

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent of: Reinhold W. Vieth et al.  
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Title: VITAMIN D COMPOSITIONS AND METHOD OF  
ADMINISTRATION TO A HUMAN BEING

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**SUPPLEMENTAL DECLARATION OF JUNE ANN MUNFORD**

MOM 1025  
MOM Enterprises v. Vieth, Elaine  
IPR2023-00726

1. My name is June Ann Munford. I am over the age of 18, have personal knowledge of the facts set forth herein, and am competent to testify to the same.
2. I earned a Master of Library and Information Science (MLIS) from the University of Wisconsin-Milwaukee in 2009. I have over ten years of experience in the library/information science field. Beginning in 2004, I have served in various positions in the public library sector including Assistant Librarian, Youth Services Librarian and Library Director. I have attached my Curriculum Vitae as Appendix CV.
3. During my career in the library profession, I have been responsible for materials acquisition for multiple libraries. In that position, I have cataloged, purchased and processed incoming library works. That includes purchasing materials directly from vendors, recording publishing data from the material in question, creating detailed material records for library catalogs and physically preparing that material for circulation. In addition to my experience in acquisitions, I have also been responsible for analyzing large collections of library materials, tailoring library records for optimal catalog

search performance and creating lending agreements between libraries during my time as a Library Director.

4. I am fully familiar with the catalog record creation process in the library sector. In preparing a material for public availability, a library catalog record describes when material would be created. A catalog record is typically created upon the library's acquisition of that item, after the library staff has determined that the material is appropriate to include within the library's public-facing collection. A library catalog record is a detailed written document describing a material owned by the library in question. After completion of the library record, the record is added to the library catalog. While catalog records used to be held by the library as a collection of physical documents, libraries have been implementing digital catalog records since the advent of the internet. The modern digital library catalog is frequently updated, accessible by library patrons anywhere with an internet connection and features robust search mechanisms which allow for complex, multi-level discovery of library materials.
5. Library catalog records are typically written in Machine Readable Catalog (herein referred to as "MARC") code and contain information such as a physical description of the material, metadata from the material's publisher,

and date of library acquisition. In particular, the 008 field of the MARC record is reserved for denoting the date of creation of the library record itself. As this typically occurs during the process of preparing materials for public access, it is my experience that an item's MARC record indicates the date of an item's public availability.

6. Typically, in creating a MARC record, a librarian would gather various bits of metadata such as book title, publisher, and subject headings among others, and assign each value to a relevant numerical field. For example, a book's physical description is tracked in field 300 while title/attribution is tracked in field 245. As this declaration will reference several MARC records and their subfields, I will be discussing the official MARC cataloging standards as published by the United States Library of Congress.
7. Attached hereto as Appendix LOC 01 are screen captures from a web page titled "005 – Date and Time of Latest Transaction" hosted by the Library of Congress at <https://www.loc.gov/marc/bibliographic/bd005.html>. According to the Library of Congress, this field indexes the date of the last change to the library record as "Sixteen characters that indicate the date and time of the latest record transaction." Updating MARC records is a common practice in library cataloging, often due to the everyday needs and concerns of the

library. A common example of modifying a MARC record would be transferring a newly acquired book from the 'New Books' section of the library to an archival facility. Appendix LOC01 also indicates "The date on which a record is first entered into machine-readable form is contained in field 008/00-05. The Date entered on file never changes."

8. Attached hereto as Appendix LOC02 are screen captures from a web page titled "008 – Fixed-Length Data Elements-General Information hosted by the Library of Congress at <https://www.loc.gov/marc/bibliographic/bd008.html>." According to the Library of Congress, this field indexes the several different pieces of information, including date entered on file, listed publication date and language of the material among others. Appendices LOC01 and LOC02 both indicate that the first six digits of the 008 field represent the date that the MARC record was entered on file. As this is the only date reflecting the inclusion of a given material within the library's proprietary collection of library records, it is my experience that an item's 008 field accurately indicates the date of an item's public availability.
9. Attached hereto as Appendix LOC03 are screen captures from a web page titled "650 – Subject Added Entry-Topical Term" hosted by the Library of

Congress at <https://www.loc.gov/marc/bibliographic/bd650.html>. This 650 field indexes various types of subject headings used to describe the subject of the material's focus. According to Appendix LOC03, MARC records can be used to document various types of subject data – including but not limited to Library of Congress Subject Headings, Library of Congress Children and Young Adults' Subject Headings, Material/Form type, geographic names, locations associated with the material and dates of activity, Subject fields such as the 650 field are invaluable to library catalogers as library catalogs can index search results by subject heading, meaning that library patrons are able to easily discover several different materials with similar topics. Subject fields are also useful for the physical library space as well, as non-fiction materials are organized and displayed for the public based on topic.

