

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**

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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 above-captioned 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}

³ EX 1001 (’742 Patent) and EX 1067

(<https://assignment.uspto.gov/patent/index.html#/patent/search/resultFilter?searchInput=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).

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

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, 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 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 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, 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”), Information Resources, Inc. (“IRI”), Symphony Health Solutions (“Symphony”), Truven Health Analytics (“Truven”), IntrinsiQ Specialty Solutions, Inc. (“IntrinsiQ”), 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, 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 1068.

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; (iv) the ’742 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 evidence of nonobviousness of the challenged claims of the '742 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[®].

V. BACKGROUND

18. Bausch & Lomb, Inc. (“Bausch & Lomb”) acquired an exclusive global license to the ’742 Patent from Eye Therapies in January 2013.⁷ The United States

⁷ EX 2124 (<https://www.prnewswire.com/news-releases/bausch--lomb-licenses-new-technology-with-potential-to-treat-millions-affected-by-ocular-redness-185856742.html>, accessed November 17, 2022). I understand that Bausch & Lomb is (and has been) an indirect 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 1069 (Bausch SEC Form 10-Q, for the period ended June 30, 2022, pg. 2, available at https://otp.tools.investis.com/clients/us/bausch_health_companies/SEC/sec-show.aspx?FilingId=16064281&Cik=0000885590&Type=PDF&hasPdf=1, accessed November 17, 2022). Exhibit 1069 is a true and accurate copy of the Bausch SEC Form 10-Q Statement that I accessed at the aforementioned website. Such SEC filings are regularly and reasonably relied upon by experts in my field

Food and Drug Administration (“FDA”) approved Bausch’s New Drug Application (“NDA”) No. 208144 for Lumify® on December 22, 2017 and Bausch launched Lumify® on May 7, 2018.⁸ Lumify® (brimonidine) is an over-the-counter (“OTC”) eye drop indicated for relief of redness of the eye due to minor eye irritations.⁹

19. I understand that Slayback filed Abbreviated New Drug Application (“ANDA”) No. 216361 with FDA seeking approval for a generic version of Lumify® (brimonidine tartrate ophthalmic solution, 0.025%). In July 2022, Dr. Reddy’s

for the purposes of forming opinions or inferences on the matters that are the subject of my work in this case.

⁸ EX 2065 (Lumify® NDA Approval, December 22, 2017) and EX 2103 (<https://ir.bauschhealth.com/news-releases/2018/05-07-2018-130249958>, accessed November 17, 2022).

⁹ EX 2191 (Lumify® Label, December 2017, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208144Orig1s000lbl.pdf, accessed November 17, 2022).

Laboratories, Ltd. announced that it entered into a license agreement with Slayback for the rights to Slayback's ANDA for a generic equivalent of Lumify[®].¹⁰

**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.

¹⁰ EX 2097 (<https://www.businesswire.com/news/home/20220729005454/en/Dr.-Reddys-Laboratories-enters-into-a-licensing-agreement-with-Slayback-Pharma-to-%E2%80%A6>1/3, accessed November 17, 2022).

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 '742 Patent.

VII. THE MARKETPLACE PERFORMANCE OF LUMIFY® FAILS TO PROVIDE OBJECTIVE INDICIA OF NONOBVIOUSNESS OF THE CHALLENGED CLAIMS OF THE '742 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 '742 Patent.¹¹ 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 Lumify®. Therefore, 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

24. The Jarosz Declaration alleges that there is a nexus between the marketplace performance of Lumify® and the challenged claims of the '742 Patent

¹¹ EX 2024 (Jarosz Declaration, par. 13).

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 non-obviousness.

25. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Furthermore, the Jarosz Declaration alleges that such features are directly related to the use of low-dose brimonidine tartrate and Lumify[®]'s unique mechanism of action.¹³ However, the Jarosz Declaration fails to address the alleged benefits of the challenged claims of the '742 Patent compared to what was known in the prior art. This causes the discussion in the Jarosz Declaration to be incomplete and unreliable.

¹² EX 2024 (Jarosz Declaration, pars. 104-105).

¹³ EX 2024 (Jarosz Declaration, par. 105).

