Case IPR2017-00905 Declaration of Richard Bergstrom, Ph.D. Under 37 C.F.R. § 1.68 in Support of Petition for *Inter Partes* Review of U.S. Patent No. 8,466,139

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INNOPHARMA LICENSING, LLC, Petitioner

v.

ASTRAZENECA AB, Patent Owner

Case IPR2017-00905 Patent No. 8,466,139

DECLARATION OF RICHARD BERGSTROM, Ph.D., UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. <u>PATENT NO. 8,466,139</u>

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I, Richard Bergstrom, Ph.D. hereby declare as follows:

I. <u>INTRODUCTION</u>

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. 8,466,139 ("the '139 patent"). I am being compensated for my time in connection with this IPR at my standard consulting rate of \$375 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 whether the blood plasma fulvestrant concentrations recited in claims 1, 3, 10, 11, 13, and 20 of the '139 patent would have been obvious to a person having ordinary skill in the art at the time of the alleged invention.

3. In preparing this Declaration, I have reviewed the '139 patent, the file history of the '139 patent, the prosecution histories of related patents, and numerous prior art references from the time of the alleged invention.

4. I have been advised and it is my understanding that patent claims in an IPR are given their broadest reasonable construction in view of the patent specification, file history, and the understanding of one having ordinary skill in the relevant art at the time of the purported invention. 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. My opinions directed to the invalidity of claims 1, 3, 10, 11, 13, and 20 of the '139 patent are based, at least in part, on the following prior art publications:

Reference	Date of Public Availability
Howell, 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)	Howell was published in 1996 and is attached as Exhibit 1007 to the IPR.
McLeskey, 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 CLIN. CANCER RESEARCH 697–711 (1998)	McLeskey was published in March 1998 and is attached as Exhibit 1008 to the IPR.
O'Regan , Effects of the Antiestrogens Tamoxifen, Toremifene, and ICI 182,780 on Endometrial Cancer Growth, 90 J. NAT'L CANCER INST. 1552–1558 (1998)	O'Regan was published in March 1998 and is attached as Exhibit 1009 to the IPR.

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