UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MOTIF FOODWORKS, INC.,
Petitioner,

v.

IMPOSSIBLE FOODS INC.,
Patent Owner.

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Case No.: IPR2023-00322
U.S. Patent No. 10,273,492

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DECLARATION OF SYLVIA D. HALL-ELLIS, Ph.D., IN SUPPORT OF PETITIONS FOR *INTER PARTES* REVIEW OF U.S. PATENT NOS. 10,273,492 AND 10,689,656

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EX-1005	Vogl et al., *Regulation of Pichia pastoris promoters and its consequences for protein production*, NEW BIOTECHNOLOGY, 30(4), 385-404 (2013) ("Vogl")
EX-1006	Lin-Cereghino et al., *Regulator of the methanol utilization pathway and peroxisomal genes in Pichia pastoris*, MOLECULAR & CELLULAR BIOLOGY, 26(3), 883-897 (2006) ("Lin-Cereghino")
EX-1011	Liu et al., *Balanced globin protein expression and heme biosynthesis improve production of human hemoglobin in Saccharomyces cerevisiae*, METABOLIC ENGINEERING, 21, 9-16 (2014) ("Liu")
EX-1012	Vedvick et al., *High-level secretion of biologically active aprotinin from the yeast Pichia pastoris*, J. INDUSTRIAL MICROBIOLOGY, 7, 197-202 (1991) ("Vedvick")
EX-1013	Engel et al., *Foods and food ingredients produced via recombinant DNA techniques*, GENETICALLY MODIFIED FOODS – ACS SYMPOSIUM SERIES, 605, Chapter 1, 1-10 (1995) ("Engel")
EX-1014	Garrocho-Villegas et al., *Plant hemoglobin: What we know six decades after their discovery*, GENE, 398, 78-85 (2007) ("Garrocho")
EX-1015	Lin-Cereghino & Cregg, *Heterologous protein expression in the methylotrophic yeast Pichia pastoris*, FEMS MICROBIOLOGY REVIEWS, 24, 45-66 (2000) ("Lin-Cereghino 2000")
EX-1016	Hartner et al., *Regulation of methanol utilisation pathway genes in yeasts*, MICROBIAL CELL FACTORIES, 5, 39 (2006) ("Hartner_2006")
EX-1017	Hartner et al., *Promoter library designed for fine-tuned gene expression in Pichia pastoris*, NUCLEIC ACIS RESEARCH, 36(12), e76 (2008) ("Hartner_2008")
EX-1018	De Schutter et al., *Genome sequence of the recombinant protein production host Pichia pastoris*, NATURE BIOTECHNOLOGY, 27(6), 561-566 (2009) ("De_Schutter")

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EX-1019	Kranthi et al., *Identification of key DNA elements involved in promoter recognition by Mxr1p, a master regulator of methanol utilization pathway in Pichia pastoris*, BIOCHIMICA ET BIOPHYSICA ACTA, 1789, 460-468 (2009) ("Kranthi_2009")
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EX-1022	Zhang et al., *Heterologous protein expression in yeasts and filamentous fungi*, MANUAL OF INDUSTRIAL MICROBIOLOGY & BIOTECHNOLOGY, 145-156 (Bull et al. ed. 2010) ("Zhang")
EX-1023	Kranthi et al., *Identification of Mxr1p-binding sites in the promoters of genes encoding dihydroxyacetone synthase and peroxin 8 of the methylotrophic yeast Pichia pastoris*, YEAST, 27, 705-711 (2010) ("Kranthi_2010")
EX-1026	Parua et al., *Pichia pastoris 14-3-3 regulates transcriptional activity of the methanol inducible transcription factor Mxr1 by direct interaction*, MOLECULAR MICROBIOLOGY, 85(2), 282-298 (2012) ("Parua")
EX-1027	Rabert et al., *Recombinants proteins for industrial uses: utilization of Pichia pastoris expression system*, BRAZILIAN J. MICROBIOLOGY, 44(2), 351-356 (2013) ("Rabert")
EX-1028	Stryjewska et al., *Biotechnology and genetic engineering in the new drug development. Part I. DNA technology and recombinant proteins*, PHARMACOLOGICAL REPORTS, 65, 1075-1085 (2013) ("Stryjewska")
EX-1029	Ahmad et al., *Protein expression in Pichia pastoris: recent achievements and perspectives for heterologous protein production*, APPLIED MICROBIOLOGY AND BIOTECHNOLOGY, 98, 5301-5317 (2014) ("Ahmad")
EX-1030	Haon et al., *Recombinant protein production facility for fungal biomass-degrading enzymes using the yeast Pichia pastoris*, FRONTIERS IN MICROBIOLOGY, 6, 1002 (2015) ("Haon")

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EX-1031	Krainer et al., *Optimizing cofactor availability for the production of recombinant heme peroxidase in Pichia pastoris*, MICROBIAL CELL FACTORIES, 14(4), 1-9 (2015) ("Krainer")
EX-1032	Guarna et al., *On-line monitoring and control of methanol concentration in shake-flask cultures of Pichia pastoris*, BIOTECHNOLOGY & BIOENGINEERING, 56(3), 279-286 (1997) ("Guarna")
EX-1033	Katakura et al., *Effect of methanol concentration on the production of human β_2-glycoprotein I Domain V by a recombinant Pichia pastoris: a simple system for the control of methanol concentration using a semiconductor gas sensor*, J. FERMENTATION & BIOENGINEERING, 86(5), 482-487 (1998) ("Katakura")
EX-1034	Hong et al., *Fermentation strategies for improved heterologous expression of laccase in Pichia pastoris*, BIOTECHNOLOGY & BIOENGINEERING, 79(4), 438-449 (2002) ("Hong")
EX-1035	Trinh et al., *Effect of methanol feeding strategies on production and yield of recombinant mouse endostatin from Pichia pastoris*, BIOTECHNOLOGY & BIOENGINEERING, 82(4), 438-444 (2003) ("Trinh")
EX-1036	Bawa et al., *Functional recombinant protein is present in the pre-induction phases of Pichia pastoris cultures when grown in bioreactors, but not shake-flasks*, MICROBIAL CELL FACTORIES 13(127), 1-13 (2014) ("Bawa")
EX-1037	Ferreira, *Heme synthesis*, ENCYCLOPEDIA OF BIOLOGICAL CHEMISTRY, 539-42 (2013) ("Ferreira")
EX-1041	Cantor & Smith, GENOMICS: THE SCIENCE AND TECHNOLOGY BEHIND THE HUMAN GENOME PROJECT, 13 (John Wiley & Sons ed. 1999)
EX-1042	Alberts et al., MOLECULAR BIOLOGY OF THE CELL, 305-312, 334-336, 538-540 (4th ed. 2002)
EX-1043	Freeman, Biological Sciences, 338-400 (2d ed. 2005)

Exhibit	Description
EX-1044	Nicola & Leach, *Structural Rearrangements Due to Ligand Binding and Haem Replacement in Myoglobin and Leghaemoglobins*, 78 EUROPEAN J. BIOCHEM. 133-40 (1977)
EX-1045	Hargrove et al., *Characterization of Recombinant Soybean Leghemoglobin a and Apolar Distal Histidine Mutants*, 266 J. MOLECULAR BIOLOGY 1032-42 (1997)
EX-1054	Benson, Dennis A., Karen Clark, Ilene Karsch-Mizrachi, David J. Lipman, James Ostell, and Eric W. Sayers. "GenBank." *Nucleic Acids Research*, vol. 42 (2014): D32-D37

I, Sylvia D. Hall-Ellis, Ph.D., declare as follows:

I. INTRODUCTION

1. I have been retained by Motif FoodWorks, Inc. ("Client" or "Petitioner") as an expert in the proceedings regarding U.S. Patent Nos. 10,273,492 and 10,689,656 ("Challenged Patents") before the United States Patent and Trademark Office Patent Trial and Appeal Board.

2. I have written this Declaration at the request of Petitioner to provide my expert opinion regarding the authenticity and public availability of several publications. This Declaration sets forth my opinions in detail and provides the bases for my opinions.

3. I reserve the right to supplement or amend my opinions, and bases for them, in response to any additional evidence, testimony, discovery, argument, and/or other additional information that may be provided to or obtained by 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 dispute. I have no other interests in these proceedings or with any of the parties.

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

II. PROFESSIONAL BACKGROUND AND 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 and Information 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 founding 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 served as the Chair for the ALA Office of Diversity's Committee on Diversity, a member of the REFORMA National Board of Directors, a member of the Editorial Board for the ALCTS premier cataloging journal, *Library Resources*

and Technical Services, and as a Co-Chair of the Membership Committee for the Library Research Round Table (LRRT) of the American Library Association. Currently I serve as a member of the LRRT Nominating Committee.

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-six times: (1) *Symantec Corp. v. Finjan*, *Inc.,* Petition for *Inter Partes Review* of U.S. Patent No. 7,613,926, IPR 2015-01892, May 26, 2016, on behalf of Symantec Corp.; (2) *Symantec Corp. v. 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 v. 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 v. 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 v. T-Mobile USA, Inc. and T-Mobile US, Inc.,* C.A. No. 13-1632 (LPS); *Intellectual Ventures II LLC v. T-Mobile USA, Inc. and T-Mobile US, Inc.,* C.A. No. 13-1633 (LPS); *Intellectual Ventures I LLC, v. 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 v. 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, v. United States Cellular Corporation*, C.A. No. 13-1636 (LPS); *Intellectual Ventures I LLC v. United States Cellular Corporation*, C.A. No. 13-1637 (LPS); *Intellectual Ventures II LLC v. AT&T Mobility LLC*, *AT&T Mobility II LLC, New Cingular Wireless Services, Inc.,* C.A. No. 15-799 (LPS); *Intellectual Ventures I LLC v. 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. v. General Access Solutions, Ltd*., Petition for *Inter Partes Review* of U.S. Patent No. 7,173,916, IPR 2017-01885, on behalf of Sprint Spectrum L.P., July 13, 2018; (6) *Nichia Corporation v. Vizio, Inc*., 8:16-cv-00545; on behalf of Vizio, Inc., October 12, 2018; (7) *Intellectual Ventures I LLC, v. 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. v. Biogen, Inc.,* Petition for *Inter Partes Review* of U.S. Patent No. 8,821,873, IPR 2017-01168, on behalf of Pfizer, November 3, 2018; (9) *Finjan, Inc. v. ESET, LLC and ESET SPOL. S.R.O.,* 3:17-cv-00183-CAB-BGS, on behalf of ESET, January 15, 2019; (10) *Finjan, Inc. v. 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. v. Blackberry Limited* 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*, District of Delaware, 1:18-cv-01519-MN, September 15, 2020, on behalf of Rapid7 Inc. and Rapid7 LLC; (14) *VLSI Technology LLC v. Intel Corporation*, Western District of Texas, 6:19-cv-00254, 6:19-cv-00255, 6:19-cv-00256, September 23, 2020, on behalf of the Intel Corporation; (15) *Finjan Inc. v. Sonicwall, Inc.,* Northern District of California, 5:17-cv-04467-BLF-HRL, October 27, 2020, on behalf of Sonicwall, Inc.; (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. 3BCOM, LLC*, Petition for *Inter Partes Review* of U.S. Patent 7,127,210, 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; and, (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; (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.; (23) *EcoFactor, Inc. v. Google, Inc.,* Western District of Texas, 6:20-cv-00075 (ADA), 6:20-0078-ADA, and 6:20-cv-00080 ADA, October 27, 2021, on behalf of Google, Inc.; (24) *Liquidia Technologies, Inc. v. United Therapeutics Corporation*, Petition for *Inter Partes Review* of U.S. Patent 10,716,793 B2, March 11, 2022, on behalf of Liquidia Technologies, Inc.; (25) *Juniper Networks, Inc. v. Swarm Technology LLC*, Petition for *Inter Partes Review* of U.S. Patent 9,852,004, May 5, 2022, on behalf of Juniper Networks, Inc.; and, (26) *ParkerVision, Inc. v.*

Intel Corporation, Western District of Texas, 6:20-cv-108 (ADA), October 26, 2022, on behalf of the Intel Corporation.

10. My full *curriculum vitae* is submitted as EX-1058.

III. PRELIMINARIES

A. Scope of this Declaration

11. 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 documents referenced herein and on when and how each of these documents was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, could have located the documents before May 11, 2015.

12. 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 documents themselves, such as the appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all of the circumstances. I am further informed that an item is considered authentic if it is at least 20 years old, in a condition that creates no suspicion of its authenticity, and in a place where, if authentic, it would likely be. Lastly, I have been informed that a

document's authenticity can be established by comparison with an authentic specimen.

13. 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.

14. 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. That is, I understand that cataloging and indexing by a library is sufficient, although 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.

15. 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. I also understand that the indicia on the face of a reference, such as printed dates and stamps, are considered as part of the totality of the evidence.

B. Person of Ordinary Skill in the Art

16. I am told by counsel that the subject matter of these proceedings relates generally to recombinant protein production.

17. 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.

18. I am told by counsel that with respect to the Challenged Patents, a person of ordinary skill in the art would have had at least a Bachelor of Science in biochemistry, chemistry, biological sciences, or an equivalent area of study. A

person of ordinary skill in the art would also have at least three years of graduate study or professional experience with recombinant techniques for protein production or general genetic modification experience.

19. It is my opinion that such a person would have been engaged in research, learning through study, and practice in the field and possibly through formal instruction the bibliographic resources relevant to his or her research. By not later than mid-2015 (and more specifically, May 2015), such a person would have had access to a vast array of long-established print resources in the field, as well as to a rich set of online resources providing indexing information, abstracts, and full text services for publications relevant to the field of this dispute.

C. Authoritative Databases

20. In preparing this report, I used authoritative databases, such as the OCLC *WorldCat*, the Library of Congress Online Catalog, the U.S. Copyright Office database, the Internet Archive and its WayBack Machine, *ResearchGate*, and *Semantic Scholar*, to confirm citation details of the various publications discussed.

21. ***OCLC WorldCat Database***. The OCLC was created "to establish, maintain and operate a computerized library network and to promote the evolution of library use, of libraries themselves, and of librarianship, and to provide processes and products for the benefit of library users and libraries, including such objectives as increasing availability of library resources to individual library patrons and

reducing the rate of rise of library per-unit costs, all for the fundamental public purpose of furthering ease of access to and use of the ever-expanding body of worldwide scientific, literary and educational knowledge and information."[1] Among other services, OCLC and its members are responsible for maintaining the *WorldCat* database,[2] used by independent and institutional libraries throughout the world.

22. ***U.S. Copyright Office***. Created by Congress in 1897, the Copyright Office is responsible for administering a complex and dynamic set of laws, which include registration, the recordation of title and licenses, a number of statutory licensing provisions, and other aspects of the *1976 Copyright Act* and the *1998 Digital Millennium Copyright Act*. The public catalog in the Copyright Office includes information filed since 1978.[3] Individuals can search by title, personal or corporate name, key word, registration number, and document number. Works filed before 1978 can be located through the Copyright Public Records Reading Room.[4]

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[1] 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.

[2] http://www.worldcat.org/.

[3] https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?DB=local&PAGE=First.

[4] https://www.copyright.gov/circs/circ23.pdf.

A researcher can find the date on which an item was published and deposited for copyright.

23. ***Internet Archive***.[5] The Internet Archive, a 501(c)(3) non-profit, is an online digital archive of Internet web sites and web pages and other cultural artifacts in digital form. Like a paper library, the Internet Archive provides free access to researchers, historians, scholars, the print disabled, and the general public. The organization's mission is to provide Universal Access to All Knowledge.

24. The Internet Archive maintains an archive of webpages collected from the Internet using software called a crawler. Crawlers automatically create a snapshot of webpages as they existed at a certain point in time. The WayBack Machine is an application using a crawler created by the Internet Archive to search its archive of web page URLs and to represent, graphically, the date of each crawler capture. The Internet Archive captures data that is openly available to users of the Internet. Some sites are "not archived because they were password protected, blocked by robots.txt, or otherwise inaccessible to [its] automated systems. Site owners might have also requested that their sites be excluded from the WayBack Machine."[6] Many Internet Archive captures made by the WayBack Machine have a

[5] https://archive.org/.

[6] https://help.archive.org/hc/en-us/articles/360004716091-Wayback-Machine-General-Information.

banner at the top with the capture date prominently displayed. Other dates when captures of the same URL have been made are indicated to the right and left of the date provided in the banner. Some captures may lack this banner. In any case, the URL for the capture begins with the identification of the Internet Archive page (e.g., http://web.archive.org/web/) followed by information that dates and time stamps the capture as follows: year in yyyy, month in mm, day in dd, time code in hh:mm:ss (e.g., 20071120082013, or November 20, 2007 at 8:20:13 a.m.). These elements are then followed by the URL of the original capture site. When links are active, the WayBack Machine is programed to produce the archived file with the closest available date (not the closest available prior date) to the page upon which the link appeared and was clicked. I and other professionals in the field of library and information resources are familiar with the Internet Archive and the Wayback Machine. As previously noted, the Internet Archive and the Wayback Machine are among the types of information reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on matters that are the subject of their work.

25. ***ResearchGate***.[7] A European-based social networking site for scientists and researchers to share papers, ask and answer questions, and find collaborators,

[7] https://www.researchgate.net/.

ResearchGate is the largest academic social network in terms of active users, although other services have more registered users. As of 2021, *ResearchGate* had more than 20 million scientists, with its largest user-bases coming from Europe and North America. Most of *ResearchGate's* users are involved in medicine, biology, engineering, computer science, agricultural sciences, and psychology.

26. Features available to *ResearchGate* members include following a research interest and the work of other individual participants, a blogging feature for users to write short reviews on peer-reviewed articles, private chat rooms for sharing data, editing documents, or discussing confidential topics, and a research-focused job board. *ResearchGate* indexes self-published information on user profiles and suggests members to connect with others who have similar interests. Member questions are fielded to others who have identified relevant expertise on their profiles.

27. ***Semantic Scholar***.[8] A project developed at the Allen Institute for Artificial Intelligence and publicly released in November 2015, *Semantic Scholar* is designed to be an AI-backed search engine for scientific journal articles which uses a combination of machine learning, natural language processing, and machine vision to add a layer of semantic analysis to the traditional methods of citation

[8] https://www.semanticscholar.org.

analysis, and to extract relevant figures, entities, and venues from papers. *Semantic Scholar* is designed to highlight important, influential papers, and to identify the connections between them.

28. As of January 2018, following a 2017 project that added biomedical papers and topic summaries, the *Semantic Scholar* corpus included more than 40 million papers from computer science and biomedicine. In March 2018, Doug Raymond, who developed machine learning initiatives for the Amazon Alexa platform, was hired to lead the *Semantic Scholar* project. As of August 2019, the number of included papers had grown to more than 173 million after the addition of the Microsoft Academic Graph records, already used by Lens.org.

D. Indexing

29. 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.

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. Before the widespread development of online databases to index articles in journals, magazines, conference papers, and technical reports, libraries purchased printed volumes of indices. Graduate library school education mandated that students learn about the bibliographic control of disciplines, the prominent indexing volumes, and searching strategies required to use them effectively and efficiently. Half of the courses that I studied in library school were focused on the bibliography and resources in academic disciplines.

32. Librarians consulted with information seekers to verify citations, check availability in union catalogs, printed books catalogs, and the OCLC database, and make formal requests for materials, *e.g.*, books, conference proceedings, journal articles. Requests were transmitted using Telex machines, rudimentary email systems, and the United States Postal Service. During my career, I have performed and supervised staff who handled these resource sharing tasks.

33. 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 no later than the publication date of the citing document.

IV. LIBRARY CATALOGING PRACTICES

A. Machine-Readable Cataloging (MARC) Standard

34. 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.[9] MARC was first developed in the 1960s 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.[10]

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[9] The full text of the standard is available from the Library of Congress at http://www.loc.gov/marc/bibliographic/.

[10] 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 December 1, 2022) ("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.

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 bibliographic metadata in libraries.[11] 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.

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

[11] 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 December 1, 2022).

> 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 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, http://www.loc.gov/marc/umb/um01to06.html#part2 (last visited December 1, 2022).

35. Thus, 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 December 1, 2022) ("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.[12]

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

36. 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 title is recorded in field 245, the primary author or creator of the work is recorded in field 100, an item's International Standard Book Number ("ISBN") is recorded in field 020, an item's International Standard Serial Number ("ISSN") is recorded in field 022, an item's Library of Congress call number is recorded in field 050, and the publication date is recorded in field 260 under the subfield "c." *Id.*[13] If a work is a periodical, then its publication frequency is recorded in field 310, alternate publication frequency is recorded in field 321, 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.[14]

37. MARC records also include several fields that include subject matter classification information. An overview of MARC record fields is available through

[13] In some MARC records, field 264 is used rather than field 260 to record publication information. *See* http://www.loc.gov/marc/bibliographic/bd264.html (last visited December 1, 2022) ("Information in field 264 is similar to information in field 260 (Publication, Distribution, etc. (Imprint)). Field 264 is useful for cases where the content standard or institutional policies make a distinction between functions").

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

the Library of Congress website.[15] For example, 6XX fields are termed "Subject Access Fields."[16] Among these, for example, is the 650 field; this is the "Subject Added Entry – Topical Term" field.[17] The 650 field is a "[s]ubject added entry in which the entry element is a topical term."[18] These authenticated subject 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))."[19]

38. Further, MARC records include call numbers, which themselves indicate a subject and physical location within the library collections. For example, the 050 field is the "Library of Congress Call Number."[20] A defined portion of the Library of Congress Call Number is the classification number, and "source of the classification number is *Library of Congress Classification* and the *LC Classification-Additions and Changes*."[21] Thus, included in the 050 field is a subject matter classification. Each item in a library has a single classification number. A

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

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

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

[18] *Id*.

[19] *Id*.

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

[21] *Id*.

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 or the National Library of Medicine Classification scheme) and uses it consistently. When the Library of Congress assigns the classification number, it appears as part of the 050 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.