26. The Jarosz Declaration claims that the efficacy of Lumify® is directly related to the challenged claims of the '742 Patent.¹⁴ However, I understand from the Laskar Declaration and the Sher Declaration (the "Petitioner's Technical Experts") that the prior art to the challenged claims of the '742 Patent includes 0.03 percent weight by volume brimonidine in Example 1 of U.S. Patent No. 6,294,553 (the "'553 Patent") and 0.02 percent weight by volume brimonidine in Walters 1991.¹⁵ I also understand that Petitioner's Technical Experts have stated that it was known in the prior art to the challenged claims of the '742 Patent that the use of brimonidine was "effective in reducing neurogenic responses" such as "redness" and reducing eye redness caused by ocular inflammation, in conjunction with refractive surgery, and in LASIK patients.¹⁶

27. I also understand that the prior art, including at least Example 4 of the '553 Patent, disclosed the topical application of brimonidine for treating ocular pain

¹⁴ EX 2024 (Jarosz Declaration, pars. 104-105).

¹⁵ EX 1003 (Laskar Declaration, par. 105) and EX 1002 (Sher Declaration, pars. 43 and 69).

¹⁶ EX 1002 (Sher Declaration, pars. 86, 91, 93, and 112) and EX 1003 (Laskar Declaration, par. 90).

and neurogenic inflammation, including redness.¹⁷ Therefore, I understand that it was known in the prior art that the administration of brimonidine in low concentrations was effective to reduce eye redness. I further understand that in Example 1 of the '553 Patent, the concentration of brimonidine is administered as a 0.03 percent weight by volume ophthalmic solution.¹⁸ I understand that the concentration of 0.03 percent weight by volume is between about 0.001 percent weight by volume and about 0.05 percent weight by volume, as stated in claim 1 of the '742 Patent.¹⁹ Furthermore, I understand that other challenged claims of the '742 Patent include a concentration of brimonidine between about 0.001 percent weight by volume and about 0.025 percent weight by volume.²⁰ However, I understand that “about 0.025” percent weight by volume of brimonidine includes 0.03 percent weight by volume (as included in the '553 Patent) and accomplishes the purpose of the claimed invention of the '742 Patent.²¹

¹⁷ EX 1002 (Sher Declaration, pars. 87 and 89).

¹⁸ EX 1003 (Laskar Declaration, pars. 76-79).

¹⁹ EX 1003 (Laskar Declaration, par. 80).

²⁰ EX 1001 ('742 Patent, 22:22-32).

²¹ EX 1003 (Laskar Declaration, pars. 57 and 63-64).

28. In addition to the '553 Patent, I understand that Walters 1991 supports that the efficacy of brimonidine (including the administration of brimonidine in low concentrations) was known in the prior art to reduce eye redness.²² More specifically, I understand that Walters 1991 discloses twice daily administration of brimonidine in concentrations of 0.02 percent weight by volume and 0.08 percent weight by volume to patients with open-angle glaucoma or ocular hypertension.²³ The Laskar Declaration states that “[t]he 0.02 [percent weight by volume brimonidine] in Walters 1991 falls within the ‘about 0.01 [percent weight by volume] to about 0.05 [percent weight by volume]’ range recited in the ’742 patent as a ‘preferred’ brimonidine concentration range for ‘scleral whitening’ and within the ‘about 0.015 [percent weight by volume] to about 0.02 [percent weight by volume]’ range which is recited as ‘even more’ preferable.”²⁴ Therefore, I

²² EX 1002 (Sher Declaration, pars. 71-73) and EX 1003 (Laskar Declaration, par. 89).

²³ EX 1003 (Laskar Declaration, pars. 83-84) and EX 1002 (Sher Declaration, pars. 71-72).

²⁴ EX 1003 (Laskar Declaration, par. 89).

understand that the claimed efficacy of Lumify[®] was known in the prior art and is not novel to the challenged claims of the '742 Patent.

