

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BAYER INTELLECTUAL PROPERTY GMBH,
Patent Owner.

Patent No. 9,539,218

DECLARATION OF NEIL E. DOHERTY, III, M.D., FACC

TABLE OF CONTENTS

I. Qualifications 1

II. Scope of Work 2

III. The '218 Patent 3

IV. Legal Standards 4

V. Level of Ordinary Skill in the art and Relevant Time 7

VI. Claim Construction 7

VII. Scientific Background 14

VIII. Background Knowledge of the POSA 23

IX. The Methods of Claims 1-4 of the '218 Patent would have been Obvious
to a POSA in view of the '610 Publication and Kubitza Abstracts. 30

X. No Unexpected Results From Once-Daily Dosing 44

XI. Concluding Statements 49

XII. Appendix – List of Exhibits 51

I, Neil E. Doherty, III, M.D., FACC, declare as follows:

I. QUALIFICATIONS

1. My name is Neil Doherty, III. I have over 25 years of experience as a practicing cardiologist. I am currently the Medical Director of the Citrus Valley Cardiology Medical Group, Inc. in Glendora, California. I am also a clinical professor of Internal Medicine/Cardiology at Western University Health Services.

2. I received a Bachelor of Arts in 1977 from the University of Pennsylvania. In 1982, I received my M.D. from Harvard Medical School. After medical school, I undertook postdoctoral training, including: Internal Medicine Internship and Residency at Cedars-Sinai Medical Center (1982-1985), General and Thoracic Surgery Residency at Duke University Medical Center (1985-1987), Surgery Research and Clinical Fellowship at Massachusetts General Hospital (1987-1988), Cardiology Fellowship at Harbor-UCLA (1988-1990) and a Cardiac MRI and Nuclear Cardiology Imaging Fellowship at UCSF (1990-1991).

3. I have been Board certified by the American Board of Internal Medicine in Internal Medicine since 1985. I was certified by the American Board of Internal Medicine in the subspecialty of Cardiovascular Disease in 1991 and recertified in 2001 and 2011. I received my nuclear cardiology license in 1992 and became certified in the subspecialty of nuclear cardiology in 2003.

4. I have been a Fellow of the American College of Cardiology, the American College of Chest Physicians and the American Society of Nuclear Cardiology. I served as Director of Cardiology at Foothill Presbyterian Hospital from 1997-2005, and on the Board of Directors of the American Heart Association, East San Gabriel Valley, from 2000-2003.

5. I have over 25 years of experiences as a practicing cardiologist and have authored or co-authored many publications for peer-reviewed journal articles and book chapters. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately. EX1052.

II. SCOPE OF WORK

6. I understand that Mylan Pharmaceuticals Inc. may file a petition for *Inter Partes* Review of U.S. Patent No. 9,539,218 (“the ’218 patent,” EX1001) with the United States Patent and Trademark Office. I have been asked by the Petitioner to provide my opinions regarding the ’218 patent.

7. I am being compensated at the rate of \$500 per hour for my work performed in conjunction with drafting this declaration. My compensation does not depend on the outcome of this matter, and I have no financial interest in the outcome of this matter.

III. THE '218 PATENT

8. The title of the '218 patent is "Prevention and Treatment of Thromboembolic Disorders." EX1001 (the '218 patent). The abstract of the '218 patent states: "The present invention relates to the field of blood coagulation, more specifically it relates to a method of treating a thromboembolic disorder by administering once daily a direct factor Xa inhibitor in oral dosage form to a patient in need thereof, wherein the factor Xa inhibitor has a plasma concentration half life indicative of a bid [twice daily] or tid [thrice daily] administration interval, e.g. of 10 hours or less." EX1001 (the '218 patent), [57].

9. Claim 1 of the '218 patent recites:

A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-((5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)-phenyl]-1,3-oxazolidin-5-yl)methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke.

EX1001 (the '218 patent), 10:63-11:5. For convenience, I refer to the compound recited in claim 1 as "rivaroxaban" throughout this declaration.

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