UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CALA HEALTH, INC.,
Petitioner,

v.

EMKINETICS INC.,
Patent Owner.

Case IPR2023-00508
U.S. Patent 9,757,584

DECLARATION OF SYLVIA D. HALL-ELLIS, PH.D.

I. INTRODUCTION

1. My name is Sylvia D. Hall-Ellis. I have been retained as an expert by Knobbe, Martens, Olson & Bear, LLP, which I understand represents Petitioner, Cala Health, Inc. (referred to herein as "Petitioner").

2. I have been asked to provide my expert opinion regarding the authenticity and public availability of the Klingler publication identified below. My Declaration sets forth my opinions in detail and provides the basis for my opinions regarding the public availability of this publication.

3. I reserve the right to supplement or amend my opinions, and bases for them, in response any additional evidence, testimony, discovery, argument, and/or other additional information that may be provided to me after the date of this Declaration.

4. I am being compensated for my time spent working on this matter at my normal consulting rate of $325 per hour, plus reimbursement for any additional reasonable expenses. My compensation is not in any way tied to the content of this Declaration, the substance of my opinions, or the outcome of this litigation. I have no other interests in this proceeding or with any of the parties.

5. All of the materials that I considered are discussed explicitly in this Declaration.

II. QUALIFICATIONS

6. I am currently an Adjunct Professor in the School of Information at San José State University. I obtained a Master of Library Science from the University of North Texas in 1972 and a Ph.D. in Library Science from the University of Pittsburgh in 1985. Over the last fifty years, I have held various positions in the field of library and information resources. I was first employed as a librarian in 1966 and have been involved in the field of library sciences since, holding numerous positions.

7. I am a member of the American Library Association (ALA) and its Association for Library Collections & Technical Services (ALCTS) Division, and I served on the Committee on Cataloging: Resource and Description (which wrote the new cataloging rules) and as the chair of the Committee for Education and Training of Catalogers and the Competencies and Education for a Career in Cataloging Interest Group. I also served as the founding Chair of the ALCTS Division's Task Force on Competencies and Education for a Career in Cataloging. Additionally, I have served as the Chair for the ALA Office of Diversity's Committee on Diversity,

as a member of the REFORMA National Board of Directors, and as a member of the Editorial Board for the ALCTS premier cataloging journal, *Library Resources and Technical Services*. Currently I serve as a Co-Chair for the Library Research Round Table of the American Library Association.

8. I have also given over one hundred presentations in the field, including several on library cataloging systems and Machine-Readable Cataloging ("MARC") standards. My current research interests include library cataloging systems, metadata, and organization of electronic resources.

9. I have been deposed twenty-two times: (1) *Symantec Corp. vs. Finjan, Inc.,* Petition for *Inter Partes Review* of U.S. Patent No. 7,613,926, May 26, 2016, on behalf of Symantec Corp.; (2) *Symantec Corp. vs. Finjan, Inc.,* 14-cv-299-HSG (N.D. Cal.), on behalf of Symantec Corp., September 14, 2017; (3) one deposition for ten matters: *Intellectual Ventures I LLC vs. AT&T Mobility LLC*; AT&T Mobility II LLC, New Cingular Wireless Services, Inc., SBC Internet Services, Inc., Wayport, Inc., and Cricket Wireless LLC, C.A. No. 12-193 (LPS); *Intellectual Ventures II LLC vs. AT&T Mobility LLC*; AT&T Mobility II LLC, New Cingular Wireless Services, Inc., SBC Internet Services, Inc., Wayport, Inc., and Cricket Wireless LLC, C.A. No. 13-1631 (LPS); *Intellectual Ventures I*

