

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. 9,833,419

---

**DECLARATION OF KEITH BRAIN, PH.D.**

**TABLE OF CONTENTS**

	Page
I. Qualifications .....	1
II. Scope of Work .....	5
III. Overview of the '419 Patent.....	6
IV. File History of the '419 Patent .....	10
V. Legal Standards.....	23
VI. Level of Ordinary Skill and Relevant Time.....	26
VII. Claim Construction.....	27
A. About.....	28
B. Coat Weight.....	30
C. Flux .....	31
D. Therapeutically Effective Amount .....	33
VIII. The State of the Art .....	34
IX. The Asserted References Disclose or Suggest the Claimed Features of the '419 Patent.....	55
A. Brief Overview of the Asserted References .....	55
i. Mueller.....	56
ii. Vivelle-Dot <sup>®</sup> Label .....	66
iii. Kanios .....	68
iv. Chien.....	72
B. Detailed Analysis of the Claims .....	74
GROUND 1. Mueller Anticipates Claims 1-2, 8, and 10-15. ....	74
i. Claim 1 .....	74
ii. Claim 2.....	82

iii. Claim 8.....	83
iv. Claims 10-14 .....	84
v. Claim 15 .....	89
GROUND 2. The Teachings of Mueller and the Vivelle-Dot <sup>®</sup> Label Render Claims 1- 2 and 8-15 Obvious.....	90
i. Claims 1 and 2.....	90
ii. Claim 8.....	99
iii. Claim 9.....	101
iv. Claims 10-14 .....	102
v. Claim 15 .....	105
GROUND 3. The Teachings of Mueller, Vivelle-Dot <sup>®</sup> Label, and Kanios Render Claims 3-7 Obvious. ....	106
i. Claims 3 and 5.....	107
ii. Claims 4 and 6.....	117
iii. Claim 7 .....	119
GROUND 4: The Teachings of Mueller, Vivelle-Dot <sup>®</sup> Label, Kanios, and Chien Render Claims 1-15 Obvious.....	124
X.Concluding Statements.....	136
XI.Appendix – List Of Exhibits .....	138

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

# 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.