10. I am familiar with the Internet Archive, a digital library formally certified by the State of California as a public library. Among other services that the Internet Archive makes available to the general public is the Wayback Machine, an online archive. The Internet Archive's Wayback Machine service archives webpages as of a certain capture date to track changes in the web over time. The Internet Archive has been in operation as a nonprofit library since 1996 and has hosted the Wayback Machine service since its

inception in 2001. During my time as a librarian, I frequently used the Internet Archive's Wayback Machine for research and instruction purposes. This includes teaching instructional classes on using the Wayback Machine to library patrons and using the Wayback Machine to research reference inquiries that require hard-to-find online resources. I consider the Internet Archive's records keeping to be as rigorous and detailed as other formal library records keeping practices such as MARC records, the Online Computer Library Center ("OCLC") records, and Dublin Core.

11. I have reviewed Exhibit MOM-1006, *Wochenbettbetreuung in der Klinik und zu Hause* by Ulrike Harder.

12. Attached hereto as Appendix HARDER01 is a true and correct copy of the MARC record for *Wochenbettbetreuung in der Klinik und zu Hause* as held by the National Library of Medicine. I secured this record myself from the library's public catalog. The MARC record contained within Appendix HARDER01 accurately describes the title, author, publisher, and ISBN number of *Wochenbettbetreuung in der Klinik und zu Hause*. In comparing Exhibit MOM-1006 to Appendix HARDER01, it is my determination that Exhibit MOM-1006 is a true and correct excerpt from *Wochenbettbetreuung*

*in der Klinik und zu Hause, Hippokrates Verlag* by Ulrike Harder,  
specifically Section 15.9.

13. The 005 field of the MARC record in Appendix in Appendix HARDER01 indicates the date of last update on that MARC record. The 005 field of Appendix HARDER01 indicates the National Library of Medicine last updated this record as of December 12, 2021. Maintaining record accuracy is a high priority for library cataloging departments. Library records are regularly updated to ensure accuracy with the library collection's physical layout, improve compatibility with catalog software, bring the record up-to-date with changing cataloging standards and modify subject headings to ensure collection continuity. The 005 field which shows the date of last update is machine-generated and will update with changes as small as fixing punctuation. This field is unrelated to the first date of record creation or a given material's date of record creation (in this case January 10, 2003).

14. The 008 field of the MARC record in Appendix HARDER01 indicates the date of record creation. The 008 field of Appendix HARDER01 indicates the National Library of Medicine first acquired this book as of January 10, 2003. Considering this information, it is my determination that

*Wochenbettbetreuung in der Klinik und zu Hause* was made available to the public shortly after its initial acquisition in January 2003.

15. The 650 field of the MARC record in Appendix HARDER01 indicates

*Wochenbettbetreuung in der Klinik und zu Hause* was indexed by subject for the purpose of discovery within a library catalog. The 650 fields included in Appendix HARDER01 indicate that the topic of *Wochenbettbetreuung in der Klinik und zu Hause* could be described as “Postnatal Care,” “Postnatal Care methods,” and “Postpartum Period.”. Library catalogers in the United States assign subject headings according to the syntax and principles of the Library of Congress, which regularly produces a guidebook of accepted terms used as subject headings. This formalized standard used to assign subject headings ensures that books of similar topics are grouped together within the library’s collection and during library catalog searches. Library users interested in these topics searching for these subjects within a library catalog would find *Wochenbettbetreuung in der Klinik und zu Hause* within the search results as well as other library materials on related topics.

16. Attached hereto as Appendix HARDER02 is a screen capture of the Internet Archive Wayback Machine entry for <http://130.14.16.150/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First>. I secured these screen captures

myself from

[https://web.archive.org/web/20230000000000\\*/http://130.14.16.150/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First](https://web.archive.org/web/20230000000000*/http://130.14.16.150/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First).

