In the United States Patent and Trademark Office

Before the Patent Trial and Appeal Board

ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach *et al.*
Issue Date: September 2, 2014
Title: Methods and Compositions for Treating Cancer

Inter Partes Review No. IPR2017-00853

DECLARATION OF MARC B. GARNICK, M.D.

I, Marc B. Garnick, M.D., do hereby declare:

I. INTRODUCTION

1. I am making this declaration at the request of Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., and Hikma Pharmaceuticals, LLC in the matter of the *Inter Partes* Review (IPR) of U.S. Patent No. 8,822,438 (the "'438 Patent"), as set forth in the above caption.

A. Education and Professional Background

2. I am a medical oncologist specializing in the care of patients with prostate cancer in the Division of Hematology and Oncology, Department of Medicine at the Beth Israel Deaconess Medical Center, Harvard Medical School, in Boston MA. My clinical and research interests have focused on urologic cancers, with a special interest in prostate cancer. I am actively involved in clinical research and in the past have devoted my professional activities to the development of drugs that are currently being used in the management of prostate cancer. I serve as the medical director for Cancer Services Brockton Hospital/Signature Health Care, Cambridge Health Alliance, which includes Cambridge Hospital and Whidden Memorial Hospital and the medical liaison for all of the cancer services that the

BIDMC provide. I am the director of Cancer Programs for Network Development at the Beth Israel Deaconess Medical Center. I am Gorman Brothers Clinical Professor of Medicine at Harvard Medical School, an endowed professorial chair in medicine.

3. I received a Bachelor of Arts degree in Biology from Bowdoin College, Brunswick, Maine. I obtained my medical degree from the University of Pennsylvania School of Medicine (now the Perelman School of Medicine at the University of Pennsylvania) in 1972. I completed my internship and residency in internal medicine at the Hospital of the University of Pennsylvania in 1974. I then completed two fellowships: one at the National Institutes of Health in the National Institute of Arthritis, Metabolism and Digestive Diseases in 1976 and then a fellowship in Medical Oncology at the Dana Farber Cancer Institute, Boston MA in 1978. My *curriculum vitae* is attached as Exhibit A.

4. From 1978 until 1996, I practiced medicine at the Dana Farber Cancer Institute and Brigham and Women's Hospital in Boston, MA. Since 1996, I have practiced at the Beth Israel Deaconess Medical Center. Between the years of 1987 and 2006, I also held positions at the Genetics Institute and Praecis Pharmaceuticals where my responsibilities dealt with the development of new drug therapies for cancer, including prostate cancer and other medical illnesses. I served as the academic principal investigator for the development and approval of leuprolide

acetate (Lupron®), one of the world's most widely-prescribed medicines for prostate cancer, and most recently served as the industry leader for abarelix, a pharmaceutical that is used for a subset of patients with prostate cancer, which was previously marketed in the United States and Europe.

5. I have been directly involved in the development of multiple drugs that have gained approval by both United States regulatory agencies and European regulatory agencies. I have participated as either an academic or industry leader and principal investigator/contributor for multiple drugs that have gained either FDA or European regulatory approvals.

6. I have had issued to me over 20 patents, mainly dealing with drug development and treatments for prostate cancer.

7. I enclose a representative sample of the types of activities I have been involved in relating to the diagnosis, treating, and evaluation of therapies for prostate cancer, with an emphasis on Lupron® and other hormonal therapies:

B. Representative sample of accomplishments related to prostate disorders, prostate cancer, and Lupron®-treated related disorders[1]

1. Prostate cancer and Lupron®-related accomplishments

a. Lupron®-related and LHRH analogue-related

- Academic Principal Investigator and one of three academic presenters to the FDA advisory committee related to the initial FDA approval of Lupron® for prostate cancer;
- Lead investigator on multiple Phase II studies and the pivotal Phase III study of Lupron® for prostate cancer, published in the New England Journal of Medicine;
- Investigator on multiple follow-on studies following the approval of Lupron®, in order to assess its post-marketing safety and efficacy;
- Lead developer of abarelix, the first approved LHRH/GnRH antagonist for prostate cancer in the U.S., Germany, and other EU Countries;
- Co-organizer (with the late William Fair, M.D.) of the annual International Conferences on Neoadjuvant Hormonal Therapy for Prostate Cancer; and

[1]Lupron® is one of the world's most prescribed therapies for prostate cancer; I served as the principal investigator that led to its approval by FDA and other worldwide regulatory bodies in the mid-1980s.

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