UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, LLC,
Petitioner

v.

ASTRAZENECA AB,
Patent Owner

Case IPR2017-00900
Patent No. 8,329,680

DECLARATION OF DORRAYA EL-ASHRY, Ph.D., UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,329,680

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I, Dorraya El-Ashry, Ph.D. hereby declare as follows:

I. INTRODUCTION

1. I have been retained as an expert witness on behalf of InnoPharma Licensing, LLC ("InnoPharma") for the above-captioned Petition for *Inter Partes* Review ("IPR") of U.S. Patent No. 8,329,680 ("the '680 patent"). I am being compensated for my time in connection with this IPR at my standard consulting rate of $500 per hour. My compensation is in no way dependent on the outcome of this matter.

2. I have been asked to provide my opinions regarding the article *Tamoxifen-resistant Fibroblast Growth Factor-transfected MCF-7 Cells Are Cross-Resistant in Vivo to the Antiestrogen ICI 182,780 and Two Aromatase Inhibitors*, 4 Clinical Cancer Research 697-711 (1998) ("the McLeskey Reference"). I am an author on the McLeskey Reference, and was the principal estrogen receptor expert on the project. The remaining authors of the McLeskey reference—including Drs. McLeskey and Kern—were growth factor experts, not estrogen receptor experts.

3. I have also been asked to respond to certain opinions set forth in the Declaration of Sandra McLeskey ("the McLeskey Declaration"), which I understand that AstraZeneca AB ("AstraZeneca") attached as Exhibit 2043 to its

Patent Owner Response in IPR2016-01316, -01324, -01325, and -01326.

4. In preparing this Declaration, I have reviewed the '680 patent, the McLeskey Reference, the McLeskey Declaration, and the article titled *Pharmacokinetics, Pharmacological and Anti-tumor Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, BRITISH J. OF CANCER, 74, p. 300-308 (1996) ("the Howell Reference").

5. In forming the opinions expressed in this Declaration, I relied upon my education and experience in the relevant field of the art, and have considered the viewpoint of a person having ordinary skill in the relevant art as of 2000.

II. BACKGROUND AND QUALIFICATIONS

6. I received my B.A. in Molecular Biology in 1984 from Vanderbilt University, and my Ph.D. in Experimental Pathology in 1989 from the University of Colorado Health Sciences Center. My dissertation focused on the cellular and molecular properties of progesterone receptors in breast cancer.

7. After completing my Ph.D., I began a Post-Doctoral Fellowship at the Georgetown Lombardi Cancer Center in 1994 in Washington, D.C. My research area was estrogen regulation of TGF-α in breast cancer. While at the Lombardi Cancer Center, I helped draft the McLeskey Reference along with my co-authors, including Dr. McLeskey and Dr. Kern.

8. I was promoted to Research Assistant Professor at the Lombardi

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