

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES S.A., AND
DR. REDDY'S LABORATORIES, INC.,

Petitioners,

v.

EYE THERAPIES, LLC,

Patent Owner.

Case No. IPR2024-00467
U.S. Patent No. 11,833,245

**EXPERT DECLARATION OF IVAN T. HOFMANN
IN SUPPORT OF PETITIONERS' REPLY**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	QUALIFICATIONS AND EXPERIENCE.....	4
III.	DOCUMENTS REVIEWED	8
IV.	SUMMARY OF OPINIONS	9
V.	BACKGROUND	10
VI.	THE DEFINITIONS OF COMMERCIAL SUCCESS AND NEXUS RELATIVE TO OBJECTIVE INDICIA OF NONOBVIOUSNESS	14
VII.	THE MARKETPLACE PERFORMANCE OF LUMIFY FAILS TO PROVIDE OBJECTIVE INDICIA OF NONOBVIOUSNESS OF THE CHALLENGED CLAIMS OF THE '245 PATENT	15
A.	The Marketplace Performance of Lumify is Driven by Features That I Understand Were Known in the Prior Art.....	17
B.	The Jarosz Declaration Fails to Appropriately Address Marketing and Promotion of Lumify, Which Also Drive the Marketplace Performance of Lumify	23
1.	DTC Advertising	26
2.	Detailing and Sampling Efforts.....	38
3.	Lack of Comparison of Promotional Expenses for Lumify Relative to Other Competing Products	47
VIII.	ADDITIONAL CRITIQUES OF THE JAROSZ DECLARATION	52
A.	The Jarosz Declaration Fails to Demonstrate That the Marketplace Performance of Lumify is Related to the Challenged Claims of the '245 Patent.....	52
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 Unreliable.....	57

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 Petitioners Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL" or the "Petitioners") to provide economic analysis in the above-captioned IPR.

3. I understand that this IPR involves U.S. Patent No. 11,833,245 (the "'245 Patent"). The '245 Patent is entitled "Vasoconstriction Compositions and Methods of Use" and issued on December 5, 2023.¹ I understand that the '245 Patent claims priority to a provisional application filed on August 1, 2008 and the '245 Patent expires on July 27, 2029.² I understand that according to United States Patent and Trademark Office ("USPTO") records, the '245 Patent is assigned to Eye

¹ EX 1001 ('245 Patent).

² EX 1001 ('245 Patent); and EX 1167

(https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208144&Appl_type=N, accessed February 14, 2025).

Therapies, LLC (“Eye Therapies”).³ I understand that the challenged claims of the ’245 Patent are claims 1, 2, 4-9, 11-17, 20-22, 25, and 27 and generally relate to low concentration compositions of brimonidine for inducing vasoconstriction.⁴

³ EX 1001 (’245 Patent) and EX 1168

(<https://assignment.uspto.gov/patent/index.html#/patent/search/resultAbstract?id=11833245&type=patNum>, accessed February 14, 2025).

⁴ EX 1013 (Declaration of Paul A. Laskar, Ph.D. in Support of Petition for Inter Partes Review of U.S. Patent No. 11,833,245, dated January 24, 2024 (the “Laskar Declaration”), par. 20) and EX 1014 (Declaration of John C. Galanis, MD, FACS in Support of Petition for Inter Partes Review of U.S. Patent No. 11,833,245, dated January 24, 2024, (the “Galanis Declaration”), pars. 47 and 50). I understand that the Declaration of John C. Jarosz, dated November 19, 2024 (the “Jarosz Declaration,” EX 2229) does not list claim 27 of the ’245 Patent as a challenged claim (Jarosz Declaration, par. 2), but understand that claim 27 is a challenged claim based on the institution decision in this matter (Paper 14 - Decision Granting Institution of *Inter Partes* Review 35 U.S.C. § 314, pgs. 2 and 40).

4. I have been asked to review and respond to the Jarosz Declaration as it relates to purported commercial success and nexus with respect to Lumify^{®5} (0.025% brimonidine) and the challenged claims of the '245 Patent.^{6, 7}

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 \$650 per hour. Gleason is also being compensated for the time spent on this matter by Gleason personnel working at my direction. Their rates are lower than my rate. Our compensation is not affected by the outcome of this matter.

⁵ I understand that the brand name Lumify has a registered trademark. However, throughout the remainder of this declaration, when referring to Lumify and other branded product names, I do not use the indication of the registered trademark symbol ("®").

⁶ EX 2229 (Jarosz Declaration, par. 13).

⁷ I understand that Petitioners have challenged claims 1, 2, 4-9, 11-17, 20-22, 25, and 27 of the '245 Patent (Paper 14 - Decision Granting Institution of *Inter Partes* Review 35 U.S.C. § 314, pg. 2).

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 demonstrating extensive 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 bar associations and organizations on the issues of intellectual property, objective indicia of nonobviousness, financial damages, valuation, financial statement analysis, and other topics.

8. I have extensive knowledge and experience in the areas of economic and market analysis. My intellectual property experience includes valuation of intellectual property, analysis of objective indicia of nonobviousness, market analysis involving product performance, royalty audits, the determination of damages associated with patent infringement and other intellectual property (including lost profits, disgorgement, and reasonable royalties, as applicable), consideration of irreparable harm, analysis of *Panduit* Factors, and analysis of *Georgia-Pacific* Factors. I have analyzed damages claims in trademark infringement, false advertising, and other cases involving the Lanham Act. I have also analyzed damages related to the misappropriation of trade secrets and copyright infringement. I also have experience in the calculation of damages for breach of contract claims, including lost profits damages and performing an analysis of the ‘but for’ world in the development of my damages claims. I have experience in a broad range of industries including pharmaceutical and life sciences, manufacturing, retail, technology, healthcare, communications, construction, extractive, and other industries.

9. My work experience includes litigation support and consulting engagements with a variety of pharmaceutical, medical device, and biologics companies. In my work in the pharmaceutical and life sciences industry, I have performed financial and economic analysis for hundreds of pharmaceutical and

biologic products, including virtually every major therapeutic class of drugs, as well as numerous medical devices. I have been asked to study and analyze objective indicia of nonobviousness (including commercial success and nexus), consider claims of irreparable harm, the balance of equities, and public interest factors (and related issues associated with bonds therewith), determine and quantify damages, perform royalty audits, and assist with licensing and settlement discussions.

10. My work experience also includes assisting clients with product pipeline consulting. Specifically, I analyze markets and assess the impact that a launch of a product may have on a relevant market. In providing product pipeline consulting, I use my extensive experience in financial modeling for pharmaceutical and life science products that have not yet launched. More precisely, I develop assumptions for financial models in order to project market formation, market penetration, market share, and pricing on a regular basis. Global pharmaceutical and life sciences companies often retain me and my firm to perform these analyses and make decisions based on the accuracy and reliability of the financial modeling that I perform.

11. In the course of my work in providing consulting and expert services, I regularly analyze and review data for the pharmaceutical and life sciences industry, including data from IQVIA, Inc. (“IQVIA”), Circana (previously Information Resources, Inc. (“IRI”)), Symphony Health Solutions (“Symphony”), Truven Health

Analytics (“Truven”), IntrinsiQ Specialty Solutions, Inc. (“IntrinsiQ”), Syneos Health (“Syneos”), and other service providers. I am knowledgeable regarding the role of pharmaceutical databases such as First Databank, Medispan, Gold Standard, and other information sources in the fulfillment of prescriptions. I am also knowledgeable regarding the process of prescription writing, fulfillment, and product substitution in the pharmaceutical and life sciences industry. I have analyzed data and information and testified as an expert witness numerous times in matters involving the pharmaceutical and life sciences industry and the role of brand versus generic competition. I have been qualified as an expert witness in pharmaceutical economics on numerous occasions by various federal courts and institutions.

12. I have been engaged by the USPTO and Office of the Solicitor as an expert to analyze and testify on economic issues involving intellectual property in proceedings for the Honorable David Kappos, while Under Secretary of Commerce for Intellectual Property and Director of the USPTO; the Honorable Michelle Lee, while Under Secretary of Commerce for Intellectual Property and Director of the USPTO; the Honorable Joseph Matal, while performing the functions and duties of Under Secretary of Commerce for Intellectual Property and Director of the USPTO; the Honorable Andrei Iancu, while Under Secretary of Commerce for Intellectual

Property and Director of the USPTO; and the Honorable Katherine Vidal, while Under Secretary of Commerce for Intellectual Property and Director of the USPTO.

