record was added to PubMed on “2010/01/22” (i.e., January 22, 2010). **EX1051**, Page 11. Field “AID” (Article identifier) shows the doi of *Giovannoni*. **EX1051**, Page 11.

25. This PubMed metadata record (**EX1051**) made *Giovannoni* discoverable in PubMed on January 22, 2010, before November 24, 2017, when the record was entered into PubMed. **EX1051**, Page 11. Interested users would have been able to search for and locate *Giovannoni* in PubMed by the authors, title, journal title, ISSN, and abstract as of January 22, 2010. Additionally, interested users would have been able to access the supplementary appendix as of January 22, 2010 from searching and locating *Giovannoni* itself, as described above.

C. Usage Records

26. *Giovannoni* was cited in the '119 application specification when it was originally filed (**EX1004**, page 467). I understand that the '119 application later issued as the '919 patent, which also cites *Giovannoni* (**EX1001**, col. 4, line 66).

D. Summary of My Opinion on *Giovannoni*

27. The publisher's copy of *Giovannoni* (**EX1007**), the PubMed records for *Giovannoni* (**EX1051**), the usage records for *Giovannoni*, and my knowledge of digital archives in particular inform my opinion that *Giovannoni* was published on January 22, 2010. Furthermore, as *Giovannoni* was originally published on January 20, 2010, and includes numerous references to its supplementary appendix, I have no reason to doubt that the supplementary appendix would have been available as of the original publication date on January 22, 2010. **EX1007**, Pages 1-4, and 7. Because *The New England Journal of Medicine* has been available as a journal, *Giovannoni* and its supplementary appendix, would have become publicly accessible when it was published online on January 22, 2010 (**EX1050**). The PubMed records show that *Giovannoni* was indexed and became searchable in PubMed on January 22, 2010 (**EX1051**), before November 24, 2017, making it possible for interested users to search for *Giovannoni* in PubMed by title, authors, journal title, ISSN, and abstract.

IV. AUTHENTICITY AND PUBLIC AVAILABILITY OF *MONTALBAN* (EX1006)

A. Authentication

28. **EX1006** is a true and correct copy of “Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study (P3.029)” (“*Montalban*”), by Montalban et al., *Neurology*, vol. 86, suppl. 16, 7 pages, that I obtained from the publisher. I began my research by searching Google Scholar by the title of *Montalban* for records, and a retrieved record led me to the publisher’s webpage for *Montalban* at https://n.neurology.org/content/86/16_Supplement/P3.029 (**EX1052**). I then printed the webpage without restriction, which shows the publisher provides open access to *Montalban*, meaning there is no restriction on user access. The freely available record on the publisher’s website constitutes the full text of *Montalban*. This publisher copy is presented as **EX1006** in this Declaration.

29. In **EX1006**, page 1 shows the title, authors, and abstract. A publication history note shows the article was first published April 4, 2016. The top of this page shows *Montalban* was published in volume 86, suppl. 16 (2016) of *Neurology* as 7 pages. **EX1006** shows *Montalban* has a total of seven pages.

30. The publisher’s copy of *Montalban* (**EX1006**) 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, **EX1006** 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 *Montalban* (**EX1006**).

B. Clarivate Analytics Web of Science Records

31. To determine whether *Montalban* was indexed before November 24, 2017, I searched Clarivate Analytics Web of Science through Pennsylvania State University by the article title for records and located a record within the database. This Clarivate Analytics Web of Science is presented as **EX1053** in this Declaration. Clarivate Analytics Web of Science Records provides researchers, administrators, faculty, and students with quick, powerful access to the world's leading citation databases. Authoritative, multidisciplinary content covers over “10,000 of the highest impact journals worldwide, including Open Access journals and over 110,000 conference proceedings.” I personally located, identified, and obtained the Clarivate Analytics Web of Science metadata record for *Montalban* (**EX1053**). I saved the metadata record as a PDF and also in .txt format to show the record details in data fields.

32. **EX1053** is a true and correct copy of the Clarivate Analytics Web of Science metadata record for *Montalban*. The top of page 1 shows a full text link to

“GET IT! PENN STATE” that takes users to the Penn State University Libraries’ link to *Montalban* wherever available in one of their subscription databases. For users of libraries other than Penn State, there would be a similar access link to the article in their own institution library system. Page 1 also shows the title, authors, and an abstract. The area beneath the title shows a note of bibliographic information, such as “Volume: 86 Supplement 16 Meeting Abstract p3.029 Published April 5 2016 Indexed 2016-04-05” **EX1053**, Page 1. The journal title, volume number, and bibliographic information match the information presented in the publisher’s copy of *Montalban* (**EX1006**) and confirm this record represents *Montalban*. This page also shows the eISSN record identifier is 1526-632X, discussed below, **EX1053**, Page 2.