39. For MARC records created by libraries other than the Library of Congress (*e.g.*, a university library or a local public library), the classification number may appear in a 09X (*e.g.*, 090) field.[22]

40. OCLC 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 were initially tape-loaded into the OCLC database through a subscription to MARC Distribution Services daily or weekly. Once the MARC record is created by a cataloger at an OCLC member institution or tape-loaded from the Library of Congress, the MARC record is then made available to any other OCLC members

[22] http://www.loc.gov/marc/bibliographic/bd09x.html.

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.

41. 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."[23] 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 attachments to this report—the date reflected next to the label "Entered" is necessarily on or after the date the library first cataloged and indexed the underlying item.

42. 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 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. It also allows librarians around the world to know that a particular MARC record is

[23] In this report, I sometimes refer to the "Entered" entry as field 008, characters 00-05. 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."

authoritative. In contrast, a hypothetical system wherein duplicative records were created would result in confusion as to which record is authoritative.

43. 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.

44. In addition to creating records for books, OCLC also hosts records for serial publications. Serial publications have the same collective title but are intended to continue 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, but the date is left open-ended with the use

of a punctuation mark such as a dash. Individual issues are not cataloged according to the current national cataloging rules outlined in *RDA: Resource and Access*.

45. MARC records for serial publication in OCLC represent the entire run of the serial title. With knowledge of the first issue published, future issues can be predicted. 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 local MARC record.

46. 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.

47. 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 the serial publications discussed below.

V. PUBLICATIONS

48. I understand that Petitioner is submitting certain non-patent-literature references as Exhibits 1005-1006, 1011-1019, 1021-1023, 1026-1037, 1041-1045, and 1054 in support of its petitions in these proceedings. For my analysis below, I independently obtained copies of each of those references from third parties, such as libraries, which are submitted as exhibits to my declaration as EX-1059. I also reviewed each of Exhibits 1005-1006, 1011-1019, 1021-1023, 1026-1037, 1041-1045, and 1054 Petitioner is submitting. I find them to be identical to the respective copies of the same references I obtained from independent sources, which are discussed in my analysis below and submitted as EX-1059.

A. Vogl article [Exhibit 1005]

49. Attached hereto as Exhibit 1005 is a copy of the journal article, "Regulation of *Pichia pastoris* Promoters and Its Consequences for Protein Production," by Thomas Vogl and Anton Glieder (hereafter "Vogl"). The Vogl article was published in Volume 30, Number 4 of the journal *New Biotechnology*. This issue is dated May 25, 2013, and the article begins on page 385.

50. I obtained Exhibit 1005 from the National Library of Medicine (Bethesda, Maryland). Exhibit 1005 is a true and correct copy of the Vogl article (pages 385-404). 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. The Vogl article is also available from the publisher, Elsevier,[24] through the National Library of Medicine,[25] and on the digital repositories *ResearchGate*[26] and *Semantic Scholar*.[27] Exhibit 1005 was found within the custody of a library, a place where an authentic

[24] https://www.sciencedirect.com/science/article/abs/pii/S1871678412008679?via%3Dihub.

[25] https://pubmed.ncbi.nlm.nih.gov/23165100/.

[26] https://www.researchgate.net/publication/233724050_Regulation_of_Pichia_pastoris_promoters_and_its_consequences_for_protein_production.

[27] https://www.semanticscholar.org/paper/Regulation-of-Pichia-pastoris-promoters-and-its-for-Vogl-Glieder/8317e52dec5c394fbd16aa8880d5fa1e8be3aa52.

copy of this article would likely be. Exhibit 1005 is a true and correct copy in a condition that creates no suspicion about its authenticity.

51. Attached hereto as Attachment 1a is a true and correct copy of the MARC record for the journal *New Biotechnology* in the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 1a occurred on April 29, 2022, as shown in field 005 ("20220429"). I personally identified and retrieved the MARC record that is Attachment 1a.

52. Based on finding a print copy of Exhibit 1005 in the National Library of Medicine and the MARC record in its online library catalog (Attachment 1a), it is my opinion that the Vogl article published in the journal *New Biotechnology* was publicly available on or shortly after August 6, 2013, as shown by the label on the cover of Exhibit 1005. This label has the general appearance of labels that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 1a also shows that Exhibit 1005 was catalogued with a descriptor term reading "Biotechnology $v periodical" (see Attachment 1b, National Library of Medicine subject heading D001709) in the 650 field.

53. As noted in the holdings information (362 field), the National Library of Medicine has received the journal *New Biotechnology* since the publication began

and continues to receive the publication. In view of the MARC record for Exhibit 1005, the Vogl article was publicly available on or shortly after August 6, 2013, because the serial title had been received, date stamped, cataloged, and indexed at the National Library of Medicine and made part of its online catalog database.

54. Attached hereto as Attachment 1c is a true and correct copy of the MARC record for the journal *New Biotechnology* 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 Attachment 1c, that library code is "NLM," which means that the MARC record for this serial was cataloged at the National Library of Medicine (Bethesda, Maryland). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the National Library of Medicine created OCLC record number 236073824 on February 4, 2008, as shown in the "Entered" field ("20080204"). 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 October 31, 2022, as shown in the "Replaced" field ("20221031"). I personally identified and retrieved the MARC record that is Attachment 1c. The "BLvl" entry in Attachment 1c is "s," which indicates that the journal *New Biotechnology* is a serial publication. Accordingly, the MARC record for Exhibit 1005 corresponds to the journal *New*

Biotechnology from the time the serial title began publication and includes the date of the Vogl article.[28]

55. Attachment 1c includes an entry in field 050 ("QH426 $b .G44")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b GE277")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("660.6")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 1c further includes a descriptor term reading "Biotechnology $v Periodicals" (see Attachment 1d, Library of Congress subject heading sh2007101988) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 1c was indexed according to its subject matter by

[28] The publication was originally known as *Gene Analysis Techniques* (January 1984-December 1989), changed the title to *Genetic Analysis, Techniques and Applications* (February 1990-December 1994), later changed the title to *Genetic Analysis: Biomolecular Engineering* (March 1995-December 1999), and then became *Biomolecular Engineering* (1999-2007), and adopted the current title, *New Biotechnology* (2008-date).

virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entry. As of February 4, 2008, the MARC record attached hereto as Attachment 1c 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.

56. Attachment 1c indicates that the journal *New Biotechnology* as cataloged at the National Library of Medicine is currently available from 59 libraries. In view of the above, this issue of the journal *New Biotechnology* was publicly available on or shortly after August 6, 2013, because by that date it had been received, cataloged, and indexed at the National Library of Medicine and made part of the OCLC bibliographic database. For these reasons, it is my opinion that Exhibit 1005 was published and accessible to the public on or shortly after August 6, 2013.

B. Lin-Cereghino article [Exhibit 1006]

57. Attached hereto as Exhibit 1006 is a copy of the journal article, "Mxr1p, A Key Regulator of the Methanol Utilization Pathway and Peroxisomal Genes in *Pichia pastoris*," by Geoffrey Paul Lin-Cerghino, Laurie Godfrey, Bernard J. de la Cruz, Sabrina Johnson, Samone Khuongsathiene, Ilya Tolstorukov, Mingda Yan,

Joan Lin-Cereghino, Marten Veenhuis, Suresh Subramani, and James M. Cregg (hereafter "Lin-Cereghino"). The Lin-Cereghino article was published in Volume 26, Number 3 of the journal *Molecular and Cellular Biology*. This issue is dated February 2006, and the article begins on page 883.

58. I obtained Exhibit 1006 from the John Peace Library at the University of Texas – San Antonio (San Antonio, Texas). Exhibit 1006 is a true and correct copy of the Lin-Cereghino article (pages 883-897). 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. The Lin-Cereghino article is also available from the publisher, The American Society for Microbiology (ASM),[29] through the National Library of Medicine,[30] and on the digital repositories *ResearchGate*[31] and *Semantic Scholar*.[32] Exhibit 1006 was found within the custody of a library, a place where an authentic

[29] https://journals.asm.org/doi/full/10.1128/MCB.26.3.883-897.2006.

[30] https://pubmed.ncbi.nlm.nih.gov/16428444/.

[31] https://www.researchgate.net/publication/7345303_Mxr1p_a_Key_Regulator_of_the_Methanol_Utilization_Pathway_and_Peroxisomal_Genes_in_Pichia_pastoris.

[32] https://www.semanticscholar.org/paper/Mxr1p%2C-a-Key-Regulator-of-the-Methanol-Utilization-Lin-Cereghino-Godfrey/31957f36672f417fe5dfa616801fe373a029feef.

copy of this article would likely be. Exhibit 1006 is a true and correct copy in a condition that creates no suspicion about its authenticity.

59. Attached hereto as Attachment 2a is a true and correct copy of the MARC record for the journal *Molecular and Cellular Biology* in the John Peace Library at the University of Texas – San Antonio. The library ownership is indicated by the presence of the library's code (TXJ) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 2a occurred on January 20, 2017, as shown in field 005 ("20170120"). I personally identified and retrieved the MARC record that is Attachment 2a.

60. Based on finding a print copy of Exhibit 1006 in the John Peace Library at the University of Texas – San Antonio and the MARC record in its online library catalog (Attachment 2a), it is my opinion that the Lin-Cereghino article published in the journal *Molecular and Cellular Biology* was publicly available on or shortly after February 1, 2006, as shown by the date stamp on the second page of Exhibit 1006. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 2a also shows that Exhibit 1006 was catalogued with two descriptor terms reading "Cytology $v Periodicals" (see Attachment 2b, Library of Congress

subject heading sh2008101999) and "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742) in the 650 fields.

61. As noted in the holdings information (362 field), the John Peace Library at the University of Texas – San Antonio has received the journal *Molecular and Cellular Biology* since the publication began in January 1981 and continues to receive the publication. In view of the MARC record for Exhibit 1006, the Lin-Cereghino article was publicly available on or shortly after February 1, 2006, because the serial title had been received, date stamped, cataloged, and indexed in the John Peace Library at the University of Texas – San Antonio and made part of its online catalog database.

62. Attached hereto as Attachment 2d is a true and correct copy of the MARC record for the journal *Molecular and Cellular Biology* 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 Attachment 2d, that library code is "NSD," which means that the MARC record for this serial was cataloged as part of the national Serials Data Program 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 6492263 on July 7, 1980, as shown in the "Entered" field ("19800707"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The

most recent enhancement to Attachment 2d occurred on September 6, 2022, as shown in the "Replaced" field ("20220906"). I personally identified and retrieved the MARC record that is Attachment 2d. The "BLvl" entry in Attachment 2d is "s," which indicates that the journal *Molecular and Cellular Biology* is a serial publication. Accordingly, the MARC record for Exhibit 1006 corresponds to the journal *Molecular and Cellular Biology* from the time the serial title began publication and includes the date of the Lin-Cereghino article.

63. Attachment 2d includes an entry in field 050 ("QH506 $b .M64")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b MO194U")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("574")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 2d further includes two descriptor terms reading "Cytology $v Periodicals" (see Attachment 2b, Library of Congress subject heading sh2008101999) and "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 2d was indexed

according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of July 7, 1980, the MARC record attached hereto as Attachment 2d 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.

64. Attachment 2d indicates that the journal *Molecular and Cellular Biology* as cataloged at the Library of Congress is currently available from 551 libraries. In view of the above, this issue of the journal *Molecular and Cellular Biology* was publicly available on or shortly after February 1, 2006, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the John Peace Library at the University of Texas – San Antonio. For these reasons, it is my opinion that Exhibit 1006 was published and accessible to the public on or shortly after February 1, 2006.

C. Liu article [Exhibit 1011]

65. Attached hereto as Exhibit 1011 is a copy of the journal article, "Balanced Globin Protein Expression and Heme Biosynthesis Improve Production of Human Hemoglobin in *Saccharomyces cerevisiae*," by Lifang Liu, José L.

Martínez, Zihe Liu, Dina Petranovic, and Jens Nielsen (hereafter "Liu"). The Liu article was published in Volume 21 of the journal *Metabolic Engineering*. This issue is dated January 2014, and the article begins on page 9.

66. I obtained Exhibit 1011 from the National Library of Medicine (Bethesda, Maryland). Exhibit 1011 is a true and correct copy of the Liu article (pages 9-16). 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. The Liu article is also available from the publisher, Elsevier,[33] and on the digital repositories *ResearchGate*[34] and *Semantic Scholar*.[35] Exhibit 1011 was found within the custody of a library, a place where an authentic copy of this article would likely be. Exhibit 1011 is a true and correct copy in a condition that creates no suspicion about its authenticity.

[33] https://www.sciencedirect.com/science/article/abs/pii/S109671761300102X?via%3Dihub.

[34] https://www.researchgate.net/publication/258280582_Balanced_globin_protein_expression_and_heme_biosynthesis_improve_production_of_human_hemoglobin_in_Saccharomyces_cerevisiae.

[35] https://www.semanticscholar.org/paper/Balanced-globin-protein-expression-and-heme-1-of-in-Liu-Mart%C3%ADnez/528fbe29d1c2c2f2dcc91716a2d886063d6d427c.

67. Attached hereto as Attachment 3a is a true and correct copy of the MARC record for the journal *Metabolic Engineering* in the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 3a occurred on April 29, 2022, as shown in field 005 ("20220429"). I personally identified and retrieved the MARC record that is Attachment 3a.

68. Based on finding a print copy of Exhibit 1011 in the National Library of Medicine and the MARC record in its online library catalog (Attachment 3a), it is my opinion that the Liu article published in the journal *Metabolic Engineering* was publicly available on or shortly after November 2, 2013, the date the first page of the Liu article indicates it was first available online. Attachment 3a also shows that Exhibit 1011 was catalogued with three descriptor terms reading "Biomedical Engineering" (see Attachment 3b, National Library of Medicine subject heading D001698), "Biotechnology" (see Attachment 1b, National Library of Medicine subject heading D001709), and "Metabolism" (see Attachment 3c, National Library of Medicine subject heading D008660) in the 650 fields.

69. As noted in the holdings information (362 field), the National Library of Medicine has received the journal *Metabolic Engineering* since the publication began in January 1999 and continues to receive the publication. In view of the

MARC record for Exhibit 1011, the Liu article was publicly available on or shortly after November 2, 2013, because by that date the serial title had been received, cataloged, and indexed in the National Library of Medicine and made part of its online catalog database.

70. Attached hereto as Attachment 3d is a true and correct copy of the MARC record for the journal *Metabolic Engineering* 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 Attachment 3d, that library code is "NSD," which means that the MARC record for this serial was cataloged as part of the National Serials Data Program 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 37861577 on October 29, 1997, as shown in the "Entered" field ("19971029"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 3d occurred on August 10, 2022, as shown in the "Replaced" field ("20220810"). I personally identified and retrieved the MARC record that is Attachment 3d. The "BLvl" entry in Attachment 3d is "s," which indicates that the journal *Metabolic Engineering* is a serial publication. Accordingly, the MARC record for Exhibit 1011 corresponds to the journal *Metabolic*

Engineering from the time the serial title began publication and includes the date of the Liu article.

71. Attachment 3d includes an entry in field 050 ("TP248.3 $b .M48")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b ME961LR")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("660")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 3d further includes two descriptor terms reading "Biochemical engineering $v Periodicals" (see Attachment 3e, Library of Congress subject heading sh2009117040) and "Metabolism $v Periodicals" (see Attachment 3f, Library of Congress subject heading sh2010101541) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 3d was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of October 29, 1997, the MARC record attached hereto as Attachment 3d 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.

72. Attachment 3d indicates that the journal *Metabolic Engineering* as cataloged at the Library of Congress is currently available from 113 libraries. In view of the above, this issue of the journal *Metabolic Engineering* was publicly available on or shortly after November 2, 2013, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1011 was published and accessible to the public on or shortly after November 2, 2013.

D. Vedvick article [Exhibit 1012]

73. Attached hereto as Exhibit 1012 is a copy of the journal article, "High-Level Secretion of Biologically Active Aprotinin from the Yeast *Pichia pastoris*," by Thomas Vedvick, Richard G. Buckholz, Michael Engel, Mary Urcan, Jennifer Kinney, Sally Provow, Robert S. Siegel, and Gregory P. Thill (hereafter "Vedvick"). The Vedvick article was published in Volume 7, Number 3 of the *Journal of Industrial Microbiology*. This issue is dated April 1991, and the article begins on page 197.

74. I obtained Exhibit 1012 from the Steenbock Library at the University of Wisconsin – Madison. Exhibit 1012 is a true and correct copy of the Vedvick article (pages 197-201). 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. The Vedvick article is also available from the publisher, the Springer-Verlag,[36] through the National Library of Medicine,[37] and on the digital repositories *Semantic Scholar*[38] and *Pascal*.[39] Exhibit 1012 was found within the custody of a library, a place where an authentic copy of this article would likely be. Exhibit 1012 is a true and correct copy in a condition that creates no suspicion about its authenticity.

75. Attached hereto as Attachment 5a is a true and correct copy of the MARC record for the *Journal of Industrial Microbiology* in the Steenbock Library at the University of Wisconsin – Madison. The library ownership is indicated by the presence of the library's code (uwmadisondb) in the fourth field 035. The library

[36] https://link.springer.com/article/10.1007/BF01575883.

[37] https://pubmed.ncbi.nlm.nih.gov/1370032/.

[38] https://www.semanticscholar.org/paper/High-level-secretion-of-biologically-active-from-Vedvick-Buckholz/e8f943fc18d846af118666930d2ef0428cfe0d83.

[39] https://pascal-francis.inist.fr/vibad/index.php?action=getRecordDetail&idt=5414998.

continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 5a occurred on September 12, 2007, as shown in field 005 ("20070912"). I personally identified and retrieved the MARC record that is Attachment 5a.

76. Based on finding a print copy of Exhibit 1012 in the Steenbock Library at the University of Wisconsin – Madison and the MARC record in its online library catalog (Attachment 5a), it is my opinion that the Vedvick article published in the *Journal of Industrial Microbiology* was publicly available on or shortly after April 30, 1991.[40] Attachment 5a also shows that Exhibit 1012 was catalogued with a descriptor term reading "Industrial microbiology $v Periodicals" (see Attachment 5b, Library of Congress subject heading sh85065899 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field.

77. As noted in the holdings information (362 field), the Steenbock Library at the University of Wisconsin – Madison has received the *Journal of Industrial Microbiology* from when the publication began in March 1986 until it ended in

[40] The *Journal of Industrial Microbiology* was published monthly and, therefore, new issues were available approximately every 30 days. Based on the frequency of publication (see Attachment 5a, field 310) and my years of experience working with serials, it is my opinion that issues would be published by the end of the month. Therefore, a public availability date of April 30, 1991, is reasonable.

1996.[41] In view of the MARC record for Exhibit 1012, the Vedvick article was publicly available on or shortly after April 30, 1991, because by that date the serial title had been received, cataloged, and indexed in the Steenbock Library at the University of Wisconsin -- Madison and made part of its online catalog database.

78. Attached hereto as Attachment 5d is a true and correct copy of the MARC record for the *Journal of Industrial Microbiology* 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 Attachment 5d, that library code is "OLA," which means that the MARC record for this serial was cataloged at the NOAA Central Library (Silver Spring, Maryland). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the NOAA Central Library created OCLC record number 13509063 on April 30, 1986, as shown in the "Entered" field ("19860430"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 5d occurred on July 13, 2022, as shown in the "Replaced" field ("20220713"). I personally identified and retrieved the MARC record that is Attachment 5d. The "BLvl" entry in Attachment 5d is "s," which

[41] The publication adopted a new title, *Journal of Industrial Microbiology and Biotechnology,* in September 1996.

indicates that the *Journal of Industrial Microbiology* is a serial publication. Accordingly, the MARC record for Exhibit 1012 corresponds to the *Journal of Industrial Microbiology* from the time the serial title began publication and includes the date of the Vedvick article.

79. Attachment 5d includes an entry in field 050 ("QR53 $b .J68")—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 060 ("W1 $b JO705E")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 5d further includes two descriptor terms reading "Industrial microbiology $v Periodicals" (see Attachment 5b, Library of Congress subject heading sh85065899 and Attachment 5c, Library of Congress subject heading sh85099890) and "Microbiology" (see Attachment 5e, Library of Congress subject heading sh85084783) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 5d was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of April 30, 1986, the MARC record attached hereto as Attachment 5d 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.

80. Attachment 5d indicates that the *Journal of Industrial Microbiology* as cataloged at the NOAA Center Library is currently available from 137 libraries. In view of the above, this issue of the *Journal of Industrial Microbiology* was publicly available on or shortly after April 30, 1991, because by that date it had been cataloged and indexed at the NOAA Central Library, made part of the OCLC bibliographic database, and received in the Steenbock Library at the University of Wisconsin – Madison. For these reasons, it is my opinion that Exhibit 1012 was published and accessible to the public on or shortly after April 30, 1991.

E. Engel conference paper [Exhibit 1013]

81. Attached hereto as Exhibit 1013 is a conference paper published in the book *Genetically Modified Foods: Safety Issues*, edited by Karl-Heinz Engel, Gary R. Takeoka, and Roy Teranishi. The conference paper titled "Foods and Food Ingredients Produced via Recombinant DNA Techniques: An Overview" by Karl-Heinz Engel, Gary R. Takeoka, and Roy Teranishi (hereafter "Engel") appears beginning on page 1. The conference papers were presented at a symposium jointly sponsored by the Divisions of Agricultural and Food Chemistry at the 208th meeting

of the American Chemical Society that was held on August 21-24, 1975, in Washington, DC. The volume is also identified as ACS Symposium Series 605. Exhibit 1013 is a true and correct copy of the Engel conference paper (pages 1-10), which I obtained from the Steenbock Library at the University of Wisconsin – Madison. The text in Exhibit 1013 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 1013 is a true and correct copy in a condition that creates no suspicion about its authenticity.

