

Filed on behalf of: Pharmacyclics LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BeiGene USA, Inc. and BeiGene, LTD.,
Petitioner,

v.

Pharmacyclics LLC,
Patent Owner.

PGR2024-00009
Patent 11,672,803

DECLARATION OF INGRID HSIEH-YEE, PH.D.

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I. Introduction

1. I have been retained as an independent expert witness on behalf of Pharmacyclics LLC (“Patent Owner” or “Pharmacyclics”) for proceedings before the United States Patent and Trademark Office (“PTO”) regarding the authenticity and public availability of a certain reference in relation to U.S. Patent No. 11,672,803 (“’803 Patent”).

2. I am being compensated for my work in this matter at my customary hourly rate of \$300. I am also being reimbursed for any reasonable expenses associated with my work and testimony in this investigation. 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 academic *curriculum vitae* (EX2017). 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 was conferred the title of Professor Emerita in December 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, Metadata, 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, social media, user interaction with information systems, and others.

6. I am very familiar with a 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 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. **EX2102** is a true and correct copy of Parts VII to X of “Understanding MARC Bibliographic: Machine-Readable Cataloging” (<http://www.loc.gov/marc/umb/um07to10.html>) from the Library of Congress that explains commonly used MARC fields. For example, the personal 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 volume and characteristics of a publication are recorded in Field 300, and topical subjects are recorded in Field 650.

8. The Online Computer Library Center (“OCLC”) is the largest bibliographic network of the world, with more than 595 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.,” OCLC 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” (source: <https://www.oclc.org/content/dam/oclc/membership/articles-of-incorporation.pdf>).

9. OCLC members can contribute original cataloging records in MARC to the system 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 for users to explore more than 10,000 libraries worldwide. Records in WorldCat, however, are not presented in MARC fields. Instead, the data elements are labeled to help users

interpret the records. 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 now 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 glossary of the *RDA: Resource Description and Access* cataloging standard, 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.” (RDA Glossary at https://original.rdatoolkit.org/rdagloss_rdaregistry.info-termList-ModelIssue-1003_1.html (subscription required for access); cited in <https://www.ccslib.org/Catalogers/index.php/Category:Serials>). 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. 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 National Library of Medicine (https://catalog.nlm.nih.gov/discovery/search?vid=01NLM_INST:01NLM_INST)
- PubMed (<https://pubmed.ncbi.nlm.nih.gov/>)
- 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 document:

Marcotte, D. J., Liu, Y. T., Arduini, R. M., Hession, C. A., Miatkowski, K., Wildes, C. P., ... & Silvian, L. F. (2010, March). Structures of human Bruton's tyrosine kinase in active and inactive conformations suggest a mechanism of activation for TEC family kinases, *Protein Science*, 19(3), 429-439, **EX2001** ("Marcotte").

17. I am not a lawyer, so I am not rendering an opinion on the legal question of whether a particular document is, or is not, "legally" a "printed publication" under the law. I am rendering my expert opinion on the authenticity of the document referenced herein and on whether it was published. I will provide my opinion on

when and how this document was publicly disseminated or otherwise made publicly available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located and retrieved this document.

18. I am informed by counsel for Pharmacyclics that an item is considered authentic if there is sufficient evidence to support a finding that the item is what it is claimed to be. I am also informed that authenticity can be established based on the contents of the documents themselves, such as the appearance, content, substance, internal patterns, protocols followed or other distinctive characteristics of the item.

19. I am informed by counsel for Pharmacyclics that a given reference is “published” if it is publicly accessible upon a satisfactory showing that such a document has been disseminated or otherwise made publicly available to the extent that persons interested and ordinarily skilled in the subject matter or art could locate it exercising reasonable diligence and obtain the document. I have also been informed by counsel that materials available in a library constitute “printed publications” if they are cataloged and indexed according to general library practices and protocols that make the references available and accessible to members of the interested public.