LLC vs. T-Mobile USA, Inc. and T-Mobile US, Inc., C.A. No. 13-1632 (LPS); *Intellectual Ventures II LLC vs. T-Mobile USA, Inc. and T-Mobile US, Inc.,* C.A. No. 13-1633 (LPS); *Intellectual Ventures I LLC, vs. Nextel Operations, Inc., Sprint Spectrum L.P., Boost Mobile, LLC and Virgin Mobile USA, L.P.,* C.A. No. 13-1634 (LPS); *Intellectual Ventures II LLC vs. Nextel Operations, Inc., Sprint Spectrum L.P., Boost Mobile, LLC and Virgin Mobile USA, L.P.,* C.A. No. 13-1635 (LPS); *Intellectual Ventures I LLC, vs. United States Cellular Corporation*, C.A. No. 13-1636 (LPS); *Intellectual Ventures I LLC vs. United States Cellular Corporation*, C.A. No. 13-1637 (LPS); *Intellectual Ventures II LLC vs. AT&T Mobility LLC*, *AT&T Mobility II LLC, New Cingular Wireless Services, Inc.,* C.A. No. 15-799 (LPS); *Intellectual Ventures I LLC vs. T-Mobile USA, Inc. and T-Mobile US, Inc.,* C.A. No. 15-800 (LPS), on behalf of AT&T Mobility LLC; AT&T Mobility II LLC, Boost Mobile, LLC Cricket Wireless LLC, Nextel Operations, Inc., New Cingular Wireless Services, Inc., SBC Internet Services, Inc., Sprint Spectrum L.P., T-Mobile USA, Inc., T-Mobile US, Inc., United States Cellular Corporation Virgin Mobile USA, L.P., and Wayport, Inc., November 15, 2016; (4) *Hitachi Maxell, LTD., v. Top Victory Electronics (Taiwan) Co. Ltd., et al.,* 2:14-cv-1121 JRG-RSP (E.D. Texas), on behalf of Top Victory Electronics (Taiwan) Co. LTD, *et. al.,* January 20, 2016;

(5) *Sprint Spectrum, L.P. vs. General Access Solutions, Ltd.*, Petition for *Inter Partes Review* of U.S. Patent No. 7,173,916, on behalf of Sprint Spectrum L.P., July 13, 2018; (6) *Nichia Corporation vs. Vizio, Inc.*, 8:16-cv-00545; on behalf of Vizio, Inc., October 12, 2018; (7) *Intellectual Ventures I LLC, vs. T-Mobile USA, Inc., T-Mobile US, Inc., Ericsson Inc., and Telefonaktiebolaget LM Ericsson*, 2:17-cv-00557 (JRG), on behalf of T-Mobile USA, Inc., T-Mobile US, Inc., Ericsson Inc., and Telefonaktiebolaget LM Ericsson, October 19, 2018; (8) Pfizer, Inc. vs. Biogen, Inc., Petition for *Inter Partes Review* of U.S. Patent No. 8,821,873, on behalf of Pfizer, November 3, 2018; (9) Finjan, Inc. vs. ESET, LLC and ESET SPOL. S.R.O., 3:17-cv-00183-CAB-BGS, on behalf of ESET, January 15, 2019; (10) *Finjan, Inc. vs. Cisco Systems, Inc.,* 5:17-cv-00072-BLF-SVK, on behalf of Cisco Systems, Inc., September 6, 2019; (11) *Facebook, Inc., Instagram, LLC and Whatsapp Inc. vs. Blackberry Limited*, Petition for *Inter Partes Review* of U.S. Patent No. 9,349,120 B2, on behalf of Facebook, Inc., Instagram, LLC and Whatsapp Inc. December 20, 2019; (12) *3Shape A/S and 3Shape Inc. v. Align Technology, Inc.,* Petition for *Inter Partes Review* of U.S. Patent No. 7,156,661, IPR 2020-00222 and IPR 2020-00223, August 10, 2020, on behalf of 3Shape A/S and 3Shape Inc.; (13) *Finjan Inc. v. Rapid7, Inc. and Rapid7 LLC*, Northern District of Delaware; 1:18-cv-01519-MN,

