PROTECTIVE ORDER MATERIAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC, Petitioner,

v.

EYE THERAPIES, LLC, Patent Owner.

Case No. IPR2022-00142 U.S. Patent No. 8,293,742

EXPERT DECLARATION OF IVAN T. HOFMANN IN SUPPORT OF PETITIONER REPLY

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

TABLE OF CONTENTS

I.	INTRODUCTION1		
II.	QUALIFICATIONS AND EXPERIENCE		
III.	DOCUMENTS REVIEWED		
IV.	SUMMARY OF OPINIONS		
V.	BACKGROUND9		
VI.	THE DEFINITIONS OF COMMERCIAL SUCCESS AND NEXUS RELATIVE TO OBJECTIVE INDICIA OF NONOBVIOUSNESS11		
VII.	PRO	THE MARKETPLACE PERFORMANCE OF LUMIFY® FAILS TO PROVIDE OBJECTIVE INDICIA OF NONOBVIOUSNESS OF THE CHALLENGED CLAIMS OF THE '742 PATENT	
	A.	The Marketplace Performance of Lumify [®] is Driven by Features That I Understand Were Known in the Prior Art	
	B.	The Jarosz Declaration Fails to Appropriately Address Marketing and Promotion of Lumify [®] , Which Also Drive the Marketplace Performance of Lumify [®]	
	1.	DTC Advertising	
	2.	Detailing and Sampling Efforts	
	3.	Lack of Comparison of Promotional Expenses for Lumify [®] Relative to Other Competing Products	
VIII. OTHER CRITIQUES OF THE JAROSZ DECI		ER CRITIQUES OF THE JAROSZ DECLARATION	
	A.	The Jarosz Declaration Fails to Demonstrate That the Marketplace Performance of Lumify [®] is Related to Claims 4-6 of the '742 Patent38	
	B.	The Jarosz Declaration's Claim That the Actions of the Patent Owner and Petitioner Related to Lumify [®] Purportedly Provide Evidence of the Marketplace Success of Lumify [®] is Flawed and Unreliable40	
	C.	The Jarosz Declaration Fails to Address the Profitability (or Lack Thereof) of Lumify [®]	

I, Ivan T. Hofmann, hereby declare as follows.

I. INTRODUCTION

1. I am over the age of eighteen and am competent to make this declaration.

2. I have been retained as an independent expert on behalf of Petitioner Slayback Pharma, LLC ("Slayback") to provide economic analysis in the abovecaptioned IPR.

3. I understand that this IPR involves U.S. Patent No. 8,293,742 B2 (the "742 Patent"). The '742 Patent is entitled "Preferential Vasoconstriction Compositions and Methods of Use" and issued on October 23, 2012.¹ I understand that the '742 Patent claims priority to a provisional application filed on August 1, 2008 and the '742 Patent expires on July 14, 2030.² I understand that according to United States Patent and Trademark Office ("USPTO") records, the '742 Patent is

¹ EX 1001 ('742 Patent).

² EX 1001 ('742 Patent); and EX 2079

⁽https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm, accessed November 17, 2022).

assigned to Eye Therapies, LLC ("Eye Therapies").³ I understand that claims 1-6 of the '742 Patent relate to compositions and methods for using ocular drops containing a certain concentration range of brimonidine as the vasoconstrictor compound to reduce eye redness.⁴

4. I have been asked to review and respond to the Declaration of John C. Jarosz, dated August 26, 2022 (the "Jarosz Declaration") as it relates to purported commercial success and nexus with respect to Lumify[®] (brimonidine) and the challenged claims of the '742 Patent.^{5, 6}

(https://assignment.uspto.gov/patent/index.html#/patent/search/resultFilter?searchI nput=8293742, accessed December 2, 2022).

⁴ EX 1003 (Declaration of Paul A. Laskar, Ph.D., dated November 4, 2021 (the "Laskar Declaration"), pars. 30, 44-47, and 51b) and EX 1002 (Declaration of Neal A. Sher, M.D., FACS, dated November 4, 2021 (the "Sher Declaration"), par. 27).
⁵ EX 2024 (Jarosz Declaration), par. 13.

⁶ I understand that Petitioner has challenged claims 1-6 of the '742 Patent (Paper

13 - Decision Granting Institution of *Inter Partes* Review 35 U.S.C. 314, 37 C.F.R. 42.4, pg. 2).

³ EX 1001 ('742 Patent) and EX 1067

5. My company, Gleason IP ("Gleason"), is being compensated for the work performed on this engagement based on the time incurred by me at a rate of \$535 per hour. Our compensation is not affected by the outcome of this matter.

II. QUALIFICATIONS AND EXPERIENCE

6. I am a Vice President and Managing Director at Gleason. Gleason is an economic, accounting, and financial consulting firm. I am the leader of the Intellectual Property Practice. Prior to joining Gleason, I worked for the global firm of Deloitte.

7. I graduated *magna cum laude* from the University of Notre Dame with a Bachelor of Business Administration degree and a double major in Economics and Accounting. I am a Certified Public Accountant ("CPA"). I am also Certified in Financial Forensics ("CFF"). I am a member of the Licensing Executives Society ("LES") and have received my Certified Licensing Professional ("CLP") designation, which is granted by the LES to professionals with demonstrated knowledge and experience in the areas of intellectual property and licensing. I am also a member of the American Economic Association. I have attended and instructed numerous continuing education seminars since the completion of my formal education and have been a speaker on numerous occasions on a variety of financial, economic, accounting, and valuation topics. I have presented to various

DOCKET A L A R M



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.