

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TAKEDA VACCINES, INC.
Petitioner,

v.

VALNEVA AUSTRIA GMBH,
Patent Owner.

Case No. IPR2023-00354
U.S. Patent No. 11,219,681

**DECLARATION OF INGRID HSIEH-YEE, PH.D. IN SUPPORT OF
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.
11,219,681**

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I. INTRODUCTION

I, Ingrid Hsieh-Yee, Ph.D., do hereby declare as follows:

1. I have been retained as an independent expert witness on behalf of Takeda Vaccines, 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. 11,219,681.

2. I am being compensated for my work in this matter at my customary hourly rate, which is \$270/hour. I am also being reimbursed for any reasonable expenses associated with my work and testimony in this matter. My compensation is not contingent on the results of my study, the substance of my opinions, or the outcome of this matter.

A. Qualifications and Professional Experience

3. My complete qualifications and professional experience are described in my curriculum vitae (**EX1167**). The following is a brief summary of my relevant qualifications and professional experience.

4. I was a professor in the Department of Library and Information Science at the Catholic University of America for 32 years and retired from that position at the end of August 2022. I have experience working in an academic library, a medical library, and a legislative library. I hold a Ph.D. in Library and

Information Studies from the University of Wisconsin-Madison and a Masters in Library and Information Studies from the University of Wisconsin-Madison.

5. I am an expert on library cataloging and classification and have published two editions on this subject, *Organizing Audiovisual and Electronic Resources for Access: A Cataloging Guide* (2000 and 2006). I taught a variety of courses, including “*Cataloging and Classification*,” “*Advanced Cataloging and Classification*,” “*Organization of Internet Resources*,” “*Organization of Information*,” “*Digital Content Creation and Management*,” “*Internet Searches and Web Design*,” “*Information Literacy Instruction*,” “*Advanced Information Retrieval and Analysis Strategies*,” and “*The Information Professions in Society*.” I am familiar with metadata schema design and implementation. In my teaching, I covered the design and implementation of metadata in databases, search engines, digital repositories, digital libraries, and digital archives. I also covered how information organization affects the discovery and access to digital resources on the Internet. My research interests cover cataloging and classification, information organization, metadata, information retrieval, information architecture, digital collections, scholarly communication, user interaction with information systems, and others.

6. I am very familiar with the library-cataloging-encoding standard known as the “Machine-Readable Cataloging” standard, also known as “MARC,”

which became the national standard for sharing bibliographic data in the United States by 1971 and the international standard by 1973. MARC remains the national and international standard for sharing bibliographic data. MARC is the primary communications protocol for the transfer and storage of bibliographic metadata in libraries. Experts in my field reasonably rely upon MARC records when forming their opinions.

7. A MARC record consists of several fields, each of which contains specific data about the work. Each field is identified by a standardized, unique, three-digit code corresponding to the type of data that follows. **EX1168** is a true and correct copy of Parts VII to X of “Understanding MARC Bibliographic: Machine-Readable Cataloging” from the Library of Congress, which explains commonly used MARC fields. For example, the personal name of the primary author of the work is recorded in field 100, the title is recorded in field 245, publisher information is recorded in field 260, the physical description of a publication is recorded in field 300, and topical terms (*e.g.*, most subject headings) subjects are recorded in the 650 fields.

8. The Online Computer Library Center (OCLC) is the largest bibliographic network of the world, with more than 540 million records and thousands of member institutions (many of which are libraries of some type) in more than 100 countries. OCLC was founded in 1967 to promote and support

library cooperation. According to the Third Article of the *Amended Articles of Incorporation of OCLC, Inc.*, the Online Computer Library Center was created “to establish, maintain and operate a computerized library network and to promote the evolution of library use, of libraries themselves, and of librarianship, and to provide processes and products for the benefit of library users and libraries, including such objectives as increasing availability of library resources to individual library patrons and reducing the rate of rise of library per-unit costs, all for the fundamental public purpose of furthering ease of access to and use of the ever-expanding body of worldwide scientific, literary, and educational knowledge and information.” **EX1181**, Page 1.

9. OCLC members can contribute original cataloging records in MARC or derive cataloging records from existing records, an activity referred to as “copy cataloging.” When an OCLC participating institution acquires a work, it can create an original MARC record for the work in OCLC’s Connexion system (a system for catalogers to create and share MARC records), and the system will automatically generate a code for the date of record creation in the yymmdd format, and the creating library’s OCLC symbol is recorded in subfield “a” of the 040 field. Once the MARC record is in Connexion, it becomes available to other OCLC members for adoption to their local online catalogs (i.e., copy cataloging).

10. After a MARC record is created in Connexion, it also becomes searchable and viewable on WorldCat, which is a free web portal (<https://www.worldcat.org/>) (**EX1189**) for the general public to explore more than 10,000 libraries worldwide. The record in WorldCat, however, is not presented in MARC record fields. Instead, the data elements are labeled to help the general public interpret the record. Thus, the information stored in MARC records in Connexion is available to the interested public through the user-friendly WorldCat web portal.

11. Library online catalogs gained acceptance in the early 1980s and many libraries migrated their systems to the World Wide Web in the mid-1990s. Library online catalogs are based on MARC records that represent their collections in order to help the public understand what materials are publicly accessible in those libraries. Most libraries with online catalogs have made their catalogs freely available on the Web. These online catalogs offer user-friendly search interfaces. Strong user interest in keyword searches and the popularity of Google have led to the “googlization” of library search systems. As a result, many library catalogs provide a single search box for users to conduct keyword searches, with additional support for searches by author, title, subject terms, and other data elements such as ISBN (International Standard Book Number). Library catalogs these days also offer features for users to narrow their search results by language, year, format, and

other elements. Many libraries display MARC records on their online catalogs with labels for the data elements to help the public interpret MARC records. Many libraries also offer the option to display MARC records in MARC fields.

12. Libraries create MARC records for works they acquire, including books, serials, motion pictures, and publications in other formats. Monograph cataloging is fairly common in libraries, and most libraries make a newly cataloged monograph available to the public soon after the cataloging work is completed, usually within a week. Libraries can create original cataloging records or use an existing record in OCLC to create a copy cataloging record. As soon as the cataloging record is completed, it is added to the library's online catalog for users. If the record is an original record, it is also entered into OCLC WorldCat. If it is a copy cataloging record, the library's holding symbol is attached to the existing, original record in OCLC WorldCat to facilitate searching and interlibrary loan.

13. The cataloging of serials and the serial check-in process are discussed here to show how libraries usually provide access to newly received serial issues. According to the Library of Congress, a serial is "[a] mode of issuance of a manifestation issued in successive parts, usually bearing numbering, that has no predetermined conclusion. A serial includes a periodical, monographic series, newspaper, etc." **EX1183**, Page 3. Because the publisher of a serial makes new issues of the serial available successively, a customary cataloging practice is to

create one bibliographic record for the serial, and the serial record (encoded in MARC) typically provides information on the beginning date and frequency of the serial, not the dates of individual issues. In other words, libraries typically do not create MARC records for individual issues of a serial. Instead, they rely on a serial check-in system to track the receipt of new issues. A common check-in practice is to date “stamp” a new issue when it arrives. This practice has become automated since the late 1990s, and libraries now vary in how they share the receipt date of a new serial issue with the public. Some libraries use a date stamp, some affix a label to indicate the receipt date, some pencil in the receipt date, and some do not provide the information to the public.

14. The serial check-in process usually takes less than an hour, and one of the steps involves placing a date stamp on the new issue to document the date the issue is checked in. After that, the holdings information of the serial is updated in the library’s catalog so that users know which issues are available for request or access. After serial check-in is completed, the new issue is placed on the shelf with the previous issues of the serial. Libraries with a public periodical room typically place new issues in the periodical room for easy user access. Because information presented in serials often reflects latest discovery, a general practice of libraries is to make new issues of serials available for user access soon after they are checked in, usually within a week.

15. 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:

- Google Scholar (<https://scholar.google.com>);
- Internet Archive (<https://archive.org/>);
- Online catalog of the Library of Congress (<https://catalog.loc.gov/>);
- Online catalog of the National Library of Medicine
(https://catalog.nlm.nih.gov/discovery/search?vid=01NLM_INST:01NLM_INST&lang=en);
- Online catalog of the University of Wisconsin-Madison General Library System (<https://search.library.wisc.edu/>); and
- WorldCat (<https://www.worldcat.org>)

B. Scope of This Declaration

16. I have been asked to offer an opinion on the authenticity and public availability date of the following documents:

- Baronti, C., Piorkowski, G., Charrel, R. N., Boubis, L., Leparco-Goffart, I., & de Lamballerie, X., (2014, June 5), “Complete Coding Sequence of Zika Virus from a French Polynesia Outbreak in

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2013,” *Genome Announcements*, vol. 2, no. 3, p. e00500-14 (**EX1160**,
“*Baronti*”);

- World Health Organization, *Current Zika Product Pipeline*, (3 March 2016), available at <https://www.who.int/publications/m/item/current-zika-product-pipeline> (**EX1161**, “*Zika Pipeline*”);
- Sifferlin, A., “U.S. Launches ‘Full-Court Press’ for a Zika Vaccine,” *TIME* (Jan. 21, 2016, 3:24 PM), <https://time.com/4188973/zika-virus-vaccine-nih/> (**EX1162**, “*Sifferlin-TIME*”);
- Srivastava, A. K., Putnak, J. R., Lee, S. H., Hong, S. P., Moon, S. B., Barvir, D. A., ... & Eckels, K. H., (14 August 2001, available online 30 July 2001), “A Purified Inactivated Japanese Encephalitis Virus Vaccine Made in Vero cells,” *Vaccine*, vol. 19, no. 3, pp. 4557-4565 (**EX1163**, “*Srivastava*”);
- Thomas, S. J., Eckels, K. H., Carletti, I., De La Barrera, R., Dessy, F., Fernandez, S., ... & Innis, B. L., (2013), “A Phase II, Randomized, Safety and Immunogenicity Study of a Re-derived, Live-attenuated Dengue Virus Vaccine in Healthy Adults,” *American Journal of Tropical Medicine and Hygiene*, vol. 88, no. 1, pp. 73-88 (**EX1164**, “*Thomas*”).

