UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC. and APOTEX CORP.

Petitioners

V.

ELI LILLY & COMPANY

Patent Owner

Patent No. 7,772,209
Filed: July 11, 2007
Issued: August 10, 2010
Inventor: Clet Niyikiza

Title: ANTIFOLATE COMBINATION THERAPIES

Inter Partes Review No.: IPR2016-01191

**DECLARATION OF MICHAEL KELLEY, M.D.
IN SUPPORT OF APOTEX, INC. AND APOTEX CORP.'S
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,772,209**

1. My name is Michel Kelley, M.D. I have been retained on behalf of Apotex, Inc. and Apotex Corp. ("Apotex"). I understand that Apotex intends to petition for *inter partes* review of U.S. Patent No. 7,772,209 ("the '209 patent") (Ex. 1001). I further understand that Apotex will seek to join a prior proceeding brought by Neptune Generics, LLC ("Neptune"). I also understand that Apotex, like Neptune, will request that the United States Patent and Trademark Office cancel claims 1-22 of the '209 patent as unpatentable. I submit this Declaration in support of Apotex's petition for *inter partes* review.

I. Qualifications and Background

A. Education and Experience; Prior Testimony

2. I am over the age of eighteen (18) and otherwise competent to make this declaration.

3. I am a Professor of Medicine at Duke University Medical Center where I am also a Member of the Duke Cancer Institute; Chief of Hematology and Oncology at Durham VA Hospital; and National Program Director for Oncology at the Department of Veterans Affairs.

4. I received an undergraduate degree in Cellular and Molecular Biology (B.S.) at the University of Michigan in 1981 where I was a member of Phi Beta Kappa. I received my medical degree (M.D.) from the University of Michigan in 1985.

5. After medical school, I completed my residency in internal medicine at Duke University Medical Center from 1985 to 1988. I became Board Certified by the American Board of Internal Medicine in 1988, and Board Certified by the American Board of Internal Medicine, Medical Oncology in 1991.

6. Following residency, I was a research associate from 1988 to 1990 at the Laboratory of Cellular and Molecular Biology at the National Cancer Institute; a clinical associate from 1990 to 1993 at the National Cancer Institute; and a senior clinical investigator from 1993 to 1995 at the Navy Medical Oncology Branch/Medicine Branch at the National Cancer Institute.

7. I also served in the United States Public Health Service from 1990 to 1998, where I achieved the rank of Commander.

8. I joined the Duke University Medical Center Department of Medicine as an assistant professor in 1998, became an associate professor in 2001, and became a full professor in 2014.

9. In 2002, I was appointed the Interim Chief of the Hematology/Oncology department at Durham VA Hospital. In 2005, I was appointed to my current position of Chief of the Hematology/Oncology department.

10. In 2007 I was appointed the National Program Director for Oncology at the Department of Veterans Affairs, and I currently hold that position.

11. My teaching responsibilities primarily concern adult oncology.

12. During my career I have published extensively on the biology of and improving outcomes for patients with cancer, particularly lung cancer (over eighty peer-reviewed articles).

13. My early publications examined the relationship between specific genetic alterations in lung cancer and clinically relevant applications including differential drug sensitivity, differentiation of metastases from second primary cancers, and application of patient-specific mutations as epitopes for immunotherapy. My research concerning the correlation of alteration of p16 with drug sensitivity led to identification of a class of CDK4 inhibitor. My research also demonstrated that tubulin mutations are uncommon in lung cancer and described the artifactual detection of pseudogenes as the origin of a prior report claiming association of tubulin mutation with taxane sensitivity, thus correcting the scientific record. I served as the primary investigator or co-investigator in all of these studies.

14. My research interests in lung cancer also involve conducting therapeutic and prevention clinical trials. These trials have primarily been translation of hypotheses derived primarily from laboratory-based biological observations including the GRP autocrine growth factor in small cell lung cancer, a phase I study of a pulmonary toxin in non-small cell lung cancer, mutation-specific

immunotherapy, and a putative chemopreventive agent for smokers. More recently, I have been an active member of the Respiratory Committee of CALGB/Alliance including serving as principal investigator on a trial testing the addition of irinotecan to treatment of patients with small cell lung cancer.

15. Through my clinical practice, I conceptualized and led a project to identify the underlying molecular basis of the May-Hegglin anomaly (a frequently misdiagnosed disorder) through classical genetics. My research also described genetic linkage for a rare familial cancer syndrome characterized by very high penetrance of chordoma, and studied regulatory-approved drugs for anti-growth activity to determine whether any could be repurposed for clinical use in patients.

16. I am a member of the American Society of Clinical Oncology, the International Association for the Study of Lung Cancer, and a Fellow of the American College of Physicians.

17. I have peer reviewed articles for, or been a member of the editorial board of, several medical journals including *Journal of Clinical Oncology* and *Journal of Thoracic Oncology*.

18. I have prescribed and administered a wide variety of intravenous, intramuscular, subcutaneous, and intrathecal medications, including anti-folates.

19. I consider myself to be an expert in the field of oncology.

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