29. With respect to safety and tolerability, I understand that it was known in the prior art that brimonidine was safe and well-tolerated, with a low rate of allergic response and that “all known side effects of brimonidine are generally minor and transient.”²⁵ Indeed, brimonidine was approved and used in the product Alphagan[®] for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension, as early as 1998.²⁶ Therefore, I understand that the claimed safety and tolerability of Lumify[®] were known in the prior art and are not novel to the challenged claims of the '742 Patent.

30. 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 '742 Patent.²⁷ I understand that the claim of a lack of rebound hyperemia or tachyphylaxis after repeated use over time is attributable to

²⁵ EX 1002 (Sher Declaration, pars. 35 and 100).

²⁶ EX 1002 (Sher Declaration, pars. 96-97).

²⁷ EX 2024 (Jarosz Declaration, pars. 104-105).

the administration of brimonidine in low concentrations.²⁸ As previously discussed, I understand that the administration of brimonidine in low concentrations (that is, within the concentration ranges disclosed in the challenged claims of the '742 Patent) was known in the prior art and is not novel to the challenged claims of the '742 Patent.²⁹ Furthermore, I understand that lack of rebound hyperemia or tachyphylaxis after repeated use over time are not listed in the challenged claims of the '742 Patent, which the Jarosz Declaration fails to appropriately address.³⁰

31. 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 '742 Patent, and therefore, I understand are not novel to the challenged claims of the '742 Patent. To the extent that the Jarosz Declaration is claiming that such features drive the marketplace performance of Lumify[®], I

²⁸ EX 1049 (Declaration of Neal A. Sher, M.D. in Support of Petitioner's Reply, dated December 16, 2022 (the "Sher Reply Declaration"), par. 111).

²⁹ EX 1002 (Sher Declaration, pars. 71-73, 87, and 89) and EX 1003 (Laskar Declaration, pars. 83-84).

³⁰ EX 1049 (Sher Reply Declaration, par. 112).

understand that there is no nexus between such features and the challenged claims of the '742 Patent.

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.”³¹ 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[®]].”³² 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. [REDACTED]

³¹ EX 2024 (Jarosz Declaration, par. 128).

³² EX 2024 (Jarosz Declaration, par. 128).

[REDACTED]

[REDACTED]

[REDACTED] 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.*³⁴

³³ For example, EX 2156 (Lumify® ECP A&U Report 2020, pgs. 18 and 30) and EX 2075 (Bausch 2021 FY Presentation, slide 22).

³⁴ EX 1070 (Bausch Fourth Quarter 2018 Earnings Call Transcript, dated February 20, 2019, pg. 12, available at <https://seekingalpha.com/article/4242568-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2018-results-earnings-call-transcript>, accessed November 17, 2022). Exhibits 1070-1073 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

- *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.³⁵*
- *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.³⁶*
- *Our team was able to drive education and awareness for [Lumify®] by collaborating with eye care professionals while driving awareness*

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.

³⁵ EX 1071 (Bausch Second Quarter 2019 Earnings Call Transcript, dated August 6, 2019, pg. 3, available at <https://seekingalpha.com/article/4282236-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q2-2019-results-earnings-call-transcript>, accessed November 17, 2022).

³⁶ EX 1072 (Bausch Fourth Quarter 2020 Earnings Call Transcript, dated February 24, 2021, pg. 14, available at <https://seekingalpha.com/article/4408646-bausch-health-companies-inc-bhc-ceo-joe-papa-on-q4-2020-results-earnings-call-transcript>, accessed November 17, 2022).

*among beauty enthusiasts with a strong television, public relations and social media presence.*³⁷

- *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.*³⁸

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

³⁷ EX 1073 (Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, pg. 8, available at <https://seekingalpha.com/article/4489552-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript>, accessed November 17, 2022).

³⁸ EX 1073 (Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, pg. 8, available at <https://seekingalpha.com/article/4489552-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript>, accessed November 17, 2022).