20. I have been informed by counsel for Pharmacyclics that the '803 Patent was filed in the United States on July 10, 2020 and that the priority date of the '803

Patent is at least June 3, 2011. I have assessed public accessibility of *Marcotte* as of June 3, 2011.

C. Person of Ordinary Skill in the Art

21. I have been informed by counsel for Pharmacyclics that the subject matter of this proceeding relates to irreversible inhibitors of Bruton's tyrosine kinase ("BTK") and their use in treatment of patients with chronic lymphocytic leukemia ("CLL") or small lymphocytic lymphoma ("SLL").

22. I have been informed by counsel for Pharmacyclics that a person of ordinary skill in the art at the time of the invention ("POSA") is a hypothetical person who is presumed to be familiar with the relevant field and its literature at the time of the inventions. This hypothetical person is also a person of ordinary creativity, capable of understanding the scientific principles and literature applicable to the pertinent field.

23. I have been informed by counsel for Pharmacyclics that the parties agree that a POSA for the '803 Patent in June 3, 2011, would have been a team, with at least one member having at least a medical degree with training in hematology and oncology, including several years of clinical experience in treating hematologic malignancies, and included at least another member having at least a Ph.D. in chemistry, organic chemistry, or related field.

24. It is my opinion that such a person would have been actively engaged in learning about the field, possibly through formal instruction through the bibliographic resources. By at least June 3, 2011, such a person would have had access to a vast array of print and electronic resources, including at least the documents referenced below.

D. Evidence Considered in Forming My Opinions

25. All of the opinions contained in this Declaration are based on the documents I considered and my education, years of professional experience, and knowledge. In the preparation of 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 would reasonably rely upon when forming their opinions.

- (1) The document referenced above in Section I.B, *i.e.*, *Marcotte*, **EX2001**;
- (2) Libr. of Cong., *Network Dev. & MARC Standards Off., pts. VII–X, Understanding MARC Bibliographic: Machine-Readable Cataloging*, <http://www.loc.gov/marc/umb/um07to10.html>, **EX2102**;
- (3) Publisher's copy of *Marcotte* obtained from <https://onlinelibrary.wiley.com/doi/epdf/10.1002/pro.321>, **EX2103**;
- (4) Library copy of *Marcotte*, obtained from the National Library of Medicine, **EX2104**;

- (5) Bibliographic and MARC records for *Protein Science* that contains *Marcotte*, available at https://catalog.nlm.nih.gov/permalink/01NLM_INST/1o1phhn/alm/a997186893406676 from the online catalog of the National Library of Medicine, **EX2105**;
- (6) LocatorPlus, the online catalog of the National Library of Medicine, archived by Internet Archive on May 12, 2009, and available at <https://web.archive.org/web/20090512190928/http://locatorplus.gov/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First> (accessed June 23, 2024), **EX2106**;
- (7) PubMed record for *Marcotte*, available at <https://pubmed.ncbi.nlm.nih.gov/20052711/> from PubMed, **EX2107**;
- (8) PubMed home page archived by Internet Archive on May 5, 2010, available at <https://web.archive.org/web/20100505013751/ncbi.nlm.nih.gov/pubmed> (accessed July 28, 2024) and PubMed Help archived by Internet Archive on May 6, 2010, available at <https://web.archive.org/web/20100506160612/http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=helppubmed&part=pubmedhelp> (accessed August 3, 2024), **EX2108**;
- (9) Citations to *Marcotte*, obtained from Google Scholar, **EX2109**;
- (10) Declaration of Nathaniel E Frank-White, Records Request Processor, Internet Archives (July 18, 2024), **EX2110**.