13. I also have extensive experience in analyzing, calculating, and determining damages and other financial and economic issues in various dispute settings. I have been designated as a testifying expert in federal and state courts, Chancery Court, the United States International Trade Commission, the Patent Trial and Appeal Board (“PTAB”), and on matters before the Supreme Court of the United States and various domestic and international arbitration panels. I have analyzed damages involving intellectual property disputes, breach of contract claims, shareholder disputes, insurance recovery, class actions, and others. I also have experience assessing claims of irreparable harm, the balance of equities, and public interest factors in connection with temporary restraining order hearings, preliminary injunction hearings, and other injunctive relief and determining whether financial damages are calculable, including issues associated with related bonds.

14. My *curriculum vitae* and list of testimony in the past four years is included as EX 1163.

III. DOCUMENTS REVIEWED

15. The bases for my opinions herein are: (i) the materials and independent research identified throughout this declaration; (ii) the exhibits set forth in this

declaration; (iii) the exhibits attached to the Jarosz Declaration and the Declaration of John Ferris, dated November 18, 2024 (the “Ferris Declaration,” EX 2230); (iv) the ’245 Patent; and (v) my knowledge, education, and experience. The materials and exhibits that I have cited and that are included in **Appendix 1** to this declaration are among the types of information reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case. Throughout this declaration, I cite portions of these documents. These citations are intended only as examples, however, and I reserve the right to rely on all portions of the documents cited herein.

16. This declaration is based on information known to me as of the date I signed this declaration and I reserve the right to amend or supplement this declaration in response to any additional information that becomes available. The work on this engagement was performed by me and others at Gleason working under my direct supervision.

IV. SUMMARY OF OPINIONS

17. The marketplace performance of Lumify does not provide objective indicia of nonobviousness of the challenged claims of the ’245 Patent for at least the following reasons:

- a. The marketplace performance of Lumify is driven by features that I understand were known in the prior art.
- b. The discussion of marketing efforts in the Jarosz Declaration is incomplete and misleading and the Jarosz Declaration fails to appropriately address that the marketing and promotional efforts by Bausch for Lumify also drive the marketplace performance of Lumify.
- c. The Jarosz Declaration fails to apportion the marketplace performance of Lumify among the challenged claims of the '245 Patent and to the other Orange Book⁸ listed patents for Lumify.

V. BACKGROUND

18. Bausch & Lomb, Inc. (“Bausch & Lomb”) acquired an exclusive global license to the '245 Patent from Eye Therapies in January 2013.⁹ The United States

⁸ Throughout this declaration, I refer to FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations as the “Orange Book.”

⁹ EX 2192 (<https://www.prnewswire.com/news-releases/bausch--lomb-licenses-new-technology-with-potential-to-treat-millions-affected-by-ocular-redness-185856742.html>). I understand that Bausch & Lomb is (and has been) an indirect

Food and Drug Administration (“FDA”) approved Bausch’s New Drug Application (“NDA”) No. 208144 for Lumify on December 22, 2017 and Bausch launched

wholly-owned subsidiary of Bausch Health Companies, Inc. (“Bausch Health”) during the period that Bausch & Lomb has marketed and sold Lumify. I further understand that Bausch & Lomb is in the process of separating from Bausch Health into an independent publicly traded entity. Throughout this declaration, I refer to the companies marketing and selling Lumify as “Bausch.” See EX 2218 (Bausch+ Lomb Corporation SEC Form 10-K for the fiscal year ended December 31, 2022, pg. 16); and EX 2219 (Bausch + Lomb Corporation, SEC Form 10-Q for the quarterly period ended September 30, 2024, pgs. 70-71 and 109-110). Exhibits 2218 and Exhibits 2219 are true and accurate copies of the Bausch SEC filings that I accessed at the aforementioned website. Such SEC filings are regularly and reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case.

Lumify on May 7, 2018.¹⁰ Lumify (brimonidine) is an over-the-counter (“OTC”) eye drop indicated for relief of redness of the eye due to minor eye irritations.¹¹

19. I understand that Slayback Pharma LLC (“Slayback”) filed Abbreviated New Drug Application (“ANDA”) No. 216361 with FDA seeking approval for a generic version of Lumify (brimonidine tartrate ophthalmic solution,

¹⁰ EX 2143 (Lumify NDA Approval, December 22, 2017); and EX 2176 (<https://ir.bauschhealth.com/news-releases/2018/05-07-2018-130249958>).

¹¹ EX 1169 (Lumify Label, February 2024, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/208144Orig1s017lbl.pdf, accessed February 14, 2025); and EX 2176 (<https://ir.bauschhealth.com/news-releases/2018/05-07-2018-130249958>). I am not a medical doctor or clinician. My understanding regarding medical and clinical issues is based on the citations identified throughout this declaration, which is the type of information I routinely review during the course of my work.

0.025%).¹² In July 2022, Dr. Reddy's Laboratories, Ltd.¹³ announced that it entered into a license agreement with Slayback for the rights to Slayback's ANDA for a therapeutic equivalent of Lumify.¹⁴

¹² EX 2160 (<https://www.businesswire.com/news/home/20220729005454/en/Dr.-Reddys-Laboratories-enters-into-a-licensing-agreement-with-Slayback-Pharma-to-%E2%80%A61/3>).

¹³ I understand that Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. are wholly owned subsidiaries of Dr. Reddy's Laboratories, Ltd. (the parent company). See EX 1170

(https://www.drreddys.com/cms/cms/sites/default/files/2024-06/DR%20REDDYS%20LABORATORIES%20LTD_0.pdf, accessed February 14, 2025, pg. 205).

¹⁴ EX 2160 (<https://www.businesswire.com/news/home/20220729005454/en/Dr.-Reddys-Laboratories-enters-into-a-licensing-agreement-with-Slayback-Pharma-to-%E2%80%A61/3>).

**VI. THE DEFINITIONS OF COMMERCIAL SUCCESS AND NEXUS
RELATIVE TO OBJECTIVE INDICIA OF NONOBVIOUSNESS**

20. It is my understanding that “commercial success” is a legal construct that has been established through case law. Analysis of commercial success is premised on the concept that if a product is economically successful, that the economic success may provide objective evidence of nonobviousness.

21. I further understand that the commercial success of the product must be attributable to the allegedly novel features of the claimed invention. I understand this to mean that, to support a finding of nonobviousness, commercial success must be driven by and attributable to the purported merits of the patented invention. In other words, there must be a causal correlation, or “nexus,” between the unique merit of the claimed invention and the success of the product. I also understand that if purported commercial success is due to an element in the prior art, no nexus exists. In essence, I understand that if the feature that creates the purported success was known in the prior art, such success is not pertinent to nonobviousness.

22. I apply this understanding to my economic analysis of the issues in this matter regarding the '245 Patent.

VII. THE MARKETPLACE PERFORMANCE OF LUMIFY FAILS TO PROVIDE OBJECTIVE INDICIA OF NONOBVIOUSNESS OF THE CHALLENGED CLAIMS OF THE '245 PATENT

23. The Jarosz Declaration alleges that Lumify has been a marketplace success and that there is a purported nexus between such claimed success and the challenged claims of the '245 Patent.¹⁵ I disagree. Based upon my analysis, the marketplace performance of Lumify is driven by features that I understand were known in the prior art and by the marketing and promotional efforts of Bausch for

¹⁵ EX 2229 (Jarosz Declaration, par. 13).

Lumify.^{16, 17} Additionally, the Jarosz Declaration fails to apportion the marketplace performance of Lumify among the challenged claims of the '245 Patent and to the

¹⁶ I previously issued a declaration on December 16, 2022, to provide economic analysis and to review and respond to the Declaration of John C. Jarosz, dated August 26, 2022 (the “Jarosz ’742 Declaration,” EX 1198) as it relates to purported commercial success and nexus with respect to Lumify (brimonidine) and the challenged claims of U.S. Patent No. 8,293,742 (the “’742 Patent”), pursuant to IPR2022-00142 (the “Hofmann ’742 Declaration,” EX 1171). I understand that Patent Owner’s appeal of the Board’s Final Written Decision in this matter (wherein the Board deemed the asserted claims of the ’742 Patent unpatentable) is pending in the Court of Appeals for the Federal Circuit in Case No. 23-2173. See Paper 31 (Petitioners’ Updated Mandatory Notices, pg. 1); and EX 1003 (Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a), dated May 15, 2023).