17. Appendix HARDER02 indicates <http://130.14.16.150/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First> was first preserved by the Internet Archive as of February 7, 2003, it is also my determination <http://130.14.16.150/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First> was first available to the public by the Internet Archive as of February 7, 2003 if not earlier via the original National Library of Medicine website.

18. Appendix HARDER02 is a screen capture of the National Library of Medicine's online library catalog search feature as of February 2003. This entry point to the library catalog includes a search bar that functions much like a modern search engine. Appendix HARDER02 indicates that library users interested in these topics may filter their search results by keyword (all fields), title, journal title, subject, author and call number. The same users may also limit their search by various types of collections – reading room collections, internet links, English only, currently published journal and audiovisual files.

19. The MARC record present in Appendix HARDER01 includes accurate descriptions of the material in the MARC fields for title, author, publisher, format and subject headings among others, it is my determination that *Wochenbettbetreuung in der Klinik und zu Hause* has been sufficiently indexed by the National Library of Medicine in accordance with the catalog standards of the library profession.

20. The web page included as Appendix HARDER02 indicates that in 2003, the year of the National Library of Medicine's listed acquisition of this material, library patrons were able to use the library's multi-dimensional search tools to search based on these indexed fields. These multi-dimensional search tools include the ability to search by title, journal title, subject, author, call number or PubMed title. Additionally, this catalog features two keyword search options which serve to mimic the functions of a standard web search such as Google. Whereas a subject search may only index subject-specific MARC fields such as 650, a keyword search derives its results from searching the MARC record as broadly as possible for relevant language. This web capture does not explicitly define which fields are being indexed when a library patron uses the web catalog, but in my experience, a standard keyword search from 2003 may provide results for title, author, subject, call number, ISBN, ISSN or publisher among others.

21. As Appendix HARDER02 indicates the National Library of Medicine's library catalog was available to public, it is reasonable to assume that any person of skill in the art of natal care, post-natal care and related fields in 2003 would have the ability to access this material via the library catalog. The 650 field of Appendix HARDER01 is designated to describe the subjects covered in *Wochenbettbetreuung in der Klinik und zu Hause*, in this case "Postnatal Care" and "Postpartum Period". In my experience, using a library catalog to search via subject will provide results indexed from the MARC record's 650 field. Subsequently, using a library catalog to search via keyword will also provide results from the 650 field. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as 'Postnatal Care' and 'Postpartum Period' in the National Library of Medicine's library catalog and be presented with *Wochenbettbetreuung in der Klinik und zu Hause* among other similar materials.

22. Considering this, is it my determination that a person of skill in the art interested in the topics of natal care, post-natal care and related fields would have been able to discover and access Harder via the National Library of Medicine's library catalog as of February 2003 if not earlier.

23. I have reviewed Exhibit MOM-1008, “Aktuelle Therapie:

Rachitisprophylaxe beim Säugling” by H. Wolf as published in the July 1970 edition of *Deutsche Medizinische Wochenschrift*.

24. Attached hereto as Appendix WOLF01 is a true and correct copy of the

MARC record for *Deutsche Medizinische Wochenschrift* as held by the Penn State University library. I secured this record myself from the library’s public catalog. The MARC record contained within Appendix WOLF01 accurately describes the title, author, publisher, and ISSN number of *Deutsche Medizinische Wochenschrift*. The ‘Availability’ field of this record visible on page 8 indicates this collection includes the July 1970 edition of *Deutsche Medizinische Wochenschrift* containing “Aktuelle Therapie: Rachitisprophylaxe beim Säugling.”

25. Attached hereto as Appendix WOLF02 is a true and correct copy of

“Aktuelle Therapie: Rachitisprophylaxe beim Säugling” as published in *Deutsche Medizinische Wochenschrift* as held by the Penn State University library. I secured these scans myself from the library’s collection. In comparing Exhibit MOM-1008 to Appendix WOLF02, it is my determination that Exhibit MOM-1008 is a true and correct copy of

“Aktuelle Therapie: Rachitisprophylaxe beim Säugling” by H. Wolf as published in the July 1970 edition of *Deutsche Medizinische Wochenschrift*.