II. Authenticity and Public Availability of *Marcotte* (EX2001)

A. Authentication

26. **EX2001** is a true and correct copy of “Structures of human Bruton’s tyrosine kinase in active and inactive conformations suggest a mechanism of activation for TEC family kinases,” (“*Marcotte*”), by Marcotte et al., *Protein Science*, 19(3), 429-439, that I received from counsel for Pharmacyclics. A mark at the lower right hand corner identifies this document as “Pharmacyclics LLC Exhibit 2001, BeiGene v. Pharmacyclics PGR2024-00009” and the pages are marked as EX2001.0001 to EX2001.0011. This document is presented as **EX2001** in this proceeding.

27. Page 1 of **EX2001** (internal page 429) shows the title, authors, abstract, and keywords of this article (“Bruton’s tyrosine kinase; BTK; Dasatinib; Celera compound; TEC-family; crystal structure”). The publication history area above the abstract shows the manuscript was “Received 12 October 2009; Revised 11 December 2009; Accepted 14 December 2009,” the article’s DOI (digital object identifier) is “10.1002/pro.321,” and the article was published online on “5 January 2010” at the journal website (proteinscience.org). The bottom of this page shows *Marcotte* was published by Wiley-Blackwell, appears in “Protein Science 2010 | Vol 19:429-439,” has a copyright date of 2010, and The Protein Society is the copyright

holder. **EX2001** shows *Marcotte* has a total of 11 pages, including three tables, four color figures, and 30 references.

28. To authenticate **EX2001**, I obtained a copy of *Marcotte* from the publisher. When I began researching this article I searched Google Scholar for records, and an entry led me to the publisher's webpage for *Marcotte* at <https://onlinelibrary.wiley.com/doi/full/10.1002/pro.321> that indicated *Marcotte* is a "Free Access" article, meaning the general public could access this article free of charge, so I followed the PDF link to download *Marcotte*. This publisher copy is presented as **EX2103** in this proceeding.

29. I have closely compared **EX2001** with the publisher copy (**EX2103**) and found them to be identical. The only difference is EX2001 carries the mark indicating it is an exhibit in the case "BeiGene v. Pharmacyclics PGR2024-00009."

30. **EX2001** is in a condition that creates no 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, **EX2001** is identical to the publisher copy (**EX2103**). I therefore see no reason to question the authenticity of **EX2001**.

B. National Library of Medicine Copy

31. To determine whether *Marcotte* was available at libraries, I searched WorldCat by the title of this article and retrieved a WorldCat record

(<https://search.worldcat.org/title/719583904>) that showed the National Library of Medicine (“NLM”) held the journal containing *Marcotte*. After verifying the holdings information in the online catalog of NLM, I obtained a scanned copy of *Marcotte* from NLM through a document vendor. This library copy is presented as **EX2104** in this proceeding.

32. **EX2104** is a true and correct copy of *Marcotte* obtained from NLM. Page 1 is an issue cover that identifies this publication as vol. 19, no. 3 of *Protein Science* that has an issue date of March 2010. This cover shows the journal is a publication of the Protein Society and the Society’s website is www.proteinscience.org. This cover carries a label that shows this issue is in the General Collection of NLM with “W1 PR788J” as the call number and the date stamp is “2010-03-26” indicating NLM received this issue on March 26, 2010. Page 2 is the publisher information page that shows John Wiley & Sons, Inc. is the publisher, and members of The Protein Society receive this journal as part of their annual membership dues. This page also shows vol. 19, no. 3 has a 2010 copyright date and The Protein Society holds the copyright. Pages 3 to 5 are the table of contents that shows *Marcotte* begins on page 429. Pages 7 to 17 (internal pages 429 to 439) are the full text of *Marcotte*. I have closely compared the NLM copy (**EX2104**) with the copy received from counsel for Pharmacyclics (**EX2001**), and

the publisher copy (**EX2103**) and found these three copies to have the same content for *Marcotte*.

C. Records of the National Library of Medicine

33. **EX2105** is a true and correct copy of the bibliographic and MARC serial records for *Protein Science* whose vol. 19, no. 3 contains *Marcotte*. I personally located, identified and obtained these records from the online catalog of NLM by searching for the journal title for records. They are the type of record experts in my field would reasonably rely upon when forming their opinions on the public availability of a document.