¹⁷ I understand that the ’245 Patent is commonly owned with, shares the same specification as, and claims priority to the same priority application as the ’742 Patent (as well as U.S. Patent No. 11,596,600 (the “’600 Patent”)). See Paper 31 (Petitioners’ Updated Mandatory Notices, pg. 1).

other Orange Book listed patents for Lumify. Therefore, the marketplace performance of Lumify fails to provide objective indicia of nonobviousness of the challenged claims of the '245 Patent.

A. The Marketplace Performance of Lumify is Driven by Features That I Understand Were Known in the Prior Art

24. The Jarosz Declaration alleges that there is a nexus between the marketplace performance of Lumify and the challenged claims of the '245 Patent without addressing whether the features that drive the marketplace performance of Lumify were known in the prior art. As previously discussed, I understand that if purported commercial success is due to an element in the prior art, then no nexus exists. In essence, if the feature or features that create the purported success were known in the prior art, such success is not pertinent to nonobviousness.

25. The Jarosz Declaration claims that the attributes of Lumify that purportedly differentiate it from other eye redness relievers include tolerability, safety, efficacy, and lack of rebound hyperemia or tachyphylaxis even after repeated use over time.¹⁸ Furthermore, the Jarosz Declaration alleges that such features are directly related to administering brimonidine as the sole active ingredient at a concentration of 0.025 percent weight by volume and Lumify's unique mechanism

¹⁸ EX 2229 (Jarosz Declaration, pars. 106-107).

of action.¹⁹ However, the Jarosz Declaration fails to address the alleged benefits of the challenged claims of the '245 Patent compared to what was known in the prior art. This causes the discussion in the Jarosz Declaration to be incomplete and unreliable and demonstrates a lack of nexus between the marketplace performance of Lumify and the challenged claims of the '245 Patent.

26. The Jarosz Declaration claims that the efficacy of Lumify is directly related to the challenged claims of the '245 Patent.²⁰ However, I understand from the Galanis Declaration that the prior art to the challenged claims of the '245 Patent includes 0.03 percent weight by volume brimonidine in Example 1 of U.S. Patent No. 6,294,553 ("Gil").²¹ This example (0.03 percent weight by volume brimonidine) compared to the challenged claims of the '245 Patent (0.025 percent weight by volume brimonidine) demonstrates that it was known in the prior art that the administration of brimonidine in low concentrations was effective to reduce eye redness. I also understand from the Galanis Declaration that it was known in the

¹⁹ EX 2229 (Jarosz Declaration, par. 107).

²⁰ EX 2229 (Jarosz Declaration, pars. 106-107).

²¹ EX 1014 (Galanis Declaration, pars. 66-67, 135-136, and 151).

prior art to the challenged claims of the '245 Patent that the use of brimonidine was effective in reducing neurogenic inflammation, which includes reducing redness.²²

27. I also understand that the prior art, including at least Example 4 of Gil, disclosed the topical application of brimonidine for treating ocular pain and neurogenic inflammation, including redness.²³ Therefore, I understand that it was known in the prior art that the administration of brimonidine in low concentrations (*i.e.*, 0.025 percent weight by volume brimonidine) was effective to reduce eye redness. I further understand that in Example 1 of Gil, the concentration of brimonidine is administered as a 0.03 percent weight by volume.²⁴ Therefore, I understand that 0.03 percent weight by volume (as included in Gil) accomplishes the purpose of the claimed invention of the '245 Patent (0.025 percent weight by volume of brimonidine).²⁵ Therefore, I understand that the claimed efficacy of Lumify was known in the prior art and lacks nexus to the challenged claims of the '245 Patent.

²² EX 1014 (Galanis Declaration, pars. 66-67, 79, and 135-136).

²³ EX 1014 (Galanis Declaration, pars. 66-67, 130, 135-136, and 151).

²⁴ EX 1014 (Galanis Declaration, pars. 66-67).

²⁵ EX 1014 (Galanis Declaration, par. 151).

28. With respect to safety and tolerability, I understand that it was known in the prior art that brimonidine was safe and well-tolerated, and that a lower concentration of brimonidine would reduce side effects.²⁶ Indeed, brimonidine was approved and used in the product Alphagan for the treatment of ocular hypertension and glaucoma, as early as 1996.²⁷ Therefore, I understand that the claimed safety and tolerability of brimonidine were known in the prior art and lack nexus to the challenged claims of the '245 Patent.

29. The Jarosz Declaration also alleges that the lack of rebound hyperemia or tachyphylaxis even after repeated use over time of Lumify is directly related to the challenged claims of the '245 Patent.²⁸ I understand that the claim of a lack of rebound hyperemia or tachyphylaxis after repeated use over time is attributable to the administration of brimonidine in low concentrations (*i.e.*, 0.025 percent weight by volume of brimonidine).²⁹ As previously discussed, I understand that the

²⁶ EX 1014 (Galanis Declaration, pars. 122 and 126-127).

²⁷ EX 1013 (Laskar Declaration, pars. 32-36) and EX 1014 (Galanis Declaration, par. 71).

²⁸ EX 2229 (Jarosz Declaration, pars. 106-107).

²⁹ EX 1014 (Galanis Declaration, par. 102).

administration of brimonidine in low concentrations (that is, at the concentration disclosed in the challenged claims of the '245 Patent) was known in the prior art (*i.e.*, 0.03 percent weight by volume of brimonidine) and lacks nexus to the challenged claims of the '245 Patent.³⁰

30. The Jarosz Declaration fails to appropriately address that the alleged features of tolerability, safety, efficacy, and lack of tachyphylaxis even after repeated use over time of Lumify are features that I understand were known in the prior art to the challenged claims of the '245 Patent, and therefore lack nexus to the challenged claims of the '245 Patent. To the extent that the Jarosz Declaration is claiming that such features drive the marketplace performance of Lumify, I understand that there is no nexus between such features and the challenged claims of the '245 Patent.

31. Indeed, the Jarosz Declaration fails to appropriately address that in the IPR proceeding for the '742 Patent, that the PTAB determined that the Patent Owner (*i.e.*, Eye Therapies) “repeatedly relies on the use of ‘low-concentration brimonidine’ as the reason for Lumify’s success.”³¹ Furthermore, the PTAB stated

³⁰ EX 1014 (Galanis Declaration, pars. 66-67, 130, 135-136, and 151).

³¹ EX 1003 (Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a), dated May 15, 2023, pg. 66).

that it agreed with Petitioner's (*i.e.*, Slayback) argument, "that the use of low-dose brimonidine was known in the art."³² The arguments in the IPR proceeding for the '742 Patent are similar to the arguments advanced by the Jarosz Declaration in this proceeding. For the same reasons previously discussed and that were determined by the PTAB in the IPR proceeding for the '742 Patent, there is no nexus between such features of Lumify claimed by the Jarosz Declaration and the challenged claims of the '245 Patent.

³² EX 1003 (Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a), dated May 15, 2023, pg. 66).

B. The Jarosz Declaration Fails to Appropriately Address Marketing and Promotion of Lumify, Which Also Drive the Marketplace Performance of Lumify

32. The Jarosz Declaration acknowledges that “[t]he marketing of Lumify matters.”³³ However, the Jarosz Declaration claims that the marketing of Lumify “is not the primary driver, to the exclusion of the benefits attributable to the claimed inventions, of the marketplace success experienced by Lumify.”³⁴ I disagree. The Jarosz Declaration fails to appropriately address the marketing and promotional efforts for Lumify, rendering the discussion in the Jarosz Declaration incomplete and unreliable.

33. Generally, the pharmaceutical industry dedicates a significant amount of financial and human resources to marketing and promotion. Companies such as Bausch are profit maximizing entities. Profit maximizing entities would not expend substantial resources on marketing and promotion if they expected no benefit from such expenditures. Bausch has utilized a “fully integrated platform” and many forms of marketing to promote Lumify, including direct to consumer (“DTC”) advertising, detailing to eye care professionals (“ECPs”), and sampling, among other marketing

³³ EX 2229 (Jarosz Declaration, par. 129).