September 15, 2020; (14) *VLSI Technology LLC v. Intel Corporation*, Western District of Texas, 6:19-cv-00254, 6:19-cv-00255, 6:19-cv-00256, on behalf of Intel Corporation, September 23, 2020; (15) *Finjan Inc. v. Sonicwall, Inc.,* Northern District of California, 5:17-cv-04467-BLF-HRL, on behalf of Sonicwall, Inc., October 27, 2020; (16) *VLSI Technology, LLC v. Intel Corporation*, District of Delaware, 1:18-cv-00966-CFC-CJB, February 5, 2021, on behalf of the Intel Corporation; (17) *Unified Patents, LLC v. Good Kaisha IP Bridge 1*, Petition for *Inter Partes Review* of U. S. Patent 7,817,868, February 11, 2021, on behalf of Unified Patents; (18) *Finjan, Inc. v. Qualsys, Inc.,* Northern District of California, 4:18-cv-07229-YGR, March 1, 2021, on behalf of Qualsys, Inc.; (19) *Qualcomm, Inc. v. Monterey Research LLC*, Petition for *Inter Partes Review* of U. S. Patent 6,534,805, May 6, 2021, on behalf of Qualcomm, Inc.; (20) *Hulu, LLC v. Sound View Innovations, LLC*, Petition for *Inter Partes Review* of U. S. Patent 5,806,062, May 14, 2021, on behalf of Hulu, LLC; (21) *VLSI Technology LLC v. Intel Corporation*, Western District of Texas, 6:19-cv-00254, 6:19-cv-00255 and 6:19-cv-00256, August 3, 2021, on behalf of Intel Corporation.; and, (22) *Liquidia Technologies, Inc. v. United Therapeutics Corporation*, Petition for *Inter Partes Review* of U. S. Patent 10,716,793 B2, October 20, 2021, on behalf of Liquidia

Technologies, Inc.

10. Exhibit 1017 is a true and correct copy of my curriculum vitae.

III. PRELIMINARIES

11. *Scope of this Declaration.* I am not an attorney and will not offer opinions on the law. I am, however, rendering my expert opinion on the authenticity of the Klingler publication referenced herein and on when and how that publication was made available to such that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the publication.

12. I am informed by counsel that a printed publication qualifies as publicly accessible as of the date it was disseminated or otherwise made available such that a person interested in and ordinarily skilled in the relevant subject matter could locate it through the exercise of ordinary diligence.

13. While I understand that the determination of public accessibility under the foregoing standard rests on a case-by-case analysis of the facts particular to an individual publication, I also understand that a printed publication is rendered "publicly accessible" if it is cataloged and indexed by a library such that a person interested in the relevant subject matter could locate it (*i.e.*, I understand that

cataloging and indexing by a library is sufficient, though there are other ways that a printed publication may qualify as publicly accessible). One manner of sufficient indexing is indexing according to subject matter category. I understand that the cataloging and indexing by a single library of a single instance of a particular printed publication is sufficient, even if the single library is in a foreign country. I understand that, even if access to a library is restricted, a printed publication that has been cataloged and indexed therein is publicly accessible so long as a presumption is raised that the portion of the public concerned with the relevant subject matter would know of the printed publication. I also understand that the cataloging and indexing of information that would guide a person interested in the relevant subject matter to the printed publication, such as the cataloging and indexing of an abstract for the printed publication, is sufficient to render the printed publication publicly accessible.

14. I understand that routine business practices, such as general library cataloging and indexing practices, can be used to establish an approximate date on which a printed publication became publicly accessible.

15. *Persons of ordinary skill in the art*. I am told by counsel that the subject matter of the patent challenged in this proceeding relates generally to methods for

performing electrical stimulation of a tibial nerve to treat overactive bladder or incontinence.

16. I have been informed by counsel that a "person of ordinary skill in the art at the time of the invention" 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 applicable to the pertinent field.

17. I am told by counsel that persons of ordinary skill in this subject matter or art would have had an undergraduate degree in the field of biomedical engineering, or a related discipline, and at least two years of experience in the design and/or analysis of biomedical devices. I understand that additional work experience could serve as a substitute for a formal degree and vice versa.

18. It is my opinion that such a person would have been engaged in research, learning, study, and practice in the field, and possibly formal instruction so that bibliographic resources relevant to his or her research would be familiar. At the relevant time, such a person would have had access to a vast array of long-established print resources as well as to a rich set of online resources providing indexing information, abstracts, and full text services for electro-mechanical

systems, regenerative medicine, tissue/organ engineering, and biologic and medical research.

