

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN TECHNOLOGIES INC.,
Petitioner,

v.

NOVEN PHARMACEUTICALS, INC.,
Patent Owner.

Patent No. 9,724,310

DECLARATION OF KEITH BRAIN, PH.D.

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I, Keith Brain, declare as follows:

I. QUALIFICATIONS

1. My name is Keith Brain. I was appointed to a full-time tenured position on faculty at the School of Pharmacy and Pharmaceutical Sciences of Cardiff University in 1969 and retired as Reader in Dermatopharmaceutics (the science of skin drug delivery) in 2011 after 42 years of continuous service. I was awarded an Honorary Senior Research Fellowship at retirement and continued research involvement with former colleagues. My career in research has covered a number of topics, focusing primarily on aspects of dermal and transdermal drug delivery. During the last 20-25 years of my research career, my work also focused on molecular interactions between polymers. My work has covered both basic science and translational and applied aspects of research.

2. During my time at Cardiff, I was responsible for a number of B. Pharm and M. Pharm courses including those on pharmaceutical chemistry, pharmaceutical analysis, drug delivery (pharmaceutics), and quality assurance. I also lectured externally for courses in the Diploma in Pharmaceutical Medicine and Dermal Toxicology MSc program.

3. I received my B. Pharm. from the University of Nottingham in 1966 and my Ph.D. in Pharmaceutical Science from the University of Bath in 1969.

4. I have authored or co-authored over 100 peer-reviewed journal articles, of which several articles present original research and data on transdermal delivery of active agents across the skin from various drug delivery systems including transdermal patches. In particular, I have co-authored an article on transdermal estradiol drug delivery. I have also authored or co-authored 22 book chapters, three books, 56 peer-reviewed papers in conference proceedings, and 140 conference abstracts, in addition to editing 22 books, including several editions of *Perspectives in Percutaneous Penetration*. I am a regular reviewer for 11 high-impact peer reviewed journals including *Nature Biotechnology*, the *Journal of Controlled Release*, and the *International Journal of Pharmaceutics*.

5. For the past 30 years, I have served as CEO of An-eX Analytical Services Ltd. An-eX Analytical Services is an independent contract research and development company that provides services in the development and evaluation of pharmaceutical materials. An-eX Analytical Services has received global recognition in the field of dermal pharmaceuticals and has provided a range of services to a wide range of international clients. Whilst most of this work has been subject to Non-Disclosure Agreements, certain studies have been published at the request of the Sponsor. These include collaborations with Organon, Mentholatum, Biomarin, Clairol, Unilever Research, Proctor and Gamble, Cosmetic Toiletries and Fragrance Association, Research Institute for Fragrance Materials and the

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