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, encourage the purchase of the OTC products (and/or some combination thereof). Bausch has 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[®].³⁹ As a result, Lumify[®]

³⁹ EX 1074 (<https://www.hg.agency/news/muse-awards>, accessed November 17, 2022). Helen & Gertrude offers a variety of services including brand development, content services, media planning, data insights and research, and web design (EX 1076 (<https://www.hg.agency/>, accessed November 17, 2022)). Exhibits 1074-1087 are true and accurate copies of online articles, campaigns, and websites that I accessed. This information relates to 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.

won two MUSE Creative awards in 2019, which recognizes excellence in media design production and distribution.⁴⁰

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.”⁴¹ Additionally, Lumify[®] won “Rose Gold” in the “Social Media - Product or Service Branding” category, by “by utilizing key social platforms to maximize reach for the most efficient cost” and by developing “a unique tone and voice for social media that created awareness around [Lumify[®]].”⁴²

⁴⁰ EX 1074 (<https://www.hg.agency/news/muse-awards>, accessed November 17, 2022) and EX 1075 (<https://museaward.com/>, accessed November 17, 2022).

⁴¹ EX 1077 (<https://museaward.com/winner-info.php?id=2187>, accessed November 17, 2022).

⁴² EX 1078 (<https://museaward.com/winner-info.php?id=2186>, accessed November 17, 2022).

38. Lumify[®] also engaged Wavemaker, a top-five global media network, to develop its marketing campaign entitled “Recharging Redness Relievers in a Beautiful Way.”⁴³ 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.”⁴⁴ Lumify[®] “even went as far to increase targeting and placement during timely, beauty-specific events such as New York Fashion Week.”⁴⁵ Furthermore, a Bausch social media campaign, developed by Helen & Gertrude in 2019, stated “we wanted [Lumify[®]] to be present in situations that fit

⁴³ EX 1079 (<https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards>, accessed November 17, 2022) and EX 1080 (<https://wavemakerglobal.com/our-work>, accessed November 17, 2022).

⁴⁴ EX 1079 (<https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards>, accessed November 17, 2022).

⁴⁵ EX 1079 (<https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards>, accessed November 17, 2022).

within the beauty lifestyle (*i.e.*, purse, gym bag, suitcase, bathroom vanity).”⁴⁶ The Jarosz Declaration fails to appropriately address that Bausch positioned Lumify[®] within the beauty segment as opposed to standard OTC medications.

39. 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”).⁴⁷ This social media campaign was centered around enticing consumers to post TikTok videos wherein users dance “with their eyes” to the beat of a Lumify[®] audio track.⁴⁸

⁴⁶ EX 1077 (<https://museaward.com/winner-info.php?id=2187>, accessed November 17, 2022).

⁴⁷ EX 1081 (<https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes>, accessed November 17, 2022).

⁴⁸ EX 1081 (<https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes>, accessed November 17, 2022).

Those who participated in the Challenge were entered to win a sweepstakes, including:⁴⁹

- 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.

40. 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 that I understand were known in the prior art.⁵⁰ However, the Jarosz Declaration

⁴⁹ EX 1081 (<https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes>, accessed November 17, 2022) and EX 1051 (Deposition of John Ferris, dated November 2, 2022 (the “Ferris Deposition”), pg. 87:4-19).

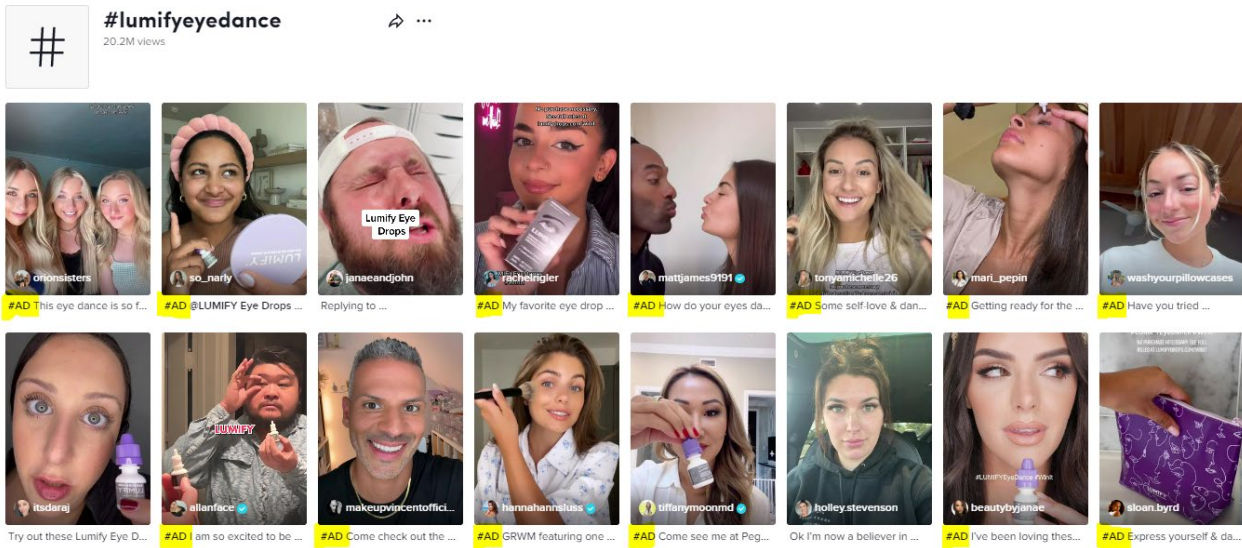
⁵⁰ EX 2024 (Jarosz Declaration, par. 115)