26. The 008 field of the MARC record in Appendix WOLF01 indicates the date of record creation. The 008 field of Appendix WOLF01 indicates the Penn State University library first acquired this journal as of August 24, 1975, and held the journal in perpetuity until 1996. Considering this information, it is my determination that the July 1970 edition of *Deutsche Medizinische Wochenschrift*, and therefore “Aktuelle Therapie: Rachitisprophylaxe beim Säugling,” was made available to the public shortly after its initial release in July 1970.

27. The 650 field of Appendix WOLF01 is designated to describe the subjects covered in *Deutsche Medizinische Wochenschrift*, in this case “General Medicine” and “Medicine”. Using the Penn State University’s library catalog, it is reasonable to assume that any person of skill in the art of general medicine and related fields would have the ability to access this material if interested via the library catalog. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as ‘General Medicine’ and ‘Medicine’ in

the Penn State University's library catalog and be presented with *Deutsche Medizinische Wochenschrift* among other similar materials.

28. I have reviewed Exhibit MOM-1010, excerpts from *European Pharmacopoeia Supplement 4.3* by The Council of Europe, published as a supplement to *European Pharmacopoeia, Fourth Edition*.

29. Attached hereto as Appendix EUROPEAN01 is a true and correct copy of the MARC record for *European Pharmacopoeia, Fourth Edition* as held by the National Library of Medicine library. I secured this record myself from the library's public catalog. The MARC record contained within Appendix EUROPEAN01 accurately describes the title, author, publisher, and ISBN number of *European Pharmacopoeia, Fourth Edition*. The 'Location Items' field of this record visible on page 3 indicates this collection includes the *European Pharmacopoeia Supplement 4.3*. I spoke with a representative from the National Library of Medicine library and was informed that it is typical for supplements to *European Pharmacopoeia* to be shipped to the library as they are released due to a subscription-style service.

30. Attached hereto as Appendix EUROPEAN02 is a true and correct copy of the MARC record for *European Pharmacopoeia, Fourth Edition* as held by

the Columbia University library. I secured this record myself from the library's public catalog. The MARC record contained within Appendix EUROPEAN02 accurately describes the title, author, publisher, and ISBN number of *European Pharmacopoeia, Fourth Edition*. The 'Location' field of this record visible on page 3 indicates this collection includes the *European Pharmacopoeia Supplement 4.3*. I spoke with a representative from the Columbia University library and was informed that it is typical for supplements to *European Pharmacopoeia* to be shipped to the library as they are released due to a subscription-style service.

31. Attached hereto as Appendix EUROPEAN03 is a true and correct copy of the MARC record for *European Pharmacopoeia, Fourth Edition* as held by the University of Cincinnati library. I secured this record myself from the library's public catalog. The MARC record contained within Appendix EUROPEAN03 accurately describes the title, author, publisher, and ISBN number of *European Pharmacopoeia, Fourth Edition*. The 'Location' field of this record visible on page 2 indicates this collection includes the *European Pharmacopoeia Supplement 4.3*. I spoke with a representative from the University of Cincinnati library and was informed that it is typical for supplements to *European Pharmacopoeia* to be shipped to the library as they are released due to a subscription-style service.

32. In comparing Exhibit MOM-1010 to Appendices EUROPEAN01, EUROPEAN02 and EUROPEAN03, it is my determination that Exhibit MOM-1010 is a true and correct copy of excerpts from *European Pharmacopoeia Supplement 4.3* by the Council of Europe as published as a supplement to *European Pharmacopoeia, Fourth Edition*.

33. As previously mentioned, I spoke with librarians from the National Library of Medicine, Columbia University, and the University of Cincinnati in regards to the publishing schedule of *European Pharmacopoeia*. Each librarian informed me that the initial purchase of *European Pharmacopoeia, Fourth Edition* included a subscription-style service in which the supplements are shipped to the library upon publication. When librarians catalog time-sensitive periodicals such magazines and newspapers, new issues of a periodical are appended to the existing record for the purpose of ensuring access as soon as possible after acquisition. In Appendices EUROPEAN01, EUROPEAN02, and EUROPEAN03, all supplements to *European Pharmacopoeia, Fourth Edition* were cataloged in this fashion – including *European Pharmacopoeia Supplement 4.3*. As such, it is my determination that these materials were cataloged in this fashion to ensure access as soon as possible after the supplement is acquired.