³⁴ EX 2229 (Jarosz Declaration, par. 129).

initiatives.³⁵ Bausch has devoted significant promotional efforts since launch and has recognized the importance and impact of such marketing efforts for Lumify, as shown in the following examples from Bausch's earnings call transcripts:

- *We are back with TV advertising [for Lumify]...[w]e think that's an important part of it, but we also think the other part of it is the integrated eye care approach we have allows our teams in ophthalmologist offices and optometry offices to drop off samples and that's the reason we are getting great referrals [for Lumify] and why we're the #1 referral product for the treatment of redness relief from ophthalmologists and optometry.*³⁶

³⁵ For example, EX 2069 (2020 Lumify ECP A&U Report (Under Seal), pgs. 18 and 30); and EX 2151 (Bausch Health Companies Inc. Q4 and FY 2021 Financial Results, pg. 23).

³⁶ EX 1172 (Bausch Fourth Quarter 2018 Earnings Call Transcript, dated February 20, 2019, pg. 15, available at <https://seekingalpha.com/article/4242568-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2018-results-earnings-call-transcript>, accessed February 17, 2025). Exhibits 1172-1175 are true and accurate copies of the earnings call transcripts that I accessed at the Seeking Alpha website. Earnings call transcripts are regularly and reasonably relied upon by experts in my field for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case.

- *Adjusted selling, advertising and promotion expense increased \$20 million on a reported basis, with the biggest drivers being the addition of the 100 sales reps and associated promotional spend in connection with the TRULANCE acquisition in the Salix segment and increased spend in [Bausch & Lomb]/International to support growth products, including LUMIFY.³⁷*
- *The mostly used example there is DTC advertising. I hope everybody on this call constantly [sees] our advertisements for our eye vitamins and for LUMIFY.³⁸*
- *Our team was able to drive education and awareness for [Lumify] by collaborating with eye care professionals while driving awareness among beauty enthusiasts with a strong television, public relations and social media presence.³⁹*

³⁷ EX 1173 (Bausch Second Quarter 2019 Earnings Call Transcript, dated August 6, 2019, pg. 4, available at <https://seekingalpha.com/article/4282236-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q2-2019-results-earnings-call-transcript>, accessed February 17, 2025).

³⁸ EX 1174 (Bausch Fourth Quarter 2020 Earnings Call Transcript, dated February 24, 2021, pg. 18, available at <https://seekingalpha.com/article/4408646-bausch-health-companies-inc-bhc-ceo-joe-papa-on-q4-2020-results-earnings-call-transcript>, accessed February 17, 2025).

³⁹ EX 1175 (Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, pg. 9, available at <https://seekingalpha.com/article/4489552-bausch->

- *We are then able to leverage the 400-plus person Bausch & Lomb sales force for detailing and distribution directly to optometrists and ophthalmologists and achieved the distinction of being the number 1 physician recommended product in the redness reliever category.*⁴⁰

34. As shown in the above examples, Bausch has repeatedly acknowledged the importance and impact of its selling, advertising, and promotional efforts for Lumify to drive the marketplace performance of Lumify.

1. DTC Advertising

35. Bausch used various marketing techniques to promote Lumify, including DTC advertising. DTC advertising is consumer focused and can impact a patient's preference for a particular product. The goal of DTC advertising is to inform patients about certain products and have patients ask healthcare professionals if that product is appropriate for their treatment, or in the case of OTC products,

health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript, accessed February 17, 2025).

⁴⁰ EX 1175 (Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, pg. 9, available at <https://seekingalpha.com/article/4489552-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript>, accessed February 17, 2025).

encourage the purchase of the OTC products (and/or some combination thereof). Bausch has utilized various DTC channels, including social media, paid influencers, digital advertising, in-store media (such as pamphlets and brochures), radio and podcast advertising, and television and streaming platform advertisements.⁴¹ Bausch has also created multiple award-winning marketing and social media campaigns for Lumify to drive the marketplace performance of Lumify.

36. Bausch engaged Helen & Gertrude, a marketing agency, to develop a social media campaign and product branding for Lumify.⁴² As a result, Lumify won

⁴¹ EX 1176 (Deposition Transcript of John Ferris, dated January 30, 2025 (the “Ferris Deposition”), pgs. 17:6-18 and 23:10-20); EX 1196 (Deposition Transcript of John Ferris, dated January 4, 2024, C.A. No. 21-16766 (the “Ferris Preliminary Injunction Deposition”), pg. 65:10-24).

⁴² EX 1178 (<https://www.hg.agency/news/muse-awards>, accessed February 17, 2025). Helen & Gertrude offers a variety of services including content services, media planning and buying, data insights and measurements, and web design and UX design (EX 1179 (<https://www.hg.agency/>, accessed February 17, 2025)). Exhibits 1177-1187, 1189-1195, and 1200 are true and accurate copies of online articles, campaigns, and websites that I accessed. This information relates to

two MUSE Creative awards in 2019, which recognizes excellence and innovation in creative design, advertising, and digital media.⁴³

37. The first award that Lumify won was Silver in the “Strategic Program - Social Media Campaign” category, wherein “media spend served messaging that drove awareness of the eye drop through education, emotion, and strong calls to action” and placement optimization was used on social media platforms “to reach as many women as possible wherever they were within social apps.”⁴⁴ Additionally, Lumify won “Rose Gold” in the “Social Media - Product or Service Branding” category, “by utilizing key social platforms to maximize reach for the most efficient

selling, advertising, and promotional efforts for pharmaceutical products that experts in my field regularly and reasonably rely upon for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case.

⁴³ EX 1178 (<https://www.hg.agency/news/muse-awards>, accessed February 17, 2025) and EX 1180 (<https://museaward.com/>, accessed February 17, 2025).

⁴⁴ EX 1181 (<https://museaward.com/winner-info.php?id=2187>, accessed February 17, 2025).

cost” and by developing “a unique tone and voice for social media that created awareness around [Lumify].”⁴⁵

38. Bausch also engaged Wavemaker, a top-five global media network, to develop its marketing campaign for Lumify entitled “Recharging Redness Relievers in a Beautiful Way.”⁴⁶ This campaign won the Gold Shopper Marketing Effie award in the “New Product/Service Introduction” category by creating “a ‘bridge’ between beauty and eye care at retail stores with targeted media across TV, social, digital, and beauty print magazines.”⁴⁷ Lumify “even went as far to increase targeting and placement during timely, beauty-specific events such as New York Fashion

⁴⁵ EX 1182 (<https://museaward.com/winner-info.php?id=2186>, accessed February 17, 2025).

⁴⁶ EX 1183 (<https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards>, accessed February 17, 2025); and EX 1184 (<https://wavemakerglobal.com/our-work>, accessed February 17, 2025).

⁴⁷ EX 1183 (<https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards>, accessed February 17, 2025).

Week.”⁴⁸ Furthermore, a Bausch social media campaign, developed by Helen & Gertrude in 2019, stated “we wanted [Lumify] to be present in situations that fit within the beauty lifestyle (*i.e.*, purse, gym bag, suitcase, bathroom vanity).”⁴⁹

39. In September 2023, Bausch launched a line of complementary beauty products related to Lumify, including a cleansing water and eye makeup remover, a lash and brow serum, and an eye cream (the “Eye Illuminations Products”), which are part of the Lumify franchise.⁵⁰ Indeed, Mr. Ferris testified that Bausch launched the Eye Illuminations Products as a line extension to Lumify (the low-dose brimonidine drops) in order to promote “healthy looking eyes without redness.”⁵¹ I

⁴⁸ EX 1183 (<https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards>, accessed February 17, 2025).

⁴⁹ EX 1181 (<https://museaward.com/winner-info.php?id=2187>, accessed February 17, 2025).

⁵⁰ EX 1185
(<https://www.businesswire.com/news/home/20230926043168/en/Bausch-Lomb-Launches-LUMIFY-EYE-ILLUMINATIONS%E2%84%A2-in-the-United-States>, accessed February 17, 2025).

