

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LANNETT HOLDINGS, INC

Petitioner

v.

ASTRAZENECA AB

Patent Owner

of U.S. Patent No. 6,750,237 to Dearn et al.

Title: PHARMACEUTICAL FORMULATIONS CONTAINING ZOLMITRIPTAN

Inter Partes Review No. Unassigned

DECLARATION OF SVEINBJORN GIZURARSON, PH.D.

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I. INTRODUCTION

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.
2. I have been retained as an expert witness on behalf of LANNETT HOLDINGS, INC. (“Lannett”)

for the above-captioned *Inter Partes Review*.

3. I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$350 per hour. I understand that the IPR petition seeks cancellation of claims 1 – 16 of U.S. Patent No 6,750,237 to Dearn et al. (“the ‘237 patent”). I understand that the ‘237 patent resulted from US Application 10/129,773 (“the ‘773 application”), filed on November 28, 200 in the United States and alleging an earliest possible priority date (“EPPD”) of December 3, 1999 based on a filing in Great Britain.

4. In preparing this declaration, I have reviewed the ‘237 patent and considered each of the documents cited therein, in light of general knowledge in the art as of the earliest possible priority date (“EPPD”) for the ‘237 patent. In formulating my opinions, I have relied upon my experience, education and knowledge in the relevant art, and I have considered the viewpoint of a person of ordinary skill in the art (“POSITA”) (i.e., a person of ordinary skill in the field of pharmaceutical formulations and in particular pharmaceutical formulations for use in nasal applications) prior to December 3, 1999.

II. MY BACKGROUND AND QUALIFICATIONS

5. I am an expert in the field of pharmaceutical formulation and have been since before December 1999. I have approximately 25 years of experience in the design of pharmaceutical formulations, including particularly and especially pharmaceutical formulations adapted for administration by the intranasal route.

6. I received my M.Sc. in Pharmacy from the University of Copenhagen in 1986.
7. My M.Sc. thesis was entitled “Drug-protein binding interactions.”
8. I received my Ph.D. in biopharmaceutics from the University of Copenhagen in 1990.

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9. My Ph.D. thesis was entitled “*Intranasal application of insulin. Pharmaceutical and physiological factors affecting successful absorption of insulin.*”

10. I received in 1994 authorization from the **Ministry of Health** in Iceland to act as an expert in the field of *Clinical Pharmacokinetics and Biopharmaceutic*.

11. Throughout my career my research interests have included design, formulation, testing and analysis of pharmaceutical products, including particularly products relating to administration of drugs by the nasal route.

12. From about 1987 to about 1990 I was a teaching assistant at the University of Copenhagen as a member of the faculty of pharmaceutical sciences (Denmark). I lectured in the topics of bio pharmacy, biopharmaceutical training and drug delivery systems. In about 1991 I became an assistant professor (lector) in pharmaceutical sciences at the University of Iceland, Faculty of Pharmaceutical Sciences. In 1993 I became associate professor (docent) and in 1998 I became full professor (tenure).

13. From about 1995 until the present, I have been a member of the patent pending committee in Iceland. As a member of this committee, it is my responsibility to reevaluate patent applications, when the applicant(s) files a formal complaint after the patent application has been rejected.

14. In 2002, I participated as a member of an expert committee formed by the United States FDA relating to nose to brain, adverse reactions.

15. From 2006 to about 2010 I was a visiting lecturer at the University of Copenhagen, faculty of pharmaceutical sciences (Denmark) in connection with advanced drug delivery systems.

16. I am the author of over 250 publications and presentations on pharmaceuticals, intellectual property, dosage forms, intranasal administration of drugs, and similar topics.

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