## IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd. et al.,

Plaintiffs,

v.

Aurobindo Pharma Limited et al.,

Defendants.

Kowa Company, Ltd. et al.,

Plaintiffs,

V.

Amneal Pharmaceuticals LLC,

Defendant.

Kowa Company, Ltd. et al.,

Plaintiffs,

V.

Mylan Inc. et al.,

Defendants.

Kowa Company, Ltd. et al.,

Plaintiffs,

V.

Orient Pharma Co., Ltd.,

Defendant.

Civil Action No. 14-CV-2497 (PAC)

Civil Action No. 14-CV-2758 (PAC)

Civil Action No. 14-CV-2647 (PAC)

Civil Action No. 14-CV-2759 (PAC)



Kowa Company, Ltd. et al.,

Plaintiffs,

v.

Zydus Pharmaceuticals (USA) Inc. et al.,

Defendants.

Kowa Company, Ltd. et al.,

Plaintiffs,

v.

Sawai USA, Inc. et al.,

Defendants.

Civil Action No. 14-CV-2760 (PAC)

Civil Action No. 14-CV-5575 (PAC)

DECLARATION OF DAVID H. SHERMAN, Ph.D. IN SUPPORT OF DEFENDANTS' JOINT OPENING CLAIM CONSTRUCTION BRIEF



#### I. INTRODUCTION.

- 1. I, Dr. David H. Sherman, submit this Declaration on behalf of Defendants Amneal Pharmaceuticals LLC, Aurobindo Pharma Limited and Aurobindo Pharma USA Inc., Mylan Pharmaceuticals Inc. and Mylan Inc., Orient Pharma Co., Ltd., Sawai USA, Inc. and Sawai Pharmaceutical Co., Ltd., Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (dba Zydus Cadila) (collectively, "Defendants") in the above-captioned actions.
- 2. I understand that the meaning of a term, as disclosed in claim 1 of U.S. Patent No. 5,856,336 ("the '336 patent"), is in dispute. I disclose herein my opinions concerning how the person of ordinary skill in the art, in the relevant timeframe, would have understood that term and the bases and reasons supporting my opinions.

### II. BACKGROUND AND QUALIFICATIONS.

- 3. My work and career primarily have specialized in the fields of medicinal chemistry, biochemistry and drug discovery.
- 4. I received a B.A. in Chemistry, with Honors, from the University of California, Santa Cruz, in 1978, and a Ph.D. in Organic Chemistry from Columbia University in 1981.
- 5. My dissertation research focused on development of organic chemistry reaction methodology and applications toward natural product total synthesis. This research involved developing synthetic schemes and processes for several small molecules, including steroids and prostaglandins.

<sup>&</sup>lt;sup>1</sup> The '336 patent is attached as Exhibit 1 to the Declaration of Thomas R. Burns in Support of Defendants' Joint Opening Claim Construction Brief ("Burns Decl."), submitted contemporaneously herewith.



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- 6. I previously served as a Postdoctoral Researcher in molecular immunology at Yale University (1981-1982) and in immunochemistry at the Massachusetts Institute of Technology (1982-1984).
- 7. I was a Research Scientist in the Department of Molecular Immunology at Biogen Research Corporation (1984-1987) and in the Department of Genetics at the John Innes Institute in Norwich, U.K. (1987-1990).
- 8. From 1990 through 2000, I progressed from Assistant Professor, to Associate Professor, to Professor in the Department of Microbiology and in the separate BioTechnology Institute at the University of Minnesota. In 2003, I was awarded the John Gideon Searle Professorship and was appointed Professor in the Departments of Microbiology & Immunology (Medical School), Medicinal Chemistry (College of Pharmacy) and Chemistry (College of Literature, Science and the Arts) at the University of Michigan. In 2007, I was awarded the Hans W. Vahlteich Professorship at the University of Michigan.
- 9. From 1996 through 1998, I served as Director of the Center for Microbial Physiology and Metabolic Engineering at the University of Minnesota. In 1997 (while on University sabbatical leave), I served as Senior Director of ChromaXome Corporation, in San Diego, California. From 1998 through 2001, I was Director of the Microbiology, Immunology and Cancer Biology Graduate Program at the University of Minnesota. Additionally, during the period 2004 through 2014, I served as the founding Director of the Center for Chemical Genomics at the University of Michigan Life Sciences Institute. I was appointed Associate Dean for Research and Graduate Education in the College of Pharmacy at the University of Michigan in 2011.



- 10. Additionally, in 2008, I founded Alluvium Biosciences with Dr. Michael Brownstein. Alluvium Biosciences focuses on various types of drug discovery and development programs, as well as other biological and chemical research projects. I am currently Chief Technical Consultant to Alluvium Biosciences.
- 11. I also currently serve as the Hans W. Vahlteich Professor of Medicinal Chemistry and Associate Dean for Research (College of Pharmacy) at the University of Michigan and hold appointments as Professor in the Department of Microbiology & Immunology (Medical School), the Department of Medicinal Chemistry (College of Pharmacy) and the Department of Chemistry (College of Literature, Science, and the Arts). I am also a Research Professor in the Life Sciences Institute at the University of Michigan.
- 12. I am currently a member of the American Chemical Society (since 1978), American Association for the Advancement of Science (since 1982), American Society for Microbiology (since 1987) and the Society for Industrial Microbiology (since 2000).
- 13. I also currently serve as a referee of research articles submitted to the following scientific journals: ACS Chemical Biology; Antimicrobial Agents and Chemotherapy; Applied Microbiology and Biotechnology; Canadian Journal of Microbiology; Gene; Journal of Applied and Environmental Microbiology; Journal of Bacteriology; Journal of Immunology; Microbiology; Molecular Microbiology; Proceedings of the National Academy of Sciences USA; Tetrahedron; Science; Nature; Journal of the American Chemical Society; Journal of Medicinal Chemistry; Journal of Organic Chemistry; Organic Letters; Chemistry & Biology; Biotechnology Progress; Journal of Natural Products; Nature Biotechnology; Nature Chemistry; and Nature Chemical Biology.



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