

Case IPR2017-00905

Declaration of Adrian L. Harris 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

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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INNOPHARMA LICENSING, LLC,  
Petitioner

v.

ASTRAZENECA AB,  
Patent Owner

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

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**DECLARATION OF ADRIAN L. HARRIS UNDER 37 C.F.R. § 1.68 IN**  
**SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S.**  
**PATENT NO. 8,466,139**

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**TABLE OF CONTENTS**

<b>I. INTRODUCTION.....</b>	<b>1</b>
<b>II. BACKGROUND AND QUALIFICATIONS .....</b>	<b>3</b>
<b>III. MATERIALS CONSIDERED FOR THIS DECLARATION.....</b>	<b>7</b>
<b>IV. LEVEL OF ORDINARY SKILL IN THE ART .....</b>	<b>7</b>
<b>V. BROADEST REASONABLE CONSTRUCTION .....</b>	<b>8</b>
<b>VI. UNDERSTANDING OF THE RELEVANT LAW .....</b>	<b>8</b>
<b>VII. OVERVIEW OF THE PATENT AT ISSUE.....</b>	<b>13</b>
<b>A. Overview of the ‘139 Patent .....</b>	<b>13</b>
<b>B. Overview of the Prosecution History of the ‘139 Patent.....</b>	<b>18</b>
<b>C. Relevant Related Prosecution Histories.....</b>	<b>18</b>
<b>1. The ‘122 Patent Prosecution History .....</b>	<b>19</b>
<b>2. The ‘680 Patent Prosecution History.....</b>	<b>21</b>
<b>VIII. AVAILABLE THERAPIES AT THE TIME OF THE INVENTION....</b>	<b>27</b>
<b>A. Tamoxifen and Other SERMs .....</b>	<b>28</b>
<b>B. Aromatase Inhibitors (AIs) .....</b>	<b>31</b>
<b>C. Fulvestrant.....</b>	<b>32</b>
<b>IX. SCOPE AND CONTENT OF THE PRIOR ART .....</b>	<b>40</b>
<b>A. Howell.....</b>	<b>40</b>
<b>B. McLeskey .....</b>	<b>42</b>
<b>C. O’Regan .....</b>	<b>43</b>

<b>X. DETAILED ANALYSIS</b> .....	44
<b>A. Summary of Opinion</b> .....	44
<b>B. Motivation for Combining The Prior Art</b> .....	45
1. Motivation to Turn to Howell.....	46
2. Motivation to Turn To McLeskey.....	55
3. Motivation to Turn To O’Regan.....	61
<b>C. A Person of Ordinary Skill Would Have Had a Reasonable         Expectation of Success in Combining the Prior Art</b> .....	62
<b>D. There Are No Secondary Considerations Warranting a Finding of         Nonobviousness</b> .....	71
1. There Is No Nexus.....	72
2. There Was No Long-Felt Need.....	74
3. There Were No Unexpected Results .....	75
<b>XI. SUPPLEMENTATION</b> .....	77
<b>XII. CONCLUSION</b> .....	77

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I, Adrian L. Harris, BSc Hons, MB ChB, MA, DPhil FRCP, FMedSci,  
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. 8,466,139 (“the ‘139 patent”). I am being compensated for my time in connection with this IPR at my standard consulting rate of \$615.00 per hour. My compensation is in no way dependent on the outcome of this matter.

2. I have been asked to provide opinions regarding whether claims 1, 3, 10, 11, 13, and 20 of the ‘139 patent are invalid, as anticipated by the prior art, or 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, 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
<b>Howell</b> , <i>Pharmacokinetics, Pharmacological and Anti-tumor Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer</i> , BRITISH J. OF CANCER, 74, p. 300-308 (1996)	Howell was published in 1996 and is attached as Exhibit 1007 to the IPR.
<b>McLeskey</b> , <i>Tamoxifen-resistant fibroblast growth factor-transfected MCF-7 cells are cross-resistant in vivo to the antiestrogen ICI 182,780 and two aromatase inhibitors</i> , 4 CLIN. CANCER RESEARCH 697–711 (1998)	McLeskey was published in March 1998 and is attached as Exhibit 1008 to the IPR.
<b>O'Regan</b> , <i>Effects of the Antiestrogens Tamoxifen, Toremifene, and ICI 182,780 on Endometrial Cancer Growth</i> , 90 J. NAT'L CANCER INST. 1552–1558	O'Regan was published in March 1998 and is attached as Exhibit 1009 to the IPR.

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