

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOGENOMICS LABORATORIES, INC.

Petitioner,

v.

NATERA, INC.

Patent Owner.

**EXPERT DECLARATION OF DECLARATION OF JAMES L. MULLINS,
Ph.D. IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S.
PATENT NO. 11,319,596**

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I, James L. Mullins, declare as follows:

1. My name is James L. Mullins.

2. I have been retained by petitioner NeoGenomics Laboratories, Inc. (“NeoGenomics”) in the above-captioned *inter partes* review relating to U.S. Patent 11,319,596 to provide opinions on various documents.

I. INTRODUCTION

3. I am presently Dean Emeritus of Libraries and Esther Ellis Norton Professor Emeritus at Purdue University. My career as a professional and academic/research spanned more than 44 years including library positions at Indiana University, Villanova University, Massachusetts Institute of Technology, and Purdue University. Ex.1075 is a true and correct copy of my curriculum vitae describing my background and experience.

4. In January 2018, I founded the firm Prior Art Documentation Librarian Services, LLC, located at 205 St. Cuthbert, Williamsburg, VA 23188 after purchasing the intellectual property of and successor to Prior Art Documentation, LLC located at 711 South Race Street, Urbana, IL 61801. Further information about my firm, Prior Art Documentation Librarian Services, LLC (PADLS), is available at <https://www.priorartdoclib.com>.

5. I have been retained by NeoGenomics to offer my opinion on the authenticity and dates of public accessibility of various documents. For this

service, I am being paid my usual hourly fee of \$275.00/hour. I have no stake in the outcome of this proceeding or any related litigation or administrative proceedings, and my compensation in no way depends on the substance of my testimony or the outcome of this proceeding.

II. QUALIFICATIONS

6. I received a Bachelor of Arts degree in History, Religion and Political Science in 1972 as well as a Master of Arts degree in Library Science in 1973 from the University of Iowa. I received my Ph.D. in Academic Library Management in 1984 from Indiana University. Over the past fifty-years, I have held various positions in the field of library and information sciences.

7. I am presently Dean Emeritus of Libraries and Esther Ellis Norton Professor Emeritus at Purdue University, and have been since January 1, 2018. I have been previously employed as follows:

Dean of Libraries and Professor and Esther Ellis Norton Professor,

Purdue University, West Lafayette, IN (2004-December 31, 2017)

Assistant/Associate Director for Administration, Massachusetts

Institute of Technology (MIT) Libraries, Cambridge, MA

(2000-2004)

University Librarian and Director, Falvey Memorial Library, Villanova

University, Villanova, PA (1996-2000)

Director of Library Services, Indiana University South Bend, South Bend, IN (1978-1996)

Part-time Instructor, School of Library and Information Science, Indiana University, Bloomington, IN (1979-1996)

Associate Law Librarian, and associated titles, Indiana University School of Law, Bloomington, IN (1974-1978)

Catalog Librarian, Assistant Professor, Georgia Southern College (now University), Statesboro, GA (1973-1974)

8. I have been a member of the American Library Association (“ALA”) since 1974. I served as the chair of the Research Committee of the Association of College and Research Libraries (“ACRL”). My service included the editorial board of the most prominent library journal, *College and Research Libraries*. I also served on the Standards Committee, College Section of the Association of College and Research Libraries, where I was instrumental in developing a re-issue of the *Standards for College Libraries* in 2000.

9. Over 20 years I was actively engaged in academic library professional associations on the international level including invited papers and lectures in Germany, Norway, Israel, Argentina, Australia, South Africa, New Zealand, Hong Kong, Israel, Turkey, Greece, Canada, France, Belgium, China,

Japan, South Korea, Finland, Sweden, Poland, Portugal, Spain, Switzerland, Singapore, and the United Kingdom.

10. I am an author of numerous publications in the field of library science, and have given presentations in library sciences at national and international conferences. During more than 44 years as an academic librarian and library science scholar, I have gained extensive experience with catalog records and online library management systems (“LMS”) built using Machine-Readable Cataloging (“MARC”) standards. As a part-time instructor at the School of Library and Information Science, Indiana University, I taught, as well as other courses, the cataloging course, “Organization of Library Materials.”

11. As an academic library administrator, I have had responsibility to ensure that students were educated to identify, locate, assess, and integrate information garnered from research library resources. I have also facilitated the research of faculty colleagues either directly or through the provision of and access to the requisite print and/or digital materials and services at the universities where I worked.

12. Based on my experience identified above and detailed in my curriculum vitae, which is attached hereto as Appendix A, I consider myself to be an expert in the field of library science and academic library administration. I have

previously offered my opinions on the public availability and authenticity of documents in over 147 cases. I have been deposed in three cases.

III. BACKGROUND ON PUBLIC ACCESSIBILITY

A. Scope Of This Declaration

13. I am not a lawyer, and I am not rendering an opinion on the legal question of whether a particular document is, or is not, a “printed publication” under the law. I am, however, rendering my expert opinion on the authenticity of a particular document referenced herein and when and how this document was disseminated or otherwise made available to the extent that people interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the document.

14. I am informed by counsel 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 document itself, such as the appearance, content, substance, internal patterns, or other distinctive characteristics of the item.

15. I am informed by counsel that a given reference qualifies as “publicly accessible” if it were 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.

16. 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. I understand that it is not necessary to prove someone actually looked at the printed publication in order to show it was publicly accessible by virtue of a library’s cataloging and indexing thereof. I understand that cataloging and indexing by a single library of a single instance of a particular printed publication is sufficient. 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.

17. I understand that evidence showing the specific date when a printed publication became publicly accessible is not necessary. Rather, 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.

B. Person Of Ordinary Skill In The Art

18. In forming the opinions expressed in this declaration, I have reviewed the documents and appendices referenced herein. These materials are records created in the ordinary course of business by publishers, libraries, indexing services, and others. From my years of experience, I have been familiar with the process for creating many of these records, and I know that these records are created by people with knowledge of the information contained within the record. Further, these records are created with the expectation that researchers and other members of the public will use them. All materials cited in this declaration and its exhibits are of a type that experts in my field would reasonably rely upon and refer to in forming their opinions.

19. Counsel has informed me that the subject matter of this proceeding relates to detecting mutations such as single nucleotide mutations in DNA.

20. I have been informed by counsel that a “person of ordinary skill in the art at the time of the inventions” (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 and/or engineering principles applicable to the pertinent field

21. Counsel has informed me that a POSA in this subject matter or art would have had at least (1) a Master's degree and/or Ph.D. in biochemistry, molecular genetics, pharmacology, or an equivalent discipline with applications in genomics and (2) at least five years of academic or industrial laboratory experience.

22. I understand that in a corresponding technical declaration in this proceeding, the expert opines that a POSA would have a deep understanding of genomics, including nucleic acid detection, quantification, and genotyping and would understand the underlying scientific principles to such.