fails to appropriately discuss the marketing efforts for Lumify® in campaigns like the Challenge.

41. 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.”⁵¹ 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 the hashtag “#AD” (or advertisement).⁵²

⁵¹ EX 1082 (<https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html>, accessed November 17, 2022).

⁵² EX 1083 (<https://www.tiktok.com/tag/lumifyeyedance?lang=en>, accessed November 17, 2022). I understand that social media posts containing “#AD” indicate that creators of endorsement messages have a “material connection” with the subject brand or product. I further understand that a “material connection”



42. Indeed, the views generated for this 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 an advertisement (#AD), but the videos also include the statement that it is a “Paid partnership.”⁵³

includes personal, family, employment, or financial relationships (EX 1084 (https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf, accessed November 17, 2022, pgs. 2 and 5)).

⁵³ For example, see EX 1085

(https://www.tiktok.com/@allanface/video/7129967072628657454?is_copy_url=1&is_from_webapp=v1&lang=en, accessed November 17, 2022) and EX 1086

43. Lumify[®] won Business Intelligence Group's 2022 Public Relations and Marketing Excellence Award for External Campaign of the Year for the Challenge.⁵⁴ 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[®]. 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.

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

⁵⁴ EX 1087 (<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 November 17, 2022).

2. Detailing and Sampling Efforts

44. Bausch not only devoted significant marketing and promotional resources targeting consumers, but also used various marketing techniques to promote Lumify[®] to ECPs. [REDACTED]

[REDACTED]

[REDACTED]