82. Attached hereto as Attachment 6a is a true and correct copy of the MARC record for this monograph from the Steenbock Library at the University of Wisconsin – Madison online catalog. The library ownership is indicated by the presence of the library's code (GZM) in the 049 field. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to the MARC record occurred on February 22, 2010, as shown in the 005 field ("20100222"). I personally identified and retrieved the library catalog record which is Attachment 6a.

83. Based on finding a print copy of the Engel conference paper in the Steenbock Library at the University of Wisconsin – Madison and MARC record in its online library catalog attached as Attachment 6a, it is my opinion that the book *Genetically Modified Foods: Safety Issues* was publicly available on or shortly after

July 24, 1995, as shown in field 008 ("950724"). The International Standard Book Number (ISBN) on Exhibit 1013 (0-8412-3320-1) matches the ISBN in field 020 of Attachment 6a. Therefore, Exhibit 1013 is the same book as the one that the cataloger in the Steenbock Library at the University of Wisconsin – Madison used to create the MARC record that is Attachment 6a.

84. Attached hereto as Attachment 6b is a true and correct copy of the MARC record for the book titled *Genetically Modified Foods: Safety Issues* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 6b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 6b, that library code is "DLC," which means that the MARC record for this book was created at the Library of Congress as part of the Cataloging in Publication (CIP) Program.[42] A cataloger prepares basic information about the forthcoming book which is included on the verso of the title page (also called the copyright page). The information is provided to save time needed for the cataloging process at the library after the book is purchased. The CIP data includes the author (field 100), title and subtitle (field 245), edition statement (field 250), ISBN (field 022), suggested subject headings (field 650), classification numbers for the Library of Congress

[42] https://www.loc.gov/publish/cip/.

classification number (field 050), and the Dewey Decimal classification number (field 082). These data elements are included in the MARC record that the Library of Congress contributes to the OCLC bibliographic database.

85. 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 32924343 on July 24, 1995, as shown in the "Entered" field ("19950724"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 6b occurred on February 19, 2022, as shown in the "Replaced" field ("20220219"). I personally identified and retrieved the MARC record that is Attachment 6b.

86. Attachment 6b further includes an entry in field 050 ("TP248.65.F66 $b G46 1995")—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 ("363.19/2")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 6b further includes six descriptor terms reading "Genetically modified foods $v Congresses" (see Attachment 6c, Library of Congress subject heading sh00006274 and Attachment 6d, Library of Congress subject heading 85031115), "Food $x Biotechnology $v Congresses" (see Attachment 6e, Library of Congress subject heading sh2009125325), "Crops $x Genetic engineering $v Congresses" (see

Attachment 6f, Library of Congress subject heading sh2009122609), "Genetic engineering" (see Attachment 6g, Library of Congress subject heading sh85053855), "Transgenic plants" (see Attachment 6h, Library of Congress subject heading sh90003137), and "Crop zones" (see Attachment 6i, Library of Congress subject heading sh85034246) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 6b 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 entries. Further, as of July 24, 1995, the MARC record attached hereto as Attachment 6b was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that acquired the book titled *Genetically Modified Foods: Safety Issues* 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.

87. Further supporting my opinion that Exhibit 1013 was publicly accessible to ordinarily skilled and interested researchers in the field is the fact that the Engel book *Genetically Modified Foods: Safety Issues* was registered with the U.S. Copyright Office as item TX0004199183 on January 2, 1996, and indicated a publication date of October 5, 1995 (see Attachment 6j, U.S. Copyright Office Public Catalog). As noted above, this would have provided a person interested in

the relevant subject matter with keyword searching capabilities and other tools to locate this book.

88. Attachment 6b indicates that the book titled *Genetically Modified Foods: Safety Issues* as cataloged at the Library of Congress is currently available from 261 libraries. In view of above, the book titled *Genetically Modified Foods: Safety Issues* was publicly available on or shortly after October 5, 1995, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the Steenbock Library at the University of Wisconsin – Madison. For these reasons, it is my opinion that Exhibit 1013 was published and accessible to the public on or shortly after October 5, 1995.

F. Garrocho-Villegas article [Exhibit 1014]

89. Attached hereto as Exhibit 1014 is a copy of the journal article, "Plant Hemoglobins: What We Know Six Decades After Their Discovery" by Verónica Garrocho-Villegas, Sabarinathan Kuttalingam Gopalasubramaniam, and Raúl Arredondo-Peter (hereafter "Garrocho-Villegas"). The Garrocho-Villegas article was published in Volume 398, Issues 1-2 of the journal *Gene*. The Garrocho-Villegas article appears beginning on page 78 of this issue dated August 15, 2007.

90. I obtained Exhibit 1014 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1014 is a true and correct copy of the Garrocho-Villegas article (pages 78-85). 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. The Garrocho-Villegas article is also available from the publisher, Elsevier,[43] through the National Library of Medicine,[44] and the digital repository *ResearchGate.*[45] Exhibit 1014 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1014 is a true and correct copy in a condition that creates no suspicion about its authenticity.

91. Attached hereto as Attachment 7a is a true and correct copy of the MARC record for the journal *Gene* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 7a occurred on October 29, 2019, as shown in field 005 field ("20191029"). I personally identified and retrieved the MARC record that is Attachment 7a.

[43] https://www.sciencedirect.com/science/article/abs/pii/S0378111907001965?via%3Dihub.

[44] https://pubmed.ncbi.nlm.nih.gov/17540516/.

[45] https://www.researchgate.net/publication/6294855_Plant_hemoglobins_What_we_know_six_decades_after_their_discovery.

92. Based on finding a copy of Exhibit 1014 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 7a, it is my opinion that the Garrocho-Villegas article published in the journal *Gene* was publicly available on or shortly after August 15, 2007, as indicated by the date stamp on the cover. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 7a also shows that Exhibit 1014 was catalogued with three descriptor terms reading "Genetic engineering $v Periodicals" (see Attachment 7b, Library of Congress subject heading sh2008117864), "Molecular cloning $v Periodicals" (see Attachment 7c, Library of Congress subject heading sh85086580 and Attachment 5c, Library of Congress subject heading sh85099890), and "Recombinant DNA $v Periodicals" (see Attachment 7d, Library of Congress subject heading sh85111851 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 fields.

93. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Gene* since 1976 and continues to receive the publication. In view of the MARC record for Exhibit 1014, the Garrocho-Villegas article was publicly available on or shortly after August 15, 2007, because by that date the serial title had been received, cataloged, and indexed

in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

94. Attached hereto as Attachment 7e is a true and correct copy of the MARC record for the journal *Gene* 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 or name. For Attachment 7e, 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 3424642 on November 16, 1977, as shown in the "Entered" field ("19771116"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 7e occurred on August 9, 2022, as shown in the "Replaced" field ("20220809"). I personally identified and retrieved the MARC record that is Attachment 7e. The "BLvl" entry in Attachment 7e is "s," which indicates that the journal *Gene* is a serial publication. Field 310 of Attachment 7e reads "Biweekly, $b <15 July 1992-." Accordingly, the MARC record for Exhibit 1014 corresponds to the journal *Gene* from the time the serial title began publication and includes the date of the Garrocho-Villegas article.

95. Attachment 7e includes an entry in field 050 ("QH442 $b .G43")—as described above, a subject matter classification number consistent with the Library

of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b GE184M")—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 ("575.1")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 7e further includes four descriptor terms reading "Genetic engineering $v Periodicals" (see Attachment 7b, Library of Congress subject heading sh2008117864), "Molecular cloning $v Periodicals" (see Attachment 7c, Library of Congress subject heading sh85086580 and Attachment 5c, Library of Congress subject heading sh85099890), "Recombinant DNA $v Periodicals" (see Attachment 7d, Library of Congress subject heading sh85111851 and Attachment 5c, Library of Congress subject heading sh85099890), and "Genetic recombination" (see Attachment 7f, Library of Congress subject heading sh85053867) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 7e was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of November 16, 1977, the MARC record attached hereto as Attachment 7e 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.

96. Attachment 7e indicates that the journal *Gene* as cataloged at the Library of Congress is currently available from 407 libraries. In view of the above, this issue of the journal *Gene* was publicly available on or shortly after August 15, 2007, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1014 was published and accessible to the public on or shortly after August 15, 2007.

G. Lin-Cereghino 2000 article [Exhibit 1015]

97. Attached hereto as Exhibit 1015 is a copy of the journal article, "Heterologous Protein Expression in the Methylotrophic Yeast *Pichia pastoris*," by Joan Lin Cereghino and James M. Cregg (hereafter "Lin-Cereghino 2000"). The Lin-Cereghino 2000 article was published in Volume 24, Number 1 of the journal *FEMS Microbiology Reviews.* This issue is dated January 2000, and the article begins on page 45.

98. I obtained Exhibit 1015 from the Steenbock Library at the University of Wisconsin – Madison. Exhibit 1015 is a true and correct copy of the Lin-

Cereghino 2000 article (pages 45-66). 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. The Lin-Cereghino 2000 article is also available from the publisher, Oxford University Press,[46] through the National Library of Medicine,[47] and on the digital repositories *ResearchGate*[48] and *Semantic Scholar*.[49] Exhibit 1015 was found within the custody of a library, a place where an authentic copy of this article would likely be. Exhibit 1015 is a true and correct copy in a condition that creates no suspicion about its authenticity.

99. Attached hereto as Attachment 8a is a true and correct copy of the MARC record for the journal *FEMS Microbiology Reviews* in the Steenbock Library at the University of Wisconsin – Madison. The library ownership is indicated by the presence of the library's code (GZM) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent

[46] https://academic.oup.com/femsre/article/24/1/45/525926?login=false.

[47] https://pubmed.ncbi.nlm.nih.gov/10640598/.

[48] https://www.researchgate.net/publication/12673101_Heterologous_protein_expression_in_the_methylotrophic_yeast_Pichia_pastoris.

[49] https://www.semanticscholar.org/paper/Heterologous-protein-expression-in-the-yeast-Pichia-Cereghino-Cregg/ad8b37c6ed6409ab4987984e9e9788c60a2988eb.

enhancement to Attachment 8a occurred on April 9, 2015, as shown in field 005 ("20150409"). I personally identified and retrieved the MARC record that is Attachment 8a.

100. Based on finding a print copy of Exhibit 1015 in the Steenbock Library at the University of Wisconsin – Madison and the MARC record in its online library catalog (Attachment 8a), it is my opinion that the Lin-Cereghino 2000 article published in the journal *FEMS Microbiology Reviews* was publicly available on or shortly after January 3, 2000, as shown by the date stamp on the cover. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 8a also shows that Exhibit 1015 was catalogued with a descriptor term reading "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742) in the 650 field.

101. As noted in the holdings information (362 field), the Steenbock Library at the University of Wisconsin – Madison has received the journal *FEMS Microbiology Reviews* since the publication adopted the current title in April 1985 and continues to receive the publication. In view of the MARC record for Exhibit 1015, the Lin-Cereghino 2000 article was publicly available on or shortly after January 3, 2000, because by that date the serial title had been received, cataloged,

and indexed in the Steenbock Library at the University of Wisconsin -- Madison and made part of its online catalog database.

102. Attached hereto as Attachment 8b is a true and correct copy of the MARC record for the journal *FEMS Microbiology Reviews* 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 Attachment 8b, that library code is "IES," which means that the MARC record for this serial was cataloged at the Eli Lilly Library (Indianapolis, Indiana). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Eli Lilly Library created OCLC record number 12105491 on June 1, 1985, as shown in the "Entered" field ("19850601"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 8b occurred on August 10, 2022, as shown in the "Replaced" field ("20220810"). I personally identified and retrieved the MARC record that is Attachment 8b. The "BLvl" entry in Attachment 8b is "s," which indicates that the journal *FEMS Microbiology Reviews* is a serial publication. Accordingly, the MARC record for Exhibit 1015 corresponds to the journal *FEMS Microbiology Reviews* from the time the serial title adopted the current title and includes the date of the Lin-Cereghino 2000 article.

103. Attachment 8b includes an entry in field 050 ("QR1 $b .F45")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b FE549D")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("576/.05")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 8b further includes two descriptor terms reading "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742) and "Microbiology" (see Attachment 5e, Library of Congress subject heading sh85084783) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 8b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of June 1, 1985, the MARC record attached hereto as Attachment 8b 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.

104. Attachment 8b indicates that the journal *FEMS Microbiology Reviews* as cataloged at the Eli Lilly Library is currently available from 215 libraries. In view of the above, this issue of the journal *FEMS Microbiology Reviews* was publicly available on or shortly after January 3, 2000, because by that date it had been cataloged and indexed at the Eli Lilly Library, made part of the OCLC bibliographic database, and received in the Steenbock Library at the University of Wisconsin – Madison. For these reasons, it is my opinion that Exhibit 1015 was published and accessible to the public on or shortly after January 3, 2000.

H. Hartner 2006 article [Exhibit 1016]

105. Exhibit 1016 is a copy of Volume 5, Article 39 of the online open access journal *Microbial Cell Factories* found in the National Library of Medicine (Bethesda, Maryland). The article "Regulation of Methanol Utilisation Pathway Genes in Yeasts" by Franz S. Hartner and Anton Glieder (hereafter "Hartner 2006") appears in this issue dated December 14, 2006.

106. I obtained Exhibit 1016 through the National Library of Medicine. Exhibit 1016 is a true and correct copy of the Hartner 2006 article (21 pages). 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 1016 was found within the custody of a library – a place where, if authentic, a copy of this online open access journal would likely be. Exhibit 1016 is a true and correct copy in a condition that creates no suspicion about its authenticity.

107. The Hartner 2006 article is also available from the publisher's website, BioMed Central Ltd., part of Springer Nature.[50] The publisher's website indicates that the issue was published online on December 14, 2006. The first page of the Hartner 2006 article also indicates a publication date of December 14, 2006.

108. Attached hereto as Attachment 9a is a true and correct copy of the MARC record for the online open access journal *Microbial Cell Factories* from the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. I personally identified and retrieved the MARC record that is Attachment 9a.

109. As noted in the holdings information (field 362), the National Library of Medicine has received the online open access journal *Microbial Cell Factories* since 2002 and continues to receive the publication. In view of the MARC record

[50] https://microbialcellfactories.biomedcentral.com/articles/10.1186/1475-2859-5-39.

for Exhibit 1016, the Hartner 2006 article was publicly available on December 14, 2006.

110. The "BLvl" entry in Attachment 9a is "s," which indicates that the online open access journal *Microbial Cell Factories* is a serial publication. Field 310 of Attachment 9a reads "Annual." Accordingly, the MARC record for Exhibit 1016 corresponds to those issues of the online open access journal *Microbial Cell Factories* from the time of the serial began publication to the present day.

111. Attachment 9a further includes five descriptor terms reading "Cells $x microbiology" (see Attachment 9b, National Library of Medicine subject headingD002477), "Biotechnology" (see Attachment 9c, National Library of Medicine subject heading D001709), "Cell Culture Techniques $x statistics & numerical data" (see Attachment 9d, National Library of Medicine subject headings D018939), "Genetics, Microbial" (see Attachment 9e, National Library of Medicine subject heading D005827), and "Recombinant Proteins" (see Attachment 9f, National Library of Medicine subject heading D011994) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 9a was indexed according to its subject matter by virtue of an independently sufficient classification: the field 650 entries. Further, as of April 24, 2002, the MARC record attached hereto as Attachment 9a 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.

112. Attachment 9g indicates that the MARC record for the online open access journal *Microbial Cell Factories* 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 Attachment 9g, that library code is "VAM," which means that the MARC record for this serial was cataloged at the Moore Health Science Library at the University of Virginia (Charlottesville, Virginia). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger in the Moore Health Science Library at the University of Virginia created OCLC record number 49659355 on April 24, 2002, as shown in the "Entered" field ("20020424"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 9g occurred on December 23, 2021, as shown in the "Replaced" field ("20211223"). I personally identified and retrieved the MARC record that is Attachment 9g. The "BLvl" entry in Attachment 9g is "s," which indicates that the online open access journal *Microbial Cell Factories* is a serial publication. Accordingly, the MARC record for Exhibit 1016 corresponds to the online open access journal *Microbial Cell*

Factories from the time the serial title began publication and includes the date of the Hartner 2006 article.

113. Attachment 9g includes an entry in field 050 ("TP248.27 $b .M53")—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 060 ("W1")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 9g further includes two descriptor terms reading "Microbial biotechnology $v Periodicals" (see Attachment 9h, Library of Congress subject heading sh89001096 and Attachment 5c, Library of Congress subject heading sh85099890) and "Recombinant proteins $x Synthesis $v Periodicals" (see Attachment 9i, Library of Congress subject heading sh90005744 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 9g was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of April 24, 2002, the MARC record attached hereto as Attachment 9g 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.

114. Attachment 9g indicates that the online open access journal *Microbial Cell Factories* as cataloged in the Moore Health Science Library at the University of Virginia is currently available from 1,287 libraries. In view of the above, this issue of the online open access journal *Microbial Cell Factories* was publicly available on or shortly after December 14, 2006, because by that date it had been cataloged and indexed in the Moore Health Science Library at the University of Virginia, made part of the OCLC bibliographic database, and received in the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1016 was published and accessible to the public on or shortly after December 14, 2006.

I. Hartner 2008 article [Exhibit 1017]

115. Exhibit 1017 is a copy of an article from Volume 36, Number 12 of the online open access journal *Nucleic Acids Research* found in the National Library of Medicine (Bethesda, Maryland). The article, "Promoter Library Designed for Fine-Tuned Gene Expression in *Pichia pastoris*" by Franz S. Hartner, Claudia Ruth, David Langenegger, Sabrina N. Johnson, Petr Hyka, Geoffrey P. Lin-Cereghino, Joan Lin-Cereghino, Karin Kovar, James M Cregg and Anton Glieder (hereafter "Hartner 2008"), appears beginning on page e76 of this issue dated July 2008.

116. I obtained Exhibit 1017 through the National Library of Medicine. Exhibit 1017 is a true and correct copy of the Hartner 2008 article (15 pages). 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 1017 was found within the custody of a library – a place where, if authentic, a copy of this online open access journal would likely be. Exhibit 1017 is a true and correct copy in a condition that creates no suspicion about its authenticity.

117. The Hartner 2008 article is also available from the publisher's website, Oxford University Press,[51] and the digital repository *ResearchGate*.[52] The publisher's website indicates that the issue was published online on June 6, 2008. The first page of the Hartner 2008 article also indicates that it was published online on June 6, 2008.

118. Attached hereto as Attachment 10a is a true and correct copy of the MARC record for the online open access journal *Nucleic Acids Research* from the National Library of Medicine. The library ownership is indicated by the presence of

[51] https://microbialcellfactories.biomedcentral.com/articles/10.1186/1475-2859-5-39.

[52] https://www.researchgate.net/publication/5317090_Promoter_library_designed_for_fine-tuned_gene_expression_in_Pichia_pastoris.

the library's code (DNLM) in field 935. I personally identified and retrieved the MARC record that is Attachment 10a.

119. As noted in the holdings information (field 362), the National Library of Medicine has received the online open access journal *Nucleic Acids Research* since January 1974 and continues to receive the publication. In view of the MARC record for Exhibit 1017, the Hartner 2008 article was publicly available on June 6, 2008.

120. The "BLvl" entry in Attachment 10a is "s," which indicates that the online open access journal *Nucleic Acids Research* is a serial publication. Field 310 of Attachment 10a reads "Twenty-four no. a year." Accordingly, the MARC record for Exhibit 1017 corresponds to those issues of the online open access journal *Nucleic Acids Research* from the time of the serial began publication to the present day.

121. Attachment 10a includes an entry in field 060 ("W1 $b NU129")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 10a further includes a descriptor term reading "Nucleic Acids $v periodical" (see Attachment 10b, National Library of Medicine subject headingD009696) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 10a was indexed

according to its subject matter by virtue of at least two independently sufficient classifications: the 060 entry and the field 650 entry. Further, as of October 15, 1974, the MARC record attached hereto as Attachment 10a 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.

122. Attachment 10c is the MARC record for the online open access journal *Nucleic Acids Research* 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 Attachment 10c, 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 1791693 on October 15, 1974, as shown in the "Entered" field ("19741015"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 10c occurred on August 4, 2020, as shown in the "Replaced" field ("20200804"). I personally identified and retrieved the MARC record that is Attachment 10c. The "BLvl" entry in Attachment 10c is "s," which indicates that the online open access journal *Nucleic Acids Research* is a

serial publication. Accordingly, the MARC record for Exhibit 1017 corresponds to the online open access journal *Nucleic Acids Research* from the time the serial title began publication and includes the date of the Hartner 2008 article.

123. Attachment 10c includes an entry in field 050 ("QP620 $b .N8")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b NU129")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("5.8/732")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 10c further includes a descriptor term reading "Nucleic acids $v Periodicals" (see Attachment 10d, Library of Congress subject heading sh85093144 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 10c was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entry. As of October 15, 1974, the MARC record attached hereto as Attachment 10c 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.

124. Attachment 10c indicates that the online open access journal *Nucleic Acids Research* as cataloged at the Library of Congress is currently available from 486 libraries. In view of the above, this issue of the online open access journal *Nucleic Acids Research* was publicly available on or shortly after June 6, 2008, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1017 was published and accessible to the public on or shortly after June 6, 2008.

J. De Schutter article [Exhibit 1018]

125. Attached hereto as Exhibit 1018 is a copy of the journal article, "Genome Sequence of the Recombinant Protein Production Host *Pichia pastoris*" by Kristof De Schutter, Yao-Cheng Lin, Petra Tiels, Annelies Van Hecke, Sascha Glinka, Jacqueline Weber-Lehmann, Pierre Rouzé, Yves Van de Peer and Nico Callewaert (hereafter "De Schutter"). The De Schutter article was published in Volume 27, Number 6 of the journal *Nature Biotechnology*. The De Schutter article appears beginning on page 561 of this issue dated June 2009.

