

Filed on behalf of: Abraxis Biosciences, LLC

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. AND APOTEX CORP.
Petitioners,

v.

ABRAXIS BIOSCIENCE, LLC
Patent Owner.

IPR2018-00151; IPR2018-00152; IPR2018-00153
U.S. Patent Nos. 8,138,229; 7,820,788; and 7,923,536

DECLARATION OF KATHERINE H.R. TKACZUK, M.D.

I. BACKGROUND & QUALIFICATIONS1

II. SUMMARY OF OPINIONS.....3

 A. The clinical results observed with the 9:1 formulation were beneficial and unexpected3

 B. The 9:1 formulation shows unexpectedly improved benefits in comparison to solvent-based paclitaxel formulations6

 C. Experience as a medical oncologist.....7

III. DECLARATION STATEMENT8

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 Apotex Inc. and Apotex Corp. (“Apotex” or “Petitioners”) in case nos. IPR2018-00151, IPR2018-00152, and IPR2018-00153 (collectively, the “Apotex 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 Wrocław Medical University Uniwersytet Medyczny im. Piastów Śląskich we Wrocławiu; Universitas Medicus Vratislaviensis in Wrocław Poland in 1978-1984. I then

Filed on behalf of: Abraxis Biosciences, LLC

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

Filed on behalf of: Abraxis Biosciences, LLC

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.