C. Evidence Considered in Forming My Opinions

17. In preparing this Declaration, I have reviewed the documents referenced below and any other 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:

- (1) The documents referenced above in Section I.B: *Baronti* (EX1160); *Zika Pipeline* (EX1161); *Sifferlin-TIME* (EX1162); *Srivastava* (EX1163); and *Thomas* (EX1164);
- (2) PubMed metadata record for *Baronti*, available at <https://pubmed.ncbi.nlm.nih.gov/24903869/>, accessed and obtained on November 10, 2022 (EX1139);
- (3) Table of contents of vol. 2, no. 3 (2014) of *Genome Announcements* that contains *Baronti*, archived on June 29, 2014 by the Internet Archive, available at <https://web.archive.org/web/20140629173328/http://genomea.asm.org/content/2/3.toc>, accessed and obtained on November 11, 2022 (EX1141);
- (4) Citations to *Baronti*, obtained from Google Scholar (EX1142), and Early Citations to *Baronti* that I compiled in a list format (EX1187);

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- (5) Copy of *Zika Pipeline* archived on March 11, 2016 by the Internet Archive, available at <https://web.archive.org/web/20160311113550/http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf>, accessed and obtained on November 10, 2022 (**EX1143**);
- (6) “WHO and Experts Prioritize Vaccines, Diagnostics and Innovative Vector Control Tools for Zika R&D,” a March 9, 2016 WHO Note for media, archived on March 9, 2016 by the Internet Archive, available at <https://web.archive.org/web/20160309222523/http://www.who.int/mediacentre/news/notes/2016/research-development-zika/en/>, accessed and obtained on December 5, 2022 (**EX1144**);
- (7) *Sifferlin-TIME* archived on January 22, 2016 by the Internet Archive, available at <https://web.archive.org/web/20160122154151/http://time.com/4188973/zika-virus-vaccine-nih/>, accessed and obtained on December 5, 2022 (**EX1145**);
- (8) Copy of *Srivastava* obtained from the University of Wisconsin-Madison Steenbock Library (**EX1146**);

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- (9) Bibliographic and MARC records for *Vaccine*, the journal that contains *Srivastava*, available at <https://search.library.wisc.edu/catalog/999552122802121>, from the online catalog of the University of Wisconsin-Madison Library System, accessed and obtained on November 11, 2022 (**EX1147**);
- (10) PubMed metadata record for *Srivastava*, available at <https://pubmed.ncbi.nlm.nih.gov/11483284/>, accessed and obtained on November 10, 2022 (**EX1148**);
- (11) *Vaccine* website archived by the Internet Archive on October 3, 2002, available at <https://web.archive.org/web/20021003015903/http://www.elsevier.com:80/locate/vaccine>, from the Internet Archive, accessed and obtained on November 26, 2022 (**EX1149**);
- (12) Citations to *Srivastava*, obtained from Google Scholar (**EX1150**), and Early Citations to *Srivastava* that I compiled in a list format (**EX1209**);
- (13) Copy of *Thomas* obtained from the National Library of Medicine (**EX1151**);
- (14) Bibliographic and MARC records of the *American Journal of*

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Tropical Medicine and Hygiene, the journal that contains *Thomas*,
available at
https://catalog.nlm.nih.gov/permalink/01NLM_INST/1o1phhn/alm
a991179293406676, from the online catalog of the National
Library of Medicine, accessed and obtained on November 15, 2022
(EX1152);

- (15) PubMed metadata record for *Thomas*, available at
<https://pubmed.ncbi.nlm.nih.gov/23208878/>, accessed and obtained
on November 10, 2022 (EX1153);
- (16) Citations to *Thomas*, obtained from Google Scholar (EX1154), and
Early Citations to *Thomas* that I compiled in a list format
(EX1208).

II. AUTHENTICITY AND PUBLIC AVAILABILITY OF *BARONTI* (EX1160)

A. Authentication

18. EX1160 is a true and correct copy of “Complete Coding Sequence of Zika Virus from a French Polynesia Outbreak in 2013” (“*Baronti*”), by Baronti et al., *Genome Announcements*, vol. 2, no. 3, p. e00500-14, that I obtained from the publisher. I began my research by searching Google Scholar by the title of *Baronti* for records, and a retrieved record led me to the publisher’s webpage for *Baronti* at

<https://journals.asm.org/doi/full/10.1128/genomeA.00500-14> (**EX1185**). The

small, red unlock icon on this webpage shows the publisher provides open access to *Baronti*, meaning there is no restriction on user access. I then followed the PDF link to download the full text of *Baronti*. This publisher copy is presented as **EX1160** in this Declaration.

19. **EX1160** is a true and correct copy of *Baronti* obtained from the publisher. Page 1 shows the title, authors, and abstract. A publication history note shows the manuscript was received on May 5, 2014, accepted May 14, 2014, and published on June 5, 2014, and its doi (digital object identifier) is 10.1128/genomeA.00500-14. A copyright note shows *Baronti* has a “2014” copyright date, and the article is an open-access article. The bottom of this page shows *Baronti* was published in volume 2, issue 3 (May/June 2014) of *Genome Announcements* as e00500-14l. **EX1160** shows *Baronti* has a total of two pages, including nine references.

20. The publisher’s copy of *Baronti* (**EX1160**) 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, **EX1160** 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 *Baronti* (**EX1160**).

B. PubMed Records

21. Because *Baronti* was published in an online open-access journal, the publication date is the public availability date. To determine whether *Baronti* was indexed, I searched PubMed by the article title for records and located a record at <https://pubmed.ncbi.nlm.nih.gov/24903869/>. This PubMed record is presented as **EX1139** 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.” **EX1186**, Page 1. I personally located, identified, and obtained the PubMed metadata record for *Baronti* (**EX1139**). I saved the metadata record as a PDF and also in PubMed format to show the record details in data fields.

22. **EX1139** is a true and correct copy of the PubMed metadata record for *Baronti*. The top of page 1 shows a full text link to “ASM Journals Open Access” that takes users to the publisher’s webpage for *Baronti*, and another link to a “Free PMC Article,” a free, full text at PMC (PubMed Central). Page 1 also shows the title, authors, and an abstract. The area above the title shows a note of “Genome Announc. 2014 Jun 5;2(3):e00500-14. doi: 10.1128/genomeA.00500-14.”

EX1139, Page 1. The journal title, issue number, pagination and doi match the information presented in the publisher's copy of *Baronti* (**EX1160**) and confirm this record represents *Baronti*. This page also shows the PubMed record identifier is 24903869, discussed below, and the PubMed Central identifier for *Baronti* is PMC4047448. **EX1139**, Page 1. The "Full Text Sources" field shows that users can find the full text of *Baronti* in Atypon, Europe PubMed Central and PubMed Central, and each source is presented as a live link for easy access to this article. **EX1139**, Page 1.

23. Page 2 of **EX1139** is the PubMed record in PubMed format to show data in specific fields. I used the "MEDLINE/PubMed Data Element (Field Descriptions)" (**EX1207**) to interpret the record. The "PMID" field shows "24903869" as the PubMed identifier for the record for *Baronti*. The "STAT" field shows the status of the record is "PubMed-not-MEDLINE" (meaning the record is in PubMed but no medical subject headings are assigned to this record and it is not elevated into the MEDLINE database). The DCOM field shows this index record was completed on "20140606" (i.e., June 6, 2014 in yyyyymmdd format). **EX1139**, Page 2. The IS fields show the ISSN (International Standard Serial Number) of the print version is "2169-8287" and the ISSN of the electronic version of this journal is also "2169-8287." *Id.* Fields VI (volume), IP (issue), DP (date of publication), TI (title), and JT (journal title) show *Baronti* was published in vol. 2, issue 3 (2014

Jun 5) of *Genome Announcements* as “e00500-14.” **EX1139**, Page 2. The first FAU (full author) field shows “Baronti, Cécile” as the first author. **EX1139**, Page 2. Field DEP (date of electronic publication) shows *Baronti* was published online on “20140605” (i.e., June 5, 2014). **EX1139**, Page 2. Field CRDT (creation date) and field EDAT (entrez date) show the metadata record was added to PubMed on “2014/06/07” (i.e., June 7, 2014). **EX1139**, Page 2. Field “AID” (Article identifier) shows the doi of *Baronti*. **EX1139**, Page 3.

24. This PubMed metadata record (**EX1139**) made *Baronti* discoverable in PubMed on June 7, 2014, when the record was entered into PubMed. June 7, 2014 is two days after the online publication date of *Baronti* on June 5, 2014. **EX1139**, Page 2. Interested users would have been able to search for and locate *Baronti* in PubMed by the authors, title, journal title, ISSN, and abstract as of June 7, 2014.

C. Internet Archive Copy

25. As evidence that *Genome Announcements* was available on the Internet at or near the time it was first published, I searched the Internet Archive for records. I began with genomea.asm.org in Wayback Machine and located the table of contents of volume 2, no. 3 at <https://web.archive.org/web/20140629173328/http://genomea.asm.org/content/2/3.toc>. I saved the archived file in PDF. This file is presented as **EX1141** in this

Declaration. I personally located, identified and obtained this table of contents.