33. Page 6 of **EX1053** is the Clarivate Analytics Web of Science record in .txt format to show data in specific fields. I used the “Data Element (Field) Descriptions” (**EX1053**) to interpret the record. The “TI” field shows “Efficacy of Cladribine Tablets as Add-on to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD STUDY” as the title identifier for the record for *Montalban*. The “EI” field shows the electronic Issue Number of the record is “1526-632X.” *Id.* Fields VL (volume), SU (supplemental), PD, PY, and JI (journal information) show *Montalban* was published in vol. 86,

suppl. 16 (APR 5 2016) of *Neurology*. **EX1053**, Pages 6-7. The first AU (author) field shows “Montalban, X” as the first author. **EX1053**, page 6.

34. This Clarivate Analytics Web of Science metadata record (**EX1053**) made *Montalban* discoverable in Clarivate Analytics Web of Science on April 5, 2016, when the record was entered into Clarivate Analytics Web of Science, **EX1053**, Page 7. Interested users would have been able to search for and locate *Montalban* in Clarivate Analytics Web of Science by the authors, title, journal title, ISSN, and abstract as of April 5, 2016.

C. Usage of *Montalban*

35. Actual usage of an article is reflected by other articles that make reference to it. The citation history of *Montalban* by *Neurology*, the publisher (**EX1054**, page 3) shows *Montalban* had been cited 1,128 times before November 2017.

D. Summary of My Opinion on *Montalban*

36. The publisher’s copy of *Montalban* (**EX1006**), the Clarivate Analytics Web of Science records for *Montalban* (**EX1053**), the usage history of *Montalban* and my knowledge of digital archives in particular inform my opinion that *Montalban* was published on April 5, 2016. Because *Neurology* has been available as a journal, *Montalban* would have become publicly accessible when it was published online on April 5, 2016 (**EX1006**). The PubMed records show that

Montalban was indexed and became searchable in Clarivate Analytics Web of Science on April 5, 2016 (**EX1053**), making it possible for interested users to search for *Montalban* in Clarivate Analytics Web of Science by title, authors, journal title, ISSN, and abstract.

V. AUTHENTICITY AND PUBLIC AVAILABILITY OF *SCHREIBER* (EX1008)

A. Authentication

37. **EX1008** is a true and correct copy of “Cladribine in the treatment of multiple sclerosis” (“*Schreiber*”), by Schreiber et al., *Clinical Investigation*, vol. 1, no. 2, pp. 317-326, that I obtained from the publisher. I began my research by searching the publisher’s website for *Clinical Investigation* and I located it at <https://www.openaccessjournals.com/journals/clinical-investigation.html>. I then used the “archive” function in the “Articles” menu to access a list of all volumes and issues of the journal. Scrolling down that page and selecting volume 1 issue 2, I accessed the table of contents from that issue and I used it to access the publisher’s webpage for *Schreiber* at <https://www.openaccessjournals.com//abstract/cladribine-in-the-treatment-of-multiple-sclerosis-7480.html> (**EX1055**). The small, blue PDF link on this webpage shows the publisher provides open access to *Schreiber*. This indicates there is no restriction on user access. I then followed the PDF link to download the full text of *Schreiber*. This publisher copy is presented as **EX1008** in this Declaration.

38. In **EX1008**, page 1 shows the title, authors, and abstract. The top of this page shows *Schreiber* was published in volume 1, number 2 (2011) of *Clinical Investigation* as 317-326. **EX1008** shows *Schreiber* has a total of ten pages, including 67 references. Because *Schreiber* was published in an online open access journal, the publication date is the public availability date.

39. The publisher's copy of *Schreiber* (**EX1008**) 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, **EX1008** 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 *Schreiber* (**EX1008**).

B. National Library of Medicine Copy of *Schreiber* (EX1008)

40. To determine whether *Schreiber* was available at libraries, I searched the National Library of Medicine for "Clinical Investigations," the journal containing *Schreiber*, for records and a retrieved record at https://catalog.nlm.nih.gov/permalink/01NLM_INST/1o1phhn/alma9915545823406676 (**EX1056**) showed the National Library of Medicine (NLM) was one of the holdings libraries. I searched the NLM online catalog to verify the holdings, and the library records confirmed the holdings information. (**EX1056**).

41. I then requested a scanned copy of *Schreiber* from the NLM, with the assistance of Wisconsin TechSearch (WTS), a document delivery service. The NLM copy of *Schreiber* is presented as **EX1008** in this Declaration.