IV. LIBRARY PROFESSIONAL PRACTICES

19. In preparing this Declaration, I used authoritative databases, such as the OCLC bibliographic database, the Library of Congress Online Catalog, and the Library of Congress Subject Authorities, to confirm citation details of the various publications discussed. Unless I note otherwise below in reference to a specific serial publication, it is my expert opinion that this standard protocol was followed for the serial publication discussed below.

20. *Indexing*. A researcher may discover material relevant to his or her topic in a variety of ways. One common means of discovery is to search for relevant information in an index of periodical and other publications. Having found relevant material, the researcher will then normally obtain it online, look for it in libraries, or purchase it from the publisher, a bookstore, a document delivery service, or other provider. Sometimes, the date of a document's public accessibility will involve both indexing and library date information. However, date information for indexing entries is often unavailable. This is especially true for online indices.

21. Indexing services use a wide variety of controlled vocabularies to

provide subject access and other means of discovering the content of documents. The Library of Congress Subject Authorities includes standard forms of terms and cross references that are included in bibliographic records. Subject headings are terms that an individual seeking a document regardless of format can enter in the search bar of the online catalog. Subjects also connect an authenticated term (one included in the Library of Congress subject headings list) with related, broader, and narrower terms. The formats in which these access terms are presented vary from service to service.

22. Online indexing services commonly provide bibliographic information, abstracts, and full-text copies of the indexed publications, along with a list of the documents cited in the indexed publication. These services also often provide lists of publications that cite a given document. A citation of a document is evidence that the document was publicly available and in use by researchers no later than the publication date of the citing document. Prominent indexing services include *Scopus,* the *IEEE Xplore* database, the *ACM Digital Library, Google Scholar,* and the digital repository *Semantic Scholar*.

V. LIBRARY CATALOGING PRACTICES

23. I am fully familiar with the library cataloging standard known as the

MARC standard, which is an industry-wide standard method of storing and organizing library catalog information.[1] MARC was first developed in the 1960's by the Library of Congress. A MARC-compatible library is one that has a catalog consisting of individual MARC records for each of its items. Today, MARC is the primary communications protocol for the transfer and storage of bibliographic metadata in libraries.[2]

24. Since at least the early 1970s and continuing to the present day, MARC has been the primary communications protocol for the transfer and storage of

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[1] The full text of the standard is available from the Library of Congress at http://www.loc.gov/marc/bibliographic/ (last visited October 18, 2021).

[2] Almost every major library in the world is MARC-compatible. *See, e.g.*, *MARC Frequently Asked Questions (FAQ)*, Library of Congress, https://www.loc.gov/marc/faq.html (last visited October 18, 2021) ("MARC is the acronym for MAchine-Readable Cataloging. It defines a data format that emerged from a Library of Congress-led initiative that began nearly fifty years ago. It provides the mechanism by which computers exchange, use, and interpret bibliographic information, and its data elements make up the foundation of most library catalogs used today."). MARC is the ANSI/NISO Z39.2-1994 (reaffirmed 2016) standard for Information Interchange Format.

bibliographic metadata in libraries.[3] As explained by the Library of Congress:

> You could devise your own method of organizing the bibliographic information, but you would be isolating your library, limiting its options, and creating much more work for yourself. Using the MARC standard prevents duplication of work and allows libraries to better share bibliographic resources. Choosing to use MARC enables libraries to acquire cataloging data that is predictable and reliable. If a library were to develop a "home-grown" system that did not use MARC records, it would not be taking advantage of an industry-wide standard whose primary purpose is to foster communication of information.
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> Using the MARC standard also enables libraries to make use of commercially available library automation systems to manage library operations. Many systems are available for libraries of all sizes and are designed to work with the MARC format. Systems are maintained and improved by the vendor so that libraries can benefit from the latest advances in computer technology. The MARC standard also allows

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[3] A complete history of the development of MARC can be found in *MARC: Its History and Implications* by Henrietta D. Avram (Washington, DC: Library of Congress, 1975) and available online from the Hathi Trust (https://babel.hathitrust.org/cgi/pt?id=mdp.39015034388556;view=1up;seq=1; last visited October 18, 2021).

libraries to replace one system with another with the assurance that their data will still be compatible.

