

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROXANE LABORATORIES., INC.,
Petitioner

v.

NOVARTIS AG,
Patent Owner

Case Not Yet Assigned
Patent 9,006,224

**DECLARATION OF KENNETH HO-MING YU, M.D., M.SC., IN
SUPPORT OF THE PETITION FOR *INTER PARTES* REVIEW OF U.S.
PATENT NO. 9,006,224**

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I. INTRODUCTION

1. I, Kenneth Ho-ming Yu, M.D., M.Sc., have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.

2. I have been retained by counsel for Roxane (Roxane Laboratories, Inc.) in this proceeding regarding U.S. Patent No. 9,006,224 (“the ’224 patent”).

3. I hereby offer this Declaration in support of the petition for *inter partes* review of the ’224 patent.

4. A list of materials that I have reviewed is attached hereto as Attachment A.

II. QUALIFICATIONS AND EXPERIENCE

5. I have been a licensed medical doctor since 1999 and am board certified in Medical Oncology. I currently serve as an Assistant Attending Physician at Memorial Hospital for Cancer & Allied Diseases in the Department of Medicine, NY, and Assistant Member of Memorial Sloan Kettering Cancer Center, NY. I also serve as an Assistant Professor at Weill Cornell Medical College, NY; Adjunct Assistant Professor at the University of Pennsylvania, Philadelphia; and Clinical Fellow at Cold Spring Harbor Laboratory, Cold Spring Harbor, NY.

6. I graduated from Harvard University, Cambridge in 1995 and completed my M.D. at John Hopkins University, Baltimore in 1999. I completed an M.Sc. qualification at the University of Pennsylvania, Philadelphia in 2009.

7. I was a Medical Intern at the Hospital of the University of Pennsylvania between 1999-2000, before becoming a Medical Resident at the Hospital of the University of Pennsylvania from 2000-2002. I was a Fellow of Hematology and Oncology at the Hospital of the University of Pennsylvania between 2002-2005.

8. I was an Attending Physician at Abramson Cancer Center in the Division of Hematology-Oncology at the Hospital of the University of Pennsylvania between 2005-2010. I am currently an Assistant Attending Physician at Memorial Hospital for Cancer & Allied Diseases at the Department of Medicine in NYC.

9. I hold several other professional memberships. I am currently a member of the American Society of Clinical Oncology. I have previously been a member of the American Association of Cancer Research, the American Gastroenterology Association and the American Society for Mass Spectroscopy.

10. I have been awarded several honors over my career to date. I was designated magna cum laude with highest honors in 1995 at Harvard University. I was also a Research Scholar at the Institute for Translational Medicine and Therapeutics, University of Pennsylvania in 2005, and received the Bernard L. Schwartz Designated Research Award in Pancreatic Cancer, AGA Foundation for Digestive Health and Nutrition in 2006.

11. I hold various editorial responsibilities in several academic journals including, for example, Gastroenterology, Journal of Gastrointestinal Cancer, Pancreatology, Oncogene, Journal of Surgical Oncology and Cancer Chemotherapy and Pharmacology.

12. I have authored more than 40 journal articles, abstracts, and other presented lectures relating primarily to the diagnosis and treatment of pancreatic cancers and other advanced solid tumors.

13. My research has been directed to various facets of pancreatic cancers, including the development of novel therapeutics and biomarkers in pancreatic ductal adenocarcinoma (PDAC). I am also the principal investigator or co-investigator on a number of clinical trials focused on pancreatic cancer and PNET.

14. My complete Curriculum Vitae is attached as Attachment B.

III. SUMMARY OF OPINIONS

15. It is my opinion for the reasons described below that claims 1 and 2 of the '224 patent would have been obvious to a person of ordinary skill in the art in view of the prior art disclosing at least the following: (1) that everolimus is effective against CA20948 pancreatic cell line which is a rat cell line which can be used as a model for pancreatic neuroendocrine tumors; (2) that 10 mg everolimus is safe and effective against advanced solid tumors; (3) that rapamycin inhibits proliferation in BON cells, a cell line established from human PNET; (4) that

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