This is the type of material experts in my field would reasonably rely upon when forming their opinions.

26. **EX1141** is a true and correct copy of the table of contents of volume 2, no. 3 of *Genome Announcements* archived by the Internet Archive. Page 1 is a screen capture of the Wayback Machine calendar that shows the original URL of this table of contents is <http://genomea.asm.org/content/2/3.toc>, the file was captured eight times from “29 Jun 2014” to “26 Jun 2018,” and this particular copy was captured on “Jun 29 2014.” The “Current Issue” area shows that this is the table of contents of “May/June 2014, Volume 2, Issue 3.” Pages 2 to 16 are the rest of the table of contents listing each article with the title, authors, issue citation, doi, and links to the abstract, full text, PDF, and Reprints and Permissions. Page 15 shows *Baronti* is included in this issue.

27. The Internet Archive is a digital library that archives websites, webpages, and other cultural artifacts on the Internet, and provides the general public and researchers with free access to its collections. I have used Internet Archive in the past and am familiar with its practice of assigning an extended URL to an archived file in the format of [http://www.archive.org/web/\[Year in yyyy\]\[Month in mm\]\[Day in dd\]\[Time code in hh:mm:ss\]/\[Archived URL\]](http://www.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]). The extended URL for the table of contents of volume 2, issue 3 of *Genome*

Announcements archived by the Internet Archive shows this webpage was archived and available at

<https://web.archive.org/web/20140629173328/http://genomea.asm.org/content/2/3.toc>.

The archive date of “20140629173328” means this webpage was archived on June 29, 2014, 5 p.m., 33 minutes, 28 seconds. Because the Internet Archive does not archive web resources as soon as they appear on the Internet, the archive date means the archived resource was available *no later than* the archive date. In this case, it means this archived copy of the table of contents of the issue containing *Baronti* was publicly accessible no later than June 29, 2014; that is, by this date, the general public would have been able to discover this table of contents.

Although the Internet Archive did not archive the abstract, full text, PDF and Reprints and Permissions for *Baronti*, the archived table of contents (**EX1141**) shows that interested users would have been able to discover *Baronti* on the journal website and access the table of contents no later than June 29, 2014 and use it to discover and access *Baronti*.

D. Usage Record

28. Actual usage of an article is reflected by other articles that make reference to it. The citation history of Google Scholar (**EX1142**) shows *Baronti* has been cited 301 times (page 1) and nine times in 2015 (page 2). **EX1187** is a list I

compiled of citations from 2015 to demonstrate early usage. The earliest citation to *Baronti* appeared in February 2015.

E. Summary of My Opinion on *Baronti*

29. The publisher's copy of *Baronti* (EX1160), the PubMed records for *Baronti* (EX1139), the Internet Archive of the table of contents of the issue containing *Baronti* (EX1141), and my knowledge of digital archives and the Internet Archive in particular inform my opinion that *Baronti* was published online on June 5, 2014, as an open access article. Because *Genome Announcements* has been available as an electronic journal, the online version of *Baronti* would have become publicly accessible on the Internet when it was published online on June 5, 2014 (EX1160). The PubMed records show that *Baronti* was indexed and became searchable in PubMed on June 7, 2014 (EX1139), making it possible for interested users to search for *Baronti* in PubMed by title, authors, journal title, ISSN, and abstract. The table of contents of the journal issue containing *Baronti* was archived on June 29, 2014 (EX1141), making it possible for the general public to discover this table of contents by the archive date, then use the table of contents to access *Baronti*. The earliest citation to *Baronti* appeared in February 2015 (EX1187).

III. AUTHENTICITY AND PUBLIC AVAILABILITY OF *ZIKA PIPELINE* (EX1161)

A. Authentication

30. **EX1161** is a true and correct copy of “Current Zika Product Pipeline,” (*“Zika Pipeline”*), a research-and-development plan of the World Health Organization (WHO), published on March 3, 2016, that I obtained from the WHO website. When I began preparing for this Declaration, I searched Google Scholar by the title of this publication for copies, and I found a link for this work on the WHO website at <https://www.who.int/publications/m/item/current-zika-product-pipeline>. I downloaded the file and saved as a PDF. This copy from the publisher is presented as **EX1161** in this Declaration.

31. **EX1188** is a screen capture of the World Health Organization webpage showing an “Overview” of the *Zika Pipeline* plan, and **EX1161** is the full text of this publication. **EX1188** shows “Current Zika Product Pipeline” as the title and “3 March 2016” as the publication date, and includes a summary of this publication, and indicates the “WHO Team” on “Immunization, Vaccines and Biologicals” initiated an emergency research and development plan. **EX1188**, Page 1. Page 1 of **EX1161** is the title page that shows the title, publication date, and the table of contents of this work. The footer shows a running title of “Zika Product Landscape – 03.03.16.” **EX1161** shows *Zika Pipeline* has a total of 16 pages, including two links on page 6 to web publications.

32. The copy of the *Zika Pipeline* (**EX1161**) is in a condition that does not create suspicion about its authenticity. Specifically, the body of the text 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, **EX1161** was obtained from the publisher's website. I therefore see no reason to question the authenticity of this copy of *Zika Pipelilne* (**EX1161**).

B. Internet Archive Copy of *Zika Pipeline*

33. As evidence that *Zika Pipeline* is available on the Internet, I searched the Internet Archive for records. **EX1143** is a true and correct copy of *Current Zika Product Pipeline* archived by the Internet Archive. I personally located, identified and obtained this webpage and saved it as a PDF. This is the type of record experts in my field would reasonably rely upon when forming their opinions.

34. Page 1 of **EX1143** is a screenshot of the Wayback Machine calendar that shows that the original URL of this webpage was <http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf>, that the file was captured 51 times from "11 Mar 2016" to "27 Jan 2022," and that this particular copy was archived on "Mar 11 2016." The top of page 1 (**EX1143**) shows the archived copy is available at <https://web.archive.org/web/20160311113550/http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf>. Page 2 of **EX1143** is the Wayback Machine

page identifying this file, and pages 3 to 18 (internal pages 1 to 16) are the full text of *Zika Pipeline*. I have closely compared the archived copy of *Zika Pipeline* (**EX1143**) with the copy of *Zika Pipeline* from the publisher's website (**EX1161**) and found them to be identical.

35. The archived copy of *Zika Pipeline* (**EX1143**) is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text appears to flow seamlessly from one paragraph to the next, and there are no visible alterations to this work. Moreover, **EX1143** is in the custody of a digital archive, a place where, if authentic, it would likely be found. Accordingly, I see no reason to question the authenticity of the Internet Archive copy of *Zika Pipeline* (**EX1143**).

36. Page 1 of **EX1143** shows that the extended URL for the archived copy of *Zika Pipeline* is available at <https://web.archive.org/web/20160311113550/http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf>. The archive date of “20160311113550” means this article was archived on March 11, 2016, 11 a.m., 35 minutes, 50 seconds. Because the Internet Archive does not always archive web resources as soon as they appear on the Internet, the archive date means the archived resource was available *no later than* the archive date. In this case, the archive date means that this archived copy of *Zika Pipeline* was publicly accessible no later than

March 11, 2016, eight days after this research-and-development plan was published by WHO on March 3, 2016.

37. As further evidence that *Zika Pipeline* was publicly accessible, I searched the Internet for reference to this publication and located a media note from WHO with the title of “WHO and Experts Prioritize Vaccines, Diagnostics and Innovative Vector Control Tools for Zika R&D” that was archived by the Internet Archive. This archived copy is saved as a PDF and presented as **EX1144** in this Declaration.

38. **EX1144** is a true and correct copy of WHO’s “Note for the media” issued on March 9, 2016 that I obtained from the Internet Archive at <https://web.archive.org/web/20160309222523/http://www.who.int/mediacentre/news/notes/2016/research-development-zika/en/>. I personally located, identified and obtained this copy. This is the type of material experts in my field would reasonably rely upon when forming their opinions.

39. Page 1 of **EX1144** is a screen capture of a Wayback Machine calendar that shows the original URL of this file is <http://www.who.int/mediacentre/news/notes/2016/research-development-zika/en/>, this file was captured 106 times from “9 Mar 2016” to “12 Oct 2022” and this particular copy was archived on “Mar 09 2016.” The top of page 1 (**EX1144**) shows this file is available at

<https://web.archive.org/web/20160309222523/http://www.who.int/mediacentre/news/notes/2016/research-development-zika/en/>, identifies this website as the World Health Organization website, and further shows that this file is stored in the “Media centre” as a “Note for the media.” **EX1144**, Page 1. The title of this note is “WHO and Experts Prioritize Vaccines, Diagnostics and Innovative Vector Control Tools for Zika R&D,” and a subtitle shows “67 groups working on experimental products.” **EX1144**, Page 1. This file is identified as a “Note for the media” released on “9 March 2016.” **EX1144**, Page 1. Pages 2 to 4 are the full text of this “Note for the media.” The “Vector control” section on page 3 of **EX1144** states that the R&D community “has responded vigorously to the need for Zika medical products and innovative vector control measures; the pipeline of candidate products is still growing” and this section includes a link to the document “Current Zika product pipeline” and a link to “Medicines and health products.” The link to “Current Zika product pipeline” on this webpage is <https://web.archive.org/web/20160309222523/http://www.who.int/entity/csr/research-and-development/zika-rd-pipeline.pdf?ua=1> and the Internet Archive shows this URL is not archived (**EX1140**). However, using the original URL <http://www.who.int/entity/csr/research-and-development/zika-rd-pipeline.pdf> to search the Internet Archive for copies, I was able to reach the archived copy of this research-and-development plan at

<https://web.archive.org/web/20160311113550/http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf>, which is the same URL for *Zika Pipeline* as presented in **EX1143** in this Declaration.