Why Is a MARC Record Necessary? LIBRARY OF CONGRESS.[4]

25. Thus, almost every major library in the world is MARC-compatible. *See, e.g.*, *MARC Frequently Asked Questions (FAQ)*, LIBRARY OF CONGRESS.[5] ("MARC is the acronym for MAchine-Readable Cataloging. It defines a data format that emerged from a Library of Congress-led initiative that began nearly fifty years ago. It provides the mechanism by which computers exchange, use, and interpret bibliographic information, and its data elements make up the foundation of most library catalogs used today."). MARC is the ANSI/NISO Z39.2-1994 standard (reaffirmed in 2016) for Information Interchange Format. The full text of the standard is available from the Library of Congress.[6]

26. A MARC record comprises 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 follow. For example, a work's

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[4] http://www.loc.gov/marc/umb/um01to06.html#part2

[5] https://www.loc.gov/marc/faq.html

[6] http://www.loc.gov/marc/bibliographic/

title is recorded in Field 245; the primary author of the work is transcribed in Field 100; an item's International Standard Book Number ("ISBN") consisting of ten or thirteen digits is transcribed in Field 020; an item's International Standard Serial Number ("ISSN") is transcribed in Field 022; the Library of Congress classification notation is recorded in Field 050; and the publication date is recorded in Field 260 under the subfield "c." If a work is a periodical, then its publication frequency is recorded in Field 310, and the publication dates (e.g., the first and last publication) are recorded in Field 362, which is also referred to as the enumeration/chronology field.[7]

27. The library that created the record is recorded in Field 040 in subfield "a" with a unique library code. When viewing the MARC record online via Online Computer Library Center's ("OCLC") bibliographic database, hovering over this code with the mouse reveals the full name of the library. I used this method of "mousing over" the library codes in the OCLC database to identify the originating library for the MARC records discussed in this Declaration. Where this "mouse over" option was not available, I consulted the Directory of OCLC Libraries in order

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[7] http://www.loc.gov/marc/bibliographic/bd3xx.html

to identify the institution that created the MARC record.[8]

28. MARC records also include several fields that include subject matter classification information. An overview of MARC record fields is available through the Library of Congress.[9] For example, 6XX fields are termed "Subject Access Fields."[10] Among these, for example, is the 650 field; this is the "Subject Added Entry – Topical Term" field.[11] The 650 field is a "[s]ubject added entry in which the entry element is a topical term." These entries "are assigned to a bibliographic record to provide access according to generally accepted thesaurus-building rules (e.g., *Library of Congress Subject Headings* (LCSH), *Medical Subject Headings* (MeSH))." *Id.* Further, MARC records include call numbers, which themselves include a classification number. For example, the 050 field is the "Library of Congress Call Number."[12] A defined portion of the Library of Congress Call (LCC) Number is the classification number, and "source of the classification number is

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[8] https://www.oclc.org/en/contacts/libraries.html

[9] http://www.loc.gov/marc/bibliographic/

[10] http://www.loc.gov/marc/bibliographic/bd6xx.html

[11] http://www.loc.gov/marc/bibliographic/bd650.html

[12] http://www.loc.gov/marc/bibliographic/bd050.html

Library of Congress Classification and the *LC Classification-Additions and Changes*." Thus, included in the 050 field is a subject matter classification. Further, the 082 field is the "Dewey Decimal Call Number."[13] A defined portion of the Dewey Decimal Call (DDC) Number is the classification number, and "source of the classification number is the *Dewey Decimal Classification and Relative Index*." Thus, included in the 082 field is a subject matter classification. Each item in a library has a single classification number. A library selects a classification scheme (*e.g.*, the Library of Congress classification scheme just described or a similar scheme such as the Dewey Decimal classification scheme) and uses it consistently. When the Library of Congress assigns the LCC classification number, it appears as part of the 050 field. When the Library of Congress assigns the DDC classification number, it appears as part of the 082 field. If a local library assigns the classification number, it appears in a 090 field. In either scenario, the MARC record includes a classification number that represents a subject matter classification.