⁵¹ EX 1196 (Ferris Preliminary Injunction Deposition, pgs. 127:15-129:3).

understand that Eye Illuminations Products are positioned alongside Lumify (the low-dose brimonidine drops) in the eye care aisle of retail stores.⁵² Furthermore, the Eye Illuminations Products are branded as Lumify and include “Lumify” on the product labeling.⁵³

40. In conjunction with launching the Eye Illuminations Products, Bausch dedicated significant advertising and promotional expenses for the Eye Illuminations Products. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] The Jarosz Declaration fails to appropriately address these

⁵² EX 1185

(<https://www.businesswire.com/news/home/20230926043168/en/Bausch-Lomb-Launches-LUMIFY-EYE-ILLUMINATIONS%E2%84%A2-in-the-United-States>, accessed February 17, 2025).

⁵³ EX 1186 (<https://www.lumifyeyes.com/eye-illuminations/>, accessed February 17, 2025).

⁵⁴ EX 2072 (Bausch + Lomb P&L Statement, September 30, 2024).

additional advertising and promotional expenses on the Eye Illuminations Products that benefited Lumify since Bausch positioned Lumify and the Eye Illuminations products within the beauty segment as opposed to standard OTC medications, marketed and sold these products together, and labeled these products with “Lumify.”

41. Additionally, in the summer of 2022, Bausch sought to “turbocharge its marketing” by “tapping into the social media craze for TikTok in a unique marketing campaign for [Lumify]” with the #LUMIFYEyeDance Challenge (the “Challenge”).⁵⁵ This social media campaign was centered around enticing consumers to post TikTok videos wherein users dance “with their eyes” to the beat

⁵⁵ EX 1187 (<https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes>, accessed February 17, 2025).

of a Lumify audio track.⁵⁶ Those who participated in the Challenge were entered to win a sweepstakes, including:⁵⁷

- A makeover with a celebrity makeup artist and Lumify eye drops brand ambassador;
- Travel and accommodations for two to New York;
- A \$500 American Express gift card; and
- A “dream kit” featuring products used during the makeover session and professionally shot photographs.

42. The Jarosz Declaration claims that Bausch’s marketing and promotional materials consistently highlight the alleged benefits of the claimed invention, which as previously discussed, I understand are attributable to features

⁵⁶ EX 1187 (<https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes>, accessed February 17, 2025).

⁵⁷ EX 1187 (<https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes>, accessed February 17, 2025); and EX 1188 (Deposition Transcript of John Ferris, dated November 2, 2022, IPR2022-00142 (the “Ferris ’742 Patent IPR Deposition”), pg. 87:4-19).

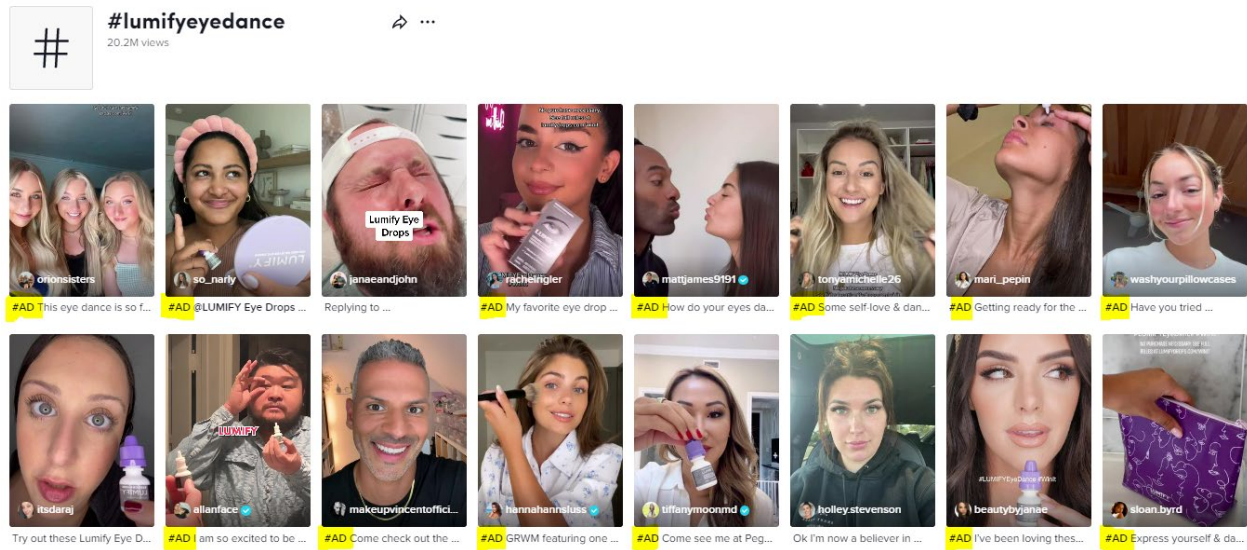
that I understand were known in the prior art.⁵⁸ However, the Jarosz Declaration fails to appropriately discuss the marketing efforts for Lumify in campaigns like the Challenge.

43. Based on my research and analysis, the Challenge was heavily supported by advertisements from social media influencers and celebrities. Social media influencers seek to influence (or persuade) users towards products or content. Indeed, “[p]rominent TikTok creators [helped] kick off the [C]hallenge by posting their own eye dance and encouraging others to participate.”⁵⁹ These prominent TikTok creators, or influencers, have a significant reach because of their extensive following. As shown below, a search of TikTok’s website using the search term #LUMIFYEyeDance shows multiple videos from influencers and celebrities with captions containing “#AD” (or advertisement).⁶⁰

⁵⁸ EX 2229 (Jarosz Declaration, par. 115)

⁵⁹ EX 1189 (<https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html>, accessed February 17, 2025).

⁶⁰ EX 1190 (<https://www.tiktok.com/tag/lumifyeyedance?lang=en>, accessed November 17, 2022). I understand that social media posts containing “#AD”



44. Indeed, the views generated for the Challenge appear to be largely derived from content created by influencers with a significant following and are often in the beauty industry. Certain influencers’ videos not only indicate that it is

indicate that creators of endorsement messages have a “material connection” with the subject brand or product. I further understand that a “material connection” includes personal, family, employment, or financial relationships (EX 1191 (https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf, accessed February 17, 2025, pgs. 2 and 5))).

an advertisement (#AD), but the videos also include the statement that it is a “Paid partnership.”⁶¹

45. Lumify won Business Intelligence Group’s 2022 Public Relations and Marketing Excellence Award for External Campaign of the Year for the Challenge.⁶² A social media challenge, aiming to persuade consumer engagement with influencer advertisements with a chance to be entered into a lucrative sweepstakes is categorically different from the Jarosz Declaration’s discussion of the purported nature of the promotional materials Bausch uses for Lumify.

⁶¹ For example, see EX 1192

(https://www.tiktok.com/@allanface/video/7129967072628657454?is_copy_url=1&is_from_webapp=v1&lang=en, accessed November 17, 2022); and EX 1193 (https://www.tiktok.com/@orionsisters/video/7124396970558459179?is_copy_url=1&is_from_webapp=v1&lang=en, accessed November 17, 2022).

⁶² EX 1194 (<https://www.prnewswire.com/news-releases/bausch--lomb-lumifyeyedance-challenge-wins-2022-public-relations-and-marketing-excellence-award-for-external-campaign-of-the-year-from-business-intelligence-group-301664009.html>, accessed February 17, 2025).

46. More recently, in 2024, Bausch promoted a brand experience event at the Coachella music festival, wherein at a “Lumify Eyes Bejeweled Bar” attendees could receive a makeover and free samples of Lumify.⁶³ Since the launch of Lumify, Bausch has invested significantly in DTC advertising for Lumify. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁶³ EX 1195 (<https://www.eventmarketer.com/article/coachella-2024-experiential-marketing/>, accessed February 17, 2025).

⁶⁴ EX 2063 (Bausch & Lomb, “LUMIFY DROPS, Quarterly Business Review,” September 2024, slide 10).

⁶⁵ EX 1176 (Ferris Deposition, pgs. 17:19-18:19).

