

AMNEAL PHARMACEUTICALS LLC,

Petitioner

v.

CUBIST PHARMACEUTICALS LLC,

Patent Owner

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CASE IPR2019-\_\_\_\_\_

U.S. PATENT NO. 9,138,456 B2

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**DECLARATION OF RAJ SURYANARAYANAN, Ph.D.**

**Mail Stop *Patent Board***  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

23970956.1

AMNEAL EX. 1003

1. I am over the age of twenty-one (21) and am competent to make this Declaration. I reside in the United States at 2025 Autumn Place, Roseville, Minnesota.

2. I am a Professor in the Department of Pharmaceutics in the College of Pharmacy at the University of Minnesota, where I currently hold the William & Mildred Peters Endowed Chair. I am also an independent consultant in the field of pharmaceutics.

**A. Engagement**

3. I have been retained by counsel for Amneal Pharmaceuticals LLC in the above-captioned *Inter Partes* Review (“IPR”) matter as an independent technical expert.

4. As part of this engagement, I have been retained to review and evaluate whether certain patents and publications disclose to a person of ordinary skill in the art (“POSA”) the subject matter of specific claims of United States Patent No. 9,138,456 (“the ‘456 Patent”) as of the time of the filing date of the application from which the ‘456 Patent issued. I expect to testify regarding the matters set forth in this declaration if asked to do so.

report, any testimony I may provide, or the ultimate outcome of the case.

**B. Background and Qualifications**

6. I received my B. Pharm. and M. Pharm. degrees in 1976 and 1978, respectively, from Banaras Hindu University, Varanasi, India. I subsequently received my M.Sc. and Ph.D. degrees in Pharmaceutics in 1981 and 1985, respectively, from the University of British Columbia, Vancouver, Canada.

7. I joined the faculty of the University of Minnesota in 1985. I am currently a Professor in the Department of Pharmaceutics in the College of Pharmacy, where I have held the William & Mildred Peters Endowed Chair since 2006.

8. I was elected a fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2002 and was awarded Outstanding Educator of the Year by the AAPS in 2010. I am also the past chair of the Teachers of Pharmaceutics Second of the American Association of Colleges of Pharmacy (AACCP).

9. I am a Morse Alumni Distinguished Teaching Professor and I was inducted into the Academy of Distinguished Teachers at the University of

career, including the following: the Distinguished Alumnus Award from Banaras Hindu University in 2007; the David Grant Research Achievement Award in Physical Pharmacy from AAPS in 2013; and the PhRMA (Pharmaceutical Research and Manufacturers of America) Foundation Excellence Award in 2013.

11. I have served as a member of the United States Pharmacopeia (USP) Expert Committee (Excipients Test Methods).

12. I am currently an associate editor for *Molecular Pharmaceutics*, and a member of the editorial advisory board of the *Journal of Pharmaceutical Sciences*.

13. My research is in the area of pharmaceutical materials science and focuses on pharmaceutical formulations, including the physical characterization of drugs and excipients, phase transitions that occur during pharmaceutical processing, specifically during freeze-drying and optimization of freeze-drying of pharmaceuticals. I have published extensively in the area of freeze-drying (lyophilization). I have written over 165 papers for publication in peer-reviewed journals, which are listed on the copy of my curriculum vitae (CV) attached hereto as Appendix B.

Feb. 24, 2014 (deposition).

- Pfizer Inc.; Wyeth, LLC; Wyeth Pharmaceuticals Inc. and PF Prism C.V., vs. \*Anchen Pharmaceuticals, Inc., et al., June 11, 2014 (deposition).
- Otsuka Pharmaceutical Co., Ltd., Plaintiff v. \*Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals India Pvt. Ltd., Defendants. Civil Action No. 1:15-cv-1585-JBS-KMW, United States District Court, District of New Jersey, September 29, 2016 (deposition)
- Fresenius Kabi USA, LLC, Plaintiff v. \*Fera Pharmaceuticals, LLC, Oakwood Laboratories, LLC, Maia Pharmaceuticals, Inc., et al, Defendants. United States District Court for the District of New Jersey, Court File No. 2:15-cv-03654-KM-MAH, February 14, 2017 (deposition)
- Janssen Inc Applicant and - Teva Canada Limited and Minister Of Health Respondents and - Millenium Pharmaceuticals, Inc. Respondent Licensee and Sub-Licenser and United States of America Represented by the Secretary, Department of Health and Human Services Court File No. T-2195-12 – Testimony at a trial in Ottawa, Canada, February 19, 2018.

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