

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner

v.

PHARMACYCLICS LLC,
Patent Owner.

U.S. Patent No. 9,795,604 to Byrd *et al.*

Issue Date: October 24, 2017

Title: Methods of Treating and Preventing Graft Versus Host Disease

Inter Partes Review No.: IPR2019–00865

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

I. INTRODUCTION

1. My name is Sylvia D. Hall-Ellis. I have been retained as an expert by Petitioner, Sandoz Inc. (“Sandoz”). I have written this report at the request of Sandoz to provide my expert opinion regarding the authenticity and public availability of several journal publications. My report sets forth my opinions in detail and provides the basis for my opinions regarding the public availability of these publications.

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

3. I am being compensated for my time spent working on this matter at my normal consulting rate of \$300 per hour, plus reimbursement for any additional reasonable expenses. My compensation is not in any way tied to the content of this report, the substance of my opinions, or the outcome of this litigation. I have no other interests in this proceeding or with any of the parties.

4. All of the materials that I considered are discussed explicitly in this declaration.

II. QUALIFICATIONS

5. I am currently an Adjunct Professor in the School of Information at San José State University. I obtained a Masters of Library Science from the University of North Texas in 1972 and a Ph.D. in Library Science from the University of

Pittsburgh in 1985. Over the last forty-five 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.

6. 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 current cataloging rules) and as the chair of the Committee for Education and Training of Catalogers and the Competencies and Education for a Career in Cataloging Interest Group. I also served as the Chair of the ALCTS Division's Task Force on Competencies and Education for a Career in Cataloging. Additionally, I have served as the Chair for the ALA Office of Diversity's Committee on Diversity. Currently, I serve as a member of the Editorial Board for the ALCTS premier cataloging journal, *Library Resources and Technical Services*.

7. 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.

8. My full curriculum vitae is attached hereto as Attachment 1.

III. SUMMARY OF OPINIONS

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

Exhibit	Publication	Publicly Available on or About
Exhibit 1003	Shimabukuro-Vornhagen, Alexander, Michael J. Hallek, Rainer F. Storb, and Michael S. von Bergwelt-Baildon. "The Role of B cells in the Pathogenesis of Graft-versus-host Disease." <i>Blood</i> , vol. 114, number 24 (3 December 2009): 4919-4927.	January 12, 2010
Exhibit 1004	Herman, Sarah E. M., Amber L. Gordon, Erin Hertlein, Asha Ramanunni, Xiaoli Zhang, Samantha Jaglowski, Joseph Flynn, Jeffrey Jones, Kristie A. Blum, Joseph J. Buggy, Ahmed Hamdy, Amy J. Johnson, and John C. Byrd. "Bruton Tyrosine Kinase Represents a Promising Therapeutic Target for Treatment of Chronic Lymphocytic Leukemia and is Effectively Targeted by PCI-32765." <i>Blood</i> , vol. 117, number 23 (9 June 2011): 6287-6296.	July 8, 2011
Exhibit 1005	Uckun, Faith M., and Sanjive Qazi. "Bruton's Tyrosine Kinase as a Molecular Target in Treatment of Leukemias and Lymphomas as well as Inflammatory Disorders and Autoimmunity." <i>Expert Opinion on Therapeutic Patents</i> , vol. 20, issue 11 (November 2010): 1457-1470.	December 6, 2010

IV. LIBRARY CATALOGING PRACTICES

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

MARC standard, which is an industry-wide standard method of storing and organizing library catalog information.¹ MARC was first developed in the 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.²

11. 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 of the work is recorded in Field 100, 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." If a work is a

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

² Almost every major library in the world is MARC-compatible. *See, e.g., MARC Frequently Asked Questions (FAQ)*, Library of Congress, <https://www.loc.gov/marc/faq.html> (last visited March 15, 2019) ("MARC is the acronym for MACHine-Readable Cataloging. It defines a data format that emerged from a Library of Congress-led initiative that began nearly forty years ago. It provides the mechanism by which computers exchange, use, and interpret bibliographic information, and its data elements make up the foundation of most library catalogs used today."). MARC is the ANSI/NISO Z39.2-1994 (reaffirmed 2016) standard for Information Interchange Format.

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