23. I understand that in a corresponding technical declaration in this proceeding, the expert opines that a POSA would stay apprised of recent literature on genomic assays, such as multiplex PCR, next-generation nucleic acid sequencing techniques, methods for detecting rare SNVs, and the use of cfDNA in genotyping. I understand that in a corresponding technical declaration in this proceeding, the expert opines that a POSA would also generally understand the

processes behind the development of DNA mutation-based illnesses, such as cancers, and would stay apprised of the recent literature in those fields.

24. It is my opinion that such a person would have been actively engaged in academic research and learning through study and practice in the field, and possibly through formal instruction through the bibliographic resources relevant to his or her research. By the 2000s, such a person with the educational background and research expectation would have had access to a vast array of print resources, including at least the documents referenced below, as well as to a fast-changing set of online resources.

C. Library Catalog Records And Other Resources

25. Some background on MARC (Machine-Readable Cataloging) formatted records, OCLC, and *WorldCat* is helpful to understand the library catalog records discussed in this declaration. 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 practices have been consistent since the MARC format was developed by the Library of Congress in the 1960s, and by the early 1970s became the U.S. national standard for disseminating bibliographic data. By the mid-1970s, MARC format

¹ The full text of the standard is available from the Library of Congress at <http://www.loc.gov/marc/bibliographic/>.

became the international standard, and persists through the present. A MARC-compatible library is one that has a catalog consisting of individual MARC records for each of its items. The underlying MARC format (computer program) underpins the online public access catalog (“OPAC”) that is available to library users to locate a particular holding of a library. Today, MARC is the primary communications protocol for the transfer and storage of bibliographic metadata in libraries.² The MARC practices discussed below were in place during the late 1990s time frame relevant to the documents referenced herein.

26. Online Computer Library Center (“OCLC”) is a not-for-profit worldwide consortium of libraries. Similar to MARC standards, OCLC’s practices have been consistent since the 1970s through the present. Accordingly, the OCLC practices discussed below were in place during the time frame discussed in my opinions section. 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

² Almost every major library in the world uses a catalog that is MARC-compatible. See, e.g., Library of Congress, *MARC Frequently Asked Questions (FAQ)*, <https://www.loc.gov/marc/faq.html> (last visited Jan. 24, 2018) (“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 forty 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 2009) standard for Information Interchange Format.

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.”³ Among other services, OCLC and its members are responsible for maintaining the *WorldCat* database (<http://www.worldcat.org/>), used by libraries throughout the world.

27. *WorldCat* is the world’s largest public online catalog, maintained by the OCLC, a not-for-profit international library consortium, built with the records created by the thousands of libraries that are members of OCLC.

D. Periodical/Serial Publications.

28. A periodical publication is a published work in a series, for example, a journal article. A library typically creates a catalog record for a periodical publication when the library receives its first issue. When the institution receives subsequent issues or volumes of the periodical, the issues or volumes are checked in, often using a date stamp, added to the institution’s holding records, and made available very soon thereafter, normally within a few days of receipt or at

³ OCLC Online Computer Library Center, Inc., *Amended Articles of Incorporation of OCLC Online Computer Library Center, Inc.*, Third Article (OCLC, Dublin, Ohio) Revised November 30, 2016, <https://www.oclc.org/content/dam/oclc/membership/articles-oA-incorporation.pdf>.

most within a few weeks of receipt. This practice continued up to the time when many scholarly journals ended printing a paper edition, and only published in digital format, depending upon the journal between 2005–2014. The date of publication on-line is confirmed on the publication itself, it evidence of its public access as of that date.

E. Cataloging / Indexing

29. A researcher may discover material relevant to a topic of interest in a variety of ways. One common means of discovery is to search for relevant information in an index of periodicals and other publications. Having found relevant material, the researcher will then normally obtain it online, look for it in libraries, or purchase it from a publisher, a bookstore, a document delivery service, or another provider.

30. Indexing services use a wide variety of controlled vocabularies to provide subject access and other means of discovering the content of documents. The formats in which these access terms are presented vary from service to service.

31. 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.

F. Databases Consulted

32. ***Google Scholar*** – This web search engine indexes full text or metadata of scholarly literature, covering numerous formats and disciplines. The size of the database is not published by Google, but researchers have estimated that it contained approximately 160 million items in 2014.

33. The database is not limited by type of publication, and includes dissertations, prepublication materials, technical reports, patents and more. Google Scholar is similar to many subscription databases, e.g., Scopus and Web of Science in its broad subject coverage.

34. ***PubMed Central (PMC)*** - PubMed Central[®] (“PMC”) is a free full-text archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health's National Library of Medicine (“NIH”/“NLM”). In keeping with NLM's legislative mandate to collect and preserve biomedical literature, PMC is part of the NLM collection, which also includes NLM's extensive print and licensed electronic journal holdings and supports contemporary biomedical and health care research and practice as well as future scholarship. Available to the public online since 2000, PMC was developed and is maintained by the National Center for Biotechnology Information (“NCBI”) at NLM.

35. Since its inception in 2000, PMC has grown from comprising only two journals, PNAS: Proceedings of the National Academy of Sciences and Molecular Biology of the Cell, to an archive of articles from thousands of journals. In addition, PMC also contains author manuscripts deposited through the NIH Manuscript Submission System (“NIHMS”), and preprints collected through the NIH Preprint Pilot.

36. The PMC archive contains more than 10 million full-text article records spanning several centuries of biomedical and life science research (late 1700s to present). This content includes articles that have been formally published in a scholarly journal, author manuscripts that have been peer-reviewed and accepted for publication in a journal, and preprint versions of articles that have been made public prior to peer review.

37. Content is deposited in the PMC archive through collaborations with publishers, societies, research funders, and international organizations.

<https://pmc.ncbi.nlm.nih.gov/about/intro/>

38. ***Science Family of Journals*** is published by the American Association for the Advancement of Science (AAAS), the world’s oldest and largest general science organization. The nonprofit AAAS serves 10 million people through primary memberships and affiliations with some 262 scientific societies and academies. A voice for science and scientists everywhere, AAAS fulfills its

mission to “advance science and serve society” by communicating the value of science to the public, helping governments formulate science policy, promoting advancements in science education and diversity, and helping scientists develop their careers. (<https://www.science.org/content/page/about-science-aaas>)

39. ***Science Direct*** - is a website which provides subscription-based access to a large database of scientific and medical research. It hosts over 12 million pieces of content from 3,500 academic journals and 34,000 e-books. The journals are grouped into four main sections: *Physical Sciences and Engineering, Life Sciences, Health Sciences, and Social Sciences and Humanities*. Article abstracts are freely available, but access to their full texts (in PDF and, for newer publications, also HTML) generally requires a subscription or pay-per-view purchase. (<https://www.elsevier.com/solutions/sciencedirect>)

IV. OPINION REGARDING AUTHENTICITY AND PUBLIC ACCESSIBILITY:

- A. **Ex.1008: Chetan Bettegowda, Mark Sausen, Rebecca J. Leary, Isaac Kinde, Yuxuan Wang, Nishant Agrawal, Bjarne R. Bartlett et al. "Detection of Circulating Tumor DNA in Early-and Late-Stage Human Malignancies." *Science Translational Medicine*, Volume 6, Number 224, ra 224. February 19, 2014. Pages 1-11. (“Bettegowda”). Bettegowda is also available in the PubMed Central database.**

1. Authentication

40. I have been asked to opine on the authenticity and public access of an article authored by Chetan Bettegowda, et al. titled: "Detection of Circulating Tumor DNA in Early-and Late-Stage Human Malignancies" published in *Science*

Translational Medicine, Volume 6, Number 224, ra 224, dated February 19, 2014, on pages 1-11 as well as the supplementary materials linked to Bettegowda. Bettegowda was also made available through PubMed Central (PMC) online on May 12, 2014.

