

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR PHARMACEUTICAL, INC.

Petitioner,

v.

JAZZ PHARMACEUTICALS, INC.

Patent Owner

Case IPR2015-01903

Patent 8,731,963

DECLARATION OF JOSEPH T. DIPIRO, PHARM.D.

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I, Joseph T. DiPiro, Pharm.D, 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, Case IPR2015-01903.

I. QUALIFICATIONS

2. I have been a registered pharmacist for over 37 years. I am currently Dean and the Archie O. McCalley Chair and Professor at Virginia Commonwealth University School of Pharmacy.

3. Prior to holding my current position, I was Executive Dean and Professor at South Carolina College of Pharmacy, the University of South Carolina, and the Medical University of South Carolina. Before that, I held various academic positions at the University of Georgia College of Pharmacy including Assistant Dean, Head of the Department of Clinical and Administrative Sciences, and Professor of Pharmacy. I also held various academic positions at the Medical College of Georgia, including Assistant Dean for Pharmacy Programs and Director of Surgical Research. A full description of my work history is provided in my *curriculum vitae*, a copy of which is attached hereto as Exhibit 1.

4. I received a Bachelor of Science degree in pharmacy from the University of Connecticut in 1978, and a Doctorate in Pharmacy from the University of Kentucky, College of Pharmacy in 1981. While obtaining my

doctorate degree, I spent three years of residency at the Albert B. Chandler Medical Center, Lexington, Kentucky. In 1990, I completed one year of postdoctoral research in clinical immunology at Johns Hopkins University. A full description of my formal education is provided in my *curriculum vitae*.

5. I have given over 100 presentations in the field of pharmacy. I am the author or co-author of over 130 papers, over 25 book chapters, and 39 books in the field of pharmacy. I am also the author of numerous letters and book reviews concerning various aspects of pharmacy, which are described in my *curriculum vitae*.

6. I was the editor of the American Journal of Pharmaceutical Education, which is the primary journal of pharmacy education in the U.S., from 2002 to 2014. I am also the President-elect of the American Association of Colleges of Pharmacy.

7. I am an expert in the practice of pharmacy, including the education and training of pharmacists.

II. MATERIALS CONSIDERED

8. I have reviewed Amneal Pharmaceuticals LLC and Par Pharmaceutical, Inc.'s ("Petitioners") Petition for *inter partes* review regarding claims 24, 26, and 27 of the '963 patent, as well as the supporting declaration of Robert J. Valuck, Ph.D., R.Ph. (Ex. 1007) regarding the same claims. I have also

reviewed the ACA materials (Exs. 1003-1006) cited in the Petition and Dr. Valuck's declaration. A list of any additional materials that I have reviewed in connection with the preparation of this declaration is attached as Exhibit 2.

III. LEGAL STANDARDS

9. I have been advised by counsel for Jazz of the following legal standards and set forth my opinions in the context of my understanding of these standards.

10. I understand that a patent claim may be invalid under 35 U.S.C. § 103 if the claim, when considered as a whole, would have been obvious to a person of ordinary skill ("POSA") as of the date of the claimed invention. For the purposes of the obviousness analysis in this report, I have been asked to use December 17, 2002 as the date of invention.

11. I understand that the obviousness analysis is objective, and requires consideration of: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill; and (4) secondary considerations of nonobviousness.

12. I understand that the prior art must be considered as a whole, including disclosures that would have taught a POSA away from the claimed invention. I also understand that the prior art must be viewed from the perspective

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