

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

YEDA RESEARCH & DEVELOPMENT CO. LTD.,  
Patent Owner.

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Case IPR2015-00644  
Patent 8,399,413

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**DECLARATION OF ROBERT WILLIAM GRISTWOOD, PH.D.  
IN SUPPORT OF YEDA'S PATENT OWNER RESPONSE**

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## I. INTRODUCTION

1. I, Robert William Gristwood, 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 Yeda Research and Development Co. Ltd. (“Respondent”) in this proceeding regarding U.S. Patent No. 8,399,413 (“the ’413 patent”).

3. I hereby offer this Declaration in support of Patent Owner’s Response to Petition for *Inter Partes* Review of the ’413 patent regarding the skilled pharmacologist’s understanding and interpretation of the pharmacokinetic data included in the Summary Basis for Approval for Copaxone® 20 mg (1996) (“SBOA”) (Ex. 1007) as of August 20, 2009.

## II. QUALIFICATIONS

4. I am a pharmacologist with nearly forty years of experience in the pharmaceutical industry.

5. As set forth in more detail in my current CV (Ex. 2130), I received a B.Sc. from North East London Polytechnic in 1976 and a Ph.D. in pharmacology through a Smith Kline collaboration with University of Oxford in 1982.

Throughout my career, I have worked at a number of companies in the pharmaceutical industry.

6. While obtaining my B.Sc., I worked as a pharmacologist within the medicinal Biology Department of Pfizer UK from 1974-1975.

7. Between 1976 and 1996 I worked within and/or had responsibility for the pharmacology departments of Smith Kline & French (“SK&F”) (now part of GlaxoSmithKline), Laboratorios Almirall, and Chiroscience Limited. At SK&F, I was an Associate Director of Pharmacology. At Almirall, I was Director of Biological Science. At Chiroscience, I was Head of Biology (R&D).

8. In May 1996, I established Stevenage Biosciences Ltd. (now Cambridge BioConsultants Ltd.), of which I am Director and Principal Consultant. Cambridge BioConsultants provides biological consultancy services to pharmaceutical companies.

9. In January 1998, I co-founded Arachnova Limited, a company that specialised in identifying new therapeutic uses for existing drugs as well as providing consultancy services to the pharmaceutical industry. I was Research and Development Director for this company until 2007.

10. In September 2000, I co-founded Arachnova Therapeutics Ltd., which was a venture capital backed pharmaceutical company that specialised in the development and commercialization of projects largely identified by Arachnova Ltd.

11. In January 2007, I co-founded Acacia Pharma Ltd., now known as Acacia Pharma PLC, a venture capital backed pharmaceutical company focused on hospital based supportive care, particularly cancer supportive care. I am currently Chief Scientific Officer of this company.

12. I have written many scientific papers and presented many lectures in the field of pharmacology. I am also a member, or have been a member, of a number of scientific organizations, including the British Pharmacological Society, Society of Medicines Research, and the Biochemical Society. I have been an editor of several pharmacological journals, including the British Journal of Pharmacology (1992 – 1997), the Journal of Cardiovascular Pharmacology (1987 – 1995), Expert Opinion on Investigational Drugs (1992 – 2006), and Current Opinion in Anti-Inflammatory and Immunomodulatory Investigational Drugs (1997 – 2000).

13. Throughout my career, I have conducted pharmacological studies and research using human and animal models in support of the development of many drugs and dosing regimens. Many of these studies involved characterizing and analyzing the pharmacokinetic and pharmacodynamic properties of a drug in humans and/or animals.

14. I consider myself an expert in the field of pharmacology.

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