41. For consistency and clarification, Bettegowda, when used in this declaration, refers not only to the Bettegowda article but also to the *Science Translational Medicine* issue in which it was published: Volume 6, Number 224 dependent on context as well as when it was available through PMC.

42. EX.1008 is a copy of Bettegowda provided to me by counsel. It appears to be from the *Science Translational Medicine* issue in which it was published: Volume 6, Number 224, February 19, 2014, most likely downloaded from the publisher's website. I will be comparing the results of my research to Ex.1008 to determine authenticity and public accessibility.

43. Ex.1076 ("A-1") is a download of Bettegowda as published in *Science Translational Medicine* that I made on December 28, 2024 available to me through Purdue University Libraries as an emeritus faculty member, at the URL:
<https://www.science.org/doi/pdf/10.1126/scitranslmed.3007094>

44. Bettegowda as published in *Science Translational Medicine* is available with a membership and/or creation of an account at URL:

[https://www.science.org/action/ssostart?redirectUri=/doi/10.1126/scitranslmed.300](https://www.science.org/action/ssostart?redirectUri=/doi/10.1126/scitranslmed.3007094)

7094

45. In addition to the Bettegowda article, there are supplementary materials that were and are available linked to Bettegowda. Bettegowda lists the supplementary materials available as follows:

SUPPLEMENTARY MATERIALS

www.sciencetranslationalmedicine.org/cgi/content/full/6/224/224ra24/DC1

Materials and Methods

Fig. S1. Comparison of methods for analysis of point mutations in plasma DNA.

Fig. S2. ctDNA in advanced malignancies, ranking of the fraction of patients with detectable ctDNA.

Fig. S3. Diagram of the assay used to confirm rearrangements in plasma DNA.

Table S1. Summary of tissue mutations, plasma mutations, and clinical information for 410 early- and advanced-stage subjects.

Table S2. Comparison of ctDNA levels assessing point mutations and rearrangements in the same specimens.

Table S3. Comparison between plasma and tumor tissue *KRAS* status in 206 patients with metastatic CRC.

Table S4. Clinical characteristics of patients with discordant tissue and plasma *KRAS* mutation data.

Table S5. Clinical characteristics of patients with false negatives in plasma *KRAS* mutation compared with tissue samples.

Table S6. Association between clinical characteristics and absolute levels of ctDNA.

Table S7. Association between clinical characteristics and ctDNA concentration (log scale) in metastatic CRC patients.

Table S8. Patient characteristics and plasma mutations detected after EGFR blockade.

Filename: generate.table.r

Filename: Table_S1_analysis.r

Filename: Table_S3_analysis.r

References (52–58)

(Ex.1007, 8 *see also* Ex.1076 (“A-1”), 8; Ex.1077 (“A-2”).)

46. I created a screen capture of the page providing access to the supplementary materials, Ex.1077 (“A-2”), on January 1, 2025 at this URL:
<https://www.science.org/doi/10.1126/scitranslmed.3007094>

47. Ex.1078 (“A-3”) is a download of the Supplementary Materials associated with Bettegowda, including the Materials and Methods; Fig. S1. Comparison of methods for analysis of point mutations in plasma DNA; Fig. S2. ctDNA in advanced malignancies, ranking of the fraction of patients with detectable ctDNA; and Fig S3. Diagram of the assay used to confirm rearrangements in plasma DNA, and a complete list of Supplementary Materials associated with Bettegowda, as shown below:

This PDF file includes:

Materials and Methods

Fig. S1. Comparison of methods for analysis of point mutations in plasma DNA.

Fig. S2. ctDNA in advanced malignancies, ranking of the fraction of patients with detectable ctDNA.

Fig. S3. Diagram of the assay used to confirm rearrangements in plasma DNA.

References (52–58)

Other Supplementary Material for this manuscript includes the following:

(available at www.sciencetranslationalmedicine.org/cgi/content/full/6/224/224ra24/DC1)

Table S1 (Microsoft Excel format). Summary of tissue mutations, plasma mutations, and clinical information for 410 early- and advanced-stage subjects.

Table S2 (Microsoft Excel format). Comparison of ctDNA levels assessing point mutations and rearrangements in the same specimens.
 Table S3 (Microsoft Excel format). Comparison between plasma and tumor tissue *KRAS* status in 206 patients with metastatic CRC.
 Table S4 (Microsoft Excel format). Clinical characteristics of patients with discordant tissue and plasma *KRAS* mutation data.
 Table S5 (Microsoft Excel format). Clinical characteristics of patients with false negatives in plasma *KRAS* mutation compared with tissue samples.
 Table S6 (Microsoft Excel format). Association between clinical characteristics and absolute levels of ctDNA.
 Table S7 (Microsoft Excel format). Association between clinical characteristics and ctDNA concentration (log scale) in metastatic CRC patients.
 Table S8 (Microsoft Excel format). Patient characteristics and plasma mutations detected after EGFR blockade.
 Filename: generate.table.r
 Filename: Table_S1_analysis.r
 Filename: Table_S3_analysis.r

(Ex.1078 (“A-3”), 1-2.)

48. Ex.1079 (“A-4”) is a PDF copy of an Excel download of the Supplementary Materials associated with Bettegowda, specifically Tables S-1 through S-8, as follows:

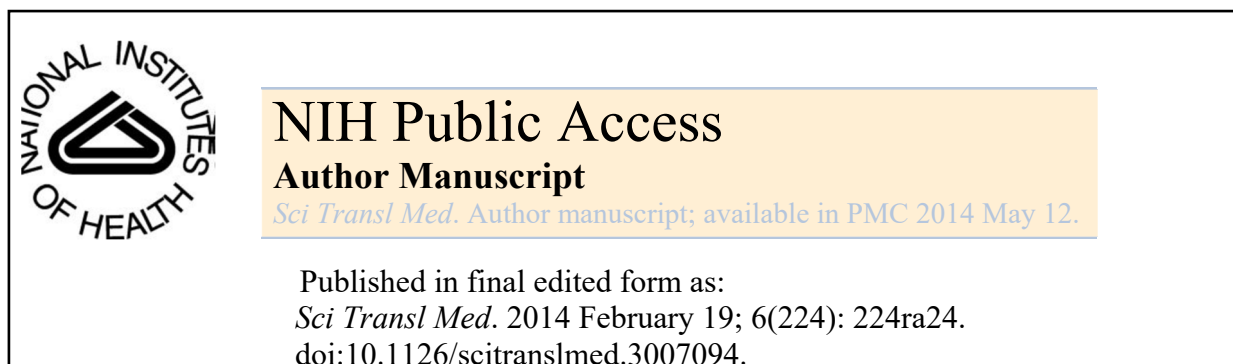
Table S1. Summary of tissue mutations, plasma mutations and clinical information for 410 early and advanced stage subjects; Table S2. Comparison of ctDNA levels assessing point mutations and rearrangements in the same specimens; Table S3. Comparison between plasma and tumor tissue *KRAS* status in 206 patients with metastatic colorectal cancer; Table S4. Clinical characteristics of patients with discordant tissue and plasma *KRAS* mutation data; Table S5. Clinical characteristics of patients with false negatives in plasma *KRAS* mutation compared

with tissue samples; Table S6. Association between clinical characteristics and absolute levels of ctDNA; Table S7. Association between clinical characteristics and ctDNA concentration (log scale) in metastatic colorectal cancer patients; and Table S8. Patient characteristics and plasma mutations detected after EGFR blockade.

49. Ex.1080 (“A-5”) is a copy of Bettegowda that I downloaded from PubMed Central (“PMC”) on December 28, 2024 at the URL:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC4017867/pdf/nihms582105.pdf>

50. The header at the top of the first page of Ex.1080 (“A-5”) details the publication of Bettegowda in *Science Translational Medicine*, in its issue published February 19, 2014, volume 6, number 224. There is a second note that states that the author manuscript was made available through PMC on May 12, 2014, as shown below.



51. After a careful review of Ex.1008 with Ex.1076 (“A-1”), Ex.1077 (“A-2”), Ex.1078 (“A-3”), Ex.1079 (“A-4”), and Ex.1080 (“A-5”) it is my opinion Bettegowda is an authentic document published in *Science Translational Medicine*,

Volume 6, Number 224, ra 224, dated February 19, 2014, on pages 1-11 and available as well in in PubMed Central. There is a slight variation in the order of the figures and tables between the two, however, all content is included without deletion or addition.

52. Therefore, I opine that Bettegowda is an authentic document. The authenticity of Bettegowda will be further examined in the Public Accessibility section below.

2. Public Accessibility

53. It is my opinion that a POSA would have been actively engaged in academic research and learning through study and practice in the field, and possibly through formal instruction through the bibliographic resources relevant to his or her research. By the 2000s, such a person with the educational background and research expectation would have had access to a vast array of print resources, including at least the documents referenced below, as well as to a fast-changing set of online resources.

54. Ex.1081 (“A-6”) is the OCLC *WorldCat* entry for Bettegowda that I completed a search and created a screen capture on December 29, 2024 at URL: <https://search.worldcat.org/title/299570656?oclcNum=299570656>

55. The *WorldCat* holding record, Ex.1081 (“A-6”), shows Bettegowda is held by 245 libraries around the world in 7 editions, which would include print

from 2009 through 2013. Beginning with Volume 6, *Science Translational Medicine* was only published digitally, i.e., available only online. No library holds a print copy Bettegowda, including the National Library of Medicine, the most likely library to receive and retain a print copy. Therefore, access to Bettegowda, *Science Translational Medicine*, Volume 6, Number 224, ra 224, dated February 19, 2014 would be by access through the internet to a library that provided online access to *Science Translational Medicine* by searching title, *Science Translational Medicine*, and/or by subject headings: *Drug development*; *Medical innovations*; *Medicine Research*; *Medicine Experimental*; and/or *Translational Medical Research*, among others.

56. Since Bettegowda was published in digital format and made available online, and not in print, there would not be a holding library of a print copy. Evidence of its publication history is given at the start of the PubMed Central article, Ex.1080 (“A-5”), as shown above and again shown below:

NIH Public Access

Author Manuscript

Sci Transl Med. Author manuscript; available in PMC 2014 May

57. To verify authenticity and public access, a citation to a publication is evidence that the publication (article, report, thesis, etc.) is considered authoritative and was publicly accessible as of the date of the published citation.

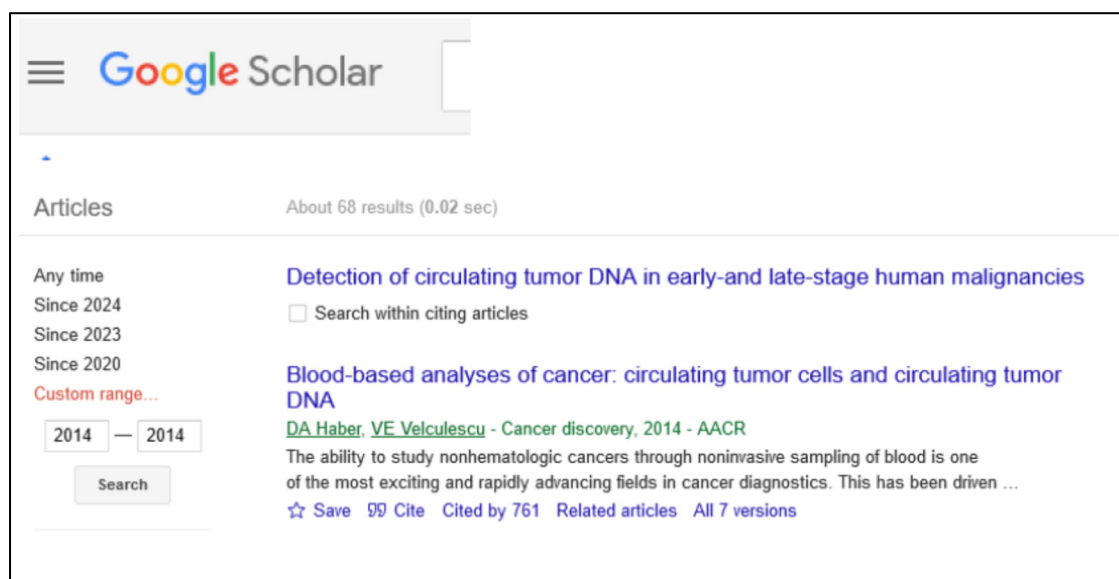
58. Ex.1082 (“A-7”) is a screen capture I made from PubMed Central on December 29, 2024. Using a combination of the subject heading, *Translational Medical Research* and Bettegowda, a set of 121 documents was retrieved. Sixth on the list was Bettegowda. This is evidence that a person with interest in this research could retrieve Bettegowda, Ex.1076 (“A1”), from PubMed Central, more likely than not, immediately after it was made accessible on PubMed Central on May 12, 2014, as shown below.

NIH Public Access

Author Manuscript

Sci Transl Med. Author manuscript; available in PMC 2014 May 12.

