

Filed: June 21, 2021

Filed on behalf of: Sarepta Therapeutics, Inc.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.
Petitioner

v.

NIPPON SHINYAKU CO., LTD.
&
NATIONAL CENTER OF NEUROLOGY AND PSYCHIATRY
Patent Owners

Case No. IPR2021-01134
Patent No. 9,708,361

I, Kelley M. Hayes Greenhill, being of full age and duly sworn, state as

follows:

1. I have prepared this Declaration in connection with the Petition of Sarepta Therapeutics, Inc. (“Sarepta”), for *inter partes review* of U.S. Patent No. 9,708,361 (“the ’361 patent”), which I understand will be filed concurrently with this Declaration.

2. I am currently a Manager, Research and Information Services at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, 901 New York Ave, NW, Washington, DC 20001-4413.

3. I am over eighteen years of age and am competent to make this Declaration. I make this Declaration based on my own personal knowledge and based on my knowledge of library science practices.

4. I earned a Master of Science in Library Science from the Catholic University of America in 1995, and a Bachelor of Arts in Political Science from Duquesne University in 1989. I have worked as a librarian for over twenty-five years. I have been employed in the Research & Information Services Department at Finnegan Henderson since 2019. Before that, from 1995-2015, I was employed in the Library Department of Sterne Kessler Goldstein & Fox. And from 2015-2019, I was employed in the Knowledge and Research Service Group (formerly, Information Research Service) at Northrop Grumman Corporation.

5. I am currently a member of the American Association of Law Libraries.

I. Summary of Opinions

6. In view of the foregoing, it is my opinion that the publications described below were publicly available on or about the corresponding date listed in the following table:

Exhibit	Publication	Publicly Available on or About
1021	Popplewell et al., “Comparative Analysis of Antisense Oligonucleotide Sequences Targeting Exon 53 of the Human DMD Gene: Implications for Future Clinical Trials,” <i>Neuromuscul. Disord.</i> (2010) 20:102-110	February 1, 2010
1022	Sazani et al., “Safety Pharmacology and Genotoxicity Evaluation of AVI-4658,” <i>Int. J. Toxicol.</i> (2010) 29(2):143-156	March 1, 2010

II. Standard Library Practices

7. I have knowledge of and experience with standard library practices regarding receipt, cataloging, and shelving of materials. For example, I have knowledge of and experience with the Machine-Readable Cataloging (“MARC”) system that libraries use to catalog materials.

8. Based on standard library practice, when a library receives an item, it stamps the item with the library name and often with a date that is within a few days

or weeks of receipt. The library will catalog the item within a matter of a few days or weeks of receiving it.

9. By the mid-1970s, standard library practice involved cataloguing items using the MARC system. The MARC system was developed in the 1960s to standardize bibliographic records so they could be read by computers and shared among libraries. By the mid-1970s, MARC had become the international standard for bibliographic data, and it is still used today.

10. After an item is cataloged, standard library practice is to then shelve the item within a matter of a few days or weeks of cataloging it.

11. Taking into account the few days or weeks between receiving an item and cataloging it, and the few days or weeks between cataloging an item and shelving it, the total time between receiving an item and shelving it ranges from a couple of weeks to a few months. The public can access an item after it is cataloged by searching the catalog and requesting the item from the library.

III. MARC Records

12. Many libraries provide public access to their MARC records via the Internet and/or their electronic cataloguing system at the library. In a MARC record, each field provides information about the cataloged item. MARC uses a simple three-digit numeric code (from 001-999) to identify each field in the record. For example, field 245 lists the title of the work and field 260 lists publisher information.

Field 060 represents the National Library of Medicine Call Number. Field 060 includes two indicators and several subfield codes. The first indicator provides information on whether the item at issue exists in the National Library of Medicine collection (blank = no information provided; 0 = item in the Library; 1 = item not in the Library). A subfield code starting with “\$b” identifies a specific item number unique to the item (“Call” number).

13. Libraries can create MARC records for various types of publications, including serial publications such as scientific journals. Serial publications are publications that have the same collective title but are published in a succession of discrete parts (e.g., volumes and issues), typically at regular intervals. MARC records for serial publications represent the entire run of the title. If a publication is a periodical, then its publication frequency is recorded in Field 310, and the publication dates (e.g., the first and last publication) are recorded in Field 362. With knowledge of the first issue or volume published, future issues or volumes can be predicted based on the information provided in the MARC record. Field 510 identifies databases in which the publication has been indexed (e.g., PubMed).

14. Attached as Exhibit A are explanations from the Library of Congress of the MARC records and fields.

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