40. **EX1143** and **EX1144** inform me that *Zika Pipeline* was published on March 3, 2016, and a WHO “Note for media” released on March 9, 2016, made reference to *Zika Pipeline* and included a link for readers to download the *Zika Pipeline* file. Furthermore, this “Note for media” itself was archived on March 9, 2016 by the Internet Archive (**EX1144**), meaning as of March 9, 2016, the general public would have been able to search the Internet for and discover *Zika Pipeline* (**EX1161**).

C. Summary of My Opinion on *Zika Pipeline*

41. The publisher’s copy of *Zika Pipeline* (**EX1161**), the copy of *Zika Pipeline* archived by the Internet Archive (**EX1143**), the WHO “Note for media” archived by the Internet Archive (**EX1144**), together with my knowledge of digital archives, and the Internet Archive in particular, inform my opinion that the *Zika Pipeline* file was published on March 3, 2016 (**EX1161**, Page 1), and archived on March 11, 2016 (**EX1143**, Page 1), while the WHO “Note for media” referencing *Zika Pipeline* was released on March 9, 2016, and archived on the same day by the Internet Archive (**EX1144**, Page 1). These dates mean that *Zika Pipeline* was published on the WHO website on March 3, 2016, and the general public would

have been able to discover and access it from that date on, and definitely no later than, March 11, 2016, when it was archived by the Internet Archive (**EX1143**).

The WHO “Note for media” became publicly accessible by March 9, 2016 (**EX1144**), showing that as of March 9, 2016, the availability of *Zika Pipeline* was further publicized. It is therefore my conclusion that users interested in the research and development of Zika-related products would have been able to reasonably discover and access *Zika Pipeline* as early as March 3, 2016, and no later than March 11, 2016.

IV. AUTHENTICITY AND PUBLIC AVAILABILITY OF *SIFFERLIN-TIME* (EX1162)

A. Authentication

42. **EX1162** is a true and correct copy of “U.S. Launches ‘Full-Court Press’ for a Zika Vaccine,” (“*Sifferlin-TIME*”), by A. Sifferlin published online by TIME on “January 21, 2016 3:24 PM EST” that I obtained from the Internet. When I began preparing for this Declaration I searched Google Scholar by the title of this article for copies, and found a link to the article at <https://time.com/4188973/zika-virus-vaccine-nih/>. I saved *Sifferlin-TIME* as a PDF from the publisher’s webpage for this article. This copy from the publisher is presented as **EX1162** in this Declaration.

43. Page 1 of **EX1162** shows “U.S. Launches ‘Full-court Press’ for a Zika Vaccine” as the title, Alexandra Sifferlin as the author, TIME as the publisher, and

“January 21, 2016 3:24 PM EST” as the publication date. The top of page 1 of

EX1162 shows the title of this webpage is “Zika Virus Has U.S. in ‘Full-court Press’ for Vaccine | Time” and the URL for this article is shown as

<https://time.com/4188973/zika-virus-vaccine-nih/>. **EX1162** shows *Sifferlin-TIME*

has a total of nine paragraphs that reports on Dr. Fauci’s caution on Thursday, January 21, 2016, that the Zika virus had “become a growing threat in the U.S.” (**EX1162**, Page 1) and scientists needed to start working on a vaccine.

44. The copy of *Sifferlin-TIME* (**EX1162**) is in a condition that does not create suspicion about its authenticity. Specifically, the body of the text 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, **EX1162** was obtained from the publisher’s website. I therefore see no reason to question the authenticity of this copy of *Sifferlin-TIME* (**EX1162**).

B. Internet Archive Copy of *Sifferlin-TIME*

45. As evidence that *Sifferlin-TIME* is available on the Internet, I searched the Internet Archive for records. **EX1145** is a true and correct copy of this article as archived by the Internet Archive. I personally located, identified, and obtained this webpage and saved it as a PDF. This is the type of record experts in my field would reasonably rely upon when forming their opinions.

46. Page 1 of **EX1145** is a screenshot of the Wayback Machine calendar that shows that the original URL of this webpage was <http://time.com/4188973/zika-virus-vaccine-nih>, the webpage was captured 73 times from “22 Jan 2016” to “19 May 2022” and this particular copy of the webpage was archived on “Jan 22 2016.” The top of page 1 of **EX1145** shows the archived copy is available at <https://web.archive.org/web/20160122154151/http://time.com/hive.org/web/20160122154151/http://time.com/4188973/zika-virus-vaccine-nih/>. Pages 2 and 3 of **EX1145** are the archived *Sifferlin-TIME* article that shows this article is in the “Health Public Health” section of *TIME Magazine* and the publication date is “Jan. 21, 2016” (**EX1145**). On page 1, a caption of “‘All hands on deck,’ top official says” appears before the main text of the article, and the end of the article on page 3 shows the article has a “2016” copyright date with Time Inc. as the copyright holder (**EX1145**). Page 1 also shows the webpage was powered by WordPress.com VIP (**EX1145**). I have closely compared the archived copy of *Sifferlin-TIME* (**EX1145**) with the publisher’s copy (**EX1162**) and found them to have the same content. The differences are that the archived copy (**EX1145**) includes the date, but not the time, of publication, and shows a caption and a copyright date. Because **EX1162** was obtained in 2022, a video of the “COVID-19 Response Press Briefing

Sept. 6, 2022” is inserted into the webpage, but the video is not part of the

Sifferlin-TIME article.

47. The archived copy of *Sifferlin-TIME* is in a condition that does not create suspicion about its authenticity. Specifically, this copy is not missing any intermediate pages, the text appears to flow seamlessly from one paragraph to the next, and there are no visible alterations to the article. Moreover, **EX1145** is in the custody of a digital archive, a place where, if authentic, it would likely be found. Accordingly, I see no reason to question the authenticity of the copy archived by Internet Archive (**EX1145**).

48. The extended URL for the archived copy of *Sifferlin-TIME* shows the *TIME* article is available at <https://web.archive.org/web/20160122154151/http://time.com/hive.org/web/20160122154151/http://time.com/4188973/zika-virus-vaccine-nih/> (**EX1145**). The archive date of “20160122154151” means this article was archived on January 22, 2016, 3 p.m., 41 minutes, 51 seconds. Because the Internet Archive does not archive web resources as soon as they appear on the Internet, the archive date means the archived resource was available no later than the archive date. In this case, the archive date means this archived copy of *Sifferlin-TIME* was publicly accessible no later than January 22, 2016.

C. Summary of My Opinion on *Sifferlin-Time*

49. The publisher's copy of *Sifferlin-TIME* (**EX1162**) and the archived copy (**EX1145**), together with my knowledge of digital archives and the Internet Archive, inform my opinion that the *Sifferlin-TIME* article was published online on January 21, 2016, and would have been publicly accessible from that date on. The archived copy (**EX1145**) shows that by at least January 22, 2016, visitors to the *TIME* website would have been able to find and access the *Sifferlin-TIME* article.

V. AUTHENTICITY AND PUBLIC AVAILABILITY OF *SRIVASTAVA* (EX1163**)**

A. Authentication

50. **EX1163** is a true and correct copy of "A Purified Inactivated Japanese Encephalitis Virus Vaccine Made in Vero Cells" ("*Srivastava*"), by Srivastava et al., *Vaccine*, vol. 19, no. 31 (14 August 2001), pp. 4557-4565, that I obtained from Elsevier, the publisher. I began my research by searching Google Scholar by the title of *Srivastava* for records, and a retrieved record led me to the publisher's webpage for *Srivastava* at <https://www.sciencedirect.com/science/article/pii/S0264410X01002080> on ScienceDirect (**EX1195**), a subscription-based online platform of Elsevier for peer-reviewed full-text publications in science, technology, life sciences, health sciences, social sciences and humanities (**EX1197**). I followed the "Purchase PDF"

link to purchase the full text of *Srivastava*. This publisher copy is presented as

EX1163 in this Declaration.

51. **EX1163** is a true and correct copy of *Srivastava* obtained from the publisher. Page 1 of **EX1163** shows the title, authors, abstract, and three keywords (“JE-PIV; Vero cells; Vaccine”) for this article. A publication history note below the list of authors shows this article was “Received 19 January 2001, received in revised form 10 April 2001; accepted 4 May 2001.” **EX1163**, Page 1. The bottom of page 1 shows *Srivastava* was published in a journal whose ISSN (International Standard Serial Number) is “0264-410X,” has a 2001 copyright date with Elsevier Science Ltd. as the copyright holder, and has an identifier of “PII: S0264-410X(01)00208-0.” **EX1163** shows *Srivastava* has a total of nine pages (pages 4557-4565), including five tables and 30 references. The publisher’s webpage for *Srivastava* at <https://www.sciencedirect.com/science/article/pii/S0264410X01002080?via%3Dihub> (**EX1195**) shows this article was “Received 19 January 2001, Revised 10 April 2001, Accepted 4 May 2001, Available online 30 July 2001.”

52. The publisher’s copy of *Srivastava* (**EX1163**) 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, **EX1163** 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 *Srivastava* (**EX1163**).

B. University of Wisconsin-Madison Copy of *Srivastava*

53. To determine whether *Srivastava* was available at libraries, I searched WorldCat by “vaccine”—the title of the journal that contains *Srivastava*—for records, and a retrieved record at <https://worldcat.org/title/10399916> (**EX1198**) showed the University of Wisconsin-Madison library system (UW) as one of the holdings libraries. I searched the UW online catalog to verify the holdings, and the library records confirmed the holdings information (**EX1147**). I then requested a scanned copy of *Srivastava* from the university, with the assistance of Wisconsin TechSearch (WTS), a document delivery service based at the University of Wisconsin-Madison. The UW copy of *Srivastava* is presented as **EX1146** in this Declaration.