34. Pages 1 to 3 of **EX2105** show the bibliographic record for *Protein Science* at NLM. Page 1 shows the journal is available at “NLM General Collection (W1 PR788J)” and online. Page 2 shows full text of the journal articles are available online at PubMed Central and Wiley Online Library All Journals, and NLM holds volumes 1 (1992) to 22 (2013). Page 3 shows details of this journal, including title, corporate creators, publisher, country of publication, language, frequency, identifiers (ISSNs and OCLC number), indexing services, MeSH subjects, notes, NLM unique ID number, and other details.

35. Pages 4 to 7 are the MARC record for this journal. The first six digits of Field 008 show that this MARC serial record was created on “920730” (*i.e.*, July 30, 1992), and the “c19929999” code following this creation date indicates that the

journal is a continuing resource that began publication in 1992 and “9999” means the journal has no predetermined end date of publication. Subfields “a” and “c” of Field 040 show that “DNLM” created the original MARC serial record. According to the *MARC Code List for Organizations* (<https://www.loc.gov/marc/organizations/org-search.php>), “DNLM” is the MARC organization code for the National Library of Medicine. Data from Fields 008 and 040 inform my opinion that the National Library of Medicine created the original serial record for *Protein Science* on July 30, 1992, and the record has made this journal discoverable in their online catalog from that date on.

36. As discussed earlier, a common library practice is to create a record for a serial, without creating records for individual issues of the serial. When new issues are received, they go through the serial check-in process, which usually takes less than an hour. After that, the newly received issues are promptly processed and placed on the shelf or in a periodical reading room for user access, usually on the same date of serial check-in or within a week after serial check-in. I know this is the customary library practice from personal experience as a cataloger, cataloging instructor and researcher of library catalogs and information systems. The date stamp on the NLM copy of *Marcotte* (**EX2104**) shows the issue was received by NLM on “2010-03-26” (*i.e.*, March 26, 2010). It is therefore my opinion that this issue (and *Marcotte*

contained therein) would have been publicly accessible no later than April 2, 2010, at NLM.

37. Field 022 of the MARC record (**EX2105**) shows “0961-8368” as the ISSN for the print version of this journal. Field 245 shows the journal title, Field 246 shows a variant title is included to help users discover this journal, Fields 260 show publisher information, Field 362 shows the journal began with vol. 1, no. 1 in January 1992, and Field 310 shows the publication frequency is “Monthly.” Fields 510 show this journal has been indexed by MEDLINE, PubMed, PMC, and Index Medicus. Field 550 shows the funding sources of this journal. Fields 710 shows the parent organization and the two funding sources are included in the record to help users discover this journal.

38. The subject of this journal is represented in Field 060 by a National Library of Medicine Classification number of “W1” that represents periodicals about general medicine, and in Fields 650 and 655 by medical subject headings that indicate the publication is a periodical about proteins. These subject representations enable users to conduct subject searches to locate this journal.

39. This MARC serial record (**EX2105**) shows that *Protein Science* is a long-running journal, and the MARC serial record has made it discoverable in the online catalog of the National Library of Medicine since the record was created on July 30, 1992. Users interested in the subject of this journal would have been able to

conduct subject searches by the classification number and the medical subject headings to discover this journal. They would also have been able to discover and access the journal by the journal title, ISSN, and three organizations related to this journal. For individual articles published in this journal since 1992, interested users would have been able to search MEDLINE and PubMed for index records to access articles of interest.

40. Internet Archive is a digital library that archives scholarly materials, cultural artifacts, and other web resources on the Internet and provides the public with free access to its collections. I have used the Internet Archive in the past and am familiar with their practice of assigning an extended URL to an archived resource 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]) to show the point of time the archived file was captured. Since Internet Archive usually does not archive web resources the moment they appear on the Internet, and a web resource must be available first before it can be archived, the archive date of a file captured by the Internet Archive means that the archived file was available before, and definitely no later than, the archive date.