126. I obtained Exhibit 1018 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1018 is a true and correct copy of the De Schutter article (pages 561-566). 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. The De Schutter article is also available from the publisher, Nature Portfolio,[53] the National Library of Medicine,[54] and the digital repository *ResearchGate.*[55] Exhibit 1018 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1018 is a true and correct copy in a condition that creates no suspicion about its authenticity.

127. Attached hereto as Attachment 11a is a true and correct copy of the MARC record for the journal *Nature Biotechnology* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 11a occurred on October 28, 2019, as

[53] https://www.nature.com/articles/nbt.1544.

[54] https://pubmed.ncbi.nlm.nih.gov/19465926/.

[55] https://www.researchgate.net/publication/26237492_Genome_sequence_of_the_recombinant_protein_production_host_Pichia_pastoris.

shown in field 005 field ("20191028"). I personally identified and retrieved the MARC record that is Attachment 11a.

128. Based on finding a copy of Exhibit 1018 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 11a, it is my opinion that the De Schutter article published in the journal *Nature Biotechnology* was publicly available on or shortly after June 15, 2009, as indicated by the date stamp and label on the cover. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 11a also shows that Exhibit 1018 was catalogued with two descriptor terms reading "Biochemical engineering $v Periodicals" (see Attachment 3e, Library of Congress subject heading sh2009117040) and "Biotechnology $v Periodicals" (see Attachment 1d, Library of Congress subject heading sh2007101988) in the 650 fields.

129. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Nature Biotechnology* since 1996 and continues to receive the publication.[56] In view of the

[56] The publication was originally titled *Bio/technology* (March 1983-February 1996) and adopted the current title, *Nature Biotechnology*, in March 1996.

MARC record for Exhibit 1018, the De Schutter article was publicly available on or shortly after June 15, 2009, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

130. Attached hereto as Attachment 11b is a true and correct copy of the MARC record for the journal *Nature Biotechnology* 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 or name. For Attachment 11b, that library code is "NSD," which means that the MARC record for this serial was cataloged as part of the National Serials Data Program 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 34160925 on February 9, 1996, as shown in the "Entered" field ("19960209"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 11b occurred on September 9, 2022, as shown in the "Replaced" field ("20220909"). I personally identified and retrieved the MARC record that is Attachment 11b. The "BLvl" entry in Attachment 11b is "s," which indicates that the journal *Nature Biotechnology* is a serial publication. Field 310 of Attachment 11b reads "Monthly, $b <Apr. 2000-." Accordingly, the MARC record for Exhibit 1018 corresponds to the journal *Nature Biotechnology*

from the time the serial title adopted the current title and includes the date of the De Schutter article.

131. Attachment 11b includes an entry in field 050 ("TP248.3 $b .B557")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b BI918LW")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("660/.6/05")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 11b further includes two descriptor terms reading "Biochemical engineering $v Periodicals" (see Attachment 3e, Library of Congress subject heading sh2009117040) and "Biotechnology $v Periodicals" (see Attachment 1d, Library of Congress subject heading sh2007101988) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 11b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of February 9, 1996, the MARC record attached hereto as Attachment 11b 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.

132. Attachment 11b indicates that the journal *Nature Biotechnology* cataloged at the Library of Congress is currently available from 591 libraries. In view of the above, this issue of the journal *Nature Biotechnology* was publicly available on or shortly after June 15, 2009, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1018 was published and accessible to the public on or shortly after June 15, 2009.

K. Kranthi article [Exhibit 1019]

133. Attached hereto as Exhibit 1019 is a copy of the journal article, "Identification of Key DNA Elements Involved in Promoter Recognition by Mxr1p, A Master Regulator of Methanol Utilization Pathway in *Pichia pastoris*" by Balla Venkata Kranthi, Ritesh Kumar, Nallani Vijay Kumar, Desirazu N. Rao, Pundi N. Rangarajan (hereafter "Kranthi 2009"). The Kranthi 2009 article was published in Volume 1789, Issue 6-8 of the journal *Biochimica et Biophysica Acta: General Subjects*. The Kranthi article appears beginning on page 460 of this issue dated June-August 2009.

134. I obtained Exhibit 1019 from the Milner Library at Illinois State University (Normal, Illinois). Exhibit 1019 is a true and correct copy of the Kranthi 2009 article (pages 460-468). 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. The Kranthi 2009 article is also available from the publisher, Elsevier,[57] the National Library of Medicine,[58] and the digital repository *Semantic Scholar*.[59] Exhibit 1019 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1019 is a true and correct copy in a condition that creates no suspicion about its authenticity.

135. Attached hereto as Attachment 12a is a true and correct copy of the MARC record for the journal *Biochimica et Biophysica Acta: General Subjecs* in the Milner Library at Illinois State University. The library ownership is indicated by the presence of the library's code (ISU) in the second field 959. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 12a occurred on April 9, 2020, as shown in field

[57] https://www.sciencedirect.com/science/article/abs/pii/S1874939909000571.

[58] https://pubmed.ncbi.nlm.nih.gov/19450714/.

[59] https://www.semanticscholar.org/paper/Identification-of-key-DNA-elements-involved-in-by-a-Kranthi-Kumar/449e55cfa6aa20962ba08cf39f15001489d7ff08.

005 field ("20200409"). I personally identified and retrieved the MARC record that is Attachment 12a.

136. Based on finding a copy of Exhibit 1019 in the Milner Library at Illinois State University and MARC record in its online library catalog attached as Attachment 12a, it is my opinion that the Kranthi 2009 article published in the journal *Biochimica et Biophysica Acta: General Subjects* was publicly available on or shortly after October 5, 2009, as indicated by the stamp on the second page of Exhibit 1019. This stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 12a also shows that Exhibit 1019 was catalogued with two descriptor terms reading "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985) and "Biophysics $v Periodicals" (see Attachment 12c, Library of Congress subject heading sh2007101987) in the 650 fields.

137. As noted in the holdings information (362 field), the Milner at Illinois State University has received the journal *Biochimica et Biophysica Acta: General Subjects* since 1964 and continues to receive the publication.[60] In view of the MARC

[60] The publication was originally titled *Biochimica et Biophysica Acta* (January 1947-December 1963) and adopted the current title, *Biochimica et Biophysica Acta: General Subjects*, in January 1964.

record for Exhibit 1019, the Kranthi 2009 article was publicly available on or shortly after October 5, 2009, because by that date the serial title had been received, cataloged, and indexed in the Milner Library at Illinois State University and made part of its online catalog database.

138. Attached hereto as Attachment 12d is a true and correct copy of the MARC record for the journal *Biochimica et Biophysica Acta: General Subjects* 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 or name. For Attachment 12d, that library code is "YNG," which means that the MARC record for this serial was cataloged at the Youngstown State University Library (Youngstown, Ohio). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Youngstown State University Library created OCLC record number 4969968 on May 16, 1979, as shown in the "Entered" field ("19790516"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 12d occurred on February 18, 2022, as shown in the "Replaced" field ("20220218"). I personally identified and retrieved the MARC record that is Attachment 12d. The "BLvl" entry in Attachment 12d is "s," which indicates that the journal *Biochimica et Biophysica Acta: General Subjects* is a serial publication. Field 310 of Attachment 12d reads "Monthly." Accordingly, the MARC record for

Exhibit 1019 corresponds to the journal *Biochimica et Biophysica Acta: General Subjects* from the time the serial title adopted the current title and includes the date of the Kranthi 2009 article.

139. Attachment 12d includes an entry in field 050 ("QD415.A1 $b B53")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment 12d further includes four descriptor terms reading "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985), "Biophysics $v Periodicals" (see Attachment 12c, Library of Congress subject heading sh2007101987), "Biochemistry" (see Attachment 12e, Library of Congress subject heading sh85014171), and "Biophysics" (see Attachment 12f, Library of Congress subject heading sh85014253) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 12d was indexed according to its subject matter by virtue of at least two independently sufficient classifications: the field 050 entry and the field 650 entries. As of May 16, 1979, the MARC record attached hereto as Attachment 12d 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.

140. Attachment 12d indicates that the journal *Biochimica et Biophysica Acta: General Subjects* cataloged at the Youngstown State University Library is currently available from 182 libraries. In view of the above, this issue of the journal *Biochimica et Biophysica Acta: General Subjects* was publicly available on or shortly after October 5, 2009, because by that date it had been cataloged and indexed at the Youngstown State University Library, made part of the OCLC bibliographic database, and received at the Miler Library at Illinois State University. For these reasons, it is my opinion that Exhibit 1019 was published and accessible to the public on or shortly after October 5, 2009.

L. Sreekrishna book excerpt article [Exhibit 1021]

141. Attached hereto as Exhibit 1021 is an excerpt published in the seven-volume set *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* edited by Michael C. Flickinger. The excerpt titled "Pichia, Optimization of Protein Expression" by Koti Sreekrishna (hereafter "Sreekrishna") appears beginning on page 3838 in volume 6.

142. Exhibit 1021 is a true and correct copy of the Sreekrishna excerpt (pages 3838-3853), which I obtained from the University of North Carolina – Raleigh Libraries. The text in Exhibit 1021 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 1021 is a true and correct copy in a condition that creates no suspicion about its authenticity.

143. Attached hereto as Attachment 14a is a true and correct copy of the MARC record for this seven-volume set from the University of North Carolina – Raleigh Libraries online catalog. The library ownership is indicated by the presence of the library's code (NRC) in the 049 field. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to the MARC record occurred on January 31, 2013, as shown in the 005 field ("20130131"). I personally identified and retrieved the library catalog record which is Attachment 14a.

144. Based on finding a print copy of the Sreekrishna excerpt in the University of North Carolina – Raleigh Libraries and MARC record in its online library catalog attached as Attachment 14a, it is my opinion that the seven-volume set titled *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* was publicly available on or shortly after December 31, 2008, as shown in field 008 ("081231"). The International Standard Book Number (ISBN) on Exhibit 1021 (978-0-4717-9930-6) matches the ISBN in the first field 020 of Attachment 14a. Therefore, Exhibit 1021 is the same set of books as the one that

the cataloger in the University of North Carolina – Raleigh Libraries used to create the MARC record that is Attachment 14a.

145. Attached hereto as Attachment 14b is a true and correct copy of the MARC record for the seven-volume set titled *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 14b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 14b, that library code is "DNLM/DLC," which means that the MARC record for this book was created at the Library of Congress as part of the Cataloging in Publication (CIP) Program.[61] A cataloger prepares basic information about the forthcoming book which is included on the verso of the title page (also called the copyright page). The information is provided to save time needed for the cataloging process at the library after the book is purchased. The CIP data includes the author (field 100), title and subtitle (field 245), edition statement (field 250), ISBN (field 022), suggested subject headings (field 650), classification numbers for the Library of Congress classification number (field 050), and the Dewey Decimal classification number (field 082). These data elements are included in the MARC record that the Library

[61] https://www.loc.gov/publish/cip/.

of Congress contributes to the OCLC bibliographic database.

146. 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 297494674 on December 31, 2008, as shown in the "Entered" field ("20081231"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 14b occurred on July 26, 2022, as shown in the "Replaced" field ("20220726"). I personally identified and retrieved the MARC record that is Attachment 14b.

147. Attachment 14b further includes an entry in field 050 ("TP248.16 $b .E53 2010")—a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W82 $b .56 2010")—a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("660.306")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 14b further includes two descriptor terms reading "Biotechnology $v Encyclopedias" (see Attachment 14c, Library of Congress subject heading sh85014263 and Attachment 14d, Library of Congress subject heading 85042997) and "Biomedical engineering" (see Attachment 14e, Library of Congress subject heading sh85014237) in the 650 fields. Thus, as of its

cataloging, the publication corresponding to the MARC record attached hereto as Attachment 14b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. Further, as of December 31, 2008, the MARC record attached hereto as Attachment 14b was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that acquired the seven-volume set titled *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* 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.

148. Attachment 14b indicates that the seven-volume set titled *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* as cataloged at the Library of Congress is currently available from 53 libraries. In view of above, the seven-volume set titled *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* was publicly available on or shortly after January 9, 2009, because by that date it had been received, cataloged, and indexed at the Library of Congress (see Attachment 14f, field 955), made part of the OCLC bibliographic database, and received in the University of North Carolina –

Raleigh Libraries. For these reasons, it is my opinion that Exhibit 1021 was published and accessible to the public on or shortly after January 9, 2009.

M. Zhang book excerpt article [Exhibit 1022]

149. Attached hereto as Exhibit 1022 is an excerpt published in the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, edited by Richard H. Baltz, Julian E. Davies, and Arnold L. Demain. The excerpt titled "Heterologous Protein Expression in Yeasts and Filamentous Fungi" by Ningyan Zhang and Zhiqiang An (hereafter "Zhang") is Chapter 11 and appears beginning on page 145.

150. Exhibit 1022 is a true and correct copy of the Zhang excerpt (pages 145-156), which I obtained from the University of Wisconsin – Madison Libraries. The text in Exhibit 1022 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 1022 is a true and correct copy in a condition that creates no suspicion about its authenticity.

151. Attached hereto as Attachment 15a is a true and correct copy of the MARC record for the *Manual of Industrial Microbiology and Biotechnology* from the University of Wisconsin – Madison Libraries online catalog. The library ownership is indicated by the presence of the library's code (GZM) in the 049 field. The library continues to update this MARC record and enhanced the MARC record

to meet current cataloging rules. The most recent enhancement to the MARC record occurred on November 5, 2010, as shown in the 005 field ("20101105"). I personally identified and retrieved the library catalog record which is Attachment 15a.

152. Based on finding a print copy of the Zhang excerpt in the University of Wisconsin – Madison Libraries and MARC record in its online library catalog attached as Attachment 15a, it is my opinion that the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, was publicly available on or shortly after January 11, 2010, as shown in field 008 ("100110"). The International Standard Book Number (ISBN) on Exhibit 1022 (978-1-55581-512-7) matches the ISBN in the first field 020 of Attachment 15a. Therefore, Exhibit 1022 is the book as the one that the cataloger in the University of Wisconsin – Madison Libraries used to create the MARC record that is Attachment 15a.

153. Attached hereto as Attachment 15b is a true and correct copy of the MARC record for the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 15b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 15b, that library code is "DNLM/DLC," which means that the MARC record for this book was created at the Library of Congress

as part of the Cataloging in Publication (CIP) Program.[62] A cataloger prepares basic information about the forthcoming book which is included on the verso of the title page (also called the copyright page). The information is provided to save time needed for the cataloging process at the library after the book is purchased. The CIP data includes the author (field 100), title and subtitle (field 245), edition statement (field 250), ISBN (field 022), suggested subject headings (field 650), classification numbers for the Library of Congress classification number (field 050), and the Dewey Decimal classification number (field 082). These data elements are included in the MARC record that the Library of Congress contributes to the OCLC bibliographic database.

154. 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 49876661 on January 11, 2010, as shown in the "Entered" field ("20100111"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 15b occurred on March 26, 2022, as shown in the "Replaced" field ("20220326"). I personally identified and retrieved the MARC record that is Attachment 15b.

[62] https://www.loc.gov/publish/cip/.

155. Attachment 15b further includes an entry in field 050 ("QR53 $b .M33 2010")—a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("QW75 $b M294 2010")—a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("660.6/2")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 15b further includes three descriptor terms reading "Industrial microbiology $v Handbooks, manuals, etc." (see Attachment 5b, Library of Congress subject heading sh85065899 and Attachment 15c, Library of Congress genre heading gf2014026109), "Biotechnology $x Encyclopedias" (see Attachment 14c, Library of Congress subject heading sh85014263 and Attachment 15c, Library of Congress genre heading gf214026109), and "Industrial microbiology" (see Attachment 5b, Library of Congress subject heading sh85065899) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 15b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. Further, as of January 11, 2010, the MARC record attached hereto as Attachment 15b was accessible through any library with access to the OCLC

bibliographic database or the online catalog at a library that acquired the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, 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.

156. Further supporting my opinion that Exhibit 1022 was publicly accessible to ordinarily skilled and interested researchers in the field is the fact that the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, was registered with the U.S. Copyright Office as item TX0007642497 on December 20, 2012 and indicated a publication date of March 23, 2010 (see Attachment 15d, U.S. Copyright Office Public Catalog). As noted above, this would have provided a person interested in the relevant subject matter with keyword searching capabilities and other tools to locate this book.

157. Attachment 15b indicates that the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, as cataloged at the Library of Congress is currently available from 182 libraries. In view of above, the book titled *Manual of Industrial Microbiology and Biotechnology*, 3rd edition, was publicly available on or shortly after March 23, 2010, because by that date it had been received, cataloged, and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the University of Wisconsin – Madison Libraries. For

these reasons, it is my opinion that Exhibit 1022 was published and accessible to the public on or shortly after March 23, 2010.

N. Kranthi 2010 article [Exhibit 1023]

158. Attached hereto as Exhibit 1023 is a copy of the journal article, "Identification of Mxr1p-Binding Sites in the Promoters of Genes Encoding Dihydroxyacetone Synthase and Peroxin 8 of the Methylotrophic Yeast *Pichia pastoris*" by Balla Venkata Kranthi, Hunsur Rajendra Vinod Kumar, and Pundi N. Rangarajan (hereafter "Kranthi 2010"). The Kranthi 2010 article was published in Volume 27, Number 9 of the journal *Yeast*. The Kranthi 2010 article appears beginning on page 705 of this issue dated September 2010.

159. I obtained Exhibit 1023 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1023 is a true and correct copy of the Kranthi 2010 article (pages 705-711). 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. The Kranthi 2010 article is also available from the publisher, Wiley,[63]

[63] https://onlinelibrary.wiley.com/doi/abs/10.1002/yea.1766.

the National Library of Medicine,[64] and the digital repositories *ResearchGate*[65] and *Semantic Scholar*.[66] Exhibit 1023 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1023 is a true and correct copy in a condition that creates no suspicion about its authenticity.

160. Attached hereto as Attachment 16a is a true and correct copy of the MARC record for the journal *Yeast* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 16a occurred on October 29, 2019, as shown in field 005 field ("20191029"). I personally identified and retrieved the MARC record that is Attachment 16a.

161. Based on finding a copy of Exhibit 1023 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog

[64] https://pubmed.ncbi.nlm.nih.gov/20198661/.

[65] https://www.researchgate.net/publication/41670479_Identification_of_Mxr1p-binding_sites_in_the_promoters_of_genes_encoding_dihydroxyacetone_synthase_and_peroxin_8_of_the_methylotrophic_yeast_Pichia_pastoris.

[66] https://www.semanticscholar.org/paper/Identification-of-Mxr1p%E2%80%90binding-sites-in-the-of-and-Kranthi-Kumar/320154c6fdf83b453b6793aa9cd39fb8d0ace8c5.

attached as Attachment 16a, it is my opinion that the Kranthi 2010 article published in the journal *Yeast* was publicly available on or shortly after September 23, 2010, as indicated by the date stamp on page three of Exhibit 1023. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 16a also shows that Exhibit 1023 was catalogued with a descriptor term reading "Yeast $v Periodicals" (see Attachment 16b, Library of Congress subject heading sh85149060 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field.

162. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Yeast* since September 1985 and continues to receive the publication. In view of the MARC record for Exhibit 1023, the Kranthi 2010 article was publicly available on or shortly after September 23, 2010, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

163. Attached hereto as Attachment 16c is a true and correct copy of the MARC record for the journal *Yeast* 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 or name. For Attachment 16c, that library code is "NSD,"

which means that the MARC record for this serial was cataloged as part of the National Serials Data Program 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 11128931 on September 7, 1984, as shown in the "Entered" field ("19840907"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 16c occurred on October 4, 2020, as shown in the "Replaced" field ("20201004"). I personally identified and retrieved the MARC record that is Attachment 16c. The "BLvl" entry in Attachment 16c is "s," which indicates that the journal *Yeast* is a serial publication. Field 310 of Attachment 16c reads "Monthly plus one additional issued in Jan., Apr., July, and Oct., $b <2005-." Accordingly, the MARC record for Exhibit 1023 corresponds to the journal *Yeast* from the time the serial title began and includes the date of the Kranthi 2010 article.

164. Attachment 16c includes an entry in field 050 ("QR151 $b .Y3")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b YE463H")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("547")—as described above, a subject matter classification

number consistent with the Dewey Decimal classification system. Attachment 16c further includes a descriptor term reading "Yeast $v Periodicals" (see Attachment 16b, Library of Congress subject heading sh85149060 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 16c was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entry. As of September 7, 1984, the MARC record attached hereto as Attachment 16c 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.

165. Attachment 16c indicates that the journal *Yeast* cataloged at the Library of Congress is currently available from 222 libraries. In view of the above, this issue of the journal *Yeast* was publicly available on or shortly after September 23, 2010, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion

that Exhibit 1023 was published and accessible to the public on or shortly after September 23, 2010.

O. Parua article [Exhibit 1026]

166. Attached hereto as Exhibit 1026 is a copy of the journal article, "*Pichia pastoris 14-3-3* Regulates Transcriptional Activity of the Methanol Inducible Transcription Factor Mxr1 by Direct Interaction" by Pabitra K. Parua, Paul M. Ryan, Kayla Trang, and Elton T. Young (hereafter "Parua"). The Parua article was published in Volume 85, Number 2 of the journal *Molecular Microbiology*. The Parua article appears beginning on page 282 of this issue dated July 2012.

167. I obtained Exhibit 1026 from the Library of Congress. Exhibit 1026 is a true and correct copy of the Parua article (pages 282-298). 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. The Parua article is also available from the publisher, Wiley,[67] the National Library of Medicine,[68] and the digital repositories *ResearchGate*[69] and

[67] https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2958.2012.08112.x.

[68] https://pubmed.ncbi.nlm.nih.gov/22625429/.

[69] https://www.researchgate.net/publication/225060036_Pichia_pastoris_14-3-3_regulates_transcriptional_activity_of_the_methanol_inducible_transcription_factor_Mxr1_by_direct_interaction.