29. The OCLC was created "to establish, maintain and operate a computerized library network and to promote the evolution of library use, of libraries

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[13] http://www.loc.gov/marc/bibliographic/bd082.html

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."[14] Among other services, OCLC and its members are responsible for maintaining the WorldCat database (http://www.worldcat.org/), used by independent and institutional libraries throughout the world.

30. OCLC also provides its members online access to MARC records through its OCLC bibliographic database. When an OCLC member institution acquires a work, it creates a MARC record for this work in its computer catalog system in the ordinary course of its business. MARC records created at the Library of Congress are tape-loaded into the OCLC database through a subscription to

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[14] Third Article, Amended Articles of Incorporation of OCLC Online Computer Library Center, Incorporated (available at https://www.oclc.org/content/dam/oclc/membership/articles-of-incorporation.pdf).

MARC Distribution Services daily or weekly. Once the MARC record is created by a cataloger at an OCLC member institution or is tape-loaded from the Library of Congress, the MARC record is then made available to any other OCLC members online, and therefore made available to the public. Accordingly, once the MARC record is created by a cataloger at an OCLC member institution or is tape-loaded from the Library of Congress or another library anywhere in the world, any publication corresponding to the MARC record has been cataloged and indexed according to its subject matter such that a person interested in that subject matter could, with reasonable diligence, locate and access the publication through any library with access to the OCLC bibliographic database or through the Library of Congress.

31. When an OCLC member institution creates a new MARC record, OCLC automatically supplies the date of creation for that record. The date of creation for the MARC record appears in the fixed Field (008), characters 00 through 05. The MARC record creation date reflects the date on which, or shortly after which, the item was first acquired or cataloged. Initially, Field 005 of the MARC record is automatically populated with the date the MARC record was created in year, month, day format (YYYYMMDD) (some of the newer library catalog systems

also include hour, minute, second (HHMMSS)). Thereafter, the library's computer system may automatically update the date in Field 005 every time the library updates the MARC record (*e.g.*, to reflect that an item has been moved to a different shelving location within the library). Field 005 is visible when viewing a MARC record via an appropriate computerized interface, but when a MARC record is printed to hardcopy, no "005" label appears. The initial Field 005 date (*i.e.*, the date the MARC record was created) does appear, however, next to the label "Entered."[15] The date upon which the most recent update to Field 005 occurred also appears, next to the label "Replaced." Thus, when an item's MARC record has been printed to hardcopy—as is the case with the exhibits to this Declaration—the date reflected next to the label "Entered" is necessarily on or after the date the library first cataloged and indexed the underlying item.

32. Once one library has cataloged and indexed a publication by creating a MARC record for that publication, other libraries that receive the publication do not

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[15] Field 005 is visible when viewing a MARC record via an appropriate computerized interface. But when a MARC record is printed directly to hardcopy from the OCLC database, the "005" label is not shown. The date in the 005 field instead appears next to the label "Replaced."

create additional MARC records—the other libraries instead rely on the original MARC record. They may update or revise the MARC record to ensure accuracy, but they do not replace or duplicate it. This practice does more than save libraries from duplicating labor. It also enhances the accuracy of MARC records. Further, it allows librarians around the world to know that a particular MARC record is authoritative (in contrast, a hypothetical system wherein duplicative records were created would result in confusion as to which record is authoritative).

33. Catalogers can create MARC records for all types of print, online, and digital resources. The date of creation of the MARC record by a cataloger at an OCLC member institution reflects when the underlying item is accessible to the public. Upwards of two-thirds to three-quarters of book sales to libraries come from a jobber or wholesaler for online and print resources. These resellers make it their business to provide books to their customers as fast as possible, often providing turnaround times of only a single day after publication. Libraries purchase a significant portion of the balance of their books directly from publishers themselves, which provide delivery on a similarly expedited schedule. In general, libraries make these purchases throughout the year as the books are published and shelve the books as soon thereafter as possible in order to make the books available to their patrons.

Thus, books are generally available at libraries across the country within just a few days of publication.