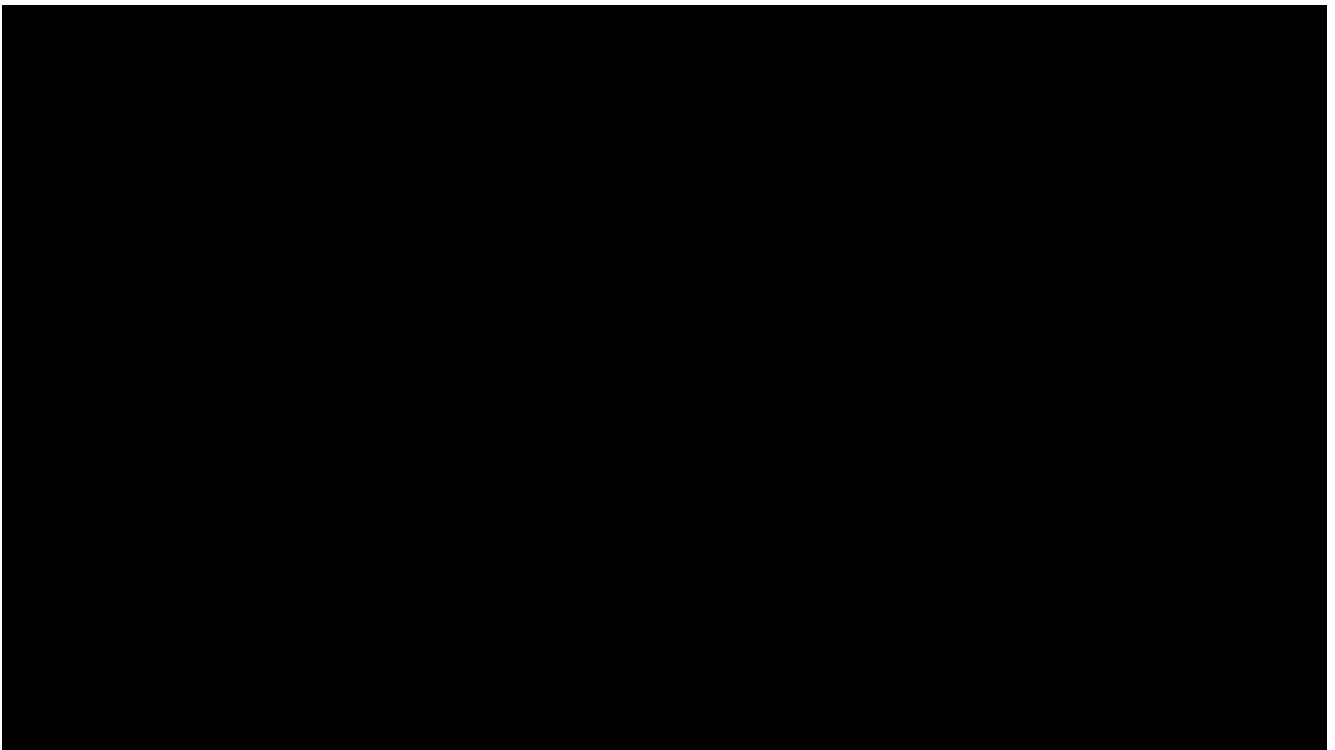
[REDACTED]

⁵⁵ EX 2156 (Lumify[®] ECP A&U Report 2020, pg. 18). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



[REDACTED]

[REDACTED] Detailing is a form of marketing where sales representatives visit or call on medical professionals and discuss products. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] This is consistent with Bausch leveraging a 400-plus person sales force for detailing and distribution directly to

⁵⁶ EX 2156 (Lumify® ECP A&U Report 2020, pg. 18).

⁵⁷ EX 2156 (Lumify® ECP A&U Report 2020, pg. 18).

optometrists and ophthalmologists in order to drive the marketplace performance of Lumify®.⁵⁸ [REDACTED]

[REDACTED]⁵⁹ Although Lumify® is an OTC product and a prescription is not needed to purchase Lumify®, Bausch dedicated resources to promoting Lumify® with ECPs to drive marketplace performance. The Jarosz Declaration's failure to appropriately address the detailing efforts of Bausch to drive the marketplace performance of Lumify® renders the Jarosz Declaration incomplete and unreliable.

46. In conjunction with detailing, Bausch also provided free samples of Lumify® to ECPs to drive the marketplace performance of Lumify®. 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]

⁵⁸ EX 1073 (Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, pg. 12, available at <https://seekingalpha.com/article/4489552-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript>, accessed November 17, 2022).

⁵⁹ EX 1051 (Ferris Deposition, pgs. 69:8-70:4).

[REDACTED]

47. [REDACTED]

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

48. In addition to providing free samples to ECPs, Bausch also held a national product “sampling tour” in four major U.S. cities as part of the Challenge.⁶³ 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

⁶⁰ EX 2156 (Lumify[®] ECP A&U Report 2020, pg. 30).

⁶¹ EX 2156 (Lumify[®] ECP A&U Report 2020, pg. 30).

⁶² EX 1051 (Ferris Deposition, pgs. 71:20-72:14).

⁶³ EX 1082 (<https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html>, accessed November 17, 2022).

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.⁶⁴

49. 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.

50. Furthermore, in the Jarosz Declaration's discussion of the marketing materials for Lumify®, the Jarosz Declaration fails to appropriately address the challenged claims 3-6 of the '742 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 resulting from an ocular condition and consisting essentially of brimonidine where the pH level of the composition is between about 5.5 and about 6.5 (claim 3);⁶⁵ a method of claim 3 where the composition is topically administered within about 24 hours after LASIK surgery

⁶⁴ EX 1082 (<https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html>, accessed November 17, 2022).