[REDACTED]

[REDACTED]

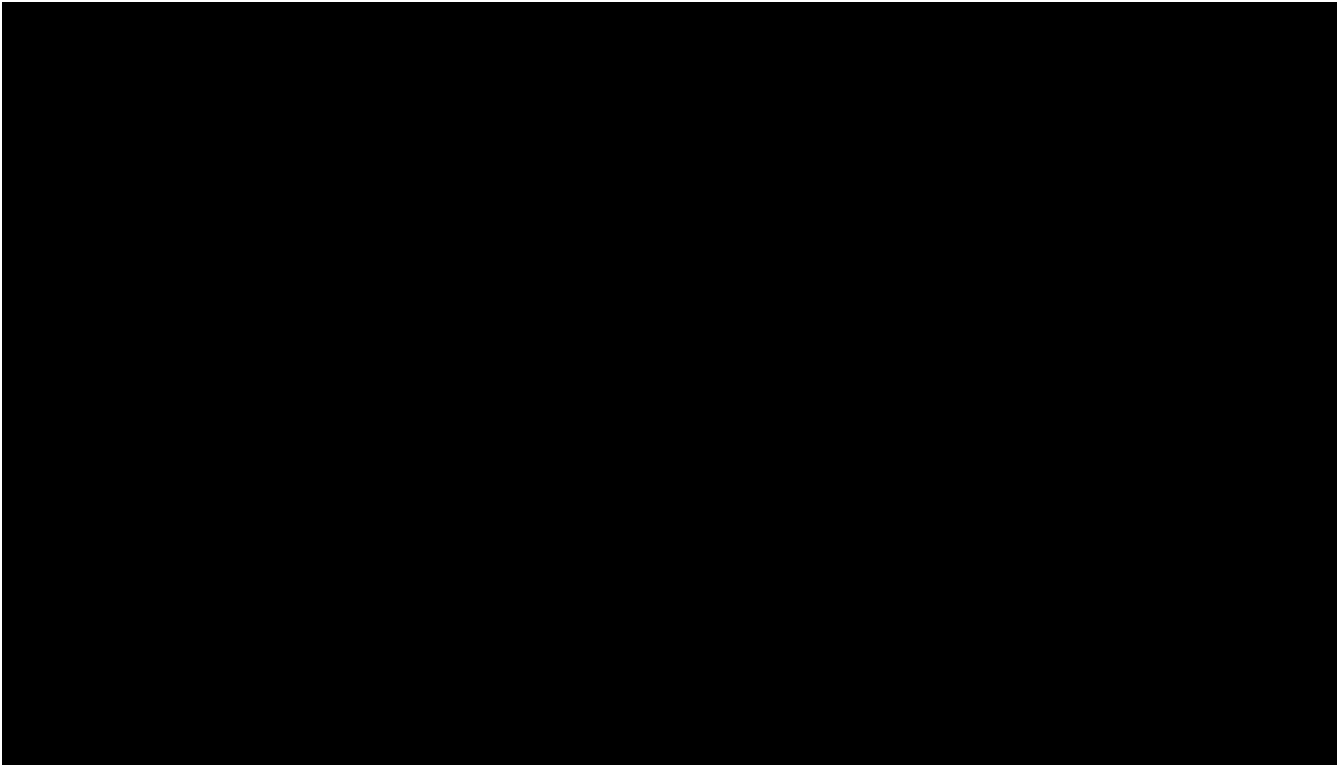
47. The significant DTC advertising used by Bausch for Lumify, that focus on features that I understand are known in the prior art, drive the marketplace performance of Lumify and the Jarosz Declaration fails to appropriately address this, rendering the Jarosz Declaration incomplete and misleading.

2. Detailing and Sampling Efforts

48. Bausch not only devoted significant marketing and promotional resources targeting consumers, but also used various marketing techniques to promote Lumify to ECPs. These marketing and promotional efforts by Bausch for Lumify include detailing, print advertising, trade journal articles, direct mail and emails, and speaker programs, which are included in the Lumify ECP A&U Report, dated March 27, 2020 (the “2020 Lumify ECP A&U Report”), as shown below:⁶⁷

⁶⁶ EX 2072 (Bausch + Lomb P&L Statement, September 30, 2024).

⁶⁷ EX 2069 (2020 Lumify ECP A&U Report (Under Seal), pg. 18).



49.

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

⁶⁸ EX 2069 (2020 Lumify ECP A&U Report (Under Seal), pg. 18).

⁶⁹ EX 2069 (2020 Lumify ECP A&U Report (Under Seal), pg. 18).

[REDACTED]

[REDACTED]

[REDACTED]

50. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁷⁰ EX 1175 (Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, pg. 9, available at <https://seekingalpha.com/article/4489552-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript>, accessed February 17, 2025).

⁷¹ EX 1188 (Ferris '742 Patent IPR Deposition, pgs. 69:8-70:4).

⁷² EX 2230 (Ferris Declaration, par. 29).

⁷³ EX 1176 (Ferris Deposition, pgs. 18:20-20:11).

51.

[REDACTED]

[REDACTED]

52.

[REDACTED]

⁷⁴ EX 2070 (2024 Lumify ECP Tracker Study (Under Seal), pg. 21).

⁷⁵ EX 2070 (2024 Lumify ECP Tracker Study (Under Seal), pg. 5).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

53. Although Lumify is an OTC product and a prescription is not needed to purchase Lumify, Bausch dedicated resources to promote Lumify with ECPs to drive marketplace performance. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁷⁶ EX 2070 (2024 Lumify ECP Tracker Study (Under Seal), pgs. 5 and 21).

54. In conjunction with detailing, Bausch also provided free samples of Lumify to ECPs and consumers to drive the marketplace performance of Lumify.⁷⁷ Samples allow physicians and patients to gain familiarity with a product immediately and at no cost to the patient. Providing samples can lead to recurring purchases and therefore influences the performance of the sampled product. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

⁷⁷ For example, see EX 1196 (Ferris Preliminary Injunction Deposition, pgs. 65:10-24, 70:24-71:2, and 91:7-14).

⁷⁸ EX 2069 (2020 Lumify ECP A&U Report (Under Seal), pg. 30).

⁷⁹ EX 2069 (2020 Lumify ECP A&U Report (Under Seal), pg. 30).

⁸⁰ EX 2070 (2024 Lumify ECP Tracker Study (Under Seal), pg. 30).

[REDACTED]

[REDACTED]

55. Furthermore, Mr. Ferris testified in the IPR proceeding related to the '742 Patent that Bausch provided approximately [REDACTED] of Lumify to ECPs in 2022 alone.⁸² Subsequently, Mr. Ferris testified that “in the past year” (referring to 2023, since the deposition was in January 2024) Bausch gave out [REDACTED]

[REDACTED] The Jarosz Declaration fails to appropriately address the significant sampling efforts of Bausch for Lumify that drive the marketplace performance of Lumify.

56. In addition to providing free samples to ECPs, Bausch also provides free samples to consumers as part of various Lumify promotional campaigns. For example, Bausch held a national product “sampling tour” in four major U.S. cities

⁸¹ EX 2070 (2024 Lumify ECP Tracker Study (Under Seal), pg. 30).

⁸² EX 1188 (Ferris '742 Patent IPR Deposition, pgs. 71:20-72:14).

⁸³ EX 1196 (Ferris Preliminary Injunction Deposition, pgs. 91:15-92:3).

as part of the Challenge.⁸⁴ This tour consisted of two-day-long pop-up events at each location, featuring a Lumify branded “tiny home” that offered visitors refreshments from popular local chains, mini masterclass sessions taught by prominent local makeup artists, and an opportunity to record TikTok Challenge videos at a selfie station with local social media influencers.⁸⁵ Furthermore, more recently in early 2025, Bausch also partnered with fitness brand Barry’s to promote Lumify, offering free samples of Lumify (the low-dose brimonidine drops) in participating studio locations and a discount code for online purchases of all Lumify brand products.⁸⁶

⁸⁴ EX 1189 (<https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html>, accessed February 17, 2025).

⁸⁵ EX 1189 (<https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html>, accessed February 17, 2025).

⁸⁶ EX 1177 (<https://strength.barrys.com/>, accessed February 19, 2025); EX 1200 (<https://www.instagram.com/barrys/reel/DFfwk5ZPoJf/>, accessed February 19, 2025).

57. Based on my analysis, the numerous marketing and promotional efforts utilized by Bausch drive the marketplace performance of Lumify and focus on features that I understand are known in the prior art.

