### UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

BEFORE THE PATENT TRIAL AND APPEAL BOARD

\_\_\_\_\_

FLATWING PHARMACEUTICALS, LLC, Petitioner,

v.

ANACOR PHAMACEUTICALS, INC., Patent Owner

Case No. IPR2018-00168 Patent No. 9,549,938

\_\_\_\_\_

DECLARATION OF MAJELLA E. LANE, PH.D. IN SUPPORT OF PATENT OWNER'S RESPONSE



### **TABLE OF CONTENTS**

1.	INTRODUCTION1		
II.	ACA	ACADEMIC AND PROFESSIONAL QUALIFICATIONS	
III.		E '938 PATENT	
IV.	TECHNICAL BACKGROUND		
	A.	Structure of the Nail Plate	7
	B.	Role of Keratin	9
	C.	Factors Affecting Nail Permeability	10
		1. Molecular Weight	11
		2. Keratin-Binding Affinity	17
		3. Other Factors	20
	D.	The Challenge of Transungual Drug Delivery	22
V.	THE	CITED REFERENCES	25
	A.	Austin	25
	B.	Brehove	26
	C.	Freeman	27
	D.	Samour	28
VI.	RESPONSE TO PETITIONER'S GROUNDS		29
	A.	The Cited Art Teaches Away from 5% Tavaborole	29
	В.	A POSA Would Have Used More than 5% Tavaborole to Overcome Tavaborole's Expected High Keratin-Binding Affinity	35
		•	



Case No. IPR2018-00168	
U.S. Patent No. 9,549,938	
CONCLUSION40	VII.



I, Majella E. Lane, Ph.D., hereby state and declare as follows:

#### I. INTRODUCTION

- 1. I have been asked by Patent Owner Anacor Pharmaceuticals, Inc. ("Anacor") to offer my expert opinions regarding the petition for *inter partes* review of U.S. Patent No. 9,549,938 ("the '938 patent") filed by Petitioner FlatWing Pharmaceuticals, LLC ("FlatWing"). This declaration contains my opinions related to the validity of claims 3, 5, and 6 of the '938 patent.
- 2. I am being compensated at my customary hourly rate, and my compensation is not dependent upon the outcome of, or the content of my testimony in, the present *inter partes* review proceeding or any litigation proceedings.
- 3. I have reviewed FlatWing's petition for *inter partes* review ("Pet.") of the '938 patent, including the declarations filed in support of the petition submitted by Dr. Stephen B. Kahl (Ex. 1003) and Dr. S. Narasimha Murthy (Ex. 1005). I have further reviewed the exhibits and articles cited in these documents, as well as the articles and documents cited in this declaration.
- 4. I have additionally reviewed the declaration of Dr. Paul J. Reider ("Reider Decl.," Ex. 2013) filed in support of Anacor's response to FlatWing's petition. I am also aware of knowledge generally available to and relied upon by persons of ordinary skill in the art ("POSA") at the time of the invention.



5. This declaration is based on information currently available to me. I reserve the right to continue my investigation and analysis, which may include a review of documents and information not yet provided. I further reserve the right to expand or otherwise modify my opinions and conclusions as my investigation and study continues, and to supplement my opinions and conclusions in response to any additional information that becomes available to me.

## II. ACADEMIC AND PROFESSIONAL QUALIFICATIONS

- 6. I received a Ph.D. in 1997 from Trinity College, Dublin, where my research focused on drug transport across biological membranes (in particular skin and mucosa), topical and transdermal formulations, mathematical modeling of topical and transdermal drug delivery, and prediction of percutaneous drug penetration. I received a B.S. in pharmacy from Trinity College in 1992.
- 7. I am currently the Director of the Skin Research Group and a Senior Lecturer in Pharmaceutics at the School of Pharmacy at the University College of London ("UCL"). I have held those positions since 2010 and 2008, respectively. From 2005 to 2008, I was a Lecturer in Pharmaceutics at UCL. Prior to that, I was the director of the Master's program in Pharmaceutical Technology at Trinity College, Dublin from 1998 to 2005, after having first worked there as a Lecturer in Pharmaceutical Chemistry starting in 1995, and a Lecturer in Pharmaceutics starting in 1997. A copy of my curriculum vitae is attached as Exhibit 2045.



# DOCKET

# 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.