Semantic Scholar.[70] Exhibit 1026 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1026 is a true and correct copy in a condition that creates no suspicion about its authenticity.

168. Attached hereto as Attachment 18a is a true and correct copy of the MARC record for the journal *Molecular Microbiology* at the Library of Congress. The library ownership is indicated by the presence of the library's name at the top of the screen. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 18a occurred on February 13, 2021, as shown in field 005 field ("20210213"). I personally identified and retrieved the MARC record that is Attachment 18a.

169. Based on finding a copy of Exhibit 1026 in the Library of Congress and MARC record in its online library catalog attached as Attachment 18a, it is my opinion that the Parua article published in the journal *Molecular Microbiology* was publicly available on or shortly after June 12, 2012, as indicated on the publisher's website and page six of Exhibit 1026. Attachment 18a also shows that Exhibit 1026 was catalogued with a descriptor term reading "Molecular microbiology $v Periodicals" (see Attachment 18b, Library of Congress subject heading sh87007715

[70] https://www.semanticscholar.org/paper/Pichia-pastoris-14%E2%80%903%E2%80%903-regulates-transcriptional-of-Parua-Ryan/7506a18ad0583b8b5cfa9064a6b6099ee844b753.

and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field.

170. As noted in the holdings information (362 field), the Library of Congress has received the journal *Molecular Microbiology* since July 1987 and continues to receive the publication. In view of the MARC record for Exhibit 1026, the Parua article was publicly available on or shortly after June 12, 2012, because by that date the serial title had been received, cataloged, and indexed in the Library of Congress and made part of its online catalog database.

171. Attached hereto as Attachment 18c is a true and correct copy of the MARC record for the journal *Molecular Microbiology* 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 or name. For Attachment 18c, 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 15473109 on April 1, 1987, as shown in the "Entered" field ("19870401"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 18c occurred on February 11, 2021, as shown in the "Replaced" field ("20210211"). I personally identified and retrieved the MARC record that is

Attachment 18c. The "BLvl" entry in Attachment 18c is "s," which indicates that the journal *Molecular Microbiology* is a serial publication. Field 310 of Attachment 18c reads "Semimonthly (except published once in Dec.), $b 1992-." Accordingly, the MARC record for Exhibit 1026 corresponds to the journal *Molecular Microbiology* from the time the serial title began and includes the date of the Parua article.

172. Attachment 18c includes an entry in field 050 ("QR74 $b .M65")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system)—an entry in field 060 ("W1 $b MO196N")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system)—and an entry in field 082 ("576/.05")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 18c further includes a descriptor term reading "Molecular microbiology $v Periodicals" (see Attachment 18b, Library of Congress subject heading sh87007715 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 18c was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the

field 060 entry, the field 082 entry, and the field 650 entry. As of April 1, 1987, the MARC record attached hereto as Attachment 18c 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.

173. Attachment 18c indicates that the journal *Molecular Microbiology* cataloged at the Library of Congress is currently available from 362 libraries. In view of the above, this issue of the journal *Molecular Microbiology* was publicly available on or shortly after June 12, 2012, because by that date it had been received, cataloged, and indexed at the Library of Congress and made part of the OCLC bibliographic database. For these reasons, it is my opinion that Exhibit 1026 was published and accessible to the public on or shortly after June 12, 2012.

P. Rabert article [Exhibit 1027]

174. Attached hereto as Exhibit 1027 is a copy of the journal article, "Recombinants Proteins for Industrial Uses: Utilization of *Pichia pastoris* Expression System" by Claudia Rabert, Daniel Weinacker, Adalberto Pessoa, Jr., and Jorge G. Farías (hereafter "Rabert"). The Rabert article was published in Volume 44, Number 2 of the *Brazilian Journal of Microbiology*. The Rabert article appears beginning on page 351 of this issue dated January 2013.

175. I obtained Exhibit 1027 from the National Library of Medicine. Exhibit 1027 is a true and correct copy of the Rabert article (pages 351-356). 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. The Rabert article is also available through the digital repository *ResearchGate.*[71] Exhibit 1027 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1027 is a true and correct copy in a condition that creates no suspicion about its authenticity.

176. Attached hereto as Attachment 19a is a true and correct copy of the MARC record for the *Brazilian Journal of Microbiology* at the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 19a occurred on April 29, 2022, as shown in field 005 field ("20220429"). I personally identified and retrieved the MARC record that is Attachment 19a.

177. Based on finding a copy of Exhibit 1027 in the National Library of Medicine and MARC record in its online library catalog attached as Attachment 19a,

[71] https://www.researchgate.net/publication/259111544_Recombinants_proteins_for_industrial_uses_Utilization_of_Pichia_pastoris_expression_system.

it is my opinion that the Rabert article published in the *Brazilian Journal of Microbiology* was publicly available on or shortly after October 30, 2013, as indicated on the National Library of Medicine website.[72] Attachment 19a also shows that Exhibit 1027 was catalogued with a descriptor term reading "Microbiology $v periodical" (see Attachment 19b, National Library of Medicine subject heading D008829) in the 650 field.

178. In view of the MARC record for Exhibit 1027, the Rabert article was publicly available on or shortly after October 30, 2013, because by that date the serial title had been received, cataloged, and indexed in the National Library of Medicine and made part of its online catalog database.

179. Attached hereto as Attachment 19c is a true and correct copy of the MARC record for the *Brazilian Journal of Microbiology* 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 or name. For Attachment 19c, 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 46773450 on April 18, 2001, as shown in the "Entered" field

[72] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3833127/.

("20010418"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 19c occurred on September 5, 2021, as shown in the "Replaced" field ("20210905"). I personally identified and retrieved the MARC record that is Attachment 19c. The "BLvl" entry in Attachment 19c is "s," which indicates that the *Brazilian J*ournal of *Microbiology* is a serial publication. Field 310 of Attachment 19c reads "Quarterly." Accordingly, the MARC record for Exhibit 1027 corresponds to the *Brazilian Journal of Microbiology* from the time the serial title began and includes the date of the Rabert article.

180. Attachment 19c includes an entry in field 050 ("QR6 $b .R46")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b RE445S")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("576/.05")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 19c further includes a descriptor term reading "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record

attached hereto as Attachment 19c was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entry. As of April 18, 2001, the MARC record attached hereto as Attachment 19c 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.

181. Attachment 19c indicates that the *Brazilian Journal of Microbiology* cataloged at the Library of Congress is currently available from 26 libraries. In view of the above, this issue of the *Brazilian Journal of Microbiology* was publicly available on or shortly after October 30, 2013, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1027 was published and accessible to the public on or shortly after October 30, 2013.

Q. Stryjewska article [Exhibit 1028]

182. Attached hereto as Exhibit 1028 is a copy of the journal article, "Biotechnology and Genetic Engineering in the New Drug Development. Part I. DNA Technology and Recombinant Proteins" by Agnieszka Stryjewska, Katarzyna

Kiepura, Tadeusz Librowski, and Stanisław Lochyński (hereafter "Stryjewska"). The Stryjewska article was published in Volume 65, Number 5 of the journal *Pharmacological Reports*. The Stryjewska article appears beginning on page 1075 of this issue dated September-October 2013.

183. I obtained Exhibit 1028 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1028 is a true and correct copy of the Stryjewska article (pages 1075-1085). 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. The Stryjewska article is also available from the publisher, Elsevier,[73] the National Library of Medicine,[74] and the digital repositories *ResearchGate*[75] and *Semantic Scholar*.[76] Exhibit 1028 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1028 is a true and correct copy in a condition that creates no suspicion about its authenticity.

[73] https://www.sciencedirect.com/science/article/abs/pii/S173411401371466X.

[74] https://pubmed.ncbi.nlm.nih.gov/24399704/.

[75] https://www.researchgate.net/publication/259627978_Biotechnology_and_genetic_engineering_in_the_new_drug_development_Part_I_DNA_technology_and_recombinant_proteins.

[76] https://www.semanticscholar.org/paper/Biotechnology-and-genetic-engineering-in-the-new-I.-Stryjewska-Kiepura/65131ce03441130a55f02e912c5097c17f8e0380.

184. Attached hereto as Attachment 20a is a true and correct copy of the MARC record for the journal *Pharmacological Report* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 20a occurred on October 30, 2019, as shown in field 005 field ("20191030"). I personally identified and retrieved the MARC record that is Attachment 20a.

185. Based on finding a copy of Exhibit 1028 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 20a, it is my opinion that the Stryjewska article published in the journal *Pharmacological Report* was publicly available on or shortly after March 11, 2014, as indicated on the publisher's website.

186. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Pharmacological Report* since it adopted its current title in January 2005 and continues to receive the publication.[77] In view of the MARC record for Exhibit 1028, the Stryjewska article

[77] The publication was originally titles *Dissertationes Pharmaceuticae et Pharmacologicae* (1966-1972), renamed the *Polish Journal of Pharmacology and Pharmacy* (Jan.-Feb. 1973-Nov.-Dec. 1992), changed title to the *Polish Journal of*

was publicly available on or shortly after March 11, 2014, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

187. Attached hereto as Attachment 20b is a true and correct copy of the MARC record for the journal *Pharmacological Report* 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 or name. For Attachment 20b, that library code is "NLM," which means that the MARC record for this serial was cataloged at the National Library of Medicine (Bethesda, Maryland). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the National Library of Medicine created OCLC record number 59004163 on November 29, 2004, as shown in the "Entered" field ("20041129"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 20b occurred on January 24, 2022, as shown in the "Replaced" field ("20220124"). I personally identified and retrieved the MARC record that is Attachment 20b. The "BLvl" entry in Attachment 20b is "s," which indicates that the journal *Pharmacological Report* is a serial publication.

Pharmacology (Jan.-Feb. 1993-Nov.-Dec. 2004), and adopted the current title, *Pharmacological Report,* in 2005.

Field 310 of Attachment 20b reads "Bimonthly." Accordingly, the MARC record for Exhibit 1028 corresponds to the journal *Pharmacological Report* from the time the serial title adopted the current title and includes the date of the Stryjewska article.

188. Attachment 20b includes an entry in field 050 ("RM1 $b .P65")—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 060 ("W1 $b PO23LS")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 20b further includes two descriptor terms reading "Pharmacology $v Periodicals" (see Attachment 20c, Library of Congress subject heading sh2008109178) and "Drug development $v Periodicals" (see Attachment 20d, Library of Congress subject heading sh97007921 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 20b was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of November 29, 2004, the MARC record attached hereto as Attachment 20b 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.

189. Attachment 20b indicates that the journal *Pharmacological Report* cataloged at the National Library of Medicine is currently available from 62 libraries. In view of the above, this issue of the journal *Pharmacological Report* was publicly available on or shortly after March 11, 2014, because by that date it had been cataloged and indexed at the National Library of Medicine, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1028 was published and accessible to the public on or shortly after March 11, 2014.

R. Ahmad article [Exhibit 1029]

190. Attached hereto as Exhibit 1029 is a copy of the journal article, "Protein Expression in *Pichia pastoris*: Recent Achievements and Perspectives for Heterologous Protein Production" by Mudassar Ahmad, Melanie Hirz, Harald Pichler, and Helmut Schwab (hereafter "Ahmad"). The Ahmad article was published in Volume 98, Number 12 of the journal *Applied Microbiology and Biotechnology*. The Ahmad article appears beginning on page 5301 of this issue dated June 2014.

191. I obtained Exhibit 1029 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1029 is a true and correct copy of the Ahmad article (pages 5301-5317). 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. The Ahmad article is also available from the publisher, Springer,[78] the National Library of Medicine,[79] and the digital repositories *ResearchGate*[80] and *Semantic Scholar*.[81] Exhibit 1029 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1029 is a true and correct copy in a condition that creates no suspicion about its authenticity.

192. Attached hereto as Attachment 21a is a true and correct copy of the MARC record for the journal *Applied Microbiology and Biotechnology* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field

[78] https://link.springer.com/article/10.1007/s00253-014-5732-5.

[79] https://pubmed.ncbi.nlm.nih.gov/24743983/.

[80] https://www.researchgate.net/publication/261757756_Protein_expression_in_Pichia_pastoris_Recent_achievements_and_perspectives_for_heterologous_protein_production.

[81] https://www.semanticscholar.org/paper/Protein-expression-in-Pichia-pastoris%3A-recent-and-Ahmad-Hirz/82369a21bf4db9f9051b53daf4044dcf3107e490.

049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 21a occurred on October 29, 2019, as shown in field 005 field ("20191029"). I personally identified and retrieved the MARC record that is Attachment 21a.

193. Based on finding a copy of Exhibit 1029 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 21a, it is my opinion that the Ahmad article published in the journal *Applied Microbiology and Biotechnology* was publicly available on or shortly after April 18, 2014, as indicated on the publisher's website.

194. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Applied Microbiology and Biotechnology* since 1984 and continues to receive the publication.[82] In view of the MARC record for Exhibit 1029, the Ahmad article was publicly available on or shortly after April 18, 2014, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

[82] The publication was originally titled *European Journal of Applied Microbiology* (1975-1977), renamed the *European Journal of Applied Microbiology and Biotechnology,* and (March 1978-December 1983), and adopted the current title, *Applied Microbiology and Biotechnology,* in 1984.

195. Attached hereto as Attachment 21b is a true and correct copy of the MARC record for the journal *Applied Microbiology and Biotechnology* 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 or name. For Attachment 21b, that library code is "LYU," which means that the MARC record for this serial was cataloged at the Lehigh University Libraries (Bethlehem, Pennsylvania). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Lehigh University Libraries created OCLC record number 10397249 on February 9, 1984, as shown in the "Entered" field ("19840209"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 21b occurred on February 18, 2022, as shown in the "Replaced" field ("20220218"). I personally identified and retrieved the MARC record that is Attachment 21b. The "BLvl" entry in Attachment 21b is "s," which indicates that the journal *Applied Microbiology and Biotechnology* is a serial publication. Field 310 of Attachment 21b reads "Two vols. of 6 issues." Accordingly, the MARC record for Exhibit 1029 corresponds to the journal *Applied Microbiology and Biotechnology* from the time the serial title adopted the current title and includes the date of the Ahmad article.

196. Attachment 21b includes an entry in field 050 ("QR53 $b .E87")—as described above, a subject matter classification number consistent with the Library

of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b AP528B")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("660/.62/05")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 21b further includes five descriptor terms reading "Industrial microbiology $v Periodicals" (see Attachment 5b, Library of Congress subject heading sh85065899 and Attachment 5c, Library of Congress subject heading sh85099890), "Microtechnology $v Periodicals" (see Attachment 21c, Library of Congress subject heading sh2001012575 and Attachment 5c, Library of Congress subject heading sh85099890), "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742), "Microbiology" (see Attachment 21d, Library of Congress subject heading sh85084783), and "Medical technology" (see Attachment 21e, Library of Congress subject heading sh85083046) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 21b was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of February 8, 1984, the MARC record attached hereto as Attachment 21b 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.

197. Attachment 21b indicates that the journal *Applied Microbiology and Biotechnology* cataloged at the Lehigh University Libraries is currently available from 247 libraries. In view of the above, this issue of the journal *Applied Microbiology and Biotechnology* was publicly available on or shortly after April 18, 2014, because by that date it had been cataloged and indexed at the Lehigh University Libraries, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1029 was published and accessible to the public on or shortly after April 18, 2014.

S. Haon article [Exhibit 1030]

198. Exhibit 1030 is a copy of an article from Volume 6 of the online open access journal *Frontiers in Microbiology* found in the National Library of Medicine (Bethesda, Maryland). The article, "Recombinant Protein Production Facility for Fungal Biomass-Degrading Enzymes Using the Yeast *Pichia pastoris*" by Mireille Haon, Sacha Grisel, David Navarro, Antoine Gruet, Jean-Guy Berrin, and

Christophe Bignon (hereafter "Haon"), appears in this issue dated September 23, 2015.

199. Exhibit 1030 is a true and correct copy of the Haon article that I obtained through the National Library of Medicine. Exhibit 1030 is a true and correct copy of the Haon article (12 pages). 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 1030 was found within the custody of a library – a place where, if authentic, a copy of this online open access journal would likely be. Exhibit 1030 is a true and correct copy in a condition that creates no suspicion about its authenticity.

200. The Haon article is also available from the publisher's website, Frontiers Media, S.A.[83] The publisher's website indicates that the issue was published online on September 23, 2015. The first page of the Haon article also indicates that it was published on September 23, 2015.

201. Attached hereto as Attachment 22a is a true and correct copy of the MARC record for the online open access journal *Frontiers in Microbiology* from the National Library of Medicine. The library ownership is indicated by the presence of

[83] https://www.frontiersin.org/articles/10.3389/fmicb.2015.01002/full.

the library's code (DNLM) in field 935. I personally identified and retrieved the MARC record that is Attachment 22a.

202. As noted in the holdings information (field 362), the National Library of Medicine has received the online open access journal *Frontiers in Microbiology* since 2010 and continues to receive the publication. In view of the MARC record for Exhibit 1030, the Haon article was publicly available on September 23, 2015.

203. The "BLvl" entry in Attachment 22a is "s," which indicates that the online open access journal *Frontiers in Microbiology* is a serial publication. Accordingly, the MARC record for Exhibit 1030 corresponds to those issues of the online open access journal *Frontiers in Microbiology* from the time of the serial began publication to the present day.

204. Attachment 22a further includes two descriptor terms reading "Microbiological Phenomena" (see Attachment 22b, National Library of Medicine subject heading D008827) and "Microbiology $x periodical" (see Attachment 19b, National Library of Medicine subject heading D008829) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 22a was indexed according to its subject matter by virtue of an independently sufficient classification: the field 650 entries. Further, as of December 6, 2010, the MARC record attached hereto as Attachment 22a 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.

205. Attachment 22c indicates that the MARC record for the online open access journal *Frontiers in Microbiology* 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 Attachment 22c, that library code is "QE2," which means that the MARC record for this serial was cataloged at the Queen Elizabeth II Library at the Memorial University of Newfoundland (St. John's, Newfoundland, Canada). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger in the Queen Elizabeth II Library at the Memorial University of Newfoundland created OCLC record number 713798955 on December 6, 2010, as shown in the "Entered" field ("20101206"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 22c occurred on September 13, 2021, as shown in the "Replaced" field ("20210913"). I personally identified and retrieved the MARC record that is Attachment 22c. The "BLvl" entry in Attachment 22c is "s," which indicates that the online open access journal *Frontiers in Microbiology* is a serial publication. Accordingly, the MARC record for Exhibit 1030 corresponds to the online open access journal *Frontiers in*

Microbiology from the time the serial title began publication and includes the date of the Haon article.

206. Attachment 22c includes an entry in field 050 ("QR1 $b .F76")—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 060 ("W1")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 22c further includes three descriptor terms reading "Microbiological Phenomena" (see Attachment 22b, National Library of Medicine subject heading D008827), "Microbiology $x periodical" (see Attachment 19b, National Library of Medicine subject heading D008829), and "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 22c was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of December 6, 2010, the MARC record attached hereto as Attachment 22c 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.

207. Attachment 22c indicates that the online open access journal *Frontiers in Microbiology* as cataloged in the Queen Elizabeth II Library at the Memorial University of Newfoundland is currently available from 372 libraries. In view of the above, this issue of the online open access journal *Frontiers in Microbiology* was publicly available on or shortly after September 23, 2015, because by that date it had been cataloged and indexed in the Queen Elizabeth II Library at the Memorial University of Newfoundland, made part of the OCLC bibliographic database, and received in the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1030 was published and accessible to the public on or shortly after September 23, 2015.

T. Krainer article [Exhibit 1031]

208. Exhibit 1031 is a copy of an article from of Volume 14 of the online open access journal *Microbial Cell Factories* found in the National Library of Medicine (Bethesda, Maryland). The article, "Optimizing Cofactor Availability for the Production of Recombinant Heme Peroxidase in *Pichia pastoris*" by Florian W. Krainer, Simona Capone, Martin Jäger, Thomas Vogl, Michaela Gerstmann, Anton Glieder, Christoph Herwig, and Oliver Spadiut (hereafter "Krainer"), appears in this issue dated January 13, 2015.

209. Exhibit 1031 is a true and correct copy of the Krainer article that I obtained through the National Library of Medicine. Exhibit 1031 is a true and correct copy of the Krainer article (9 pages). 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 1031 was found within the custody of a library – a place where, if authentic, a copy of this online open access journal would likely be. Exhibit 1031 is a true and correct copy in a condition that creates no suspicion about its authenticity.

210. The Krainer article is available from the publisher's website, BioMed Central Ltd., part of Springer Nature.[84] The publisher's website indicates that the issue was published online on January 13, 2015.

211. Attached hereto as Attachment 23a is a true and correct copy of the MARC record for the online open access journal *Microbial Cell Factories* from the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. I personally identified and retrieved the MARC record that is Attachment 23a.

[84] https://microbialcellfactories.biomedcentral.com/articles/10.1186/s12934-014-0187-z.

212. As noted in the holdings information (field 362), the National Library of Medicine has received the online open access journal *Microbial Cell Factories* since 2002 and continues to receive the publication. In view of the MARC record for Exhibit 1031, the Krainer article was publicly available on January 13, 2015.

213. The "BLvl" entry in Attachment 23a is "s," which indicates that the online open access journal *Microbial Cell Factories* is a serial publication. Field 310 of Attachment 23a reads "Annual." Accordingly, the MARC record for Exhibit 1031 corresponds to those issues of the online open access journal *Microbial Cell Factories* from the time of the serial began publication to the present day.

214. Attachment 23a further includes five descriptor terms reading "Cells $x microbiology" (see Attachment 9b, National Library of Medicine subject heading D002477), "Biotechnology" (see Attachment 9c, National Library of Medicine subject heading D001709), "Cell Culture Techniques $x statistics & numerical data" (see Attachment 9d, National Library of Medicine subject headings D018939), "Genetics, Microbial" (see Attachment 9e, National Library of Medicine subject heading D005827), and "Recombinant Proteins" (see Attachment 9f, National Library of Medicine subject heading D011994) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 23a was indexed according to its subject matter by virtue of at least one independently sufficient classification: the field 650 entries. Further, as of April 24,

2002, the MARC record attached hereto as Attachment 23a 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.