58. Furthermore, in the Jarosz Declaration's discussion of the marketing materials for Lumify, the Jarosz Declaration fails to appropriately address the challenged claims 1, 2, 4, 5, 7, 8, 9, 11, 12, 14, 15, 17, 20, and 22 of the '245 Patent (which I understand are attributable to features that were known in the prior art). I understand that these challenged claims relate to a method for reducing eye redness to a human subject having ocular hyperemia and consisting of brimonidine as the sole active ingredient where benzalkonium chloride was a preservative and the pH level of the composition is between 5.5 and 6.5 (claims 1 and 8);⁸⁷ a method of claims 1, 2, 8, or 9 where the eye redness is not associated with an ocular disease or the result of a surgical procedure (claims 4, 11, 15, 17, 20, and 22);⁸⁸ a method of claims 1, 2, 4, 8, 9, or 11 where the method retains normal intraocular pressure in

⁸⁷ EX 1014 (Galanis Declaration, pars. 55, 76-85, 90-93); EX 1013 (Laskar Declaration, par. 21).

⁸⁸ EX 1014 (Galanis Declaration, pars. 104-107).

the eye (claims 5, 7, 12, 14, 17, and 22).⁸⁹ The Jarosz Declaration fails to provide evidence showing marketing materials for Lumify that promote the pH levels of the composition of Lumify, the use of Lumify where the treatment of eye redness is not associated with an ocular disease or the result of a surgical procedure, or the use of Lumify where the method retains normal intraocular pressure. Therefore, the Jarosz Declaration fails to demonstrate that the marketing materials of Lumify promote the alleged features of Lumify covered by challenged claims 1, 2, 4, 5, 7, 8, 9, 11, 12, 14, 15, 17, 20, and 22 of the '245 Patent, all which contain limitations other than redness reduction.

3. Lack of Comparison of Promotional Expenses for Lumify Relative to Other Competing Products

59. Despite acknowledging that the marketing of Lumify matters to its marketplace performance, the Jarosz Declaration fails to appropriately discuss differences in the sales and marketing efforts for Lumify relative to competing products.⁹⁰ Based upon my analysis previously discussed, Lumify has benefited from significant marketing efforts, including attaining a significant share of voice (“SOV”).

⁸⁹ EX 1014 (Galanis Declaration, pars. 108-112).

⁹⁰ EX 2229 (Jarosz Declaration, par. 129).

60. Indeed, Mr. Ferris testified in the IPR proceeding related to the '742 Patent (in 2022) that [REDACTED] [REDACTED] SOV is generally described as a brand's advertising weight expressed as a percentage of a market in a given time period. SOV is a function of the competitive landscape and analyzing SOV reflects how much health care professionals (including ECPs) and consumers are hearing (or not hearing) about competing products from a marketing perspective. The Jarosz Declaration fails to discuss the SOV of Lumify relative to competing products.

61. Given the numerous examples of Bausch executives describing the importance and magnitude of marketing and promotional efforts for Lumify as previously discussed, the Jarosz Declaration's claims that it does not appear that the purported success of Lumify is driven by aggressive or non-patent-oriented persuasive advertising,⁹² absent any analysis of comparative marketing spend is incomplete, speculative, and unreliable.

62. The Jarosz Declaration again fails to appropriately address that in the IPR proceeding related to the '742 Patent, that the PTAB determined that "the

⁹¹ EX 1188 (Ferris '742 Patent IPR Deposition, pgs. 75:15-77:4).

⁹² EX 2229 (Jarosz Declaration, par. 136).

evidence of success is also due to Bausch’s sales and marketing campaigns that are unrelated to the claimed invention.”⁹³ Indeed, the sales and marketplace performance of Lumify used by the Jarosz Declaration includes the entire period of sales and marketplace performance of Lumify that was previously included in the IPR proceeding for the ’742 Patent. Although the Jarosz Declaration submitted in this proceeding provides updated financial data through the third quarter of 2024, the Jarosz Declaration does not explain why the additional period of sales of Lumify are not also predominantly driven by the sales and marketing efforts of Bausch (coupled with what was known in the prior art), as previously determined by the PTAB.

63. In an attempt to defend against this conclusion by the PTAB, the Jarosz Declaration claims that Bausch’s sales and marketing efforts are not driving the marketplace performance of Lumify because Bausch has increased sales of Lumify [REDACTED] I disagree. [REDACTED]

⁹³ EX 1003 (Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a), dated May 15, 2023, pg. 67).

⁹⁴ EX 2229 (Jarosz Declaration, pars. 139-140).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Therefore, for at least the same reasons that were determined by the PTAB in the IPR proceeding for the '742 Patent, the claimed success of Lumify is due to Bausch's sales and marketing efforts and are unrelated to the challenged claims of the '245 Patent. Thus, the purported claims in the Jarosz Declaration are flawed and misleading.

64. Furthermore, the Jarosz Declaration is directly contradicted by Bausch's internal documents, which indicate that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

⁹⁵ EX 2072 (Bausch + Lomb P&L Statement, September 30, 2024).

[REDACTED]

[REDACTED]

65. Additionally, the Jarosz Declaration presents advertising and promotional expense as a percentage of “Gross Net Revenue.”⁹⁷ This metric is misleading and understates the impact of Bausch’s promotional efforts on the performance of Lumify. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Comparing advertising and promotional expense to net sales would be a more appropriate metric, as it properly accounts for these additional deductions. Comparing expenses to net sales (rather than gross net revenue) is more appropriate because it illustrates the percentage of the advertising and promotional expense of the net sales realized. Whereas the gross net revenue amount used by the Jarosz

⁹⁶ EX 2072 (Bausch + Lomb P&L Statement, September 30, 2024); and EX 2063 (Bausch & Lomb, “LUMIFY DROPS, Quarterly Business Review,” September 2024, slide 10).

⁹⁷ EX 2229 (Jarosz Declaration, par. 140).

⁹⁸ EX 2072 (Bausch + Lomb P&L Statement, September 30, 2024).

Declaration does not represent the realized net sales as there are additional deductions to arrive at the realized net sales. Therefore, the Jarosz Declaration understates advertising and promotional expenses as a percentage of net sales for Lumify.

66. Furthermore, the Jarosz Declaration fails to appropriately account for expenses related to detailing Lumify. [REDACTED]

[REDACTED]

[REDACTED]

This would mean that advertising and promotional expenses that the Jarosz Declaration relies on are lower than if they included the cost of sales representatives, which further demonstrates that advertising and promotional expenses as a percentage of sales for Lumify in the Jarosz Declaration is understated.

VIII. ADDITIONAL CRITIQUES OF THE JAROSZ DECLARATION

A. The Jarosz Declaration Fails to Demonstrate That the Marketplace Performance of Lumify is Related to the Challenged Claims of the '245 Patent

67. The Jarosz Declaration claims that Lumify is a commercial embodiment of “certain claims” of the '245 Patent and that Lumify has been a

⁹⁹ EX 1176 (Ferris Deposition, pgs. 17:19-18:19).

marketplace success.¹⁰⁰ However, the Jarosz Declaration is unclear which of the challenged claims of the '245 Patent allegedly provide evidence of commercial success. Indeed, Mr. Jarosz testified that he relied upon Dr. Robert J. Noecker for his understanding that Lumify is an embodiment of “certain claims” of the '245 Patent, and that he did not undertake any effort to determine which specific claims Lumify is an alleged commercial embodiment.¹⁰¹

68. I understand that the challenged claims of the '245 Patent are 1, 2, 4-9, 11-17, 20-22, 25, and 27.¹⁰² I understand that the challenged claims generally relate to low concentration compositions of brimonidine for inducing vasoconstriction.¹⁰³

69. Furthermore, the Jarosz Declaration fails to quantify the sales of Lumify on a claim-by-claim basis for each of the challenged claims of the '245 Patent (if any). Therefore, the Jarosz Declaration fails to demonstrate how the

¹⁰⁰ EX 2229 (Jarosz Declaration, pars. 2, 13, 38, 106, and 142).

¹⁰¹ EX 1197 (Deposition Transcript of John C. Jarosz, dated February 12, 2025, IPR2024-00563 (the “Jarosz Deposition”), pg. 13:15-20).

¹⁰² EX 1013 (Laskar Declaration, par. 20) and EX 1014 (Galanis Declaration, par. 50).

¹⁰³ EX 1014 (Galanis Declaration, pars. 47 and 50).

marketplace performance of Lumify is related to each challenged claim and the Jarosz Declaration's discussion of claimed marketplace success and purported nexus of Lumify should not be used as purported objective evidence to support the challenged claims of the '245 Patent.

