Filed on behalf of: Abraxis Biosciences, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD. Petitioner,

v.

ABRAXIS BIOSCIENCE, LLC Patent Owner.

IPR2018-00162; IPR2018-00163; IPR2018-00164 U.S. Patent Nos. 8,138,229; 7,820,788; and 7,923,536

DECLARATION OF DAVID OUPICKY, Ph.D.

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2. Desai does not inherently disclose a ratio of 9:1
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(b) Dr. Desai provided additional evidence showing a loss of paclitaxel during manufacturing
(c) A POSA would expect loss of paclitaxel in view of the references in the Peppas Decl. and in view of Kadima
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(c) A POSA would not have been motivated to adjust the Capxol TM ratio with a reasonable expectation of success
(d) The benefits of albumin teach away from reducing the albumin-to-paclitaxel ratio 40
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Filed on behalf of: Abraxis Biosciences, LLC

I, David Oupicky, Ph.D., hereby declare and state as follows:

I. <u>INTRODUCTION</u>

I submit this declaration on behalf of Abraxis Bioscience, LLC ("Abraxis" or "Patent Owner"), Patent Owner of U.S. Pat. Nos. 7,820,788 ("the '788 patent"), 7,923,536 ("the '536 patent"), and 8,138,229 ("the '229 patent") (collectively, "the Abraxis Patents") to provide my opinions on certain matters in connection with the petitions for inter partes reviews filed by Cipla Ltd. ("Cipla" or "Petitioner") in case nos. IPR2018-00162, IPR2018-00163, and IPR2018-00164 (collectively, the "Cipla IPR Petitions").

II. BACKGROUND & QUALIFICATIONS

- 2. My areas of expertise include formulation development of macromolecular and particulate delivery systems of small molecule drugs and therapeutic nucleic acids using self-assembly, bioconjugation, and encapsulation methods. The main focus of my research is the design of novel polymerbased systems for improved delivery and therapeutic efficacy of combination treatments.
- 3. My research laboratories at the University of Nebraska Medical Center and China Pharmaceutical University currently work on the development of

injectable anti-metastatic self-assembled polymers and nanoparticles as well as nanoparticles for improved drug delivery in the treatment of inflammatory bowel disease, pulmonary fibrosis, and kidney injury. My research centers on multiple aspects related to the chemical synthesis, pharmaceutical formulation and characterization, and in vitro and in vivo assessment of delivery and efficacy in relevant disease models.

- 4. I received an M.S. in Polymer Engineering from the Institute of Chemical Technology in Prague, Czech Republic in December 1993 and a Ph.D. in Macromolecular Chemistry from the Institute of Macromolecular Chemistry of the Czech Academy of Sciences in May 1999. From 1999 to 2002, I was a postdoctoral fellow in gene delivery at the CRC Institute for Cancer Studies at the University of Birmingham, United Kingdom.
- 5. I am currently appointed as the Parke-Davis Professor of Pharmaceutics and Co-Director of the Center for Drug Delivery and Nanomedicine in the Department of Pharmaceutical Sciences at the University of Nebraska Medical Center. I am also appointed as part-time Changjiang Scholar Chair Professor at China Pharmaceutical University in Nanjing, China.
- Previously, I was an Assistant Professor (2002-2007) and an Associate
 Professor (2007-2013) in the Department of Pharmaceutical Sciences at

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