215. Attachment 23b indicates that the MARC record for the online open access journal *Microbial Cell Factories* 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 Attachment 23b, that library code is "VAM," which means that the MARC record for this serial was cataloged at the Moore Health Science Library at the University of Virginia (Charlottesville, Virginia). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger in the Moore Health Science Library at the University of Virginia created OCLC record number 49659355 on April 24, 2002, as shown in the "Entered" field ("20020424"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 23b occurred on December 23, 2021, as shown in the "Replaced" field ("20211223"). I personally identified and retrieved the MARC record that is Attachment 23b. The "BLvl" entry in Attachment 23b is "s," which indicates that the online open access journal *Microbial Cell Factories* is a serial publication. Accordingly, the MARC

record for Exhibit 1031 corresponds to the online open access journal *Microbial Cell Factories* from the time the serial title began publication and includes the date of the Krainer article.

216. Attachment 23b includes an entry in field 050 ("TP248.27 $b .M53")—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 060 ("W1")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 23b further includes two descriptor terms reading "Microbial biotechnology $v Periodicals" (see Attachment 9h, Library of Congress subject heading sh89001096 and Attachment 5c, Library of Congress subject heading sh85099890) and "Recombinant proteins $x Synthesis $v Periodicals" (see Attachment 9i, Library of Congress subject heading sh90005744 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 23b was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of April 24, 2002, the MARC record attached hereto as Attachment 23b 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.

217. Attachment 23b indicates that the online open access journal *Microbial Cell Factories* as cataloged in the Moore Health Science Library at the University of Virginia is currently available from 1,287 libraries. In view of the above, this issue of the online open access journal *Microbial Cell Factories* was publicly available on or shortly after January 13, 2015, because by that date it had been cataloged and indexed in the Moore Health Science Library at the University of Virginia, made part of the OCLC bibliographic database, and received in the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1031 was published and accessible to the public on or shortly after January 13, 2015.

U. Guarna article [Exhibit 1032]

218. Attached hereto as Exhibit 1032 is a copy of the journal article, "On-Line Monitoring and Control of Methanol Concentration in Shake-Flask Cultures of *Pichia pastoris*" by M.M. Guarna, G.J. Lesnicki, B.M. Tam, J. Robinson, C.Z. Radziminski, D. Hasenwinkle, A. Boraston, E. Jervis, R.T. MacGillivray, R.F. Turner, and D.G. Kilburn (hereafter "Guarna"). The Guarna article was published

in Volume 56, Number 3 of the journal *Biotechnology and Bioengineering*. The Guarna article appears beginning on page 279 of this issue dated November 5, 1997.

219. I obtained Exhibit 1032 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1032 is a true and correct copy of the Guarna article (pages 279-286). 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. The Guarna article is also available from the publisher, Wiley,[85] the National Library of Medicine,[86] and the digital repository *Semantic Scholar*.[87] Exhibit 1032 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1032 is a true and correct copy in a condition that creates no suspicion about its authenticity.

220. Attached hereto as Attachment 24a is a true and correct copy of the MARC record for the journal *Biotechnology and Bioengineering* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library

[85] https://onlinelibrary.wiley.com/doi/10.1002/%28SICI%291097-0290%281997 1105%2956%3A3%3C279%3A%3AAID-BIT5%3E3.0.CO%3B2-G.

[86] https://pubmed.ncbi.nlm.nih.gov/18636643/.

[87] https://www.semanticscholar.org/paper/On-line-monitoring-and-control-of-methanol-in-of-Guarna-Lesnicki/c3d8686ea1307193443b652686c6c7867c8d8073.

ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 24a occurred on October 30, 2019, as shown in field 005 field ("20191030"). I personally identified and retrieved the MARC record that is Attachment 24a.

221. Based on finding a copy of Exhibit 1032 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 24a, it is my opinion that the Guarna article published in the journal *Biotechnology and Bioengineering* was publicly available on or shortly after October 7, 1997, as indicated by the date stamp on the third page of Exhibit 1032. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked.

222. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Biotechnology and Bioengineering* since February 1959 and continues to receive the publication.[88] In view of the MARC record for Exhibit 1032, the Guarna article was publicly available on or shortly after October 7, 1997, because by that date the serial title had been

[88] The publication was originally titled *Journal of Biochemical and Microbiological Technology and Engineering* (February 1959-December 1961) and adopted the current title, *Biotechnology and Bioengineering,* in 1962.

received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

223. Attached hereto as Attachment 24b is a true and correct copy of the MARC record for the journal *Biotechnology and Bioengineering* 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 or name. For Attachment 24b, that library code is "NLM," which means that the MARC record for this serial was cataloged at the National library of Medicine (Bethesda, Maryland). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the National Library of Medicine created OCLC record number 1224461 on March 19, 1975, as shown in the "Entered" field ("19750319"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 24b occurred on August 13, 2022, as shown in the "Replaced" field ("20220813"). I personally identified and retrieved the MARC record that is Attachment 24b. The "BLvl" entry in Attachment 24b is "s," which indicates that the journal *Biotechnology and Bioengineering* is a serial publication. Field 310 of Attachment 24b reads "Eighteen issues yearly, $b 2006-." Accordingly, the MARC record for Exhibit 1032 corresponds to the journal *Biotechnology and Bioengineering* from the time the serial title began and includes the date of the Guarna article.

224. Attachment 24b includes an entry in field 050 ("QH324 $b .B5")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b BI918N")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("574")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 24b further includes eight descriptor terms reading "Biotechnology $v Periodicals" (see Attachment 1d, Library of Congress subject heading sh2007101988), "Bioengineering $v Periodicals" (see Attachment 24c, Library of Congress subject heading sh2009117061), "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985), "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742), "Technology $v Periodicals" (see Attachment 24d, Library of Congress subject heading sh85133164), "Biochemistry" (see Attachment 24e, Library of Congress subject heading sh85014171), "Microbiology" (see Attachment 21d, Library of Congress subject heading sh85084783), and "Technology" (see Attachment 24f, Library of Congress subject heading sh85133147) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as

Attachment 24b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of March 19, 1975, the MARC record attached hereto as Attachment 24b 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.

225. Attachment 24b indicates that the journal *Biotechnology and Bioengineering* cataloged at the National Library of Medicine is currently available from 448 libraries. In view of the above, this issue of the journal *Biotechnology and Bioengineering* was publicly available on or shortly after October 7, 1997, because by that date it had been cataloged and indexed at the National Library of Medicine, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1032 was published and accessible to the public on or shortly after October 7, 1997.

V. Katakura article [Exhibit 1033]

226. Attached hereto as Exhibit 1033 is a copy of the journal article, "Effect of Methanol Concentration on the Production of Human β2-Glycoprotein I Domain

V by a Recombinant *Pichia pastoris*: A Simple System for the Control of Methanol Concentration Using a Semiconductor Gas Sensor" by Yoshio Katakura, Wenhui Zhang, Guoqiang Zhuang, Takeshi Omasa, Michimasa Kishimoto, Yuji Goto, and Ken-Ichi Suga (hereafter "Katakura"). The Katakura article was published in Volume 86, Number 5 of the *Journal of Fermentation and Bioengineering*. The Katakura article appears beginning on page 482 of this issue dated 1998.

227. I obtained Exhibit 1033 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1033 is a true and correct copy of the Katakura article (pages 482-487). 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. The Katakura article is also available from the publisher, Elsevier,[89] and through the Food and Agriculture Organization of the United Nations (AGRIS).[90] Exhibit 1033 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1033 is a true and correct copy in a condition that creates no suspicion about its authenticity.

[89] https://www.sciencedirect.com/science/article/abs/pii/S0922338X98801566.

[90] https://agris.fao.org/agris-search/search.do?recordID=JP1999003555.

228. Attached hereto as Attachment 25a is a true and correct copy of the MARC record for the *Journal of Fermentation and Bioengineering* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 25a occurred on October 29, 2019, as shown in field 005 field ("20191029"). I personally identified and retrieved the MARC record that is Attachment 25a.

229. Based on finding a copy of Exhibit 1033 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 25a, it is my opinion that the Katakura article published in the *Journal of Fermentation and Bioengineering* was publicly available on or shortly after December 30, 1998, as indicated by the date stamp on the first page of Exhibit 1033. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked.

230. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the *Journal of Fermentation*

and Bioengineering since February 1959 and continues to receive the publication.[91] In view of the MARC record for Exhibit 1033, the Katakura article was publicly available on or shortly after December 30, 1998, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

231. Attached hereto as Attachment 25b is a true and correct copy of the MARC record for the *Journal of Fermentation and Bioengineering* 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 or name. For Attachment 25b, that library code is "WPG," which means that the MARC record for this serial was cataloged at the Worcester Polytech Institute Library (Worcester, Massachusetts). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the Worcester Polytech Institute Library created OCLC record number 19468128 on March 28, 1989, as shown in the "Entered" field ("19890328"). The library continues to update this MARC record and enhanced the

[91] The publication was originally titled *Jōzōgaku zasshi* (1923-1944), changed the title to *Hakkō kōgaku zasshi* (1944-1976), later changed the title to the *Journal of Fermentation Technology* (1977-1988), changed the title to the *Journal of Fermentation and Bioengineering* (1989-1998), and adopted the current title, the *Journal of Bioscience and Bioengineering,* in 1999.

MARC record to meet current cataloging rules. The most recent enhancement to Attachment 25b occurred on April 3, 2022, as shown in the "Replaced" field ("20220403"). I personally identified and retrieved the MARC record that is Attachment 25b. The "BLvl" entry in Attachment 25b is "s," which indicates that the *Journal of Fermentation and Bioengineering* is a serial publication. Field 310 of Attachment 25b reads "Monthly." Accordingly, the MARC record for Exhibit 1033 corresponds to the *Journal of Fermentation and Bioengineering* from the time the serial title began and includes the date of the Katakura article.

232. Attachment 25b includes an entry in field 050 ("QR151 $b .J68")—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 060 ("W1 $b JO659F")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 25b further includes six descriptor terms reading "Fermentation $v Periodicals" (see Attachment 25c, Library of Congress subject heading sh2008120394), "Bioengineering $v Periodicals" (see Attachment 24c, Library of Congress subject heading sh2009117061), "Industrial microbiology $v Periodicals" (see Attachment 5b, Library of Congress subject heading sh85065899 and Attachment 5c, Library of Congress subject heading gsh8099890), "Biomedical

engineering" (see Attachment 14e, Library of Congress subject heading sh85014237), and "Fermentation" (see Attachment 25d, Library of Congress subject heading sh85047829) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 25b was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of March 28, 1989, the MARC record attached hereto as Attachment 25b 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.

233. Attachment 25b indicates that the *Journal of Fermentation and Bioengineering* cataloged at the Worcester Polytech Institute Library is currently available from 161 libraries. In view of the above, this issue of the *Journal of Fermentation and Bioengineering* was publicly available on or shortly after December 30, 1998, because by that date it had been cataloged and indexed at the Worcester Polytech Institute Library, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering &

Technology. For these reasons, it is my opinion that Exhibit 1033 was published and accessible to the public on or shortly after December 30, 1998.

W. Hong article [Exhibit 1034]

234. Attached hereto as Exhibit 1034 is a copy of the journal article, "Fermentation Strategies for Improved Heterologous Expression of Laccase in *Pichia pastoris*" by Feng Hong, Nina Q. Meinander, and Leif J. Jönsson (hereafter "Hong"). The Hong article was published in Volume 79, Number 4 of the journal *Biotechnology and Bioengineering*. The Hong article appears beginning on page 438 of this issue dated August 20, 2002.

235. I obtained Exhibit 1034 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1034 is a true and correct copy of the Hong article (pages 438-449). 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. The Hong article is also available from the publisher, Wiley,[92] the National Library of Medicine,[93] and the digital repositories *ResearchGate*[94] and

[92] https://onlinelibrary.wiley.com/doi/abs/10.1002/bit.10297

[93] https://pubmed.ncbi.nlm.nih.gov/12115407/.

[94] https://www.researchgate.net/publication/11264103_Fermentation_strategies_for_improved_heterologous_expression_of_laccase_in_Pichia_pastoris.

Pascal.[95] Exhibit 1034 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1034 is a true and correct copy in a condition that creates no suspicion about its authenticity.

236. Attached hereto as Attachment 26a is a true and correct copy of the MARC record for the journal *Biotechnology and Bioengineering* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 26a occurred on October 30, 2019, as shown in field 005 field ("20191030"). I personally identified and retrieved the MARC record that is Attachment 26a.

237. Based on finding a copy of Exhibit 1034 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 26a, it is my opinion that the Hong article published in the journal *Biotechnology and Bioengineering* was publicly available on or shortly after June 13, 2002, as indicated on the publisher's website.

[95] https://pascal-francis.inist.fr/vibad/index.php?action=getRecordDetail&idt=13807820.

238. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Biotechnology and Bioengineering* since February 1959 and continues to receive the publication.[96] In view of the MARC record for Exhibit 1034, the Hong article was publicly available on or shortly after June 13, 2002, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

239. Attached hereto as Attachment 26b is a true and correct copy of the MARC record for the journal *Biotechnology and Bioengineering* 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 or name. For Attachment 26b, that library code is "NLM," which means that the MARC record for this serial was cataloged at the National library of Medicine (Bethesda, Maryland). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the National Library of Medicine created OCLC record number 1224461 on March 19, 1975, as shown in the "Entered" field ("19750319"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules.

[96] The publication was originally titled *Journal of Biochemical and Microbiological Technology and Engineering* (February 1959-December 1961) and adopted the current title, *Biotechnology and Bioengineering,* in 1962.

The most recent enhancement to Attachment 26b occurred on August 13, 2022, as shown in the "Replaced" field ("20220813"). I personally identified and retrieved the MARC record that is Attachment 26b. The "BLvl" entry in Attachment 26b is "s," which indicates that the journal *Biotechnology and Bioengineering* is a serial publication. Field 310 of Attachment 26b reads "Eighteen issues yearly, $b 2006-." Accordingly, the MARC record for Exhibit 1034 corresponds to the journal *Biotechnology and Bioengineering* from the time the serial title began and includes the date of the Hong article.

240. Attachment 26b includes an entry in field 050 ("QH324 $b .B5")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b BI918N")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("574")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 26b further includes eight descriptor terms reading "Biotechnology $v Periodicals" (see Attachment 1d, Library of Congress subject heading sh2007101988), "Bioengineering $v Periodicals" (see Attachment 24c, Library of Congress subject heading sh2009117061), "Biochemistry $v Periodicals" (see Attachment 12b,

Library of Congress subject heading sh2007101985), "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742), "Technology $v Periodicals" (see Attachment 24d, Library of Congress subject heading sh85133164), "Biochemistry" (see Attachment 24e, Library of Congress subject heading sh85014171), "Microbiology" (see Attachment 21d, Library of Congress subject heading sh85084783), and "Technology" (see Attachment 24f, Library of Congress subject heading sh85133147) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 26b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of March 19, 1975, the MARC record attached hereto as Attachment 26b 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.

241. Attachment 26b indicates that the journal *Biotechnology and Bioengineering* cataloged at the National Library of Medicine is currently available from 448 libraries. In view of the above, this issue of the journal *Biotechnology and Bioengineering* was publicly available on or shortly after June 13, 2002, because by

that date it had been cataloged and indexed at the National Library of Medicine, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1034 was published and accessible to the public on or shortly after June 13, 2002.

X. Trinh article [Exhibit 1035]

242. Attached hereto as Exhibit 1035 is a copy of the journal article, "Effect of Methanol Feeding Strategies on Production and Yield of Recombinant Mouse Endostatin from *Pichia pastoris*" by L.B. Trinh, J.N. Phue, and Joseph Shiloach (hereafter "Trinh"). The Trinh article was published in Volume 82, Number 4 of the journal *Biotechnology and Bioengineering*. The Trinh article appears beginning on page 438 of this issue dated May 20, 2003.

243. I obtained Exhibit 1035 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1035 is a true and correct copy of the Trinh article (pages 438-444). 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. The Trinh article is also available from the publisher, Wiley,[97] the

[97] https://onlinelibrary.wiley.com/doi/abs/10.1002/bit.10587.

National Library of Medicine,[98] and the digital repository *Semantic Scholar*.[99] Exhibit 1035 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1035 is a true and correct copy in a condition that creates no suspicion about its authenticity.

244. Attached hereto as Attachment 27a is a true and correct copy of the MARC record for the journal *Biotechnology and Bioengineering* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 27a occurred on October 30, 2019, as shown in field 005 field ("20191030"). I personally identified and retrieved the MARC record that is Attachment 27a.

245. Based on finding a copy of Exhibit 1035 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 27a, it is my opinion that the Trinh article published in the journal *Biotechnology and Bioengineering* was publicly available on or shortly after April 29, 2003, as shown by the date stamp on the third page of Exhibit 1035. This

[98] https://pubmed.ncbi.nlm.nih.gov/12632400/.

[99] https://www.semanticscholar.org/paper/Effect-of-methanol-concentration-on-the-production-Katakura-Zhang/74d844361ffc9aa8f690299c914b2fb40c1d763a.

date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked.

246. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the journal *Biotechnology and Bioengineering* since February 1959 and continues to receive the publication.[100] In view of the MARC record for Exhibit 1035, the Trinh article was publicly available on or shortly after April 29, 2003, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

247. Attached hereto as Attachment 27b is a true and correct copy of the MARC record for the journal *Biotechnology and Bioengineering* 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 or name. For Attachment 27b, that library code is "NLM," which means that the MARC record for this serial was cataloged at the National library of Medicine (Bethesda, Maryland). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the National Library of Medicine created OCLC record number 1224461 on March 19,

[100] The publication was originally titled *Journal of Biochemical and Microbiological Technology and Engineering* (February 1959-December 1961) and adopted the current title, *Biotechnology and Bioengineering,* in 1962.

1975, as shown in the "Entered" field ("19750319"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 27b occurred on August 13, 2022, as shown in the "Replaced" field ("20220813"). I personally identified and retrieved the MARC record that is Attachment 27b. The "BLvl" entry in Attachment 27b is "s," which indicates that the journal *Biotechnology and Bioengineering* is a serial publication. Field 310 of Attachment 27b reads "Eighteen issues yearly, $b 2006-." Accordingly, the MARC record for Exhibit 1035 corresponds to the journal *Biotechnology and Bioengineering* from the time the serial title began and includes the date of the Trinh article.

248. Attachment 27b includes an entry in field 050 ("QH324 $b .B5")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b BI918N")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("574")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 27b further includes eight descriptor terms reading "Biotechnology $v Periodicals" (see Attachment 1d, Library of Congress subject heading sh2007101988),

"Bioengineering $v Periodicals" (see Attachment 24c, Library of Congress subject heading sh2009117061), "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985), "Microbiology $v Periodicals" (see Attachment 2c, Library of Congress subject heading sh2008107742), "Technology $v Periodicals" (see Attachment 24d, Library of Congress subject heading sh85133164), "Biochemistry" (see Attachment 24e, Library of Congress subject heading sh85014171), "Microbiology" (see Attachment 21d, Library of Congress subject heading sh85084783), and "Technology" (see Attachment 24f, Library of Congress subject heading sh85133147) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 27b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of March 19, 1975, the MARC record attached hereto as Attachment 27b 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.

249. Attachment 27b indicates that the journal *Biotechnology and Bioengineering* cataloged at the National Library of Medicine is currently available

from 448 libraries. In view of the above, this issue of the journal *Biotechnology and Bioengineering* was publicly available on or shortly after April 29, 2003, because by that date it had been cataloged and indexed at the National Library of Medicine, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1035 was published and accessible to the public on or shortly after April 29, 2003.

Y. Bawa article [Exhibit 1036]

250. Exhibit 1036 is a copy of Volume 13, Article 127 of the online open access journal *Microbial Cell Factories* found in the National Library of Medicine (Bethesda, Maryland). The article "Functional Recombinant Protein is Present in the Pre-Induction Phases of *Pichia Pastoris* Cultures When Grown in Bioreactors, But Not Shake-Flasks" by Zharain Bawa, Sarah J. Routledge, Mohammed Jamshad, Michelle Clare, Debasmita Sarkar, Ian Dickerson, Markus Ganzlin, David R. Poyner, and Roslyn M. Bill (hereafter "Bawa") appears in this this issue dated 2014.

251. Exhibit 1036 is a true and correct copy of the Bawa article that I obtained this copy of the article through the National Library of Medicine. Exhibit 1036 is a true and correct copy of the Bawa article (13 pages). 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 1036 was found within the custody of a library – a place where, if authentic, a copy of this online open access journal would likely be. Exhibit 1036 is a true and correct copy in a condition that creates no suspicion about its authenticity.

252. The Bawa article is available from the publisher's website—BioMed Central Ltd., part of Springer Nature[101]—and the digital repository *Semantic Scholar*.[102] The publisher's website indicates that the issue was published online on September 4, 2014.

253. Attached hereto as Attachment 28a is a true and correct copy of the MARC record for the online open access journal *Microbial Cell Factories* from the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. I personally identified and retrieved the MARC record that is Attachment 28a.

254. As noted in the holdings information (field 362), the National Library of Medicine has received the online open access journal *Microbial Cell Factories*

[101] https://microbialcellfactories.biomedcentral.com/articles/10.1186/s12934-014-0127-y.

[102] https://www.semanticscholar.org/paper/Functional-recombinant-protein-is-present-in-the-of-Bawa-Routledge/28b96e7b891328a83e38c21d4d66e0cde533ff5a.

since 2002 and continues to receive the publication. In view of the MARC record for Exhibit 1036, the Bawa article was publicly available on September 4, 2014.