59. Ex.1083 (“A-8”) is a screen capture from Google Scholar that I made on January 5, 2025 that indicates the number of citations to Bettegowda during the year 2014. Limiting the retrieval of citations to Bettegowda to the year 2014 resulted in “about 68 citations” as shown below.



60. Among the citations accessible through Ex.1083 (“A-8”) at URL: https://scholar.google.com/scholar?hl=en&as_sdt=5%2C47&sciodt=0%2C47&cites=3985254756830939879&scipsc=&as_ylo=2014&as_yhi=2014 is an article by Paula Cunnea and Euan A. Stronach titled “Modeling Platinum Sensitive and Resistant High-Grade Serous Ovarian Cancer: Development and Applications of Experimental Systems” published in *Frontiers in Oncology*, volume 4, April 17, 2014, article 81, pages 1-8. (“Cunnea”) Ex.1084 (also referred to herein as “A-9”).

61. I downloaded Cunnea on January 5, 2025 through the open access URL: <https://www.frontiersin.org/journals/oncology/articles/10.3389/fonc.2014.00081/full>

62. In Cunnea, on page 8, in References, citation number 74 reads as shown below:

74. Bettgowda C, Sausen M, Leary RJ, Kinde I, Wang Y, Agrawal N, et al. Detection of circulating tumor DNA in early- and late-stage human malignancies. <i>Sci Transl Med</i> (2014) 6:224ra224. doi:10.1126/scitranslmed.3007094

63. Therefore, as of the publication date of Cunnea in *Frontiers in Oncology*, volume 4, April 17, 2014, article 81, pages 1-8, Bettgowda was considered both authoritative, having been published in a scholarly journal, and known and publicly accessible as evidenced by citation April 17, 2014.

3. Conclusion

64. Based on the evidence presented here, including publication in a scholarly journal, access provided by a research university library, Purdue University, to a scholarly database, *Science*, and a citation to Bettegowda published April 17, 2014, it is my opinion that Ex.1008, Bettegowda, is an authentic document that was publicly accessible by April 17, 2014.

B. EX.1007: Kinde, Isaac, Chetan Bettegowda, Yuxuan Wang, Jian Wu, Nishant Agrawal, Ie-Ming Shih, Robert Kurman et al. "Evaluation of DNA from the Papanicolaou Test to Detect Ovarian and Endometrial Cancers." *Science Translational Medicine*, volume 5, number 167 (January, 2013): 167ra4-167ra4, pages 1-10. ("Kinde") Kinde is also available in the PubMed Central database.

1. Authentication

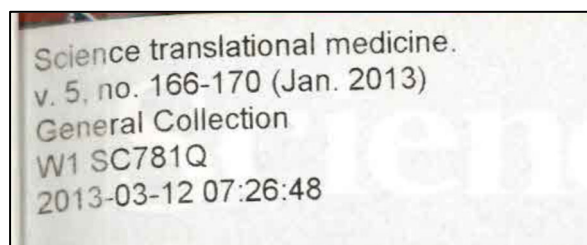
65. I have been asked to opine on the authenticity and public access of an article authored by Isaac Kinde, Chetan Bettegowda, Yuxuan Wang, Jian Wu, Nishant Agrawal, Ie-Ming Shih, Robert Kurman et al. titled "Evaluation of DNA from the Papanicolaou Test to Detect Ovarian and Endometrial Cancers" published in *Science Translational Medicine*, Volume 5, Number 167, January 2013: 167ra4-167ra4, pages 1-10. Kinde is also accessible within the PubMed Central ("PMC") database.

66. For consistency and clarification, Kinde, when used in this declaration, refers not only to the Kinde article but also to the *Science*

Translational Medicine issue in which it was published: Volume 5, Number 167, January 2013, depending on context.

67. Ex.1007 is a copy of Kinde provided to me by counsel. It appears to be from the *Science Translational Medicine* issue in which it was published: Volume 5, Number 167, January 2013, most likely downloaded from the publishers website. I will be comparing the results of my research to Ex.1007 to determine authenticity and public accessibility.

68. Ex.1085 (“B-1”) is a copy of Kinde provided to me by counsel. It appears to be the copy received and owned by the National Library of Medicine (“NLM”). It includes the cover of the issue, *Science Translational Medicine*, Volume 5, Number 166-170, January 2013, there is a label that provides a date that this issue of *Science Translational Medicine* was received by NLM that reads, “2013-03-12”, that is: March 12, 2013, as shown below; a second label that reads, “Property of the National Library of Medicine”, as shown below; Journal Information pages (2); Contents pages (2); and Kinde article, titled: “Evaluation of DNA from the Papanicolaou Test to Detect Ovarian and Endometrial Cancers.”





69. The labels applied to Ex.1085 (“B-1”) are consistent with those that I have seen over the years applied to materials retrieved from the National library of Medicine, therefore, I have no doubt that Ex.1085 (“B-1”) has been retrieved and provided to counsel by the National Library of Medicine from its print collections.

70. Ex.1086 (“B-2”) is a copy of Kinde that I downloaded from the Science database through Purdue University Libraries at this URL:
<https://www.science.org/doi/pdf/10.1126/scitranslmed.3004952>

71. It appears that Kinde is available through the URL above as an open access publication.

72. In addition to the Kinde article there are supplementary materials that were and are available linked to Kinde. Kinde lists the supplementary materials available as follows:

SUPPLEMENTARY MATERIALS

www.sciencetranslationalmedicine.org/cgi/content/full/5/167/167ra4/DC1

Materials and Methods

Table S1. Summary characteristics of endometrial cancers (endometrioid subtype) studied by whole-exome sequencing.

Table S2. Mutations identified by whole-exome sequencing in 22 endometrioid endometrial cancers.

Table S3. Clinical characteristics and mutations assessed in Pap specimens.

Table S4. Primers used to assess individual mutations in Pap specimens.

Table S5. Primers used to simultaneously assess 12 genes in Pap specimens with the multiplexed Safe-SeqS strategy.

Table S6. Mutations identified in Pap specimens through simultaneous assessment of 12 genes with the multiplexed Safe-SeqS strategy.

(Ex.1007, 8; *see also* Ex.1086 (“B-2”), 8; Ex.1085 (“B-1”), 13.)

73. Ex.1087 (“B-3”) was downloaded from

https://www.science.org/doi/suppl/10.1126/scitranslmed.3004952/suppl_file/5-167ra4_sm.pdf, linked at the Science Translational Medicine website

<https://www.science.org/doi/10.1126/scitranslmed.3004952>. Ex.1087 (“B-3”) includes a “Materials and Methods” section and a complete description of the “Supplementary Materials,” as shown below.

This PDF file includes:

Materials and Methods

Other Supplementary Material for this manuscript includes the following:

(available at www.sciencetranslationalmedicine.org/cgi/content/full/5/167/167ra4/DC1)

Table S1 (Microsoft Excel format). Summary characteristics of endometrial cancers (endometrioid subtype) studied by whole-exome sequencing.

Table S2 (Microsoft Excel format). Mutations identified by whole-exome sequencing in 22 endometrioid endometrial cancers.