34. *Journals.* Catalogers can create MARC records for all types of print, online, and digital resources. For example, MARC records cover serial publications, including both serially-published monographs and journals. OCLC hosts MARC records for more than 320 million serial publications. Serial publications are those publications that have the same collective title but are intended to be continued indefinitely with enumeration such as a volume or issue number (*e.g.*, magazines, journals, etc.). In the OCLC bibliographic database, the first issue of the serial publication is typically cataloged (*i.e.*, a corresponding MARC record is created), but the date is left open-ended with the use of a punctuation mark such as a dash. OCLC serial publication MARC records represent the entire run of the serial title. With knowledge of the first issue published, future issues can be predicted based on the information provided in the MARC record, for example in field 362. In my extensive professional experience, is it highly unusual for a library to stop collecting and shelving a serial publication prior to the end of its publication run. If a subscription to a serial publication ends its run or is cancelled before the end of its

run, the library will denote that it has stopped receiving new volumes by filling in the end date in the MARC record.

35. The handling of printed journal subscriptions is shown on the cover or the first few pages of individual issues. As was the best practice among libraries, issues arrived at a central facility and were immediately received, verified as part of a subscription, checked in, and stamped or labeled with the institution's name and date. Determining that the issue was part of the library subscription ensured that the entire set of publications for the year had been received so that they could be professionally bound and retained. This process also verified that all of the published issues arrived so that the library staff did not have to request or claim an issue that did not arrive as expected. In large public libraries with branches and multi-campus libraries within academic institutions, the journals were sorted and delivered to the subscribing unit. The new issue was placed in the public area; the older issue was stored so that it remained available.

36. The foregoing process has been standard library practice longer than I have been working in the profession. I first learned the steps in the process in the late 1970s and later supervised it. Although the checking in process has become automated and now links electronically to holdings records for the MARC record

for each serial title, the manual placement of a stamp or label and placing the issue in a public area has not changed for 50 years. Unless I note otherwise below in reference to a specific serial publication, it is my expert opinion that this standard protocol was followed for all of the serial publications discussed below.

VI. PUBLICATION

A. Document 1: Exhibit 1009, "Use of Peripheral Neuromodulation of the S3 Region for Treatment of Detrusor Overactivity: A Urodynamic-Based Study" by H. C. Klingler, A. Pycha, J. Schmidbauer, and M. Marberger ("Klingler")

37. Exhibit 1009 is a true and correct copy of portions of Volume 56, Issue 5 of the journal *Urology*, including the cover, table of contents, and the journal article "Use of Peripheral Neuromodulation of the S3 Region for Treatment of Detrusor Overactivity: A Urodynamic-Based Study" by H. C. Klingler, A. Pycha, J. Schmidbauer, and M. Marberger (hereafter "Klingler"). The journal issue corresponding to Exhibit 1009 was found in the Veterinary Library at Cornell University (Ithaca, New York). Exhibit 1009 includes every page (766-771) of the Klingler article as it appears in the *Urology* issue dated November 1, 2000. Specifically, the text of the article is complete; no pages are missing, and the text on each page appears to flow seamlessly from one page to the next; further, there are no visible alterations to the document. Exhibit 1009 was found within the custody

of a library – a place where an authentic copy of this journal would likely be. Exhibit 1009 is a true and correct copy in a condition that creates no suspicion about its authenticity.

38. The Klingler article is also available from the publisher's website,[16] through the National Library of Medicine[17] and the digital repository *Semantic Scholar*.[18]

39. Exhibit 1014 is a true and correct copy of the MARC record for the journal *Urology* in the Veterinary Library at Cornell University online catalog. The library ownership is indicated by the presence of the library's name at the top of the screen. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Exhibit 1014 occurred on December 5, 2015, as shown in field 005 ("20151205"). I personally identified and retrieved the MARC record that is Exhibit 1014 and Exhibit 1015s.