54. **EX1146** is a copy of *Srivastava* obtained from the Steenbock Memorial Library of the University of Wisconsin-Madison. Page 1 of **EX1146** is the cover that shows that *Vaccine* is “The Official Journal of the International Society for Vaccines,” the issue is vol. 19, no. 31 and has a “14 August 2001” issue date, and Elsevier as the publisher (**EX1146**). Page 2 of **EX1146** is the table of contents that shows a library stamp of “Steenbock Memorial Library SEP 05

2001 U.W.-Madison” that indicates the library received this issue on September 5, 2001 (**EX1146**). The top of page 2 shows the ISSN of *Vaccine* is “0264-410X” and the journal is available online at www.elsevier.com/locate/vaccine (**EX1199**). Page 3 of **EX1146** shows *Srivastava* is a “Regular Paper[]” that begins on page 4557 and ends on 4565. Page 4 is the copyright page that shows “*Vaccine* is an international journal published 32 times a year by Elsevier Science Ltd.” and this issue has a 2001 copyright, with Elsevier Science Ltd. as the copyright holder (**EX1146**). Pages 5 to 13 (internal pages 4557 to 4565) is the *Srivastava* article that has nine pages, including five tables and 30 references (**EX1146**).

55. I have closely compared the UW copy of *Srivastava* (**EX1146**) with the publisher’s copy of *Srivastava* (**EX1163**) and found them to be identical. The UW copy of *Srivastava* (**EX1146**) 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, **EX1146** is in the custody of a university library, a place where, if authentic, it would likely be found. Accordingly, I see no reason to question the authenticity of the UW copy of *Srivastava* (**EX1146**).

C. University of Wisconsin Library Records

56. **EX1147** is a true and correct copy of the bibliographic and MARC records for *Vaccine* that contains *Srivastava*. I personally located, identified and obtained these records from the UW online catalog. These are the type of records experts in my field would reasonably rely upon when forming their opinions.

57. Pages 1 to 3 of **EX1147** are the bibliographic record for *Vaccine*, the journal containing *Srivastava*. Page 1 shows the journal title and the holdings information that indicates *Vaccine* is available online and the print issues are held by the Steenbock Library, shelved by title and for in-library use only (**EX1147**). A note on page 1 shows “Paper copy cancelled end of v.23, no. 5 (2004)” and page 2 shows a variant title, format, language, publisher information, publication dates, physical details, ISSNs, OCLC record numbers, notes, and subjects of this journal (**EX1147**).

58. Pages 3 to 6 of **EX1147** are the MARC record saved as a PDF. The first six digits of field 008 show the MARC record was created on “840210” (*i.e.*, February 10, 1984), and the code of “c19839999” following the record creation date indicates that this journal is a continuing resource that began publication in 1983 and has no publication end date yet (**EX1147**). Subfields “a” and “c” of field 040 show “NSD” (the National Serials Data Program) created this MARC record, and subfields “d” show “NLM” (*i.e.*, the National Library of Medicine) and

“GZM” modified the original MARC record (**EX1147**). According to the *Directory of OCLC Members*, “GZM” is the OCLC library symbol for the University of Wisconsin, Madison, General Library System (**EX1200**). Fields 008 and 040 inform my opinion that *Vaccine* began publication in 1983, and the University of Wisconsin-Madison General Library System used the original serial MARC record created by the National Serial Data Program to create their copy cataloging record, making the journal discoverable by the public in their library catalog (**EX1147**).

59. Field 022 of **EX1147** shows the ISSN for the print version of this journal, field 245 shows the journal title, field 246 shows a variant title is provided to help users discover this journal, and field 260 shows information about the first publisher, Butterworths, that began publishing this journal in 1983. Field 362 shows that the journal began publication with volume 1, no. 1 in December 1983, and field 310 shows that since 1999 the publication frequency has been “Semimonthly.” **EX1147**, Page 4. Field 530 shows *Vaccine* is also available on the Internet and pages 4 to 6 are the MARC record for the electronic version of this journal (**EX1147**).

60. Pages 3 and 4 of **EX1147** are the serial MARC record for the print version of *Vaccine*. Subjects of this journal are represented in field 060 by a National Library of Medicine classification number of “W1” that represents serials

and periodicals in general medicine (**EX1202**), but this number is not used at the Steenbock Library because journals are shelved by title at this library. Subjects are represented in fields 650 by a National Library of Medicine medical subject heading (“Vaccines \$v periodicals”) and a Library of Congress subject heading (“Vaccines \$v Periodicals), with “\$v” (subfield v) representing a form subdivision (**EX1147**, Page 4). The subject headings show this publication is a journal that focuses on vaccines. These subject representations enable users to conduct subject searches to discover this journal.

61. The MARC record (**EX1147**) shows *Vaccine* is a long-running journal that was originally cataloged by the National Serial Data Program on February 10, 1984, and the University of Wisconsin-Madison General Library System used the original MARC record to create their copy cataloging record, making the journal discoverable by the ISSN, title, variant title, and subject headings. Because vol. 19, no. 31 (14 August 2001) of *Vaccine* that contains *Srivastava* was received by the Steenbock Library on September 5, 2001 (**EX1146**), this journal would have been publicly discoverable by at least September 5, 2001, if not earlier.

D. Library Date Stamp

62. The “SEP 05 2001” date stamp on the table of contents of the UW copy of *Srivastava* (**EX1146**) has the appearance of a typical library serial check-in date stamp that indicates the Steenbock Library of the University of Wisconsin-

Madison received vol. 19, no. 31 of *Vaccine* that contains *Srivastava* on September 5, 2001. **EX1146**, Page 2. 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 article of the journal. 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 the copy of vol. 19, no. 31 of *Vaccine* that contains *Srivastava* (**EX1146**) would have become publicly accessible no later than September 12, 2001, at the Steenbock Library of the University of Wisconsin-Madison.

E. PubMed Records

63. To determine whether *Srivastava* was indexed, I searched PubMed by the article title for records and located a record at <https://pubmed.ncbi.nlm.nih.gov/11483284/>. This PubMed record is presented as **EX1148** in this Declaration. I personally located, identified and obtained the PubMed metadata record for *Srivastava* (**EX1148**). I saved the metadata record as a PDF and also in PubMed format to show the record details in data fields.

64. **EX1148** is a true and correct copy of the PubMed metadata record for *Srivastava*. The top of page 1 shows a full text link to “Elsevier Full-Text Article” that takes users to the publisher’s webpage for *Srivastava* at <https://www.sciencedirect.com/science/article/pii/S0264410X01002080?via%3Dihub> (**EX1195**), and this webpage shows this article was “Received 19 January 2001, Revised 10 April 2001, Accepted 4 May 2001, Available online 30 July 2001.” Page 1 of the PubMed record (**EX1148**) shows the title, authors, and an abstract. The area above the title shows a note of “Vaccine. 2001 Aug 14;19(31):4557-65” that indicates when and where *Srivastava* was published. **EX1148**, Page 1. The PubMed record shows the record identifier is “11483284” and the doi (digital object identifier) of *Srivastava* is “10.1016/s0264-410x(01)00208-0.” **EX1148**, Page 2-3.

65. Pages 2 and 3 of **EX1148** are the PubMed record in PubMed format to show data in specific fields. I used the “MEDLINE/PubMed Data Element (Field) Descriptions” (**EX1207**) to interpret the record. The “PMID” field shows “11483284” as the PubMed identifier for the record for *Srivastava* (**EX1148**). The “STAT” field shows the status of the record is “MEDLINE” (meaning Medical subject headings were assigned to the article), and the DCOM field shows this index record was completed on “20010927” (*i.e.*, September 27, 2001) (**EX1148**). The IS field shows the ISSN (International Standard Serial Number) for the print

version of this journal is “0264-410X.” Fields VI (volume), IP (issue), DP (date of publication), TI (title), PG (pages) and JT (journal title) show *Srivastava* was published in vol. 19, no. 31 (2001 Aug 14) of *Vaccine*, pp. 4557-65 (**EX1148**). The first FAU (full author) field shows “Srivastava, A K” as the first author, field CRDT (creation date) and field EDAT (entrez date) show the metadata record was added to PubMed on “2001/08/03” (*i.e.*, August 3, 2001), and field MHDA (MeSH date) shows medical subject headings were added to the record on “2001/09/28” (*i.e.*, September 28, 2001). (**EX1148**). The PubMed record shows 14 medical subject headings (“MH”) were assigned to indicate the subjects of *Srivastava*. Field “AID” (Article identifier) shows the doi of *Srivastava* (**EX1148**).

66. This PubMed metadata record (**EX1148**) shows *Srivastava*, which was available online on July 30, 2001 (**EX1195**), was indexed by PubMed on August 3, 2001, and became discoverable in PubMed from that date on. Interested users would have been able to search for *Srivastava* in PubMed by the authors, title, journal title, ISSN, and abstract. After medical subject headings were added to enrich the PubMed record on September 28, 2001 (**EX1148**), interested users would have been able to conduct subject searches to discover *Srivastava*.

F. Internet Archive Copy of *Vaccine* Website

67. The publisher’s copy of *Srivastava* (**EX1163**) and the UW copy of *Srivastava* (**EX1146**) indicate *Vaccine* is available in print and also online at

<http://www.elsevier.com/locate/vaccine> (**EX1199**). As evidence that *Vaccine* has been available on the Internet, I searched the Internet Archive for records of the journal website and located an archived copy at <https://web.archive.org/web/20021003015903/http://www.elsevier.com/locate/vaccine>. This archived copy is presented as **EX1149** in this Declaration. I personally located, identified and obtained this record. This is the type of material experts in my field would reasonably rely upon when forming their opinions.