Table S3 (Microsoft Excel format). Clinical characteristics and mutations assessed in Pap specimens.

Table S4 (Microsoft Excel format). Primers used to assess individual mutations in Pap specimens.

Table S5 (Microsoft Excel format). Primers used to simultaneously assess 12 genes in Pap specimens with the multiplexed Safe-SeqS strategy.

Table S6 (Microsoft Excel format). Mutations identified in Pap specimens through simultaneous assessment of 12 genes with the multiplexed Safe-SeqS strategy.

74. The listed Supplementary Materials in Ex.1087 (“B-3”) appear to correspond to the Supplementary Materials in Ex.1007.

75. Ex.1088 (“B-4”), is a PDF copy of an Excel document that includes Supplementary Tables S1-S6, as follows: Table S1. Summary Characteristics of Endometrial Cancers (Endometrioid Subtype) Studied by Whole-Exome Sequencing; Table S2. Mutations Identified by Whole-Exome Sequencing in 22 Endometrioid Endometrial Cancers; Table S3. Clinical Characteristics and Mutations Assessed in Pap Specimens; Table S4. Primers Used to Assess Individual Mutations in Pap Specimens; Table S5: Primers Used to Simultaneously Assess 12 Genes in Pap Specimens with the Multiplexed Safe-SeqS Strategy; and table S6. Mutations Identified in Pap Specimens through Simultaneous Assessment

of 12 Genes, that I downloaded, on January 1, 2025 from URL:

<https://www.science.org/doi/10.1126/scitranslmed.3004952>

76. Ex.1089 (“B-5”) is a copy of Kinde that I downloaded on January 1, 2025 from the PubMed Central at URL:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC3757513/pdf/nihms496169.pdf>

77. After careful review of Ex.1007 with Ex.1085 (“B-1”), Ex.1086 (“B-2”), Ex.1087 (“B-3”), Ex.1088 (“B-4”), and Ex.1089 (“B-5”) it is my opinion that Kinde is an authentic document published in *Science Translational Medicine*, Volume 5, Number 167 (January 2013): 167ra4-167ra4, pages 1-10. Kinde is also accessible within the PubMed Central (“PMC”). There is a slight variation in the order of the figures and tables between the two, however, all content is included without deletion or addition.

78. Therefore, I opine that Kinde is an authentic document. The authenticity will be further examined in the public access section below.

2. Public Accessibility

79. Ex.1090 (“B-6”) is the OCLC *WorldCat* entry for Kinde that I completed a search and created a screen capture on January 2, 2025 at URL:

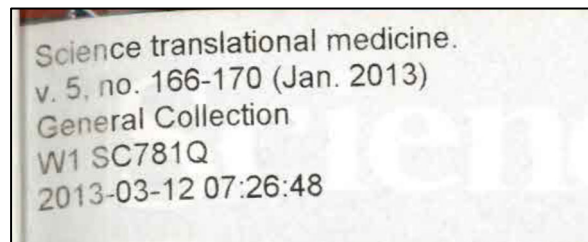
<https://search.worldcat.org/title/299570656>

80. The *WorldCat* holding record, Ex.1097 (C-6), shows Kinde is held by 246 libraries around the world in 7 editions, which would include print from

2009. The National Library of Medicine, the most likely library to receive and retain a print copy, is the second library on the holding list.

81. Therefore, access to Kinde, through *WorldCat*, to *Science Translational Medicine*, Volume 5, Number 167 (January, 2013, is by title: *Science Translational Medicine*; and/or by subject heading: *Drug development*; *Medical innovations*; *Medicine Research Medicine, Experimental* and/or *Translational Medical Research*, among others.

82. Ex.1085 (“B-1”) was received by the National Library of Medicine and labeled on March 12, 2013 (as shown below on the cover label) and consistent with my professional experience, would have been available in the National Library of Medicine within 10 days, or by March 22, 2013.



83. To verify authenticity and public access, a citation to a publication is evidence that the publication (article, report, thesis, etc.) is considered authoritative and was publicly accessible as of the date of the published citation.

84. Ex.1091 (“B-7”) is an article by Philippe L. Bedard, Aaron R. Hansen, Mark J. Ratain, and Lillian L. Siu, titled “Tumour heterogeneity in the

clinic.” published in *Nature*, Volume 501, Number. 7467, September 19, 2013 on pages 355-364 (“Bedard”).

85. I downloaded Bedard on January 2, 2025 through Purdue University Libraries after authentication at URL:

<https://link.springer.com/content/pdf/10.1038/nature12627>

86. It is available through PubMed Central at URL:
<https://pmc.ncbi.nlm.nih.gov/articles/PMC5224525/pdf/nihms839168.pdf>

87. In Bedard (Ex.1091, 9), in the [References], citation number 47 reads as shown below:

47. Kinde I, et al. Evaluation of DNA from the papanicolaou test to detect ovarian and endometrial cancers. <i>Sci. Transl. Med.</i> 2013; 5 167ra164.
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88. Therefore, as of the publication date of Bedard in *Nature*, Volume 501, Number 7467, September 19, 2013 on pages 355-364 Kinde was considered both authoritative, having been published in a scholarly journal, and known and publicly accessible as evidenced by citation in September 19, 2013.

3. Conclusion

89. Based on the evidence presented here, including publication in a scholarly journal, *Science Translational Medicine*; a print copy of Kinde held by a research library, National Library of Medicine (“NLM”); and access provided by a research university library, Purdue University, to the digital version of Kinde, I

opine that Kinde, Ex.1007, is an authentic document, and that Kinde was publicly accessible through the National Library of Medicine no later than March 22, 2013.

- C. **Ex.1006: Diaz Jr, Luis A., and Alberto Bardelli. "Liquid Biopsies: Genotyping Circulating Tumor DNA." *Journal of Clinical Oncology* 32, no. 6 (2014): 579-586. ("Diaz"). Diaz is also available through the PubMed Central database.**

1. Authentication

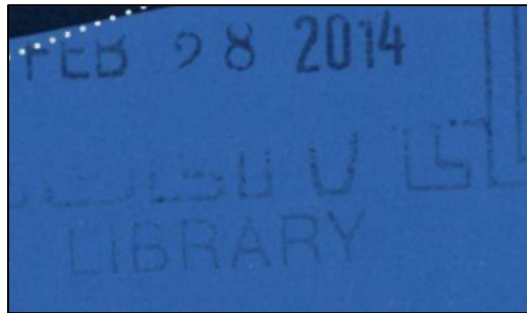
90. I have been asked to opine on the authenticity and public access of an article authored by Luis A. Diaz, Jr. and Alberto Bardelli titled "Liquid Biopsies: Genotyping Circulating Tumor DNA" published in *Journal of Clinical Oncology*, Volume 32, Number 6, February 20, 2014 on pages 579-586. ("Diaz").

91. For consistency and clarification, Diaz, when used in this declaration, refers not only to the Diaz article but also to the *Journal of Clinical Oncology* issue in which it was published: Volume 32, Number 6, February 20, 2014, depending on context.