34. Attached hereto as EUROPEAN04 is a true and correct copy of a document entitled ‘Statutory Report 2002 / Last updated 17 January 2003’ as published by the Council of Europe. I secured screen captures of this document from <https://rm.coe.int/16804a1147>. This document was created by the Council of Europe to describe the entity’s 2002 activities. On page 3 of this document, the following section describes the publication schedule for supplements to *European Pharmacopoeia, Fourth Edition*: “The three supplements of the 4<sup>th</sup> edition of the European Pharmacopoeia were published: 285 new or revised texts update the 4th Edition . . . . The online and CD-ROM versions of version of Supplement 4.1, 4.2 and 4.3 are cumulative.” This quotation indicates that *European Pharmacopoeia Supplement 4.3* was published by the Council of Europe within the year of 2002.

35. The 650 field of Appendices EUROPEAN01, EUROPEAN02 and EUROPEAN03 is designated to describe the subjects covered in *European Pharmacopoeia Supplement 4.3*.

36. For Appendix EUROPEAN01, the 650 field reads “Pharmaceutical Preparations”. Using the National Library of Medicine’s library catalog, it is reasonable to assume that any person of skill in the art of pharmaceutical

preparations and related fields interested in this topic would have the ability to access this material via searching the library's collection. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as 'Pharmaceutical Preparations' the National Library of Medicine's library catalog and be presented with *European Pharmacopoeia Supplement 4.3* among other similar materials.

37. For Appendix EUROPEAN02, the 650 fields read "Pharmacopoeias", "Medical instruments and apparatus", "Pharmacopoeias as Topic" and "Equipment and Supplies". Using Columbia University's library catalog, it is reasonable to assume that any person of skill in the art of pharmacology, medical instrumentation and related fields, if interested, would have the ability to access this material via searching the library's collection. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as "Pharmacopoeias", "Medical instruments and apparatus", "Pharmacopoeias as Topic" and "Equipment and Supplies" in Columbia University's library catalog and be presented with *European Pharmacopoeia Supplement 4.3* among other similar materials.

38. For Appendix EUROPEAN03, the 650 fields read “Pharmacopoeias”, “Drugs”, “Medical instruments and apparatus” and “Pharmacopoeias as Topic”. Using University of Cincinnati’s library catalog, it is reasonable to assume that any person of skill in the art of pharmacology, medical instrumentation and related fields would have the ability to access this material, if interested, via searching the library’s collection. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as “Pharmacopoeias”, “Drugs”, “Medical instruments and apparatus” and “Pharmacopoeias as Topic” in University of Cincinnati’s library catalog and be presented with *European Pharmacopoeia Supplement 4.3* among other similar materials.

39. Attached hereto as Appendix EUROPEAN05 is a screen capture of the Internet Archive Wayback Machine entry for <http://www.pheur.org:80/index.php3>. I secured these screen captures myself from <https://web.archive.org/web/20021001154404/http://www.pheur.org:80/index.php3>.

40. Appendix EUROPEAN05 is a screen capture of the European Directorate for the Quality of Medicines webpage as archived by the Internet Archive’s

Wayback Machine as of October 1, 2002. The ‘Available soon’ section of this webpage indicates the Council of Europe was offering copies of *European Pharmacopoeia, Fourth Edition* for purchase in the book, online and CD-ROM formats. The ‘Official Press Releases’ section contains a section advertising the ‘Release of Supplement 4.3 of the European Pharmacopoeia.’

41. The 008 fields of the MARC records represented in Appendices EUROPEAN01, EUROPEAN02, and EUROPEAN03 indicate the date of record creation. The 008 field of Appendices EUROPEAN01 and EUROPEAN03 indicates the National Library of Medicine and the University of Cincinnati library first acquired *European Pharmacopoeia, Fourth Edition* as of September 24, 2001, while Appendix EUROPEAN02 indicates the Columbia University library first acquired *European Pharmacopoeia, Fourth Edition* as of November 8, 2001. These same MARC records also confirm that each library received supplements to *European Pharmacopoeia, Fourth Edition* and appended those supplements to the primary record for the purpose of ensuring prompt public access to time-sensitive materials.

