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 KATHERINE H.R. TKACZUK, M.D.

Filed on behalf of: Abraxis Biosciences, LLC

I, Katherine H.R. Tkaczuk, M.D, submit the following declaration on behalf of Patent Owner Abraxis BioScience LLC ("Abraxis"), 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").

I. BACKGROUND & QUALIFICATIONS

1. Since 1991, I have been a board certified medical oncologist involved in the clinical management of cancer patients and in clinical drug development in phase 1-3 clinical trials.

2. I am currently Professor of Medicine and Oncology at the University of Maryland Medical School and Director of the Breast Evaluation and Treatment Program at the Marlene and Stewart Greenebaum Cancer Center, also at the University of Maryland Medical Center.

3. I received my undergraduate and M.D. degrees from Wroclaw Medical University Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu; Universitas Medicus Vratislaviensis in Wroclaw Poland in 1978-1984. I then conducted research in the Pathology Department at Hahnemann Hospital in

Philadelphia, Pennsylvania. I completed an internship and residency in Internal Medicine at St. Agnes Hospital in Baltimore, Maryland, and a fellowship in Hematology/Oncology from the University of Maryland Cancer Center in Baltimore, Maryland and the Veterans Administration Medical Center, also in Baltimore.

4. I see approximately 35 stage 0-4 breast cancer patients every week. I regularly use paclitaxel products and other chemotherapeutic agents with these patients, and have prescribed Abraxane® in my practice since it was approved by FDA in 2005.

5. In addition to seeing patients, I also conduct research focusing on clinical drug development in breast cancer and other solid tumor malignancies. From 1992 to the present, I have been involved in more than 100 phase 1-3 clinical trials, and have served as the institutional principal investigator on the majority of the University of Maryland Greenebaum Comprehensive Cancer Center (UMGCCC) breast cancer specific clinical trials. As the Director of UMGCCC Breast Evaluation and Treatment Program, a multidisciplinary program with commitment to comprehensive, multidisciplinary breast cancer care, I have overseen the clinical and research aspects of the program for several years. The UMGCCC clinical breast program continues to work in the area of clinical drug development with the focus on hormone resistance, role of microtentacles in breast

cancer metastasis, the significance of brown adipose tissue in pathogenesis and progression of breast cancer, the GP-88 circulating marker and its significance in patients with breast cancer and in screening for breast cancer.

6. I have authored 74 peer reviewed publications, as well as two book chapters.

7. I have been recognized as one of America's Top Doctors (2009-2014), one of American's Top Doctors for Cancer (2005-2013) and have been awarded CMS Meaningful Use Stage 1 Certification. I have received the UMGCC Patient Choice Award, Favorite Physician.

8. A copy of my CV is attached as Appendix A.

9. Due to my background and experience, I am well-qualified to opine on the clinical effects of Abraxane® and to opine on clinical study data.

10. I am being compensated for my time spent in connection with this matter at a rate of $ 650 per hour. My compensation does not depend on the outcome of the proceeding or the conclusions in my declaration.

II. SUMMARY OF OPINIONS

A. The clinical results observed with the 9:1 formulation were beneficial and unexpected

11. I was asked by counsel to review the declaration of Dr. Desai, dated April 14, 2010. I understand that Dr. Desai's declaration was submitted to the United States Patent and Trademark Office ("USPTO") during prosecution of the

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