

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC

PETITIONER

V.

ELI LILLY & COMPANY

PATENT OWNER

CASE NO.: UNASSIGNED
PATENT NO. 7,772,209
FILED: JULY 11, 2007
ISSUED: AUGUST 10, 2010
INVENTOR: CLET NIYIKIZA

TITLE: ANTIFOLATE COMBINATION THERAPIES

DECLARATION OF SCOTT BENNETT, Ph.D.

I, Scott Bennett, hereby declare as follows:

I. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

1. I make this declaration based on my personal knowledge, consideration of the materials I discuss herein, and my expert opinions.

2. I am a retired academic librarian working as a Managing Partner in Prior Art Documentation Services LLP, at 711 South Race Street, Urbana, IL, 61801-4132. I have over 27 years of research librarian experience.

3. From 1974-1981, I was employed as an Instructor, Assistant, and Associate Professor of Library Administration at the University of Illinois at Urbana-Champaign, Urbana, IL.

4. From 1981-1989, I was employed as the Assistant University Librarian for Collection Management at Northwestern University, Evanston, IL.

5. From 1989-1994, I was employed as the Director of the Milton S. Eisenhower Library at the Johns Hopkins University, Baltimore, MD.

6. From 1994-2001, I was employed as the University Librarian at Yale University, New Haven, CT.

7. I received an A.B. in English from Oberlin College (1960), a Ph.D. in English from Indiana University (1967), and an M.A. in Library Science from the University of Illinois (1976)

8. Additional details of my education and experience are set forth in my curriculum vitae, a copy of which is attached as Exhibit 1029. Information about my company is available at <http://www.priorartdocumentation.com>.

II. SCOPE OF THIS REPORT

9. I have been asked to authenticate the following documents and establish their availability prior to the earliest priority date of June 30, 1999, and prior to June 30, 2000 (the filing date of the Provisional Application for the U. S. Patent No. 7,772,209):

- a. Niyikiza, C, et al. MTA (LY231514): Relationship of vitamin metabolite profile, drug exposure, and other patient characteristics to toxicity. *Annals of Oncology*, Vol. 9, Suppl. 4, (1998): 126-127, Abstract 609P (hereinafter “Niyikiza”).
- b. Carrasco, M., et al. Acute megaloblastic anemia: homocysteine levels are useful for diagnosis and follow-up. *Haematologica*, 84.8 (August 1999): 767-768 (hereinafter “Carrasco”).

10. I reserve the right to supplement my opinion and/or this declaration in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available.

III. FEES

11. My compensation for time spent working on this matter is based on a rate of \$85 per hour. This compensation is not contingent on my opinions, my performance or the outcome of the *inter partes* review, or any issues in or related to this *inter partes* review.

IV. INTRODUCTORY INFORMATION

12. **Conference papers.** *Niyikiza* is an abstract of a paper presented at a conference. Conference papers enter the realm of public discourse at the time they are presented at the conference. The circumstances of such presentation vary substantially, especially as regards the prominence of the conference, the number of conference participants, and the organization of the conference. Formal publication of papers presented at conferences also varies widely. Sometimes, the papers are published before the conference so as to be available to conference participants. Sometimes, papers are published only after the conference, and in some cases only abstracts of the papers are published.

13. **Library catalog records.** Libraries world-wide use the MARC format for catalog records; this format was developed at the Library of Congress in the 1960s. WorldCat is the world's largest public online catalog (see <https://en.wikipedia.org/wiki/OCLC>). Its records appear in many different catalogs, including the Statewide Illinois Library Catalog.

14. **Library management of periodicals.** For periodical publications, a library will typically create a catalog record for the periodical when the library orders or receives its first issue. When the institution receives subsequent issues/volumes of the periodical, the issues/volumes are checked in (often using a date stamp), added to the institution's holdings records, and made publicly accessible very soon thereafter—normally within a few days of receipt or (at most) within a few weeks of receipt.

15. **Indexing.** An ordinarily skilled researcher will typically begin his or her search for relevant information in an index of periodical and other publications. Having found relevant material, the researcher will then obtain it online, look for it in libraries, or purchase it from the publisher, a bookstore, or other provider.

V. DOCUMENTS REPRESENTED AS PRIOR ART

A. *Niyikiza*

1. Authentication

16. *Niyikiza* is an abstract of a research paper presented at a conference and published in the *Annals of Oncology*; a copy of *Niyikiza* is available online from Oxford University Press Journals (Ex. 1031 at 2). Ex. 1032 is the relevant entry from University of Illinois at Urbana-Champaign Library directory to electronic journals.

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