42. Based on the information contained in Appendix EUROPEAN04, the Council of Europe indicates *European Pharmacopoeia Supplement 4.3* was published within the calendar year of 2002. Based on the information contained within Appendix EUROPEAN05, the European Directorate for the Quality of Medicines was making new supplements to *European Pharmacopoeia* available for online purchase upon its release in 2002 and advertised the release of the 4.3 supplement as of October 2002. Considering this information, it is my determination *European Pharmacopoeia Supplement 4.3* was made available to the public shortly after its initial publication in autumn 2002 and no later than December 31, 2002.

43. I have reviewed Exhibit MOM-1011, “Suckling- and Sucrose-Induced Analgesia in Human Newborns” by Elliott M. Blass and Lisa B. Watt as published in the December 1999 edition of *Pain*.

44. Attached hereto as Appendix BLASS01 is a true and correct copy of the MARC record for *Pain* as held by the Penn State University library. I secured this record myself from the library’s public catalog. The MARC record contained within Appendix BLASS01 accurately describes the title, author, publisher, and ISSN number of *Pain*. The ‘Availability’ field of this record visible on page 4 indicates this collection includes the December

1999 edition of *Pain* containing “Suckling- and Sucrose-Induced Analgesia in Human Newborns.”

45. Attached hereto as Appendix BLASS02 is a true and correct copy of “Suckling- and Sucrose-Induced Analgesia in Human Newborns” as published in *Pain* as held by the Penn State University library. I secured this file myself from the library’s collection. In comparing Exhibit MOM-1011 to Appendix BLASS02, it is my determination that Exhibit MOM-1011 is a true and correct copy of “Suckling- and Sucrose-Induced Analgesia in Human Newborns” by Elliott M. Blass and Lisa B. Watt as published in the December 1999 Edition of *Pain*.

46. The 008 field of the MARC record in Appendix BLASS01 indicates the date of record creation. The 008 field of Appendix BLASS01 indicates the Penn State University library first acquired this journal as of May 15, 1998, and still holds it in perpetuity. Considering this information, it is my determination that the December 1999 edition of *Pain*, and therefore “Suckling- and Sucrose-Induced Analgesia in Human Newborns,” was made available to the public shortly after its initial release in December 1999.

47. For Appendix BLASS01, the 650 fields read “Pain”, “Neurophysiology”, “Neurology” and “Anesthesia”. Using Penn State University’s library catalog, it is reasonable to assume that any person of skill in the art of neurophysiology, neurology, anesthesiology and related fields would have the ability to access this material via searching the library’s collection. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as “Pain”, “Neurophysiology”, “Neurology” and “Anesthesia” in Penn State University’s library catalog and be presented with the periodical *Pain* among other similar materials.

48. I have reviewed Exhibit MOM-1012, “Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake” by Lawrence M. Gartner as published in the April 2003 Edition of *Pediatrics*.

49. Attached hereto as Appendix GARTNER01 is a true and correct copy of the MARC record for *Pediatrics* as held by the Penn State University library. I secured this record myself from the library’s public catalog. The MARC record contained within Appendix GARTNER01 accurately describes the title, author, publisher, and ISSN number of *Pediatrics*.

50. Attached hereto as Appendix GARTNER02 is a true and correct copy of “Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake” as published in *Pediatrics* and as held by the Penn State University library. I secured this file myself from the library’s collection. In comparing Exhibit MOM-1012 to Appendix GARTNER02, it is my determination that Exhibit MOM-1012 is a true and correct copy of “Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake” by Lawrence M. Gartner as published in the April 2003 edition of *Pediatrics*.

51. The 008 field of the MARC record in Appendix GARTNER01 indicates the date of record creation. The 008 field of Appendix GARTNER01 indicates the Penn State University library first acquired this journal as of March 12, 1998, and held the journal in perpetuity. Considering this information, it is my determination that the April 2003 edition of *Pediatrics*, and therefore “Prevention of Rickets and Vitamin D Deficiency: New Guideline for Vitamin D Intake,” was made available to the public shortly after its initial release in April 2003.