92. Ex.1006 is a copy of Diaz provided to me by counsel. It appears to be from the *Journal of Clinical Oncology*, Volume 32, Number 6 (2014) most likely downloaded from the publishers website. I will be comparing the results of my research to Ex.1007 to determine authenticity and public accessibility.

93. Ex.1092 ("C-1") is also a copy of Diaz provided to me by counsel. It includes the cover of the issue, *Journal of Clinical Oncology* Volume 5, Number 166-170, January 2013 there is a stamp that is nearly illegible, GSU Library is hard

to discern but the date, FEB 28, 2014 is readable, as shown below. The vendor, Wisconsin Tech Search (“WTS”), Ex.1093 (“C-2”), stated that it was retrieved from Georgia Southern University–Armstrong Campus (evidence of the holdings of that library will be explored later in this declaration); Contents pages (3); Editor Roster; Journal information pages (2); and Diaz article, titled: “Liquid Biopsies: Genotyping Circulating Tumor DNA.”



94. The stamp applied to Ex.1092 (“C-1”) is consistent with those that I have seen over the years applied to materials retrieved from academic libraries. I have no reason to doubt that Ex.1092 (“C-1”) has been retrieved and provided to counsel by Wisconsin Tech Search from Georgia Southern University.

95. Ex.1094 (“C-3”) is a copy of Diaz that I downloaded from the Science database through Purdue University Libraries at this URL:

<https://oce.ovid.com/article/00005083-201432060-00016/PDF>

96. Diaz is available through this open access URL:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC4820760/pdf/jco.2012.45.2011.pdf>

97. Ex.1095 (“C-4”) is a copy of Diaz that I downloaded on January 2, 2025 from PubMed Central at URL:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC4820760/>

98. After careful review of Ex.1006 with Ex.1092 (“C-1”), Ex.1094 (“C-3”), and Ex.1095 (“C-4”) it is my opinion that Diaz is an authentic document published in *Journal of Clinical Oncology*, Volume 32, Number 6, February 20, 2014 on pages 579-586 Diaz is also accessible within the PubMed Central (“PMC”). There is a slight variation in the order of the figures and tables between the two, however, all content is included without deletion or addition.

99. Therefore, I opine that Diaz is an authentic document. The authenticity will be further examined in the public access section below.

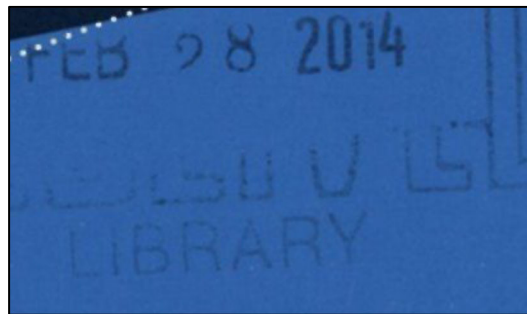
2. Public Accessibility

100. Ex.1096 (“C-5”) is the OCLC *WorldCat* entry for Diaz that I completed a search and created a screen capture on January 2, 2025 at URL:
<https://search.worldcat.org/title/8320014>

101. The *WorldCat* holding record, Ex.1096 (“C-5”), when Georgia was used as the geographical limiter, shows Diaz is held by 1018 libraries around the world in 11 editions, which would include print from 1983. Georgia Southern University–Armstrong Campus is the first library on the holding list.

102. Therefore, access to Diaz, through *WorldCat*, to *Journal of Clinical Oncology* is by title: *Journal of Clinical Oncology*; and/or by subject heading: *cancer, medical oncology, and/or oncology* among others.

103. Ex.1092 (“C-1”) was received by the Georgia Southern University–Armstrong Campus Library on FEB 28 2014 (as shown below on the cover label) and consistent with my professional experience, would have been available in the Georgia Southern University–Armstrong Campus Library within 10 days, or by March 10, 2014.



104. Ex.1097 (“C-6”) is a screen capture from the online catalog (“OPAC”) from the Georgia Southern University Libraries (“GSU”) that I created on December 27, 2024. Within this record there is evidence that GSU Libraries has Diaz within its print collections through its holdings record.




JOURNAL
Journal of clinical oncology : official journal of the American Society of Clinical Oncology.
 New York, N.Y. : Grune & Stratton ©1983-
 Available at Lane Library Periodicals, 2nd floor (RC254.A1 J68) >

LOCATION ITEMS

Lane Library
 Available , Periodicals, 2nd floor ; RC254.A1 J68
 Holdings: v.22-v.38(2004-2020)

105. The holdings record above indicates volumes held are: v.22-38 (2004-2020), inclusive of Volume 32, Number 6, 2014, Diaz would indeed be held within the GSU Libraries.

106. To verify authenticity and public access, a citation to a publication is evidence that the publication (article, report, thesis, etc.) is considered authoritative and was publicly accessible as of the date of the published citation.

107. Ex.1098 (“C-7”) is an article by Alix-Panabières, Catherine, and Klaus Pantel. “Challenges in Circulating Tumour Cell Research” *Nature Reviews Cancer*, volume 14, number 9, July 2014, on pages 623-631. (“Alix-Panabières”).

108. I downloaded Alix-Panabières on January 2, 2025 through Purdue University Libraries after authentication at URL:
<https://link.springer.com/content/pdf/10.1038/nrc3820>

109. In Alix-Panabières, (Ex.1098, 9), in the [References], citation number 97 reads as shown below:

97. Diaz, L. A. Jr & Bardelli, A. Liquid biopsies: genotyping circulating tumor DNA. <i>J. Clin. Oncol.</i> 32 , 579–586 (2014).

110. Therefore, as of the publication date of Alix-Panabières in *Nature Reviews Cancer*, Volume 14, Number 9, July 2014, on pages 623-631. Diaz was considered both authoritative, having been published in a scholarly journal, and known and publicly accessible as evidenced by citation in July 2014.

3. Conclusion

111. Based on the evidence presented here, including publication in a scholarly journal, *Science Translational Medicine*; print copy of Diaz held by a research library, Georgia Southern University; and access provided by a research university library, Purdue University, to the digital version of Diaz, and accessible digitally through the PubMed database, I opine that Diaz, Ex.1006, is an authentic document, and that Diaz was publicly accessible through the Georgia Southern University Libraries no later than March 10, 2014.

D. Ex.1010: Fleischhacker, Michael, and Bernd Schmidt. "Circulating Nucleic Acids (CNAs) and Cancer—A Survey." *Biochimica et Biophysica Acta (BBA)-Reviews on Cancer* 1775, no. 1 (2007): 181-232.

1. Authentication

112. I have been asked to opine on the authenticity and public access of an article authored by Michael Fleischhacker and Bernd Schmidt, titled: “Circulating Nucleic Acids (CNAs) and Cancer—A Survey” published in *Biochimica et Biophysica Acta (BBA)*, in volume 1775, number 1, January 2007 on pages 181-232. (“Fleischhacker”)

113. For consistency and clarification, Fleischhacker, when used in this declaration, refers not only to the Fleischhacker article but also the journal volume and issue in which it was published: *Biochimica et Biophysica Acta (BBA)*, Volume 1775, Number 1, January 2007.