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[16] https://www.goldjournal.net/article/S0090-4295(00)00727-5/fulltext

[17] https://pubmed.ncbi.nlm.nih.gov/11068296/

[18] https://www.semanticscholar.org/paper/Use-of-peripheral-neuromodulation-of-the-S3-region-Klingler-Pycha/65b2e3231a0a061bf465c6606b093e0ef1bd3c06

40. Based on finding a print copy of the Klingler article in the Veterinary Library at Cornell University and MARC record in its online library catalog attached as Exhibit 1014, it is my opinion that the Klingler article published in the journal *Urology* was publicly available on or shortly after November 28, 2000, as shown on the cover. Exhibit 1014 also shows that the Klingler article was catalogued with a descriptor term reading "Urology $v Periodicals" (*see* Exhibit 1016, Library of Congress subject heading sh2010117600) in the 650 field. Exhibit 1016 is a true and correct copy of the MARC display for the authority record of the descriptor term "Urology $v Periodicals" as found in the Library of Congress Authorities database. Exhibit 1016 appears in field 650 of Exhibit 1014 and Exhibit 1015.

41. As noted in the holdings information (362 field), the Veterinary Library at Cornell University has received the journal *Urology* since January 1973 and continues to receive the publication in a digital format. The Klingler article was publicly available on or shortly after November 28, 2000, because the serial title had been received, cataloged, and indexed in the Veterinary Library at Cornell University and made part of its online catalog database.

42. Exhibit 1015 is a true and correct copy of the MARC record for the journal *Urology* obtained from the OCLC bibliographic database. As previously

noted, the library that created the record is recorded in field 040 with a unique library code. For Exhibit 1015, that library code is "DLC," which means that the MARC record for this serial was cataloged at the Library of Congress. As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Library of Congress created OCLC record number 1785123 on May 31, 1973, as shown in the "Entered" field ("19730531"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 1c occurred on February 18, 2020, as shown in the "Replaced" field ("20200218"). I personally identified and retrieved the MARC record that is Exhibit 1015. The "BLvl" entry in Attachment 1c is "s," which indicates that the journal *Urology* is a serial publication. Field 310 of Attachment 1c reads "Monthly." Accordingly, the MARC record for the Klingler article corresponds to the journal *Urology* from the time the serial title began using the current title and includes the date of the Klingler article.

43. Exhibit 1015 includes an entry in field 050 ("RC870 $b .U77")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system) and an entry in field 082 ("616.6"), a subject matter consistent with the

Dewey Decimal classification system. Exhibit 1015 further includes a descriptor term reading "Urology $v Periodicals" (*see* Exhibit 1016, Library of Congress subject heading sh2010117600) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Exhibit 1015 was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 082 entry, and the field 650 entry. As of May 31, 1973, the MARC record attached hereto as Exhibit 1015 was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that subscribed to the serial, which means that the corresponding publication was publicly available on or before that same date through any library with access to the OCLC bibliographic database or through an individual library.

44. Exhibit 1015 indicates that the journal *Urology* as cataloged in the Library of Congress is currently available from 554 libraries. In view of the above, the issue of the journal *Urology* corresponding to Exhibit 1009, which included the Klingler article, was publicly available in print on or shortly after November 28, 2000, because by that date it had been cataloged and indexed by the Library of Congress, made part of the OCLC bibliographic database, and received in the

Veterinary Library at Cornell University. For these reasons, it is my opinion that Exhibit 1009 was published and accessible to the public on November 28, 2000.

45. Further supporting my opinion that Exhibit 1009 was publicly accessible to ordinarily skilled and interested researchers in the field on or around November 28, 2000 is the fact that the journal *Urology* was, at that time, included in the well-known indexes *Excerpta Medica, Biological Abstracts, Energy Research Abstracts, Index Medicus, Life Sciences Collection* and *Current Contents*. *See* field 510 entry in Exhibit 1014. As noted above, this would have provided a POSITA with keyword searching capabilities and other tools to locate this article.

46. In view of the foregoing, it is my opinion that the publication corresponding to Exhibit 1009 (Klingler) was publicly available on or about November 28, 2000.

47. In signing this Declaration, I recognize that the Declaration will be filed as evidence in a 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 and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

48. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

DATED: October 22, 2021

By: Sylvia D. Hall-Ellis
Dr. Sylvia D. Hall-Ellis

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