

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.
PATENT NO. 8,466,139**

Mail Stop: Patent Board
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

I. INTRODUCTION..... 1

II. BACKGROUND AND QUALIFICATIONS..... 3

III. MATERIALS CONSIDERED FOR THIS DECLARATION 6

IV. SUMMARY OF OPINIONS..... 6

V. TECHNICAL OVERVIEW OF PHARMACOKINETICS AND
PHARMACODYNAMICS 7

 A. Pharmacokinetics 7

 B. Pharmacodynamics..... 14

VI. OVERVIEW OF THE ‘139 PATENT AND ITS PROSECUTION HISTORY
..... 16

 A. Overview of the ‘139 Patent..... 16

 B. Overview of the Prosecution History of the ‘139 Patent and Related
 Applications 21

 (1) Prosecution History of the ‘122 Patent..... 21

 (2) Prosecution History of the ‘680 Patent..... 23

 (3) Prosecution History of the ‘139 Patent..... 29

VII. LEVEL OF ORDINARY SKILL IN THE PERTINENT ART..... 29

VIII. BROADEST REASONABLE CONSTRUCTION..... 30

IX. UNDERSTANDING OF THE LAW 31

X. SCOPE AND CONTENT OF THE PRIOR ART..... 36

 A. Howell..... 36

 B. McLeskey..... 39

C. O'Regan.....	40
XI. DETAILED INVALIDITY ANALYSIS.....	41
A. The Claimed Blood Plasma Fulvestrant Concentrations Are Obvious.....	42
(1) Howell Expressly Discloses the Claimed Blood Plasma Fulvestrant Concentrations.....	42
(2) A Person of Ordinary Skill in the Art Would Be Motivated to Achieve the Claimed Blood Plasma Fulvestrant Concentrations ..	44
(3) A Person of Skill in the Art Would Have a Reasonable Expectation of Success in Achieving the Claimed Blood Plasma Fulvestrant Concentrations	47
B. A Person of Skill in the Art Would Reasonably Expect that the Formulation Disclosed in McLeskey Would Exhibit the Same or Very Similar Pharmacokinetics as Howell	50
XII. CONCLUSION.....	56

I, Richard Bergstrom, 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. 8,466,139 (“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
<p>Howell, <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)</p>	<p>Howell was published in 1996 and is attached as Exhibit 1007 to the IPR.</p>
<p>McLeskey, <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)</p>	<p>McLeskey was published in March 1998 and is attached as Exhibit 1008 to the IPR.</p>
<p>O'Regan, <i>Effects of the Antiestrogens Tamoxifen, Toremifene, and ICI 182,780 on Endometrial Cancer Growth</i>, 90 J. NAT'L CANCER INST. 1552-1558 (1998)</p>	<p>O'Regan was published in March 1998 and is attached as Exhibit 1009 to the IPR.</p>

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.