255. The "BLvl" entry in Attachment 28a is "s," which indicates that the online open access journal *Microbial Cell Factories* is a serial publication. Field 310 of Attachment 28a reads "Annual." Accordingly, the MARC record for Exhibit 1036 corresponds to those issues of the online open access journal *Microbial Cell Factories* from the time of the serial began publication to the present day.

256. Attachment 28a further includes five descriptor terms reading "Cells $x microbiology" (see Attachment 9b, National Library of Medicine subject heading D002477), "Biotechnology" (see Attachment 9c, National Library of Medicine subject heading D001709), "Cell Culture Techniques $x statistics & numerical data" (see Attachment 9d, National Library of Medicine subject headings D018939), "Genetics, Microbial" (see Attachment 9e, National Library of Medicine subject heading D005827), and "Recombinant Proteins" (see Attachment 9f, National Library of Medicine subject heading D011994) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 28a was indexed according to its subject matter by virtue of an independently sufficient classification: the field 650 entries. Further, as of April 24, 2002, the MARC record attached hereto as Attachment 28a 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.

257. Attachment 28b indicates that the MARC record for the online open access journal *Microbial Cell Factories* 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 Attachment 28b, that library code is "VAM," which means that the MARC record for this serial was cataloged at the Moore Health Science Library at the University of Virginia (Charlottesville, Virginia). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger in the Moore Health Science Library at the University of Virginia created OCLC record number 49659355 on April 24, 2002, as shown in the "Entered" field ("20020424"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 28b occurred on December 23, 2021, as shown in the "Replaced" field ("20211223"). I personally identified and retrieved the MARC record that is Attachment 28b. The "BLvl" entry in Attachment 28b is "s," which indicates that the online open access journal *Microbial Cell Factories* is a serial publication. Accordingly, the MARC record for Exhibit 1036 corresponds to the online open access journal *Microbial Cell*

Factories from the time the serial title began publication and includes the date of the Bawa article.

258. Attachment 28b includes an entry in field 050 ("TP248.27 $b .M53")—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 060 ("W1")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 28b further includes two descriptor terms reading "Microbial biotechnology $v Periodicals" (see Attachment 9h, Library of Congress subject heading sh89001096 and Attachment 5c, Library of Congress subject heading sh85099890) and "Recombinant proteins $x Synthesis $v Periodicals" (see Attachment 9i, Library of Congress subject heading sh90005744 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 28b was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of April 24, 2002, the MARC record attached hereto as Attachment 28b 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.

259. Attachment 28b indicates that the online open access journal *Microbial Cell Factories* as cataloged in the Moore Health Science Library at the University of Virginia is currently available from 1,287 libraries. In view of the above, this issue of the online open access journal *Microbial Cell Factories* was publicly available on or shortly after September 4, 2014, because by that date it had been cataloged and indexed in the Moore Health Science Library at the University of Virginia, made part of the OCLC bibliographic database, and received in the National Library of Medicine. For these reasons, it is my opinion that Exhibit 1036 was published and accessible to the public on or shortly after September 4, 2014.

Z. Ferreira book excerpt [Exhibit 1037]

260. Attached hereto as Exhibit 1037 is an excerpt published in the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, edited by William J. Lennarz and M. Daniel Lane (hereafter "Ferreira"). The excerpt titled "Heme Synthesis" by C.C. Ferreira is from volume 2 and appears beginning on page 539.

261. I obtained Exhibit 1037 from the Library of Congress. Exhibit 1037 is a true and correct copy of the Ferreira excerpt (pages 539-542). The text in Exhibit

1037 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 1037 is a true and correct copy in a condition that creates no suspicion about its authenticity.

262. Attached hereto as Attachment 29a is a true and correct copy of the MARC record for this book from the Library of Congress online catalog. The library ownership is indicated by the presence of the library's code (DLC) in the 040 field. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to the MARC record occurred on November 12, 2015, as shown in the 005 field ("20151112"). I personally identified and retrieved the library catalog record which is Attachment 29a.

263. Based on finding a print copy of the Ferriera excerpt in the Library of Congress and MARC record in its online library catalog attached as Attachment 29a, it is my opinion that the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, was publicly available on or shortly after September 3, 2013, as shown in field 008 ("1130903"). The International Standard Book Number (ISBN) for the four-volume set on Exhibit 1037 (978-0-123-78630-2) matches the ISBN in the first field 020 of Attachment 29a. Therefore, Exhibit 1037 is the set of

books that the cataloger in the Library of Congress used to create the MARC record that is Attachment 29a.

264. Attached hereto as Attachment 29b is a true and correct copy of the MARC record for the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 29b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 29b, that library code is "DLC," which means that the MARC record for this book was created at the Library of Congress.

265. 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 842339140 on September 3, 2013, as shown in the "Entered" field ("20130903"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 29b occurred on June 13, 2022, as shown in the "Replaced" field ("20220613"). I personally identified and retrieved the MARC record that is Attachment 29b.

266. Attachment 29b further includes an entry in field 050 ("QD415.A25 $b E53 2013")—a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("QU 13 $b E554 2013")—a subject matter

classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("572.03")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 29b further includes two descriptor terms reading "Biochemistry $v Encyclopedias" (see Attachment 24e, Library of Congress subject heading sh85014171 and Attachment 14d, Library of Congress subject heading sh85042997) and "Biochemistry" (see Attachment 24e, Library of Congress subject heading sh85014171) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 29b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. Further, as of September 3, 2013, the MARC record attached hereto as Attachment 29b was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that acquired the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, 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.

267. Further supporting my opinion that Exhibit 1037 was publicly accessible to ordinarily skilled and interested researchers in the field is the fact that

the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, was registered with the U.S. Copyright Office as item TX0007714784 on May 6, 2013 and indicated a publication date of February 15, 2013 (see Attachment 29c, U.S. Copyright Office Public Catalog). As noted above, this would have provided a person interested in the relevant subject matter with keyword searching capabilities and other tools to locate this book.

268. Attachment 29b indicates that the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, as cataloged at the Library of Congress is currently available from 32 libraries. In view of above, the four-volume set titled *Encyclopedia of Biological Chemistry*, 2nd edition, was publicly available on or shortly after September 3, 2013, because by that date it had been received, cataloged, and indexed at the Library of Congress and made part of the OCLC bibliographic database. For these reasons, it is my opinion that Exhibit 1037 was published and accessible to the public on or shortly after September 3, 2013.

AA. Cantor book excerpt [Exhibit 1041]

269. Attached hereto as Exhibit 1041 is an excerpt published in the book titled *Genomics: The Science and Technology Behind the Human Genome Project* by Charles R. Cantor and Cassandra Smith (hereafter "Cantor"). The excerpt titled "DNA Chemistry and Biology" is from Chapter 1 and appears beginning on page 12.

270. I obtained Exhibit 1041 from the University of Wisconsin – Madison Libraries. Exhibit 1041 is a true and correct copy of the Cantor excerpt (pages 12-14). The text in Exhibit 1041 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 1041 is a true and correct copy in a condition that creates no suspicion about its authenticity.

271. Attached hereto as Attachment 30a is a true and correct copy of the MARC record for this book from the University of Wisconsin – Madison Libraries online catalog. The library ownership is indicated by the presence of the library's code (GZM) in the 049 field. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to the MARC record occurred on November 16, 2006, as shown in the 005 field ("20061116"). I personally identified and retrieved the library catalog record which is Attachment 30a.

272. Based on finding a print copy of the Cantor excerpt in the University of Wisconsin – Madison Libraries and MARC record in its online library catalog attached as Attachment 30a, it is my opinion that the book titled *Genomics: The Science and Technology Behind the Human Genome Project* was publicly available on or shortly after August 5, 1998, as shown in field 008 ("980805"). The International Standard Book Number (ISBN) on Exhibit 1041 (0-471-59908-5)

matches the ISBN in the first field 020 of Attachment 30a. Therefore, Exhibit 1041 is the book as the one that the cataloger in the University of Wisconsin – Madison Libraries used to create the MARC record that is Attachment 30a.

273. Attached hereto as Attachment 30b is a true and correct copy of the MARC record for the book titled *Genomics: The Science and Technology Behind the Human Genome Project* obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 30b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 30b, that library code is "DLC," which means that the MARC record for this book was created at the Library of Congress as part of the Cataloging in Publication (CIP) Program.[103] A cataloger prepares basic information about the forthcoming book, which is included on the verso of the title page (also called the copyright page). The information is provided to save time needed for the cataloging process at the library after the book is purchased. The CIP data includes the author (field 100), title and subtitle (field 245), edition statement (field 250), ISBN (field 022), suggested subject headings (field 650), classification numbers for the Library of Congress classification number (field 050), and the Dewey Decimal classification number (field 082). These data elements are included

[103] https://www.loc.gov/publish/cip/.

in the MARC record that the Library of Congress contributes to the OCLC bibliographic database.

274. 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 39700016 on August 5, 1998, as shown in the "Entered" field ("19980805"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 30b occurred on July 18, 2022, as shown in the "Replaced" field ("20220718"). I personally identified and retrieved the MARC record that is Attachment 30b.

275. Attachment 30b further includes an entry in field 050 ("QP624 $b .C36 1999")—a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("QU 58.5 $b C232g 1999")—a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("572.8/6")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 30b further includes three descriptor terms reading "DNA analysis" (see Attachment 30c, Library of Congress subject heading sh2008117525), "Nucleotide sequence" (see Attachment 30d, Library of Congress subject heading sh85093159), and "Gene mapping" (see Attachment 30e,

Library of Congress subject heading sh85025386) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 30b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. Further, as of August 5, 1998, the MARC record attached hereto as Attachment 30b was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that acquired the book titled *Genomics: The Science and Technology Behind the Human Genome Project* 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.

276. Further supporting my opinion that Exhibit 1041 was publicly accessible to ordinarily skilled and interested researchers in the field is the fact that the book titled *Genomics: The Science and Technology Behind the Human Genome Project* was registered with the U.S. Copyright Office as item TX0004936725 on February 19, 1999 and indicated a publication date of February 2, 1999 (see Attachment 30f, U.S. Copyright Office Public Catalog). As noted above, this would have provided a person interested in the relevant subject matter with keyword searching capabilities and other tools to locate this book.

277. Attachment 30b indicates that the book titled *Genomics: The Science and Technology Behind the Human Genome Project* as cataloged at the Library of Congress is currently available from 543 libraries. In view of above, the book titled *Genomics: The Science and Technology Behind the Human Genome Project* was publicly available on or shortly after February 2, 1999, because by that date it had been received, cataloged, and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the University of Wisconsin – Madison Libraries. For these reasons, it is my opinion that Exhibit 1041 was published and accessible to the public on or shortly after February 2, 1999.

BB. Alberts book excerpts [Exhibit 1042]

278. Attached hereto as Exhibit 1042 are excerpts published in the book titled *Molecular Biology of the Cell*, 4th edition, by Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, and Peter Walter (hereafter "Alberts"). The excerpts are from Chapter 6, "How Cells Read the Genome: From DNA to Protein" (pages 305-312 and 333-336) and Chapter 8, "Manipulating Proteins, DNA, and RNA" (pages 537-540).

279. I obtained Exhibit 1042 from the University of Wisconsin – Madison Libraries. Exhibit 1042 is a true and correct copy of the Alberts excerpts. The text in Exhibit 1042 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 1042 is a true and correct copy in a condition that creates no suspicion about its authenticity.

280. Attached hereto as Attachment 31a is a true and correct copy of the MARC record for this book from the University of Wisconsin – Madison Libraries online catalog. The library ownership is indicated by the presence of the library's code (uwmadisondb) in the second 035 field. The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to the MARC record occurred on August 5, 2015, as shown in the 005 field ("20150805"). I personally identified and retrieved the library catalog record which is Attachment 31a.

281. Based on finding a print copy of the Alberts excerpts in the University of Wisconsin – Madison Libraries and MARC record in its online library catalog attached as Attachment 31a, it is my opinion that the book titled *Molecular Biology of the Cell*, 4th edition, was publicly available on or shortly after October 4, 2001, as shown in field 008 ("011004"). The International Standard Book Number (ISBN) on Exhibit 1042 (0-8153-4072-9) matches the ISBN in the second field 020 of Attachment 31a. Therefore, Exhibit 1042 is the book as the one that the cataloger in the University of Wisconsin – Madison Libraries used to create the MARC record that is Attachment 31a.

282. Attached hereto as Attachment 31b is a true and correct copy of the MARC record for the book titled *Molecular Biology of the Cell*, 4th edition, obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 31b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 31b, that library code is "DLC," which means that the MARC record for this book was created at the Library of Congress as part of the Cataloging in Publication (CIP) Program.[104] A cataloger prepares basic information about the forthcoming book which is included on the verso of the title page (also called the copyright page). The information is provided to save time needed for the cataloging process at the library after the book is purchased. The CIP data includes the author (field 100), title and subtitle (field 245), edition statement (field 250), ISBN (field 022), suggested subject headings (field 650), classification numbers for the Library of Congress classification number (field 050), and the Dewey Decimal classification number (field 082). These data elements are included in the MARC record that the Library of Congress contributes to the OCLC bibliographic database.

283. 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

[104] https://www.loc.gov/publish/cip/.

48122761 on October 4, 2001, as shown in the "Entered" field ("20011004"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 31b occurred on July 22, 2022, as shown in the "Replaced" field ("20220722"). I personally identified and retrieved the MARC record that is Attachment 31b.

284. Attachment 31b further includes an entry in field 050 ("QH581.2 $b .M64 2002")—a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("QH581.2 $b M718 2002")—a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and an entry in field 082 ("571.6")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 31b further includes three descriptor terms reading "Cytology" (see Attachment 31c, Library of Congress subject heading sh85035240), "Molecular microbiology" (see Attachment 18b, Library of Congress subject heading sh87007715), and "Cells" (see Attachment 31d, Library of Congress subject heading sh85021678) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 31b was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry,

and the field 650 entries. Further, as of October 4, 2001, the MARC record attached hereto as Attachment 31b was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that acquired the book titled *Molecular Biology of the Cell*, 4th edition, 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.

285. Attachment 31b indicates that the book titled *Molecular Biology of the Cell*, 4th edition, as cataloged at the Library of Congress is currently available from 911 libraries. In view of above, the book titled *Molecular Biology of the Cell*, 4th edition, was publicly available on or shortly after October 4, 2001, because by that date it had been received, cataloged, and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received in the University of Wisconsin – Madison Libraries. For these reasons, it is my opinion that Exhibit 1042 was published and accessible to the public on or shortly after October 4, 2001.

CC. Freeman book excerpts [Exhibit 1043]

286. Attached hereto as Exhibit 1043 are excerpts published in the book titled *Biological Science*, 2nd edition, by Scott Freeman (hereafter "Freeman"). The excerpts are titled Chapter 16, "Transcription and Translation" (pp. 338-361); Chapter 17, "Control of Gene Expression in Bacteria" (pp. 362-381); and Chapter 18, "Control of Gene Expression in Eukaryotes" (pp. 382-400).

287. I obtained Exhibit 1043 from the Health Science Library at the University of Washington (Seattle, Washington). Exhibit 1043 is a true and correct copy of the Freeman excerpts. The text in Exhibit 1043 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 1043 is a true and correct copy in a condition that creates no suspicion about its authenticity.

288. Attached hereto as Attachment 32a is a true and correct copy of the MARC record for this book from the Health Science Library at the University of Washington online catalog.[105] The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to the MARC record occurred on March 24, 2022, as shown in the 005 field ("20220324"). I personally identified and retrieved the library catalog record which is Attachment 32a.

289. Based on finding a print copy of the Freeman excerpts in the Health Science Library at the University of Washington and MARC record in its online library catalog attached as Attachment 32a, it is my opinion that the book titled

[105] https://orbiscascade-washington.primo.exlibrisgroup.com/discovery/fulldisplay?docid=alma991412525400014 52&context=L&vid=01ALLIANCE_UW:UW&lang=en&search_scope=UW_EVERYTHING&adaptor=Local%20Search%20Engine&tab=UW_default&query=any,contains,0-13-140941-7&offset=0.

Biological Science, 2nd edition, was publicly available on or shortly after November 15, 2004, as shown in field 008 ("041115"). The International Standard Book Number (ISBN) on Exhibit 1043 (0-13-140941-7) matches the ISBN in the first field 020 of Attachment 32a. Therefore, Exhibit 1043 is the book as the one that the cataloger in the Health Science Library at the University of Washington used to create the MARC record that is Attachment 32a.

290. Attached hereto as Attachment 32b is a true and correct copy of the MARC record for the book titled *Biological Science*, 2nd edition, obtained from the OCLC bibliographic database. I personally identified and retrieved the MARC record that is Attachment 32b. As previously noted, the library that created the record is recorded in field 040 with a unique library code. For Attachment 32b, that library code is "DLC," which means that the MARC record for this book was created at the Library of Congress as part of the Cataloging in Publication (CIP) Program.[106] A cataloger prepares basic information about the forthcoming book, which is included on the verso of the title page (also called the copyright page). The information is provided to save time needed for the cataloging process at the library after the book is purchased. The CIP data includes the author (field 100), title and subtitle (field 245), edition statement (field 250), ISBN (field 022), suggested subject headings

[106] https://www.loc.gov/publish/cip/.

(field 650), classification numbers for the Library of Congress classification number (field 050), and the Dewey Decimal classification number (field 082). These data elements are included in the MARC record that the Library of Congress contributes to the OCLC bibliographic database.

291. 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 57008006 on November 15, 2004, as shown in the "Entered" field ("20041115"). The library continues to update and enhance this MARC record to meet current cataloging rules. The most recent enhancement to Attachment 32b occurred on March 24, 2022, as shown in the "Replaced" field ("20220324"). I personally identified and retrieved the MARC record that is Attachment 32b.

292. Attachment 32b further includes an entry in field 050 ("QH308.2 $b .F73 2005")—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 ("570")—a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 32b further includes a descriptor term reading "Biology" (see Attachment 32c, Library of Congress subject heading sh85014203) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 32b 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. Further, as of November 15, 2004, the MARC record attached hereto as Attachment 32b was accessible through any library with access to the OCLC bibliographic database or the online catalog at a library that acquired the book titled *Biological Science*, 2nd edition, 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.

293. Further supporting my opinion that Exhibit 1043 was publicly accessible to ordinarily skilled and interested researchers in the field is the fact that the book titled *Biological Science*, 2nd edition, was registered with the U.S. Copyright Office as item TX0006086750 on April 11, 2005 and indicated a publication date of December 28, 2004 (see Attachment 32d, U.S. Copyright Office Public Catalog). As noted above, this would have provided a person interested in the relevant subject matter with keyword searching capabilities and other tools to locate this book.

294. Attachment 32b indicates that the book titled *Biological Science*, 2nd edition, as cataloged at the Library of Congress is currently available from 107 libraries. In view of above, the book titled *Biological Science*, 2nd edition, was publicly available on or shortly after December 28, 3004, because by that date it had been cataloged and indexed at the Library of Congress and made part of the OCLC

bibliographic database. For these reasons, it is my opinion that Exhibit 1043 was published and accessible to the public on or shortly after December 28, 2004.

DD. Nicola article [Exhibit 1044]

295. Attached hereto as Exhibit 1044 is a copy of the journal article, "Structural Rearrangements Due to Ligand Binding and Haem Replacement in Myoglobin and Leghaemoglobins" by Nicos A. Nicola and Sydney J. Leach (hereafter "Nicola"). The Nicola article was published in Volume 78, Issue 1 of the *European Journal of Biochemistry*. The Nicola article appears beginning on page 133 of this issue dated August 1977.

296. I obtained Exhibit 1044 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1044 is a true and correct copy of the Nicola article (pages 133-140). 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. The Nicola article is also available from the publisher, Wiley,[107] and through the National Library of Medicine.[108] Exhibit 1044 was found within the custody of a library – a place where an authentic copy of this journal would likely

[107] https://febs.onlinelibrary.wiley.com/doi/full/10.1111/j.1432-1033.1977.tb11722.x.

[108] https://pubmed.ncbi.nlm.nih.gov/913393/.

be. Exhibit 1044 is a true and correct copy in a condition that creates no suspicion about its authenticity.

297. Attached hereto as Attachment 33a is a true and correct copy of the MARC record for the *European Journal of Biochemistry* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 33a occurred on October 29, 2019, as shown in field 005 field ("20191029"). I personally identified and retrieved the MARC record that is Attachment 33a.

298. Based on finding a copy of Exhibit 1044 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 33a, it is my opinion that the Nicola article published in the *European Journal of Biochemistry* was publicly available on or shortly after September 13, 1977, as indicated on shown on the cover. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 33a also shows that Exhibit 1044 was catalogued with a descriptor term reading "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985) in the 650 field.

299. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the *European Journal of Biochemistry* since March 1967 and continues to receive the publication. In view of the MARC record for Exhibit 1044, the Nicola article was publicly available on or shortly after September 13, 1977, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

300. Attached hereto as Attachment 33b is a true and correct copy of the MARC record for the *European Journal of Biochemistry* 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 or name. For Attachment 33b, that library code is "MUL," which means that the MARC record for this serial was cataloged as part of the Minnesota Union List of Serials at the University of Minnesota Libraries (Minneapolis, Minnesota). As can be seen in the "Entered" field in the MARC record for this exhibit, a cataloger at the University of Minnesota Libraries created OCLC record number 1568454 on August 24, 1975, as shown in the "Entered" field ("19750824"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 33b occurred on December 30, 2020, as shown in the "Replaced" field ("20201230"). I personally identified and retrieved the

MARC record that is Attachment 33b. The "BLvl" entry in Attachment 33b is "s," which indicates that the *European Journal of Biochemistry* is a serial publication. Field 310 of Attachment 33b reads "Twice monthly, $b <1990-2004." Accordingly, the MARC record for Exhibit 1044 corresponds to the *European Journal of Biochemistry* from the time the serial title began publication and includes the date of the Nicola article.

