

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. 7,157,456

DECLARATION OF JACK HIRSH, M.D.

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I, Jack Hirsh, declare as follows:

I. QUALIFICATIONS

1. My name is Jack Hirsh. I am currently a consultant to the Faculty of Health Sciences at McMaster University and the Hamilton Health Sciences Corporation regarding intellectual property and commercialization matters as well as a Professor Emeritus in the Department of Medicine at McMaster University in Ontario, Canada. I have over 50 years of experience in the field of medicine.

2. I received a Bachelor of Medicine, Bachelor of Surgery degree from the Melbourne University in 1958 and an M.D. from Melbourne University in 1962. I began my medical career as an Assistant Hematologist at the Royal Melbourne Hospital in Victoria, and continued as a Research Fellow at the Department of Internal Medicine at Washington University in St. Louis, Missouri. I have also served as a Visiting Research Scientist in the Department of Medicine and Blood and Vascular Research Unit at the University of Toronto, Ontario, Canada.

3. I have also served as an Assistant Professor, and as a Professor, in the Department of Pathology and Medicine at McMaster University in Ontario Canada, after which I became a Chairman of the Department Medicine at McMaster. From 1988 to 2003 I served as Director of the Hamilton Civic Hospitals Research Center in Ontario, Canada. I served as Vice-President of Research at Vascular Therapeutics

Inc. from 1994-1999, at GlycoDesign, Inc. from 1999-2003, at Hamilton Health Sciences from 2000-2002, and at Inflazyme from 2003-2004.

4. My research has been funded by many grants and scholarships from organizations such as the Canadian Heart and Stroke Foundation, the Ministry of Health, and the Ontario Research Development Challenge Fund. I have served on the editorial board of peer-reviewed journals such as *Haemostasis*, *Blood*, *Thrombus Research*, the *American Journal of Hematology*, *Review of Haematological Practice*, *Thrombosis & Haemostasis*, *Arteriosclerosis and Thrombosis*, and the *American Journal of Medicine*.

5. I have authored or co-authored many hundreds of publications of peer-reviewed journal articles as well as hundreds book chapters. I have received numerous honors and awards, including the Canadian Cardiovascular Society Research Achievement Award, the Outstanding Service Award as well as the Distinguished Research Professorship Award from the Heart and Stroke Foundation of Ontario, the Gairdner Foundation International Award for Achievement in Medical Science, the Henry M. Stratton Medal from the American Society of Hematology, and the Queen Elizabeth II Diamond Jubilee Medal.

6. 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. EX1005.

II. SCOPE OF WORK

7. I have been informed that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 7,157,456 (“the ’456 patent,” EX1001). I have been asked to analyze the ’456 patent. As part of my analysis, I reviewed the ’456 patent and portions of its prosecution history. EX1006. I have cited in this declaration various other documents that I reviewed in preparing my opinions. I have listed those documents in the Appendix in Section XI.

8. I am being compensated at the rate of \$700 per hour for my work. My compensation does not depend on the outcome of this matter.

III. OVERVIEW OF THE ’456 PATENT

9. The ’456 patent is titled “Substituted Oxazolidinones and their use in the field of Blood Coagulation.” Claims 1-6, 10, 14, and 16 of the ’456 patent recite oxazolidinones. Claim 16 is the most specific of these claims and recites the following:

16. A compound having the following formula:

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