68. **EX1149** is a true and correct copy of the website for *Vaccine* archived by the Internet Archive. Page 1 is a screen capture of the Wayback Machine calendar that shows that the original URL of this website is <http://www.elsevier.com/locate/vaccine>, the website has been archived 298 times from “23 Feb 1999” to “7 Oct 2022” and this particular copy was archived on “Oct 03 2002” (**EX1149**). Page 2 is the archived journal website saved as a PDF. The top of page 2 shows a message from the publisher about online access to full-text articles. This message is saved as a PDF and presented below.

Please note! As of December 2001 online access to full-text articles is available to all readers whose library

1. subscribes to the journal via [ScienceDirect](#) or
2. has a print subscription and has registered for the corresponding [ScienceDirect Web Editions](#).

This note indicates that as of “December 2001” users of libraries that subscribed to the journal *Vaccine* via ScienceDirect or had a print subscription and registered for

journal access via ScienceDirect would have been able to access full-text articles of this journal online (EX1149). Because *Srivastava* was available online on July 30, 2001 (EX1195), became discoverable in PubMed on August 3, 2001 (EX1148), and appeared in the print version of vol. 19, no. 31 that has a “14 August 2001” issue date (EX1146), interested users would have been able to discover this article by August 3, 2001 by searching in PubMed. They would also have been able to access the online copy (EX1163) of *Srivastava* no later than December 2001 if their libraries had a subscription to *Vaccine* via ScienceDirect or a registration to access ScienceDirect Web Editions.

69. The extended URL for the *Vaccine* website archived by the Internet Archive shows the website was archived and available at <https://web.archive.org/web/20021003015903/http://www.elsevier.com/locate/vaccine> (EX1149). The archive date of “20021003015903” means the journal website was archived on October 3, 2002, 1 a.m., 59 minutes, 3 seconds. Because the Internet Archive does not archive web resources as soon as they appear on the Internet, the archive date means the archived resource was available *no later than* the archive date. In this case, it means this archived copy of the website for *Vaccine* was publicly accessible no later than October 3, 2002, meaning that by this date the general public would have learned that online access to full-text articles published in *Vaccine* had been provided by the publisher since December

2001 (**EX1149**). This Internet Archive (**EX1149**) copy of the website of *Vaccine* informs my opinion that users who visited the *Vaccine* website by October 3, 2002 would have known about online access to full-text articles of this journal via ScienceDirect.

G. Usage Record

70. Actual usage of an article is reflected by other articles that make reference to it. The publisher's webpage for *Srivastava* (**EX1195**) shows it became available online on July 30, 2001, and later in a print issue (**EX1146**) of *Vaccine* with a "14 August 2001" issue date. The citation history of Google Scholar shows *Srivastava* has been cited 124 times (**EX1150**). Page 1 of **EX1150** is a screen capture of Google Scholar showing 124 articles made reference to *Srivastava*, and page 2 is a screen capture of Google Scholar showing that 13 citations appeared in 2002 and 2003. **EX1209** is a list of citations from 2002 and 2003 that I compiled to demonstrate early usage; the earliest citation appeared in July 2002.

H. Summary of My Opinion on *Srivastava*

71. Taken together, the publisher's copy of *Srivastava* (**EX1163**) and the publisher's webpage (**EX1195**), the University of Wisconsin-Madison copy of *Srivastava* (**EX1146**), the bibliographic and MARC records of the journal containing *Srivastava* (**EX1147**), and PubMed records for *Srivastava* (**EX1148**) inform my opinion that *Srivastava* was first available online on July 30, 2001, then

in the “14 Aug 2001” print issue of *Vaccine*, and a copy of the print issue was received by the Steenbock Library of the University of Wisconsin-Madison on September 5, 2001 (EX1146). This receipt date of vol. 19, no. 31 (EX1163, Page 1) and the serial record for *Vaccine* at the UW library (EX1147, Page 3) inform my opinion that *Vaccine* would have been discoverable in the library online catalog from 1984, and the print issue of *Vaccine* containing *Srivastava* would have been publicly accessible by September 12, 2001, which is a week after serial check-in of this issue. *Srivastava* was indexed by PubMed and has been discoverable in that system since the PubMed record was added to the system on August 3, 2001 (EX1148). Interested users would have been able to search for this article by authors, title, journal title, ISSN and abstract. After medical subject headings were added to the PubMed record on September 28, 2001 (EX1148, Page 3), users would have been able to search for *Srivastava* in PubMed by subject. The Internet Archive copy of the website of *Vaccine* (EX1149) shows that by October 2002, users of the journal website would have learned that since December 2001, access to full-text articles via ScienceDirect had been provided since December 2001. Citation history shows the earliest citation was published in July 2002 (EX1209).

VI. AUTHENTICITY AND PUBLIC AVAILABILITY OF *THOMAS* (EX1164)

A. Authentication

72. **EX1164** is a true and correct copy of “A Phase II, Randomized, Safety and Immunogenicity Study of a Re-Derived, Live-Attenuated Dengue Virus Vaccine in Healthy Adults” (“*Thomas*”), *American Journal of Tropical Medicine and Hygiene*, vol. 88, no. 1, pp. 73-88, that I obtained from the publisher. I began my research by searching Google Scholar by the title of *Thomas* for records, and a retrieved record led me to the publisher’s webpage for *Thomas* at <https://www.ajtmh.org/view/journals/tpmd/88/1/article-p73.xml> (**EX1204**) that shows the publisher provides “open access” to *Thomas*, meaning there is no restriction on user access. I then followed the PDF link to download the full text of *Thomas*. This publisher copy is presented as **EX1164** in this Declaration.

73. **EX1164** is a true and correct copy of *Thomas* obtained from the publisher. Page 1 (internal page 73) shows the title, authors, abstract, and a note above the title showing *Thomas* was published with a doi of “10.4269/ajtmh.2012.12-0361” and carries a “2013” copyright date, with The American Society of Tropical Medicine and Hygiene as the copyright holder. **EX1164** shows *Thomas* has a total of 16 pages, including eight tables, six figures (some color), and 23 references. Page 15 (internal page 87) shows the manuscript

was “[r]eceived June 5, 2012. Accepted for publication September 29, 2012.

Published online December 3, 2012” (**EX1164**).

74. The publisher’s copy of *Thomas* (**EX1164**) 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, **EX1164** 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 *Thomas* (**EX1164**).

B. National Library of Medicine Copy of *Thomas*

75. To determine whether *Thomas* was available at libraries, I searched WorldCat for “American journal of tropical medicine and hygiene,” the journal containing *Thomas*, for records and a retrieved record at <https://worldcat.org/title/1724826> (**EX1205**) 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 (**EX1152**). I then requested a scanned copy of *Thomas* from the NLM, with the assistance of Wisconsin TechSearch (WTS), a document delivery service based at the University of Wisconsin-Madison. The NLM copy of *Thomas* is presented as **EX1151** in this Declaration.

76. **EX1151** is a scanned copy obtained from NLM. Page 1 is the cover that carries a check-in label, showing this issue is “American journal of tropical medicine and hygiene, v. 88, no. 1 (Jan. 2013), General Collection W1 AM527, 2013-02-13 08:57:09,” meaning that vol. 88, no. 1 of this journal was received by NLM on February 13, 2013, it is part of the General Collection, and its call number is W1 AM527.

77. The cover shows this journal is the official journal of the *American Society of Tropical Medicine and Hygiene* and identifies this issue as volume 88, number 1, with an issue date of January 2013 (**EX1151**). The front and back covers present the table of contents of this issue, the front cover shows *Thomas* runs from pages 73 to 88, and the back cover (page 2) shows this journal is available online at www.ajtmh.org. **EX1151**, Page 1-2. Page 4 is the copyright page that shows the ISSN (International Standard Serial Number) of this journal is “0002-9637” and this issue has a “2013” copyright date, with The American Society of Tropical Medicine and Hygiene as the copyright holder (**EX1151**). Pages 5 to 20 (internal pages 73-88) are the *Thomas* article.

78. I have closely compared the NLM copy of *Thomas* (**EX1151**) with the publisher’s copy of *Thomas* (**EX1164**) and found them to be identical. The NLM copy of *Thomas* (**EX1151**) 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, **EX1151** 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 *Thomas* (**EX1151**).

C. National Library of Medicine Records

79. **EX1152** is a true and correct copy of the bibliographic and MARC records for the *American Journal of Tropical Medicine and Hygiene* that contains *Thomas*. I personally located, identified and obtained these records from the NLM online catalog. These are the type of records experts in my field would reasonably rely upon when forming their opinions.

80. Pages 1 to 4 of **EX1152** are the bibliographic record for the journal. Page 1 shows the title, publisher, the ISSN of the print version (“0002-9637”), and the ISSN of the electronic version (“1476-1645”). It also shows this journal is available “at NLM General Collection (W1 AM527)” and online. The URL of this bibliographic record is shown on page 1 of **EX1152**.

81. The “Full text availability” area on page 2 of **EX1152** shows “Available from 2010 volume: 82. Most recent 1 year(s) not available” in PubMed Central, meaning issues of this journal from 2010, except for issues of the most recent year, have been archived by PubMed Central which is a free digital repository produced by the National Library of Medicine to archive full-text

scholarly articles published in biomedical and life sciences journals. The record shows that the full text of articles, from the 1952 issue on, are also available at the NLM Reading Room.

82. Page 3 of **EX1152** shows details of the bibliographic record including the NLM title abbreviation, title, other title, creator, publisher, frequency, identifiers, indexes that index this journal, medical subject headings, and notes. Page 4 of **EX1152** shows links to the MARC record and other sources.