41. As evidence that NLM had an online catalog in operation when the journal issue containing *Marcotte* was received by the library on March 26, 2010, I searched Internet Archive for records. **EX2106** is a true and correct copy of

LocatorPlus, the NLM online catalog, archived by Internet Archive on May 12, 2009. I personally located, identified, and obtained this record. This is the type of record experts in my field would reasonably rely upon when forming their opinions.

42. Page 1 is a screenshot of a Wayback Machine calendar that shows LocatorPlus was archived 211 times between “19 Apr 2001” and “1 Apr 2022” and this particular copy was archived on May 12, 2009, and available at <https://web.archive.org/web/20090512190928/http://locatorplus.gov/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First>. I accessed this archived copy of LocatorPlus on June 23, 2024. Page 2 is the PDF of this archived copy that shows that by May 12, 2009, interested users would have been able to search this online catalog on the Internet to explore collections of the National Library of Medicine.

D. PubMed Record

43. To locate index records of *Marcotte*, I searched PubMed by the title of *Marcotte* for records. PubMed is an authoritative system that contains “more than 37 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” (source: <https://pubmed.ncbi.nlm.nih.gov>).

44. **EX2107** is a true and correct metadata record for *Marcotte* (<https://pubmed.ncbi.nlm.nih.gov/20052711/>) that I personally located, identified

and obtained from PubMed. This is the type of record experts in my field would reasonably rely upon when forming their opinions. I saved the metadata record in PDF and added the PubMed format of the record to show the record creation dates and data in specific fields.

45. Page 1 of **EX2107** shows a full text link to “Wiley Free Full Text” (<https://onlinelibrary.wiley.com/doi/10.1002/pro.321>) where users can download *Marcotte* for free. This PubMed metadata record shows the title, authors, journal and issue where *Marcotte* was published, and abstract of this article. It also shows the PubMed identifier (PMID) for this record is “20052711” and the article DOI is “10.1002/pro.321.” Page 2 shows four colored figures from *Marcotte*.

46. Pages 4 to 6 of **EX2107** are the PubMed record saved in PubMed format to show the data in specific fields. I use the “MEDLINE/PubMed Data Element (Field) Descriptions” (<https://www.nlm.nih.gov/bsd/mms/medlineelements.html>) to interpret the record. The “PMID” field shows “20052711” as the PubMed unique identifier for the metadata record for *Marcotte*. The “STAT” field shows the status of the record is “MEDLINE” (meaning the record has been indexed with Medical subject headings and completed the quality assurance routines to be elevated to MEDLINE status). The DCOM field shows that the PubMed record was completed on “20100520” (*i.e.*, May 20, 2010). The second IS field shows the print journal’s ISSN is “0961-8368.” Fields VI (volume), IP (issue), DP (date of publication), Ti

(title) and PG (pages) show *Marcotte* was published in vol. 19, no. 3 (2010 Mar), pp. 429-39. The first FAU (full author) field shows “Marcotte, Douglas J” as the first author. The JT (journal title) field on page 5 shows this article appears in *Protein Science*. The MH (MeSH terms) fields show 13 medical subject headings were assigned to indicate the subjects of *Marcotte*. Field “MHDA” (date of medical subject headings) shows subject index terms were added to this PubMed record on “2010/05/21” (*i.e.*, May 21, 2010). The “AID” (article identifier) field shows the doi of *Marcotte* is “10.1002/pro.321.”

47. This PubMed record (**EX2107**) made *Marcotte* discoverable in PubMed on May 20, 2010, when the PubMed record was completed, and the record was indexed with medical subject headings on May 21, 2010. These dates show that by May 21, 2010, users would have been able to search for *Marcotte* in PubMed by the authors, title, ISSN, journal title, abstract, and medical subject headings assigned to this article.

