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. 8,329,680

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

<u>DECLARATION OF RICHARD BERGSTROM, Ph.D., UNDER 37 C.F.R.</u> § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. <u>PATENT NO. 8,329,680</u>

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Con	cent	rations Are Obvious43				
(1)						
	(a)	(a) Howell Discloses Fulvestrant Concentrations of At Least 2.5 ngml ⁻¹ After Four Weeks				
	(b) The Prior Art Discloses Fulvestrant Concentrations of Least 8.5 ngml ⁻¹ After Four Weeks					
		(i) Howell Teaches Fulvestrant Concentrations of At Least 8.5 ngml ⁻¹ After Four Weeks				
		(ii) Howell and DeFriend Teach Fulvestrant Concentrations of At Least 8.5 ngml ⁻¹ After Four Weeks				
(2)	A Person of Ordinary Skill in the Art Would Be Motivated to Achieve Therapeutically Significant Blood Plasma Fulvestrant Concentrations					
	(a)	A Person of Skill in the Art Would Be Motivated to Achieve the Positive Results Reported in Howell				
	(b)	A Person of Skill in the Art Would Be Further Motivated to Increase Dose and Blood Concentration to Achieve Complete Downregulation of Estrogen Receptors				
		(i) DeFriend Would Motivate a Person of Skill in the Art to Double the Dose in Howell				
		(ii) DeFriend Would Motivate a Person of Skill in the Art to Use a Loading Dose				
	(c)	Rebuttal to AstraZeneca's Arguments				
(3)	A Person of Skill in the Art Would Have a Reasonable Expectation of Success in Achieving Therapeutically Significant Blood Plasma Fulvestrant Concentrations					
	(a) A Person of Skill in the Art Would Have a Reasonable					



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		Expectation of Success in Achieving Fulvestrant Concentrations of At Least 2.5 ngml ⁻¹ For Four Weel	ks66
	(b)	A Person of Skill in the Art Would Have a Reasonab Expectation of Success in Achieving Fulvestrant Concentrations of At Least 8.5 ngml ⁻¹ For Four Weel	
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Petition for Inter Partes Review of U.S. Patent No. 8,329,680

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

I. INTRODUCTION

- I have been retained as an expert witness on behalf of InnoPharma 1. 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 \$375 per hour. My compensation is in no way dependent on the outcome of this matter.
- I have been asked to provide my opinions regarding whether the 2. therapeutically significant blood plasma fulvestrant concentrations recited in claims 1-3 and 6 of the '680 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 '680 patent, the file histories of the '680 patent and related patents, and numerous prior art references from the time of the alleged invention.
- I have been advised and it is my understanding that patent claims in 4. 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.
 - In forming the opinions expressed in this Declaration, I relied upon 5.



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