UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC. and WOCKHARDT BIO AG, Petitioners, v. JAZZ PHARMACEUTICALS, INC. Patent Owner Case IPR2015-00554¹ Patent 7,668,730

DECLARATION OF DAVID A. HOLDFORD, PH.D., FAPhA

¹ Case IPR2015-01818 has been joined with this proceeding.



- I, David A. Holdford, Ph.D., FAPhA, 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. 7,668,730 (the "'730 patent") in connection with this *inter partes* review, Case IPR2015-00554.
- 2. I have been engaged in the profession of pharmacy for 34 years as a pharmacist, educator, researcher, and consultant.
- 3. I received a Bachelor of Science degree in pharmacy from the University of Illinois at Chicago in 1980, a Master of Science degree in pharmacy from Ohio State University in 1981, and a Ph.D. in Pharmacy Administration from the University of South Carolina in 1995.
- 4. I am currently a Professor in the Department of Pharmacotherapy and Outcomes Science at Virginia Commonwealth University School of Pharmacy. I teach and conduct research in the areas of health outcomes, practice management, and pharmacoeconomics. Prior to entering academia, I practiced as a hospital pharmacist in Chicago and South Carolina.
- 5. As part of my teaching duties, I have designed, managed, and instructed in several courses including PHAR 660 Pharmacy Practice Management I, Community Practice; PHAR 661 Pharmacy Practice Management II Institutional Practice, and PHAR 547 Managing Professional Patient Centered Practice. These courses are required for all of our pharmacy students. In addition, I



authored the textbooks for PHAR 600 and 661 and am completing the textbook manuscript for PHAR 547.

- 6. At the American Association of Colleges of Pharmacy (AACP), I am currently the Chair of the Social and Administrative Sciences Section. In my roles at AACP, I have studied the curricula at schools of pharmacy across the US and am familiar with what topics are commonly taught. I have received awards from the FDA and the Academy for Healthcare Improvement for my work on curricula in medication safety and quality.
- 7. In my various academic roles, I have become familiar with commonly-used sources of information for pharmacists to consult as aids in distributing, managing, and providing education about pharmaceuticals. These are the information sources that will be relevant and useful to the students' pharmacy practice once they have graduated and are practicing, registered pharmacists. I do not teach about the Federal Register, nor do I consider it one of the commonly-used sources of information at US pharmacy schools.



Executed this 6^{th} day of November 2015. I declare under penalty of perjury that the foregoing is true and correct.

David A. Holdford, Ph.D., FAPhA

Exhibit 1



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