

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.

Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-01903

Patent 8,731,963

DECLARATION OF BRYAN BERGERON, MD, FACMI

TABLE OF CONTENTS

	<u>Page</u>
I. QUALIFICATIONS	1
II. MATERIALS CONSIDERED	4
III. LEGAL STANDARDS	5
IV. THE CHALLENGED PATENT AND THE RELEVANT PERSON OF ORDINARY SKILL IN THE ART	7
V. CLAIM CONSTRUCTION.....	8
VI. THE ACA MATERIALS WOULD NOT HAVE DISCLOSED, TAUGHT, OR SUGGESTED THE LIMITATION IN CLAIM 27: “WHEREIN THE CURRENT PATTERN OR THE ANTICIPATED PATTERN [OF ABUSE] ARE IDENTIFIED USING PERIODIC REPORTS GENERATED FROM THE SINGLE COMPUTER DATABASE”	12
VII. A POSA WOULD NOT HAVE BEEN MOTIVATED TO COMBINE THE ACA WITH KORFHAGE TO ARRIVE AT THE CLAIMED “CENTRAL COMPUTER DATABASE BEING DISTRIBUTED OVER MULTIPLE COMPUTERS”	17
VIII. SUPPLEMENTAL OR AMENDED OPINIONS	21

I, Bryan Bergeron, MD, FACMI, hereby declare and state as follows:

1. I submit this declaration on behalf of Jazz Pharmaceuticals, Inc. (“Jazz”), Patent Owner of U.S. Patent No. 8,731,963 (the “’963 patent”) in connection with this *inter partes* review (“IPR”), Case IPR2015-01903.

I. QUALIFICATIONS

2. I am currently the President of Archetype Technologies, Inc. which specializes in the development and evaluation of new technologies. Archetype Technologies, Inc. specifically focuses on medical and healthcare computer hardware and software systems, for academia, governmental and commercial customers.

3. I obtained my B.S. degree in Psychology, with honors, with additional emphases in physics and chemistry, from Tulane University in 1980. I obtained my Doctor of Medicine (M.D.) degree from Louisiana State University Medical Center in 1984.

4. Following medical school, I was a post-doctoral research fellow in medical informatics at Brigham & Women’s Hospital, a Harvard Medical School teaching hospital. Medical informatics—also referred to as healthcare informatics—is a discipline at the intersection of information science, computer science, and health care. It deals with the resources, devices, and methods for optimizing the acquisition, storage, retrieval, and use of information in various

medical environments. During the fellowship, I studied computer science at Harvard University.

5. Following my post-doctoral fellowship, I began working as an instructor at Harvard Medical School, as well as an Assistant Director of the post-doctoral fellowship program in medical informatics at Brigham & Women's Hospital and Harvard University. In addition to these positions, I have held multiple academic positions at Harvard Medical School, Massachusetts Institute of Technology ("MIT"), the Harvard-MIT Division of Health Sciences and Technology, and Massachusetts General Hospital Institute for Healthcare Professionals. I have taught in the Harvard/MIT system for over 30 years, including courses on both medicine and medical informatics. For the past decade, I have taught a course on medical informatics that includes lessons on systems to address medical errors, including those that occur in the pharmacy. For a more comprehensive list of my work experience, please see my *curriculum vitae*, attached hereto as Exhibit 1.

6. As a result of my academic and non-academic work, I have extensive experience with Electronic Medical Record (EMR) and Electronic Health Record (EHR) systems. I have worked with, studied, or been exposed to a variety of EMR and EHR systems—including at LDS Hospital in Salt Lake City, Utah, Duke University, Indiana University Medical Center, and Massachusetts General

Hospital. I have also served as faculty advisor to many Masters and Ph.D. students on projects or theses that included EMR systems and large database design.

7. Over my career, I have designed and helped implement multimedia patient simulator systems, including those with EMR functionality. The EMR components of the simulators have included medical history, physician orders, pharmacy, laboratory, and progress notes.

8. My EMR and EHR experience includes an ongoing project (2004 to present) to help develop and extend an enterprise-wide data warehouse. The data warehouse provides a central repository of EMR data from a variety of clinical and administrative systems, including pharmacy, radiology, and ER. The system provides tools for analytics, forecasting, and diagnostic support that enable physicians to provide high quality, affordable health care in a timely fashion. My work on the data warehouse project has been documented in three books.

9. I also have extensive experience with computer hardware and software programming, especially as used and implemented in the medical industry. I have held a variety of posts in organizations that focus on the application of computing to the practice of medicine. For example, I have served as Chairman of the Mathematical Modeling & Simulation Committee for the Symposium on Computer Applications in Medical Care (SCAMC), Chairman of the SCAMC Human-Computer Interfacing Committee. I was also Chairman of the

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