48. As evidence that PubMed was in operation when the PubMed record for *Marcotte* was completed in May 2010, I searched Internet Archive for records of PubMed. **EX2108** is a true and correct copy of the PubMed home page and the PubMed Help page archived by Internet Archive. I personally located, identified, and obtained these archived webpages. They are the type of record experts in my field would reasonably rely upon when forming their opinions.

49. Page 1 of **EX2108** is a screenshot of a Wayback Machine calendar that shows the PubMed home page (<http://ncbi.nlm.nih.gov/pubmed>) was archived, 59,318 times between “15 Jun 1997” and “28 Jul 2024” and this particular copy was archived on “MAY 05 2010” and available at <https://web.archive.org/web/20100505013751/ncbi.nlm.nih.gov/pubmed>. I accessed this archived copy of PubMed home page on July 28, 2024. Page 1 shows PubMed offers simple search, advanced search, and limits to refine search results. Page 2 is the PDF of the archived copy that shows resources on how to use PubMed and other NLM services were available to users by May 5, 2010.

50. Page 3 is a screen capture of a Wayback Machine calendar that shows the webpage for PubMed Help was archived 278 times between “20 Feb 2009” and “27 Jan 2024” and this particular copy was archived on “MAY 06 2010” and available at <https://web.archive.org/web/20100506160612/http://www.ncbi.nlm.nih.gov/books/helf/br.fcgi?book=helppubmed&part=pubmedhelp>. I accessed this archived copy of PubMed Help on August 3, 2024. Pages 4 to 52 are the PDF of the archived webpage that shows this webpage was last updated on “April 5, 2010.” The archived webpage describes the scope of PubMed and indicates that “PubMed is a free resource that is developed and maintained by the National Center for Biotechnology Information (NCBI), at the U.S. National Library of Medicine (NLM),” and journal publications

“can submit their citations to NCBI and then provide access to the full-text of articles at journal Web sites using LinkOut.” The archive pages include FAQs and a PubMed Quick Start section that shows users how to conduct searches in PubMed. **EX2108** shows PubMed and PubMed Help were already in operation when the PubMed record for *Marcotte* was completed.

E. Declaration of Nathaniel E. Frank-White

51. My analysis of the archived copies of the NLM online catalog, LocatorPlus (**EX2106**) and the PubMed home page and PubMed Help webpage (**EX2018**) is supported by the declaration of Mr. Nathaniel E Frank-White of the Internet Archive (**EX2110**) that I received 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” (Page 1, ¶ 2). He further explains that “[t]he Internet Archive assigns a URL on its site to the archived files in the format `http://www.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” (Page 1, ¶ 5). He also makes explicit that “in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary

HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates” (Page 1, ¶ 5).

52. In Paragraph 6 Mr. Frank-White states that files included in his Exhibit A “are true and accurate copies of browser 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” (Page 1, ¶ 6).

53. Pages 82 and 83 of **EX2110** show the same URL and archived copy of LocatorPlus as the archived record in **EX2016**. This portion of Exhibit A of Mr. Frank-White’s declaration confirms that LocatorPlus, the online catalog of NLM, was archived by Internet Archive on May 12, 2009, and the record in **EX2016** is authentic and accurate.

54. Pages 80 and 81 of **EX2110** show the same URL and archived copy of the PubMed home page as the archived records in **EX2018**, confirming that the PubMed home page was archived on May 5, 2010, and the records in **EX2018** are authentic and accurate. These two exhibits show different total number of file capture, because they were produced at different times. I produced the PubMed home page records in **EX2018** on July 28, 2024. The later exhibit production time of **EX2018** means the file capture activities after **EX2110** was signed on July 18,

2024, were added to the total count listed in that copy, hence the higher total number of file capture in **EX2018**.