52. For Appendix GARTNER01, the 650 field reads “Pediatrics”. Using Penn State University’s library catalog, it is reasonable to assume that any person

of skill in the art of pediatrics and related fields would have the ability to access this material if interested via searching the library's collection. As such, it is reasonable to assume that any member of the public would be able to perform subject or keyword searches for phrases such as "Pediatrics" in Penn State University's library catalog and be presented with the periodical *Pediatrics* among other similar materials.

53.I have reviewed Exhibit MOM-1013, "Introduction of Oral Vitamin D Supplementation and the Rise of the Allergy Pandemic" by Matthias Wjst as published in the November 2009 edition of *Allergy, Asthma & Clinical Immunology*.

54.Attached hereto as Appendix WJST01 is a true and correct copy of the MARC record for *Allergy, Asthma & Clinical Immunology* as held by the Penn State University library. I secured this record myself from the library's public catalog. The MARC record contained within Appendix WJST01 accurately describes the title, author, publisher, and ISSN number of *Allergy, Asthma & Clinical Immunology*.

55.Attached hereto as Appendix WJST02 is a true and correct copy of "Introduction of Oral Vitamin D Supplementation and the Rise of the

Allergy Pandemic” as published in *Allergy, Asthma & Clinical Immunology* as held by the Penn State University library. I secured this file myself from the library’s collection. In comparing Exhibit MOM-1013 to Appendix WJST02, it is my determination that Exhibit MOM-1013 is a true and correct copy of “Introduction of Oral Vitamin D Supplementation and the Rise of the Allergy Pandemic” by Matthias Wjst as published in the November 2009 edition of *Allergy, Asthma & Clinical Immunology*.

56. The 008 field of the MARC record in Appendix WJST01 indicates the date of record creation. The 008 field of Appendix WJST01 indicates the Penn State University library first acquired this journal as of June 30, 2006, and holds the journal in perpetuity. Considering this information, it is my determination that the November 2009 edition of *Allergy, Asthma & Clinical Immunology*, and therefore “Introduction of Oral Vitamin D Supplementation and the Rise of the Allergy Pandemic,” was made available to the public shortly after its initial release in November 2009.

57. I have reviewed Exhibit MOM-1014, “The Case Against Ergocalciferol (Vitamin D<sub>2</sub>) as a Vitamin Supplement” by Reinhold Vieth as published in the October 2006 edition of *The American Journal of Clinical Nutrition*.

58. Attached hereto as Appendix VIETH01 is a true and correct copy of the MARC record for *The American Journal of Clinical Nutrition* as held by the Penn State University library. I secured this record myself from the library's public catalog. The MARC record contained within Appendix VIETH01 accurately describes the title, author, publisher, and ISSN number of *The American Journal of Clinical Nutrition*. The 'Availability' field of this record visible on page 9 indicates this collection includes the October 2006 edition of *The American Journal of Clinical Nutrition* containing "The Case Against Ergocalciferol (Vitamin D<sub>2</sub>) as a Vitamin Supplement."

59. Attached hereto as Appendix VIETH02 is a true and correct copy of "The Case Against Ergocalciferol (Vitamin D<sub>2</sub>) as a Vitamin Supplement" as published in *The American Journal of Clinical Nutrition* as held by the Penn State University library. I secured these scans myself from the library's collection. In comparing Exhibit MOM-1014 to Appendix VIETH02, it is my determination that Exhibit MOM-1014 is a true and correct copy of "The Case Against Ergocalciferol (Vitamin D<sub>2</sub>) as a Vitamin Supplement" by Reinhold Vieth as published in the October 2006 edition of *The American Journal of Clinical Nutrition*.

60. The 008 field of the MARC record in Appendix VIETH01 indicates the date of record creation. The 008 field of Appendix VIETH01 indicates the Penn State University library first acquired this journal as of February 5, 1982, - and held the journal in perpetuity until 2011. Considering this information, it is my determination that the October 2006 edition of *The American Journal of Clinical Nutrition*, and therefore “The Case Against Ergocalciferol (Vitamin D2) as a Vitamin Supplement,” was made available to the public shortly after its initial release in October 2006.