70. In addition to the Jarosz Declaration failing to demonstrate that the marketplace performance of Lumify is related to claims 1, 2, 4-9, 11-17, 20-22, 25, and 27 of the '245 Patent, the Jarosz Declaration also fails to attribute the claimed marketplace success of Lumify to other patents that are listed in the Orange Book for Lumify.¹⁰⁴ The following patents are listed in the Orange Book for Lumify:¹⁰⁵

¹⁰⁴ EX 1167

(https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208144&Appl_type=N, accessed February 14, 2025).

¹⁰⁵ EX 1167

(https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208144&Appl_type=N, accessed February 14, 2025).

U.S. Patent Number	Date of Issuance ¹⁰⁶	Expiration Date
'742 Patent	October 23, 2012	July 14, 2030
9,259,425 (the "'425 Patent")	February 16, 2016	July 14, 2030
'600 Patent	March 7, 2023	July 27, 2029
'245 Patent	December 5, 2023	July 27, 2029

71. From an economic perspective, the Jarosz Declaration is essentially attributing the entire value of the marketplace performance of Lumify to the challenged claims of the '245 Patent, without apportioning any value to the other patents listed in the Orange Book for Lumify.

72. Furthermore, as previously discussed, Mr. Jarosz previously asserted in the Jarosz '742 Declaration that Lumify's alleged commercial success had a nexus to the '742 Patent therein.¹⁰⁷ Likewise, Mr. Jarosz also issued a declaration in an IPR proceeding relating to the '600 Patent that is occurring on the same schedule as this IPR proceeding related to the '245 Patent. In that declaration, Mr. Jarosz

¹⁰⁶ EX 1001 ('245 Patent); EX 1001 (U.S. Patent No. 11,596,600 in IPR2024-00563); EX 1171 (Hofmann '742 Declaration, par. 3); and EX 1201 (U.S. Patent No. 9,259,425).

¹⁰⁷ EX 1198 ('742 Patent Jarosz Declaration, par. 13).

asserted commercial success and nexus related to the '600 Patent therein.¹⁰⁸ Therefore, Mr. Jarosz has essentially treated the '742 Patent, the '245 Patent, and the '600 Patent as interchangeable, and uses the same marketplace performance information to purportedly support alleged commercial success and nexus for each of these patents (despite the fact that I understand that the PTAB has already invalidated the '742 Patent).¹⁰⁹

73. The Jarosz Declaration fails to isolate or apportion alleged commercial success and nexus among the challenged claims of the '245 Patent and to these other patents that Mr. Jarosz previously asserted commercial success and nexus as well as those listed in the Orange Book for Lumify. Rather, the Jarosz Declaration uses similar sales and marketplace performance data for Lumify to purportedly claim commercial success and nexus to the '245 Patent, as well as the '600 Patent and the '742 Patent. This is economically unsound. The Jarosz Declaration's failure to present an economic analysis that apportions the marketplace performance of Lumify among the challenged claims of the '245 Patent and to the other Orange

¹⁰⁸ EX 2229 (Jarosz Declaration in IPR2024-00563).

¹⁰⁹ EX 1003 (Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a), dated May 15, 2023, pg. 69).

Book listed patents renders the Jarosz Declaration flawed, incomplete, and unreliable.

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 Unreliable

74. As a “starting point” of its discussion regarding purported marketplace success, the Jarosz Declaration discusses “whether the economic decisions and behavior of the participants in the business are consistent with a belief that the product will be or has been a marketplace success.”¹¹⁰ The Jarosz Declaration claims that “responsible economic decision-makers should allocate resources to activities that are expected to generate the highest net return (*i.e.*, benefits minus costs) that are available, given the opportunities and constraints facing the decision-makers.”¹¹¹ The Jarosz Declaration thus claims that the behavior and decisions of DRL, Eye Therapies, and Bausch strongly suggest that these companies regarded and continue

¹¹⁰ EX 2229 (Jarosz Declaration, par. 51).

¹¹¹ EX 2229 (Jarosz Declaration, par. 52).

to regard Lumify as a marketplace success.¹¹² For the reasons listed below, the discussion in the Jarosz Declaration is misleading and unreliable.

75. From the Patent Owner's perspective, the Jarosz Declaration claims that since Eye Therapies and Bausch have allegedly devoted significant investments to obtaining, developing, and commercializing Lumify, this provides evidence that Lumify has been, and will continue to be, a marketplace success.¹¹³ Similarly, the Jarosz Declaration claims that Petitioners' costs associated with licensing in Slayback's ANDA and the costs Petitioners will incur in this IPR are evidence that DRL believes Lumify is a marketplace success.¹¹⁴ The Jarosz Declaration is overly simplistic and misleading.

76. As an initial matter, under the theory described in the Jarosz Declaration, essentially every product that a company devotes resources to and is marketed and sold by a pharmaceutical company is a marketplace success. If that were the case, there would be no need for an analysis of marketplace success, because the simple fact that a company invested in a product and that product is

¹¹² EX 2229 (Jarosz Declaration, par. 53).

¹¹³ EX 2229 (Jarosz Declaration, pars. 59 and 65).

¹¹⁴ EX 2229 (Jarosz Declaration, pars. 54-56).

marketed and sold would theoretically demonstrate that a product is purportedly successful in the market. This is unreasonable. Similarly, under the Jarosz Declaration's theory, essentially every product for which a generic product is offered would be a purported marketplace success. This is an overly simplistic and flawed claim in the Jarosz Declaration.

77. Furthermore, the decision by a company to file an ANDA (and license in an ANDA) with respect to a reference listed drug merely reflects the normal course of business for generic pharmaceutical companies and does not necessarily reflect the success of the reference product. In my experience, it is well established that there are significant financial and economic differences between the business models of branded and generic pharmaceutical companies, including the role of research and development costs and sales and marketing costs, which result in the pursuit of a generic product and simply do not provide evidence of purported marketplace success.

78. Branded pharmaceutical companies have different cost structures compared to generic pharmaceutical companies. In general, branded pharmaceutical products have higher selling prices, but also have higher associated costs, including research and development and sales and marketing costs. Branded pharmaceutical companies, even in the OTC marketplace, also typically incur significant costs to

develop and establish the market for the product. Generic companies typically do not incur similar levels of costs for the generic product.

79. In my experience, pharmaceutical companies often pursue generic versions of numerous brand products, with varying market sizes, given the limited costs for a generic pharmaceutical company to bring a product to market and/or the desire to maintain a portfolio of products.

80. Therefore, the decision by DRL to pursue selling a generic alternative to Lumify fails to provide evidence of purported marketplace success of Lumify.

* * * * *

PROTECTIVE ORDER MATERIAL

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted,



Ivan T. Hofmann

Dated: February 25, 2025

Appendix

Appendix 1

Exhibit/ Paper No.	Document
Paper 2	Petition for IPR IPR2024-00467.pdf
Paper 6	Patent Owner's Preliminary Response [SEALED] IPR2024-00467.pdf
Paper 14	Institution Decision IPR2024-00467.pdf
Paper 15	Scheduling Order.pdf
Paper 25	Patent Owner's Preliminary Response (IPR2024-00467)
Paper 31	Petitioners' Updated Mandatory Notices
1001	U.S. Patent No. 11,833,245 (filed January 30, 2023) (issued December 5, 2023)
1003	Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a), dated May 15, 2023
1012	Declaration of Reza Dana, MD, MSc, MPH, in Support of Petition for Inter Partes Review of U.S. Patent No. 11,833,245, dated January 24, 2024
1013	Declaration of Paul A. Laskar, Ph.D. in Support of Petition for Inter Partes Review of U.S. Patent No. 11,833,245, dated January 24, 2024
1014	Declaration of John C. Galanis, MD, FACS in Support of Petition for Inter Partes Review of U.S. Patent No. 11,833,245, dated January 24, 2024
1015	Declaration of Radojka Savic, Ph.D., in Support of Petition for Inter Partes Review of U.S. Patent No. 11,833,245, dated January 24, 2024
1163	Ivan T. Hofmann CV and Testimony
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1196	Deposition Transcript of John Ferris, dated January 4, 2024, C.A. No. 21-16766
1197	Deposition Transcript of John C. Jarosz, dated February 12, 2025, IPR2024-00563
1198	Declaration of John C. Jarosz, dated August 26, 2022 (Under Seal)

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