83. Pages 5 to 9 of **EX1152** are the MARC record saved as a PDF. The first six digits of field 008 show the MARC record was created on “730925” (*i.e.*, September 25, 1973), and the code of “c19529999” following the record creation date shows that this journal is a continuing resource that began publication in 1952 and has no publication end date yet. Field 040 shows “DNLM” created this MARC record. According to the *MARC Code List for Organizations*, “DNLM” is the MARC code for the United States, National Library of Medicine (**EX1206**). Field 008 and 040 inform my opinion that the *American Journal of Tropical Medicine and Hygiene* began publication in 1952, and the National Library of Medicine created a serial MARC record for the journal on September 25, 1973, making the journal discoverable by the public in their library catalog from then on.

84. Field 022 of **EX1152** shows the ISSNs for the print and electronic versions of the journal, field 245 shows the journal title, fields 246 show several

variant titles are included to help users discover this journal. Fields 260 show the publisher information. Field 362 shows that the journal began with volume 1 in January 1952, and field 310 shows the publication frequency is monthly. The first two fields 510 show the journal articles from vol. 14, no. 5 (September 1965), and have been indexed by PubMed and MEDLINE. These two 510 notes inform users that articles published in this journal since September 1965 have been discoverable in PubMed and MEDLINE. Field 710 shows that the publisher is included as an access point to help the public discover this journal.

85. Subjects of this journal are represented in field 060 of **EX1152** by a National Library of Medicine classification number of “W1” that represents serials and periodicals in general medicine (**EX1202**), and by two medical subject headings in fields 650 and 655 showing this publication is a journal that focuses on tropical medicine. These subject headings enable users to conduct subject searches to discover this journal.

86. The MARC record (**EX1152**) shows the *American Journal of Tropical Medicine and Hygiene* is a long-running journal that was cataloged by the National Library of Medicine on September 25, 1973, and became discoverable in their library catalog from then on. Interested users would have been able to conduct subject searches to discover this journal. They would also have been able to use the ISSNs, title, variant titles, and publisher to discover this journal. The

MARC record also shows that articles published in this journal since volume 14, no. 5 (September 1965) have been indexed and discoverable in PubMed and MEDLINE.

D. Library Date Stamp

87. The “2013-02-13” date stamp on the journal cover of the NLM copy of *Thomas* (EX1151) has the appearance of a typical library serial check-in date stamp that indicates that the National Library of Medicine received vol. 88, no. 1 that contains *Thomas* on February 13, 2013. 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. 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. 88, no. 1 of the *American Journal of Tropical Medicine and Hygiene* that contains *Thomas* was received by the National Library of Medicine on February 13, 2013 (EX1151, Page 1) and the copy would have become publicly accessible no later than February 20, 2013.

E. PubMed Records

88. To determine whether *Thomas* was indexed, I searched PubMed by the article title for records and located a record at <https://pubmed.ncbi.nlm.nih.gov/23208878/>. This PubMed record is presented as **EX1153** in this Declaration. I personally located, identified and obtained the PubMed metadata record for *Thomas* (**EX1153**). I saved the metadata record as a PDF and also in PubMed format to show the record details in data fields.

89. **EX1153** is a true and correct copy of the PubMed metadata record for *Thomas*. The top of page 1 shows a full text link to “Full Text *The American Journal of Tropical Medicine and Hygiene*” that takes users to the publisher’s webpage for *Thomas*, and another link to a free full text at PMC (PubMed Central). Page 1 also shows the title, authors, and an abstract. The area above the title shows a note of “Clinical Trial Am J Trop Med Hyg. 2013 Jan;88(1):73-88. doi: 10.4269/ajtmh.2012.12-0361. Epub 2012 Dec 3,” which indicates that *Thomas* is about a clinical trial, was first published online on December 3, 2012, and published later in the print version of vol. 88, no. 1, that has a “January 2013” issue date, and that the doi of *Thomas* is “10.4269/ajtmh.2012.12-0361” (**EX1153**). The PubMed record shows that the record identifier is “23208878” and *Thomas* is a “Free PMC article,” and the PMC identifier for the archived copy of *Thomas* is “3541749” (**EX1153**). The “Trial registration” field below the abstract shows the

clinical study is identified as “NCT00350337” on the ClinicalTrials.gov site

(**EX1153**). This PubMed record also shows six figures from the *Thomas* article.

The “LinkOut” field on page 2 shows the full text of *Thomas* is available at Europe PubMed Central, PubMed Central, and Sheridan PubFactory, and each source is presented as a live hyperlink to facilitate access to the full text.

90. Pages 3 and 4 of **EX1153** are the PubMed record in PubMed format to show data in specific fields. I use the “MEDLINE/PubMed Data Element (Field) Descriptions” (**EX1207**) to interpret the record. The “PMID” field shows “23208878” as the PubMed identifier for the record for *Thomas*. The “STAT” field shows the status of the record is “MEDLINE” (meaning Medical subject headings were assigned to the article), and the DCOM field shows this index record was completed on “20130226” (*i.e.*, February 26, 2013) (**EX1153**, Page 3). The IS fields show the ISSN (International Standard Serial Number) of the electronic version of this journal is “1476-1645” and the ISSN of the print journal is “0002-9637” (**EX1153**, Page 3). Fields VI (volume), IP (issue), DP (date of publication), TI (title), PG (pages), and JT (journal title) show *Thomas* was published in vol. 88, no. 1 (2013 Jan) of *The American Journal of Tropical Medicine and Hygiene*, pp. 73-88 (**EX1153**, Page 3). The first FAU (full author) field shows “Thomas, Stephen J” as the first author (**EX1153**, Page 3). Field DEP (date of electronic publication) on page 4 shows *Thomas* was published online on “20121203” (*i.e.*,

December 3, 2012) (**EX1153**, Page 4). Field CRDT (creation date) and field EDAT (entrez date) show the metadata record was added to PubMed on “2012/12/05” (*i.e.*, December 5, 2012), and field MHDA (MeSH date) shows medical subject headings were added to the record on “2013/02/27” (*i.e.*, February 27, 2013) (**EX1153**, Page 4). The PubMed record shows five medical subject headings were assigned to indicate the subjects of the *Thomas* article. Field “AID” (Article identifier) shows the doi of *Thomas* (**EX1153**, Page 4).

91. This PubMed metadata record (**EX1153**) made *Thomas* discoverable in PubMed on December 5, 2012, when the record was entered into PubMed. Interested users would have been able to search for *Thomas* in PubMed by the authors, title, journal title, ISSN, and abstract. After medical subject headings were added to enrich the PubMed record on February 27, 2013, interested users would have been able to conduct subject searches to discover *Thomas*.

F. Usage Record

92. Actual usage of an article is reflected by other articles that make reference to it. The citation history of Google Scholar shows *Thomas* has been cited 106 times. Page 1 of **EX1154** is a screen capture of Google Scholar showing 106 citations made reference to *Thomas*, and page 2 is a screen capture of Google Scholar showing 33 citations appeared in 2013 and 2014. **EX1208** is a list I

compiled to present four 2013 citations and one 2014 citation to demonstrate early usage. The earliest citation appeared in June 2013 (**EX1208**).

G. Summary of My Opinion on *Thomas*

93. Taken together, the publisher's copy of *Thomas* (**EX1164**), the National Library of Medicine's copy of *Thomas* (**EX1151**), the bibliographic and MARC records for the journal containing *Thomas* (**EX1152**), and PubMed records for *Thomas* (**EX1153**) inform my opinion that *Thomas* was published online on December 3, 2012 (**EX1164**, Page 15). Because the *American Journal of Tropical Medicine and Hygiene* has been available as an electronic journal and as a print journal, the electronic version of *Thomas* would have become publicly accessible on the Internet when it was published online on December 3, 2012 (**EX1164**, Page 15). The PubMed records show that *Thomas* was indexed and became searchable in PubMed on December 5, 2012 (**EX1153**, Page 4). After medical subject headings were added to the PubMed record on February 27, 2013 (**EX1153**, Page 4), users would have been able to search for *Thomas* in PubMed by subject as well. The print version of *Thomas* was received by the National Library of Medicine on February 13, 2013 (**EX1151**, Page 1), and the copy would have been publicly accessible by February 20, 2013. Citation history shows the earliest citation appeared in June 2013 (**EX1208**).

VII. INTERNET ARCHIVE AFFIDAVIT

94. My analysis of **EX1141**, **EX1143**, **EX1144**, and **EX1145** above is supported by the Declaration of Mr. Nathaniel E. Frank-White of the Internet Archive (**EX1166**), which I obtained from counsel. Mr. Frank-White states that “[t]he Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public” (**EX1166**, Page 1). He further explains that “[t]he Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]` aka an ‘extended URL’ ... The date indicated by an extended URL applies to a preserved instance of a file for a given URL.” (**EX1166**, Page 1). He then states that Exhibit A to his declaration “are true and accurate copies of screenshots of the Internet Archive’s records of the archived files for the URLs and the dates specified in the attached coversheet of each printout” (**EX1166**, Page 1).

95. Mr. Frank-White’s Exhibit A (**EX1166**, Pages 4 to 6) shows the URL and the archived copy of *Sifferlin-TIME* that is the same as the URL and content presented in **EX1145**, and thus confirms that this archived webpage includes “true and accurate copies of screenshots of the Internet Archive’s records of the archived

files” (**EX1166**, Page 1) and that this webpage was indeed archived on January 22, 2016, by the Internet Archive.