114. I have evaluated the Fleischhacker reference in three ways: (1) by assessing a copy of Fleischhacker (Ex.1010) provided to me by counsel; (2) accessing and assessing a scan of Fleischhacker, Ex.1099 (“D-1”), I obtained from the print copy owned by the Linda Hall Library, Kansas City, Missouri, a pre-eminent research library in the areas of science, engineering and technology on December 30, 2024; and (3) by retrieving and reviewing a download, Ex.1100 (“D-2”), I made through Purdue University Libraries by my emeritus faculty status

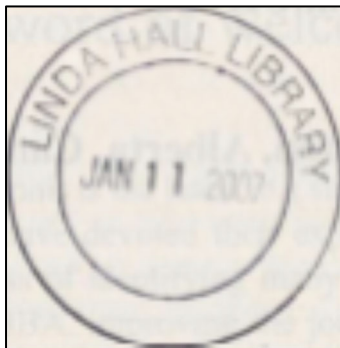
from *Science Direct* at URL:

<https://www.sciencedirect.com/science/article/abs/pii/S0304419X0600059X>

115. Fleischhaker is available for a fee at this URL:

<https://www.sciencedirect.com/getaccess/pii/S0304419X0600059X/purchase>

116. Ex.1099 (“D-1”) is a scan of Fleischhacker owned by the Linda Hall Library that includes the issue cover of *Biochimica et Biophysica Acta (BBA)*, Volume 1775, Number 1, January 2007; title page with a stamp that reads “LINDA HALL LIBRARY JAN 11 2007”, as shown below (quite faint), that indicates ownership and date of receipt by the Linda Hall Library, Kansas City, Missouri. The date indicates it was received and “checked-in” to the collections of the Linda Hall Library, on January 11, 2007; and the Fleischhacker article, pages 181-232.



117. All identifying characteristics, such as the stamp on Ex.1099 (“D-1”) are consistent with library practice and procedure that I have observed during my career as a professional librarian. I have no cause for concern about the authenticity or accuracy of these identifying attributes. Ex.1099 (“D-1”) was

found within the custody of a library, the Linda Hall Library, one of the most likely locations for an authentic publication.

118. Ex.1100 (“D-2”) is a copy of Fleischhacker that I retrieved on December 27, 2024, from through the Purdue University Libraries by my emeritus faculty status through the *Science Direct* database, as described above, at this URL: <https://www.sciencedirect.com/science/article/abs/pii/S0304419X0600059X>

119. Fleischhacker is available for a fee at this URL:
<https://www.sciencedirect.com/getaccess/pii/S0304419X0600059X/purchase>

120. After comparing Fleischhacker as it appeared in Ex.1099 (“D-1”) and Ex.1100 (“D-2”), I conclude, based on finding Fleischhacker in print in a library – Linda Hall – and online through a reputable, publisher database, *Science Direct*, that Fleischhacker is an authentic document, and that Ex.1099 (“D-1”) and Ex.1100 (“D-2”) are authentic and accurate copies of Fleischhacker. I then compared Ex.1099 (“D-1”) and Ex.1100 (“D-2”) with Ex. 1010, provided by counsel, and I found no difference.

121. Therefore, I conclude and affirm Fleischhacker is an authentic document.

2. Public Accessibility

122. Ex.1101 (“D-3”) is a true and correct copy of the *WorldCat* entry for Fleischhacker, Fleischhacker was included among the articles published in

Biochimica et Biophysica Acta (BBA), volume 1575, number 1, January 2007, on pages 181-232.

123. I obtained Ex.1101 (“D-3”) by completing a search on *WorldCat* on January 3, 2025. The document cataloged in this record is a periodical record for *Biochimica et Biophysica Acta (BBA)* as verified by title: *Biochimica et Biophysica Acta (BBA)*; publisher and publication date: Elsevier, 1947–1947 - indicates an ‘open entry’, that is, a serial that continues that started in 1947.

124. When undertaking the search of *WorldCat* as described above using the geographical location of Kansas City, Missouri, the Linda Hall Library was second on list of 951 libraries that hold *Biochimica et Biophysica Acta (BBA)* worldwide.

125. *Biochimica et Biophysica Acta (BBA)*, Fleischhacker, could have been identified and located in a library in print by searching title: *Biochimica et Biophysica Acta (BBA)*; and/or by subject headings: *Biochemistry* and/or *Biophysics*.

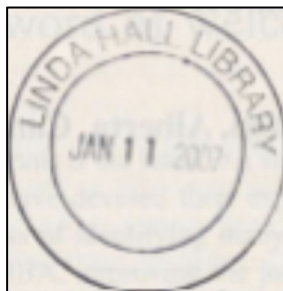
126. Ex.1102 (“D-4”) is a screen capture I made from the Linda Hall Library OPAC (online catalog) on January 3, 2025. The document cataloged in this record is a periodical record for: *Biochimica et Biophysica Acta (BBA)*, publisher and publication date: Elsevier, 1947. The 1947- indicates an ‘open entry’, that is, a serial that will continue that started in 1947. Under “Item in

Place” it reads as follows: “v.1775-1776 (2007)”, as shown below, this string indicates that the Linda Hall Library holds the issue that includes the article by Fleischhacker.



127. Fleischhacker could have been located by searching on the Linda Hall Library OPAC (online catalog) for the title: *Biochimica et Biophysica Acta (BBA)*; and/or by searching the subject heading: *Biochemistry* and/or *Biophysics*

128. On Ex.1099 (“D-1”) is the ownership and date stamp on the cover that reads “LINDA HALL JAN 11 2007 LIBRARY”, as shown below. The date of January 11, 2007 would be when receipt and the processing began on *Biochimica et Biophysica Acta (BBA)*, volume 1775, number 1, January 2007 by the Linda Hall Library.



129. Consistent with standard library policy and practice, this issue would have been accessible on the shelf in the Linda Hall Library within a week to ten days after receipt by the library, that is, no later than January 21, 2007.

3. Conclusion

130. I conclude that Fleischhacker, Ex.1010, is an authentic document and would have been publicly accessible through the Linda Hall Library, more likely than not, January 21, 2007.

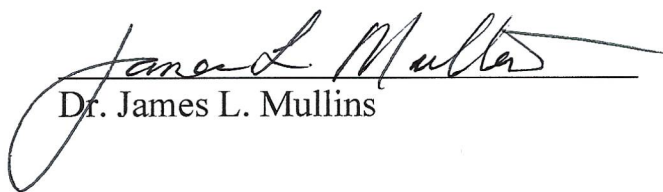
V. RIGHT TO SUPPLEMENT

131. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available to me.

VI. JURAT

132. 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 full 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 U.S. Code.

Dated: January 14, 2025


Dr. James L. Mullins