55. Furthermore, page 45 and 46 of **EX2110** show the same URL and archived copy of the PubMed Help webpage as the archived record in **EX2018**. **EX2018** shows a slightly higher total number of file capture because this exhibit was produced on August 3, 2024, while **EX2110** was produced on July 18, 2024. **EX2110** and **EX2018** show the same PubMed Help webpage that includes a “Last update: April 5, 2010” note. This portion of Exhibit A of Mr. Frank-White’s declaration confirms that the PubMed Help webpage was archived on May 6, 2010, and the PubMed Help record in **EX2018** is authentic and accurate.

56. In short, the declaration of Mr. Frank-White together with his Exhibit A (**EX2110**) confirms the archived records presented in **EX2106** and **EX2108** are authentic and accurate copies archived by the Internet Archive. **EX2110** supports my findings that LocatorPlus, the online catalog of NLM, was in operation in May 2009, and that the PubMed home page and the PubMed Help webpage were publicly available by May 2010.

F. Usage Record

57. Actual usage of a publication is reflected by the publications that make reference to it. The citation history on Google Scholar shows *Marcotte* has been cited 161 times. **EX2109** is a list I compiled from Google Scholar to demonstrate

early usage of this article. This list includes five citations published in 2010, and shows the earliest citation appeared in June 2010.

G. Summary of My Opinion on *Marcotte*

58. **EX2001** is authentic because it contains no signs to raise questions about its authenticity. Furthermore, **EX2001** is identical to the publisher's copy of *Marcotte* (**EX2103**), and has the same content as the NLM copy of *Marcotte* (**EX2104**).

59. The library copy shows a "2010-03-26" date stamp indicating NLM received the issue containing *Marcotte* on March 26, 2010. The NLM bibliographic and MARC serial records for *Protein Science* (**EX2105**) show that *Protein Science* is a long-running journal that has been discoverable since July 30, 1992, when NLM created the MARC serial record on that date. The NLM online catalog ("LocatorPlus"), archived by Internet Archive on May 12, 2009 (**EX2106**), shows LocatorPlus was in operation before NLM received the journal issue containing *Marcotte* on March 26, 2010. It is therefore my opinion that *Marcotte* was publicly accessible at NLM by April 2, 2010, a week after serial check-in was completed.

60. The PubMed record for *Marcotte* (**EX2107**) and my knowledge of PubMed and MEDLINE inform my opinion that the PubMed record for *Marcotte* was completed on May 20, 2010, and indexed with medical subject headings on May 21, 2010, making this record discoverable on PubMed by subject terms and other

data element from that date on. A copy of the PubMed home page and the webpage for PubMed Help archived by Internet Archive on May 5, 2010 and May 6, 2010 (**EX2108**) shows PubMed was in operation before the *Marcotte* was indexed by MEDLINE on May 21, 2010. The declaration of Mr. Frank-White of Internet Archive (**EX2110**) supports my analysis of **EX2106** and **EX2108** and confirms LocatorPlus and PubMed were in operation when the journal issue containing *Marcotte* became publicly available at NLM and when the PubMed record for *Marcotte* became publicly discoverable. Citation records (**EX2109**) show the earliest citation to *Marcotte* was published in June 2010, confirming my opinion that the journal issue containing *Marcotte* was publicly accessible in April 2010 at NLM and *Marcotte* was discoverable and publicly accessible in PubMed in May 2010.

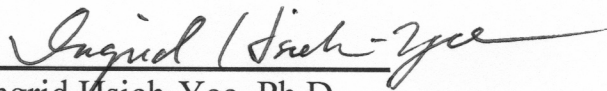
III. Conclusion

61. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case. If cross-examination is required of me, I will appear at a reasonable time and place to be agreed upon.

62. I hereby declare that all statements made herein on 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 statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code. I declare under penalty of perjury that the foregoing is true and correct.

Executed on 8-6-2024 (date), in Annapolis, Md. (city, state).


Ingrid Hsieh-Yee, Ph.D.