96. Mr. Frank-White’s Exhibit A (**EX1166**, Pages 7 and 9) shows the URL and the archived copy of the WHO “Note for media” that are the same as the URL and content presented in **EX1144**, and thus confirms that this archived webpage includes “true and accurate copies of screenshots of the Internet Archive’s records of the archived files” (**EX1166**, Page 1) and that the WHO “Note for media” was indeed archived on March 9, 2016, by the Internet Archive.

97. Mr. Frank-White’s Exhibit A (**EX1166**, Pages 10 to 24) shows the URL and the archived copy of the table of contents of volume 2, issue 3 of *Genome Announcements* that contains *Baronti* that are the same as the URL and content presented in **EX1141**, and confirms that the pages include “true and accurate copies of screenshots of the Internet Archive’s records” of the archived files (**EX1166**, Page 1) and that this archived webpage was indeed archived on June 29, 2014, by the Internet Archive.

98. Mr. Frank-White’s Exhibit B (**EX1166**, Pages 27 to 42) shows the URL and the archived copy of the webpages of “Current Zika Product Pipeline” that are the same as the URL and content presented in **EX1143**, and thus confirms that these archived pages include “true and accurate copies of screenshots of the Internet Archive’s records of the archived files” (**EX1166**, Page 1) and that this

copy of “Current Zika Product Pipeline” was indeed archived on March 11, 2016, by the Internet Archive.

VIII. LIST OF DOCUMENTS CONSIDERED

<i>Exhibit #</i>	<i>Description</i>
1139	PubMed metadata record for <i>Baronti</i> , available at https://pubmed.ncbi.nlm.nih.gov/24903869/ , accessed and obtained on November 10, 2022
1140	Wayback Machine response page indicating that the old URL of “Current Zika product pipeline” at https://web.archive.org/web/20160309222523/http://www.who.int/entity/csr/research-and-development/zika-rd-pipeline.pdf?ua=1 was not archived by the Internet Archive. The Wayback Machine response page was accessed and obtained on December 15, 2022
1141	Table of contents of vol. 2, no. 3 (2014) of <i>Genome Announcements</i> that contains <i>Baronti</i> , archived on June 29, 2014 by the Internet Archive, available at https://web.archive.org/web/20140629173328/http://genomea.asm.org/content/2/3.toc , accessed and obtained on November 11, 2022
1142	Citations to <i>Baronti</i> , obtained from Google Scholar
1143	Copy of <i>Zika Pipeline</i> archived on March 11, 2016 by the Internet Archive, available at https://web.archive.org/web/20160311113550/http://www.who.int/csr/research-and-development/zika-rd-pipeline.pdf , accessed and obtained on November 10, 2022
1144	“WHO and Experts Prioritize Vaccines, Diagnostics and Innovative Vector Control Tools for Zika R&D,” a March 9, 2016 WHO Note for media, archived on March 9, 2016 by the Internet Archive, available at https://web.archive.org/web/20160309222523/http://www.who.int/mediacentre/news/notes/2016/research-development-zika/en/ , accessed and obtained on December 5, 2022

Inter Partes Review of U.S. Patent 11,219,681
Declaration of Ingrid Hsieh-Yee, Ph.D.

<i>Exhibit #</i>	<i>Description</i>
1145	<i>Sifferlin-TIME</i> archived on January 22, 2016 by the Internet Archive, available at https://web.archive.org/web/20160122154151/http://time.com/4188973/zika-virus-vaccine-nih/ , accessed and obtained on December 5, 2022
1146	Copy of <i>Srivastava</i> obtained from the University of Wisconsin-Madison Steenbock Library
1147	Bibliographic and MARC records for <i>Vaccine</i> that contains <i>Srivastava</i> , available at https://search.library.wisc.edu/catalog/999552122802121 , from the online catalog of the University of Wisconsin-Madison Library System, accessed and obtained on November 11, 2022
1148	PubMed metadata record for <i>Srivastava</i> , available at https://pubmed.ncbi.nlm.nih.gov/11483284/ , accessed and obtained on November 10, 2022
1149	<i>Vaccine</i> website archived by the Internet Archive on October 3, 2002, available at https://web.archive.org/web/20021003015903/http://www.elsevier.com:80/locate/vaccine , from the Internet Archive, accessed and obtained on November 26, 2022
1150	Citations to <i>Srivastava</i> obtained from Google Scholar
1151	Copy of <i>Thomas</i> obtained from the National Library of Medicine
1152	Bibliographic and MARC records of <i>The American Journal of Tropical Medicine and Hygiene</i> that contains <i>Thomas</i> , available at https://catalog.nlm.nih.gov/permalink/01NLM_INST/1o1phhn/alma991179293406676 , from the online catalog of the National Library of Medicine, accessed and obtained on November 15, 2022
1153	PubMed metadata record for <i>Thomas</i> , available at https://pubmed.ncbi.nlm.nih.gov/23208878/ , accessed and obtained on November 10, 2022
1154	Citations to <i>Thomas</i> , obtained from Google Scholar
1160	Baronti, C., Piorkowski, G., Charrel, R. N., Boubis, L., Leparc-Goffart, I., & de Lamballerie, X., (2014, June 5), “Complete Coding Sequence of Zika Virus from a French Polynesia Outbreak in 2013,” <i>Genome Announcements</i> , vol. 2, no. 3, p. e00500-14

Inter Partes Review of U.S. Patent 11,219,681
Declaration of Ingrid Hsieh-Yee, Ph.D.

<i>Exhibit #</i>	<i>Description</i>
1161	World Health Organization, <i>Current Zika Product Pipeline</i> , (3 March 2016), available at https://www.who.int/publications/m/item/current-zika-product-pipeline
1162	Sifferlin, A., “U.S. Launches ‘Full-Court Press’ for a Zika Vaccine,” <i>TIME</i> (Jan. 21, 2016, 3:24 PM), https://time.com/4188973/zika-virus-vaccine-nih/
1163	Srivastava, A. K., Putnak, J. R., Lee, S. H., Hong, S. P., Moon, S. B., Barvir, D. A., ... & Eckels, K. H., (14 August 2001, available online 30 July 2001), “A Purified Inactivated Japanese Encephalitis Virus Vaccine Made in Vero cells,” <i>Vaccine</i> , vol. 19, no. 3, pp. 4557-4565
1164	Thomas, S. J., Eckels, K. H., Carletti, I., De La Barrera, R., Dessy, F., Fernandez, S., ... & Innis, B. L., (2013), “A Phase II, Randomized, Safety and Immunogenicity Study of a Re-derived, Live-attenuated Dengue Virus Vaccine in Healthy Adults,” <i>American Journal of Tropical Medicine and Hygiene</i> , vol. 88, no. 1, pp. 73-88
1166	Declaration of Mr. Nathaniel E. Frank-White of the Internet Archive
1167	Curriculum Vitae of Ingrid Hsieh-Yee, Ph.D.
1168	“Understanding MARC Bibliographic: Machine-Readable Cataloging,” Library of Congress, Parts VII to X, available at https://www.loc.gov/marc/umb/um07to10.html
1181	Amended Articles of Incorporation of OCLC, Inc., revised June 23, 2017
1183	“Discussion Paper No. 2020-DP16: Recording the Mode of Issuance for Manifestations,” Library of Congress, May 29, 2020
1185	Publisher’s webpage for <i>Baronti</i> , available at https://journals.asm.org/doi/full/10.1128/genomeA.00500-14
1186	PubMed Website, available at https://pubmed.ncbi.nlm.nih.gov/https://pubmed.ncbi.nlm.nih.gov/%20
1187	List of early citations to <i>Baronti</i>
1188	World Health Organization webpage for <i>Current Zika Pipeline</i> , available at http://www.who.int/publications/m/item/current-zika-product-pipeline

Inter Partes Review of U.S. Patent 11,219,681
Declaration of Ingrid Hsieh-Yee, Ph.D.

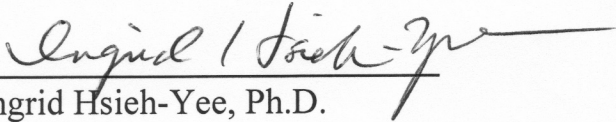
<i>Exhibit #</i>	<i>Description</i>
1189	WorldCat website, available at https://www.worldcat.org
1195	Publisher's webpage for <i>Srivastava</i> , available at https://www.sciencedirect.com/science/article/pii/S0264410X01002080?via%3Dihub
1197	Webpage for ScienceDirect, available at https://www.elsevier.com/solutions/sciencedirect
1198	WorldCat webpage for <i>Vaccine</i> , available at https://worldcat.org/title/10399916
1199	ScienceDirect webpage for <i>Vaccine</i> , available at www.elsevier.com/locate/vaccine
1200	Directory of OCLC Members, available at https://www.oclc.org/en/contacts/libraries.html
1202	National Library of Medicine Classification Schedule, "W General Medicine. Health Professions," available at https://classification.nlm.nih.gov/schedules/w
1204	Publisher's webpage for <i>Thomas</i> , available at https://www.ajtmh.org/view/journals/tpmd/88/1/article-p73.xml
1205	WorldCat webpage for <i>Thomas</i> , available at https://worldcat.org/title/1724826
1206	Description of MARC Org Code DNLM, MARC Code List for Organizations
1207	MEDLINE/PubMed Data Element (Field) Descriptions, available at https://www.nlm.nih.gov/bsd/mms/medlineelements.html
1208	List of early citations to <i>Thomas</i>
1209	List of early citations to <i>Srivastava</i>

IX. CONCLUSION

99. In signing this Declaration, I recognize that this Declaration will be filed as evidence in a Petition for *Inter Partes* Review before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to deposition in the case. If deposition is required of me, I will appear at a reasonable time and place to be agreed upon.

100. 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,


Ingrid Hsieh-Yee, Ph.D.

Date: December 19, 2022