301. Attachment 33b includes an entry in field 050 ("QP501 $b .E87")—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 060 ("W1 $b EU68")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system). Attachment 33b further includes a descriptor term reading "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 33b was indexed according to its subject matter by virtue of at least three independently sufficient classifications: the field 050 entry, the field 060 entry, and the field 650 entries. As of August 24, 1975, the MARC record attached hereto as Attachment 33b 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.

302. Attachment 33b indicates that the *European Journal of Biochemistry* as cataloged at the University of Minnesota Libraries is currently available from 493 libraries. In view of the above, this issue of the *European Journal of Biochemistry* was publicly available on or shortly after September 13, 1977, because by that date it had been cataloged and indexed at the University of Minnesota Libraries, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1044 was published and accessible to the public on or shortly after September 13, 1977.

EE. Hargrove article [Exhibit 1045]

303. Attached hereto as Exhibit 1045 is a copy of the journal article, "Characterization of Recombinant Soybean Leghemoglobin A and Apolar Distal Histidine Mutants" by Mark S. Hargrove, Jennifer K.Barry, Eric Allen Brucker, Michael B. Berry, George N. Phillips Jr., John S. Olson, Raúl Arredondo-Peter, Jeanenne M. Dean, Robert V. Klucas, and Gautam Sarath (hereafter "Hargrove"). The Hargrove article was published in Volume 266, Number 5 of the *Journal of*

Molecular Biology. The Hargrove article appears beginning on page 1032 of this issue dated March 14, 1997.

304. I obtained Exhibit 1045 from the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). Exhibit 1045 is a true and correct copy of the Hargrove article (pages 1032-1042). 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. The Hargrove article is also available from the publisher, Elsevier[109] and through the National Library of Medicine.[110] Exhibit 1045 was found within the custody of a library – a place where an authentic copy of this journal would likely be. Exhibit 1045 is a true and correct copy in a condition that creates no suspicion about its authenticity.

305. Attached hereto as Attachment 34a is a true and correct copy of the MARC record for the *Journal of Molecular Biology* at the Linda Hall Library of Science, Engineering & Technology (Kansas City, Missouri). The library ownership is indicated by the presence of the library's code (LHL) in field 049. The library continues to update and enhance the MARC record to meet current cataloging rules.

[109] https://www.sciencedirect.com/science/article/abs/pii/S0022283696908335?via%3Dihub

[110] https://pubmed.ncbi.nlm.nih.gov/9086279/.

The most recent enhancement to Attachment 34a occurred on October 28, 2019, as shown in field 005 field ("20191028"). I personally identified and retrieved the MARC record that is Attachment 34a.

306. Based on finding a copy of Exhibit 1045 in the Linda Hall Library of Science, Engineering & Technology and MARC record in its online library catalog attached as Attachment 34a, it is my opinion that the Hargrove article published in the *Journal of Molecular Biology* was publicly available on or shortly after March 26, 1997, as indicated by the date stamp on page 2 of Exhibit 1045. This date stamp has the general appearance of date stamps that libraries have long affixed to periodicals to show when an issue was received, verified, and checked. Attachment 34a also shows that Exhibit 1045 was catalogued with three descriptor terms reading "Biology $v Periodicals" (see Attachment 34b, Library of Congress subject heading sh2007101986), "Biochemistry $v Periodicals" (see Attachment 21d, Library of Congress subject heading sh2007101985), and "Molecular biology $v Periodicals" (see Attachment 34c, Library of Congress subject heading sh2008107896) in the 650 fields.

307. As noted in the holdings information (362 field), the Linda Hall Library of Science, Engineering & Technology has received the *Journal of Molecular Biology* since April 1959 and continues to receive the publication. In view of the MARC record for Exhibit 1045, the Hargrove article was publicly available on or

shortly after March 26, 1997, because by that date the serial title had been received, cataloged, and indexed in the Linda Hall Library of Science, Engineering & Technology and made part of its online catalog database.

308. Attached hereto as Attachment 34d is a true and correct copy of the MARC record for the *Journal of Molecular Biology* 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 or name. For Attachment 34d, 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 1452923 on November 12, 1974, as shown in the "Entered" field ("19741112"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 34d occurred on July 13, 2022, as shown in the "Replaced" field ("20220713"). I personally identified and retrieved the MARC record that is Attachment 34d. The "BLvl" entry in Attachment 34d is "s," which indicates that the *Journal of Molecular Biology* is a serial publication. Field 310 of Attachment 34d reads "Twenty-four no. a year, $b <2013-." Accordingly, the MARC record for Exhibit 1045 corresponds to the *Journal of Molecular Biology* from the time the serial title began publication and includes the date of the Hargrove article.

309. Attachment 34d includes an entry in field 050 ("QH301 $b .J73")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b JO773")—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 ("574.8/8/05")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 34d further includes six descriptor terms reading "Biology $v Periodicals" (see Attachment 34b, Library of Congress subject heading sh2007101986), "Biochemistry $v Periodicals" (see Attachment 12b, Library of Congress subject heading sh2007101985), and "Molecular biology $v Periodicals" (see Attachment 34c, Library of Congress subject heading sh2008107896), "Bacteriology" (see Attachment 34e, Library of Congress subject heading sh85010864), "Biochemistry" (see Attachment 34f, Library of Congress subject heading sh85014171), and "Biology" (see Attachment 34g, Library of Congress subject heading sh85014203) in the 650 fields. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 34d was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entries. As of November 12, 1974, the MARC

record attached hereto as Attachment 34d 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.

310. Attachment 34d indicates that the *Journal of Molecular Biology* as cataloged at the Library of Congress is currently available from 780 libraries. In view of the above, this issue of the *Journal of Molecular Biology* was publicly available on or shortly after March 26, 1997, because by that date it had been cataloged and indexed at the Library of Congress, made part of the OCLC bibliographic database, and received at the Linda Hall Library of Science, Engineering & Technology. For these reasons, it is my opinion that Exhibit 1045 was published and accessible to the public on or shortly after March 26, 1997.

FF. Benson article [Exhibit 1054]

311. Exhibit 1054 is a copy of an article from Volume 42 of the online open access journal *Nucleic Acids Research* found in the National Library of Medicine (Bethesda, Maryland). The article, "GenBank" by Dennis A. Benson, Karen Clark, Ilene Karsch-Mizrachi, David J. Lipman, James Ostell, and Eric W. Sayers (hereafter "Benson"), appears beginning on page D32 of this issue dated January 2014.

312. I obtained Exhibit 1054 through the National Library of Medicine. Exhibit 1054 is a true and correct copy of the Benson article (D32-D37). 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 1054 was found within the custody of a library – a place where, if authentic, a copy of this online open access journal would likely be. Exhibit 1054 is a true and correct copy in a condition that creates no suspicion about its authenticity.

313. Attached hereto as Attachment 35a is a true and correct copy of the MARC record for the online open access journal *Nucleic Acids Research* from the National Library of Medicine. The library ownership is indicated by the presence of the library's code (DNLM) in field 935. I personally identified and retrieved the MARC record that is Attachment 35a.

314. As noted in the holdings information (field 362), the National Library of Medicine has received the online open access journal *Nucleic Acids Research* since 1974 and continues to receive the publication. In view of the MARC record for Exhibit 1054 and the notation on page 3 (right-hand column) of Exhibit 1054, the Benson article was publicly available on September 28, 2014.

315. The "BLvl" entry in Attachment 35a is "s," which indicates that the online open access journal *Nucleic Acids Research* is a serial publication. Field 310

of Attachment 35a reads "Twenty-four no. a year." Accordingly, the MARC record for Exhibit 1054 corresponds to those issues of the online open access journal *Nucleic Acids Research* from the time of the serial began publication to the present day.

316. Attachment 35a includes an entry in field 060 ("W1 $b NU129")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system). Attachment 35a further includes a descriptor term reading "Nucleic Acids $v periodical" (see Attachment 35b, National Library of Medicine subject heading D009696) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 35a was indexed according to its subject matter by virtue of two independently sufficient classifications: the field 060 entry and the field 650 entry. Further, as of October 15, 1974, the MARC record attached hereto as Attachment 35a 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.

317. Attachment 35c indicates that the MARC record for the online open access journal *Nucleic Acids Research* 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 Attachment 35c, 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 1791693 on October 15, 1974, as shown in the "Entered" field ("19741015"). The library continues to update this MARC record and enhanced the MARC record to meet current cataloging rules. The most recent enhancement to Attachment 35c occurred on August 4, 2020, as shown in the "Replaced" field ("20200804"). I personally identified and retrieved the MARC record that is Attachment 35c. The "BLvl" entry in Attachment 35c is "s," which indicates that the online open access journal *Nucleic Acids Research* is a serial publication. Accordingly, the MARC record for Exhibit 1054 corresponds to the online open access journal *Nucleic Acids Research* from the time the serial title began publication and includes the date of the Benson article.

318. Attachment 35c includes an entry in field 050 ("QP620 $b .N8")—as described above, a subject matter classification number consistent with the Library of Congress classification system (analogous to the Dewey Decimal classification system), an entry in field 060 ("W1 $b NU129")—as described above, a subject matter classification number consistent with the National Library of Medicine classification system (analogous to the Dewey Decimal classification system), and

an entry in field 082 ("574.8/732")—as described above, a subject matter classification number consistent with the Dewey Decimal classification system. Attachment 35c further includes a descriptor term reading "Nucleic acids $v Periodicals" (see Attachment 35d, Library of Congress subject heading sh85093144 and Attachment 5c, Library of Congress subject heading sh85099890) in the 650 field. Thus, as of its cataloging, the publication corresponding to the MARC record attached hereto as Attachment 35c was indexed according to its subject matter by virtue of at least four independently sufficient classifications: the field 050 entry, the field 060 entry, the field 082 entry, and the field 650 entry. As of October 15, 1974, the MARC record attached hereto as Attachment 35d 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.

319. Attachment 35c indicates that the online open access journal *Nucleic Acids Research* as cataloged in the Library of Congress is currently available from 486 libraries. In view of the above, this issue of the online open access journal *Nucleic Acids Research* was publicly available on or shortly after January 28, 2014, because by that date it had been cataloged and indexed in the Library of Congress, made part of the OCLC bibliographic database, and received in the National Library

of Medicine. For these reasons, it is my opinion that Exhibit 1054 was published and accessible to the public on or shortly after January 28, 2014.

VI. CONCLUSION

320. In view of the foregoing, it is my opinion that the publications described above were publicly available no later than the corresponding dates listed in the table below:

Doc.	Publication	Publicly Available No Later Than
1005	Vogl, Thomas, and Anton Glieder. "Regulation of *Pichia pastoris* promoters and its consequences for protein production." *New Biotechnology,* vol. 30, no. 4 (25 May 2013): 385-404.	August 6, 2013
1006	Lin-Cereghino, Geoffrey Paul, Laurie Godfrey, Bernard J. de la Cruz, Sabrina Johnson, Samone Khuongsathiene, Ilya Tolstorukov, Mingda Yan, Joan Lin-Cereghino, Marten Veenhuis, Suresh Subramani, and James M. Cregg. "Mxr1p, a key regulator of the methanol utilization pathway and peroxisomal genes in *Pichia pastoris*." *Molecular and Cellular Biology,* vol. 26, no. 3 (February 2006): 883-897.	February 1, 2006
1011	Liu, Lifang, José L Martínez, Zihe Liu, Dina Petranovic, and Jens Nielsen. "Balanced globin protein expression and heme biosynthesis improve production of human hemoglobin in Saccharomyces cerevisiae." *Metabolic Engineering,* vol. 21 (January 2014): 9-16.	November 2, 2013

Doc.	Publication	Publicly Available No Later Than
1012	Vedvick, Thomas, Richard G. Buckholz, Michael Engel, Mary Urcan, Jennifer Kinney, Sally Provow, Robert S. Siegel, and Gregory P. Thill. "High-level secretion of biologically active aprotinin from the yeast *Pichia pastoris*." *Journal of Industrial Microbiology,* vol. 7, no. 3 (April 1991): 197-201.	April 30, 1991
1013	Engel, Karl-Heinz, Gary R. Takeoka, and Roy Teranishi. Chapter 1, "Foods and Food Ingredients Produced via Recombinant DNA Techniques: An Overview." *Genetically Modified Foods: Safety Issues* (pp. 1-10). American Chemical Society Symposium Series, Volume 605. New York: American Chemical Society, 1995.	October 5, 1995
1014	Garrocho-Villegas, Verónica, Sabarinathan Kuttalingam Gopalasubramaniam, and Raúl Arredondo-Peter. "Plant hemoglobins: What we know six decades after their discovery." *Gene,* vol. 398, issue 1-2 (15 August 2007): 78-85.	August 15, 2007
1015	Lin-Cereghino, Joan and James M. Cregg. "Heterologous protein expression in the methylotrophic yeast *Pichia pastoris*." *FEMS Microbiology Reviews,* vol. 24, no. 1 (January 2000): 45-66.	January 3, 2000
1016	Hartner, Franz S., and Anton Glieder. "Regulation of methanol utilisation pathway genes in yeasts." *Microbial Cell Factories,* vol. 5, article number 39 (14 December 2006).	December 14, 2006
1017	Hartner, Franz S., Claudia Ruth, David Langenegger, Sabrina N. Johnson, Petr Hyka, Geoffrey P. Lin-Cereghino, Joan Lin-Cereghino, Karin Kovar, James M Cregg and Anton Glieder. "Promoter library designed for fine-tuned gene expression in *Pichia pastoris*." *Nucleic Acids Research,* vol. 36, no. 12 (July 2008): e76, pp. 1-15.	June 6, 2008

Doc.	Publication	Publicly Available No Later Than
1018	De Schutter, Kristof, Yao-Cheng Lin, Petra Tiels, Annelies Van Hecke, Sascha Glinka, Jacqueline Weber-Lehmann, Pierre Rouzé, Yves Van de Peer and Nico Callewaert. "Genome sequence of the recombinant protein production host *Pichia pastoris*." *Nature Biotechnology,* vol. 27, no. 6 (June 2009): 561-566.	June 15, 2009
1019	Kranthi, Balla Venkata, Ritesh Kumar, Nallani Vijay Kumar, Desirazu N. Rao, Pundi N. Rangarajan. "Identification of key DNA elements involved in promoter recognition by Mxr1p, a master regulator of methanol utilization pathway in *Pichia pastoris*." *Biochimica et Biophysica Acta: General Subjects,* vol. 1789, issue 6-8 (June-August 2009): 460-468.	October 5, 2009
1021	Sreekrishna, Koti. "Pichia, Optimization of Protein Expression." *Encyclopedia of Industrial Biotechnology: Bioprocess, Bioseparation, and Cell Technology* (v. 6, pp. 3838-3853). 7 vols. New York: Wiley & Sons, 2010.	January 9, 2009
1022	Zhang, Ningyan, and Zhiqiang An. Chapter 11, "Heterologous Protein Expression in Yeasts and Filamentous Fungi" (pp. 145-156). *Manual of Industrial Microbiology and Biotechnology.* 3rd ed., edited by Richard H. Baltz, Julian E. Davies, and Arnold L. Demain. New York: Wiley & Sons, Inc., 2010.	March 23, 2010
1023	Kranthi, Balla Venkata, Hunsur Rajendra Vinod Kumar, and Pundi N. Rangarajan. "Identification of Mxr1p-binding sites in the promoters of genes encoding dihydroxyacetone synthase and peroxin 8 of the methylotrophic yeast *Pichia pastoris*." *Yeast,* vol. 27, no. 9 (September 2010): 705-711.	September 23, 2010

Doc.	Publication	Publicly Available No Later Than
1026	Parua, Pabitra K., Paul M. Ryan, Kayla Trang, and Elton T. Young. "Pichia pastoris 14-3-3 regulates transcriptional activity of the methanol inducible transcription factor Mxr1 by direct interaction." *Molecular Microbiology,* vol. 85, no. 2 (July 2012): 282-298.	June 12, 2012
1027	Rabert, Claudia, Daniel Weinacker, Adalberto Pessoa, Jr., and Jorge G. Farías. "Recombinants proteins for industrial uses: utilization of *Pichia pastoris* expression system." *Brazilian Journal of Microbiology,* vol. 44, no. 2 (January 2013): 351-356.	October 30, 2013
1028	Stryjewska, Agnieszka, Katarzyna Kiepura, Tadeusz Librowski, and Stanisław Lochyński. "Biotechnology and genetic engineering in the new drug development. Part I. DNA technology and recombinant proteins." *Pharmacological Reports,* vol. 65, no. 5 (September-October 2013): 1075-1085.	March 11, 2014
1029	Ahmad, Mudassar, Melanie Hirz, Harald Pichler, and Helmut Schwab. "Protein expression in *Pichia pastoris*: recent achievements and perspectives for heterologous protein production." *Applied Microbiology and Biotechnology,* vol. 98, no. 12 (June 2014): 5301-5317.	April 18, 2014
1030	Haon, Mireille, Sacha Grisel, David Navarro, Antoine Gruet, Jean-Guy Berrin, and Christophe Bignon. "Recombinant protein production facility for fungal biomass-degrading enzymes using the yeast *Pichia pastoris*. *Frontiers in Microbiology,* vol. 6 (23 September 2015).	September 23, 2015

Doc.	Publication	Publicly Available No Later Than
1031	Krainer, Florian W., Simona Capone, Martin Jäger, Thomas Vogl, Michaela Gerstmann, Anton Glieder, Christoph Herwig, and Oliver Spadiut. "Optimizing cofactor availability for the production of recombinant heme peroxidase in *Pichia pastoris*." *Microbial Cell Factories,* vol. 14, issue 4 (13 January 2015).	January 13, 2015
1032	Guarna, M. M., G. J. Lesnicki, B. M. Tam, J. Robinson, C. Z. Radziminski, D. Hasenwinkle, A. Boraston, E. Jervis, R. T. MacGillivray, R. F. Turner, and D. G. Kilburn. "On-Line Monitoring and Control of Methanol Concentration in Shake-Flask Cultures of *Pichia pastoris*." *Biotechnology and Bioengineering,* vol. 56, no, 3 (5 November 1997): 279-286.	October 7, 1997
1033	Katakura, Yoshio, Wenhui Zhang, Guoqiang Zhuang, Takeshi Omasa, Michimasa Kishimoto, Yuji Goto, and Ken-IchiSuga. "Effect of methanol concentration on the production of human β2-glycoprotein I domain V by a recombinant *Pichia pastoris*: A simple system for the control of methanol concentration using a semiconductor gas sensor." *Journal of Fermentation and Bioengineering,* vol. 86, no. 5 (1998): 482-487.	December 30, 1998
1034	Hong, Feng, Nina Q. Meinander, and Leif J. Jönsson. "Fermentation strategies for improved heterologous expression of laccase in *Pichia pastoris*." *Biotechnology and Bioengineering,* vol. 79, no. 4 (20 August 2022): 438-449.	June 13, 2002
1035	Trinh, L. B., J. N. Phue, and Joseph Shiloach. "Effect of methanol feeding strategies on production and yield of recombinant mouse endostatin from *Pichia pastoris*." *Biotechnology and Bioengineering,* vol. 82, no. 4 (20 May 2003): 438-444.	April 29, 2003

Doc.	Publication	Publicly Available No Later Than
1036	Bawa, Zharain, Sarah J. Routledge, Mohammed Jamshad, Michelle Clare, Debasmita Sarkar, Ian Dickerson, Markus Ganzlin, David R. Poyner, and Roslyn M. Bill. "Functional recombinant protein is present in the pre-induction phases of Pichia pastoris cultures when grown in bioreactors, but not shake-flasks." *Microbial Cell Factories*, vol. 13, article number 127 (2014).	September 4, 2014
1037	Ferreira, G. C. "Heme Synthesis." *Bioenergetics* (v. 2, pp. 539-542). *Encyclopedia of Biological Chemistry,* edited *by* William J. Lennarz and M. Daniel Lane. 2nd ed. 4 vols. New York: Academic Press, 2013.	September 3, 2013
1041	Cantor, Charles R., and Cassandra Smith. *Genomics: the science and technology behind the human genome project* (p. 13). New York: Wiley, c1999.	February 2, 1999
1042	Alberts, Bruce, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, and Peter Walter. *Molecular Biology of the Cell*. 4th ed. Chapter 6, "How Cells Read the Genome: From DNA to Protein" (pp. 305-312; 33-336); Chapter 8, "Manipulating Proteins, DNA, and RNA" (pp. 538-540). New York: Garland Science, c2002.	October 4, 2001
1043	Freeman, Scott. *Biological Science*. 2nd ed. Upper Saddle River, NJ: Pearson Education, c2005. Chapter 16, "Transcription and Translation" (pp. 338-361); Chapter 17, "Control of Gene Expression in Bacteria" (pp. 362-381); and, Chapter 18, "Control of Gene Expression in Eukaryotes" (pp. 382-400).	December 28, 2004
1044	Nicola & Leach, *Structural Rearrangements Due to Ligand Binding and Haem Replacement in Myoglobin and Leghaemoglobins*, 78 EUROPEAN J. BIOCHEM. 133-40 (1977)	September 13, 1977

Doc.	Publication	Publicly Available No Later Than
1045	Hargrove et al., *Characterization of Recombinant Soybean Leghemoglobin a and Apolar Distal Histidine Mutants*, 266 J. MOLECULAR BIOLOGY 1032-42 (1997)	March 26, 1997
1054	Benson, Dennis A., Karen Clark, Ilene Karsch-Mizrachi, David J. Lipman, James Ostell, and Eric W. Sayers. "GenBank." *Nucleic Acids Research*, vol. 42 (2014): D32-D37.	January 28, 2014

321. In signing this Declaration, I recognize that the Declaration will be filed as evidence in proceedings 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.

322. I, Sylvia D. Hall-Ellis, do hereby declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false 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.

Executed on January 27, 2023

Sylvia D. Hall-Ellis, Ph.D.