42. **EX1057** is a scanned copy obtained from NLM. Page 1 is the cover that carries a check-in label, showing this issue is “Clinical investigation, v. 1 no. 2 (Feb. 2011), General Collection W1 IN7165, 2011-07-14 16:02:55,” meaning that vol. 1, no. 2 of this journal was received by NLM on July 14, 2011, it is part of the General Collection, and its call number is W1 IN7165. The cover shows this journal is the Clinical Investigation and identifies this issue as volume 1, number 2, with an issue date of February 2011 (**EX1057**). Page 2 is the contents page that cites *Schreiber* at page 317 of this issue. Page 2 shows the ISSN (International Standard Serial Number) of this journal is 2041-6792 and this issue has a “2011” copyright date, with Future Science Ltd as the copyright holder (**EX1057**). Pages 3 to 12 (internal pages 317-326) are the *Schreiber* article. I have closely compared the NLM copy of *Schreiber* (**EX1057**) with the publisher’s copy of *Schreiber* (**EX1008**) and found them to be identical. The NLM copy of *Schreiber* (**EX1057**) 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, **EX1057** is in the custody of a national library, a place

where, if authentic, it would likely be found. Accordingly, I see no reason to question the authenticity of the NLM copy of *Schreiber* (EX1057).

C. Library Date Stamp

43. The “2011-07-14” date stamp on the journal cover of the NLM copy of *Schreiber* (EX1057) has the appearance of a typical library serial check-in date stamp that indicates that the National Library of Medicine received vol. 1, no. 2 that contains *Schreiber* on July 14, 2011. As discussed above, a customary library practice is to create a record for the entire journal to make the journal discoverable, without the need to create separate records for each issue or articles of the journal.

44. To record the receipt of individual issues of a journal, a customary library practice is to use a serial check-in process to record the receipt of the issues and include the issue information in the holdings record to inform the public of the issues available for public access. Because journals usually report on new discoveries, it is a common library practice to process newly received journal issues quickly for public access, usually within a week of serial check-in. It is therefore my opinion that vol. 1, no. 2 of the Clinical Investigation that contains *Schreiber* was received by the National Library of Medicine on July 14, 2011 (EX1057, page 1) and the copy would have become publicly accessible no later than July 15, 2011.

D. Summary of My Opinion on *Schreiber*

45. The publisher's copy of *Schreiber* (EX1008), the National Library of Medicine's copy of *Schreiber* (EX1057), and my knowledge of digital archives in particular inform my opinion that *Schreiber* was published in 2011, as an open access article. Because *Clinical Investigation* has been available as a journal, *Schreiber* would have become publicly accessible when it was published online February, 2011 (EX1008).

VI. LIST OF DOCUMENTS CONSIDERED

<i>Exhibit #</i>	<i>Description</i>
1001	U.S. Patent No. 10,849,919 B2 to Dangond et al., "Cladribine Regimen for Treating Progressive Forms of Multiple Sclerosis," (filed November 23, 2018; issued December 1, 2020).
1002	Declaration of Aaron Miller, M.D.
1006	Montalban, X., et al., "Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study P3.029," published Apr. 4, 2016. ("Montalban")
1007	Giovannoni, G., et al., "A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis," <i>The New England Journal of Medicine</i> , 362 (5), (Feb. 4, 2010). ("Giovannoni")
1008	Schreiber, K., et al., "Cladribine in the Treatment of Multiple Sclerosis," <i>Clinical Investigation</i> , 1 (2), (2011). ("Schreiber")
1009	Alvarez-Gonzalez, C., et al., "Cladribine to Treat Disease Exacerbation after Fingolimod Discontinuation in Progressive Multiple Sclerosis," <i>Annals of Clinical and Translational Neurology</i> , 4 (7), (March 17, 2017). ("Alvarez-Gonzalez")
1048	Publisher's Record of Alvarez-Gonzalez (EX1009)
1049	PubMed's Record of Alvarez-Gonzalez (EX1009)
1050	Publisher's Record of Giovannoni (EX1007)

Inter Partes Review of U.S. Patent No. 10,849,919
Declaration of Nancy E. Adams Ed.D.

<i>Exhibit #</i>	<i>Description</i>
1051	PubMed's Record of Giovannoni (EX1007)
1052	Publisher's Record of Montalban (EX1006)
1053	Clarivate Analytics Web of Science's Record of Montalban (EX1006)
1054	Citation History of Montalban (EX1006)
1055	Publisher's Record of Schreiber (EX1008)
1056	National Library of Medicine's Record of Schreiber (EX1008)
1057	National Library of Medicine's Copy of Schreiber (EX1008)

VII. CONCLUSION

46. 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: 2/8/23