61. I have reviewed Exhibit MOM-1015, “Effect of Vitamin D Replacement on Musculoskeletal Parameters in School Children: A Randomized Controlled Trial” by Reinhold Vieth as published in the February 2006 edition of *The Journal of Clinical Endocrinology & Metabolism*, February 2006.

62. Attached hereto as Appendix VIETH03 is a true and correct copy of the MARC record for *The Journal of Clinical Endocrinology & Metabolism* as held by the Penn State University library. I secured this record myself from the library’s public catalog. The MARC record contained within Appendix VIETH03 accurately describes the title, author, publisher, and ISSN number of *The Journal of Clinical Endocrinology & Metabolism*.

63. Attached hereto as Appendix VIETH04 is a true and correct copy of “Effect of Vitamin D Replacement on Musculoskeletal Parameters in School Children: A Randomized Controlled Trial” as published in *The Journal of Clinical Endocrinology & Metabolism* as held by the Penn State University library. I secured this file myself from the library’s collection. In comparing Exhibit MOM-1015 to Appendix VIETH04, it is my determination that Exhibit MOM-1015 is a true and correct copy of “Effect of Vitamin D Replacement on Musculoskeletal Parameters in School Children: A Randomized Controlled Trial” by Reinhold Vieth as published in the February 2006 edition of *The Journal of Clinical Endocrinology & Metabolism*.

64. The 008 field of the MARC record in Appendix VIETH03 indicates the date of record creation. The 008 field of Appendix VIETH03 indicates the Penn State University library first acquired this journal as of December 22, 1998, and holds the journal in perpetuity. Considering this information, it is my determination that the February 2006 edition of *The Journal of Clinical Endocrinology & Metabolism*, and therefore “Effect of Vitamin D Replacement on Musculoskeletal Parameters in School Children: A Randomized Controlled Trial,” was made available to the public shortly after its initial release in February 2006.

65.I have reviewed Exhibit MOM-1016, “Public Health Practices in Germany”

by W.W. Bauer as published in the September 1950 edition of *American Journal of Public Health and The Nation’s Health*.

66.Attached hereto as Appendix BAUER01 is a true and correct copy of the

MARC record for *American Journal of Public Health and The Nation’s*

*Health* as held by the Penn State University library. I secured this record

myself from the library’s public catalog. The MARC record contained

within Appendix BAUER01 accurately describes the title, author, publisher,

and ISSN number of *American Journal of Public Health and The Nation’s*

*Health*. The ‘Dates of Publication’ field of this record visible on page 3

indicates this collection includes the September 1950 edition of *American*

*Journal of Public Health and The Nation’s Health* containing “Public Health

Practices in Germany.”

67.Attached hereto as Appendix BAUER02 is a true and correct copy of

“Public Health Practices in Germany” as published in *American Journal of*

*Public Health and The Nation’s Health* as held by the Penn State University

library. I secured this file myself from the library’s collection. In comparing

Exhibit MOM-1016 to Appendix BAUER02, it is my determination that

Exhibit MOM-1016 is a true and correct copy of “Public Health Practices in Germany” by W.W. Bauer as published in the September 1950 edition of *American Journal of Public Health and The Nation’s Health*.

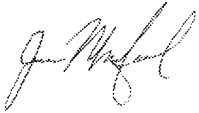
68. The 008 field of the MARC record in Appendix BAUER01 indicates the date of record creation. The 008 field of Appendix BAUER01 indicates the Penn State University library first acquired this journal as of May 16, 2008, containing all publications from 1928 to 1970. Considering this information, it is my determination that the September 1950 edition of *American Journal of Public Health and The Nation’s Health* and therefore “Public Health Practices in Germany” was made available to the public shortly after its initial acquisition in May 2008 and likely earlier in its original publication.

69. I have been retained on behalf of the Petitioner to provide assistance in the above-illustrated matter in establishing the authenticity and public availability of the documents discussed in this declaration. I am being compensated for my services in this matter at the rate of \$100.00 per hour plus reasonable expenses. My statements are objective, and my compensation does not depend on the outcome of this matter.

70. I declare under penalty of perjury that the foregoing is true and correct. 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 Section 1001 of Title 18 of the United States Code.

Dated: 11/7/2023

A handwritten signature in cursive script, appearing to read "June Ann Munford".

June Ann Munford