⁶⁵ EX 1002 (Sher Declaration, pars. 141, 145, 146, and 153).

(claim 4);⁶⁶ a method to reducing eye redness in claim 1 where the ocular condition is chronic red eye (claim 5);⁶⁷ and a method to reducing eye redness in claim 3 where the ocular condition is chronic red eye (claim 6).⁶⁸ 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[®] after LASIK surgery, or the use of Lumify[®] for chronic red eye. Therefore, the Jarosz Declaration fails to demonstrate that the marketing materials of Lumify[®] promote the alleged features of Lumify[®] covered by challenged claims 3-6 of the '742 Patent.

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

51. 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.⁶⁹ Based upon my analysis previously discussed, Lumify[®] has benefited

⁶⁶ EX 1002 (Sher Declaration, par. 169).

⁶⁷ EX 1002 (Sher Declaration, par. 173).

⁶⁸ EX 1002 (Sher Declaration, par. 174).

⁶⁹ EX 2024 (Jarosz Declaration, par. 128).

from significant marketing efforts, including attaining a significant share of voice (“SOV”).

52. [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 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.

53. 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,⁷¹ absent any analysis of comparative marketing spend is incomplete, speculative, and unreliable.

⁷⁰ EX 1051 (Ferris Deposition, pgs. 75:15-77:4).

⁷¹ EX 2024 (Jarosz Declaration, par. 135).

VIII. OTHER 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 Patent

54. The Jarosz Declaration claims that Lumify® is a commercial embodiment of “certain claims” of the '742 Patent and that Lumify® has been a marketplace success.⁷² However, the Jarosz Declaration is unclear which of the challenged claims of the '742 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 '742 Patent, and that he did not undertake any effort to determine of which specific claims Lumify® is an alleged commercial embodiment.⁷³

55. I understand that claims 4-6 of the '742 Patent relate to a method for reducing eye redness in claim 3 where the composition is topically administered within about 24 hours after LASIK surgery (claim 4);⁷⁴ a method to reducing eye

⁷² EX 2024 (Jarosz Declaration, pars. 2, 13, and 37).

⁷³ EX 1052 (Deposition of John C. Jarosz, dated November 11, 2022 (the “Jarosz Deposition”), pgs. 24:6-26:3).

⁷⁴ EX 1002 (Sher Declaration, par. 169).

redness in claim 1 where ocular condition is chronic red eye (claim 5);⁷⁵ and a method to reducing eye redness in claim 3 where ocular condition is chronic red eye (claim 6).⁷⁶

56. The Jarosz Declaration fails to discuss or provide an understanding that Lumify® is an embodiment of claims 4-6 of the '742 Patent. Furthermore, the Jarosz Declaration fails to quantify the sales of Lumify® that practice claims 4-6 of the '742 Patent (if any).⁷⁷ Therefore, the Jarosz Declaration fails to demonstrate that the marketplace performance of Lumify® is related to claims 4-6 of the '742 Patent 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 claims 4-6 of the '742 Patent.

57. In addition to the Jarosz Declaration failing to demonstrate that the marketplace performance of Lumify® is related to claims 4-6 of the '742 Patent, the Jarosz Declaration also fails to attribute the claimed marketplace success of Lumify® among the remaining challenged claims of the '742 Patent. Furthermore, the Jarosz

⁷⁵ EX 1002 (Sher Declaration, par. 173).

⁷⁶ EX 1002 (Sher Declaration, par. 174).

⁷⁷ For example, see EX 1052 (Jarosz Deposition, pgs. 83:8-84:3).

Declaration fails to address that Bausch has listed U.S. Patent No. 9,259,425 (the “’425 Patent”) in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”) as allegedly covering Lumify®.⁷⁸ 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 ’742 Patent, without apportioning any value to the ’425 Patent. The Jarosz Declaration’s failure to present an economic analysis that apportions the marketplace performance of Lumify® among the challenged claims of the ’742 Patent and to the ’425 Patent 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

58. 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.”⁷⁹ The Jarosz Declaration claims

⁷⁸ EX 2079.

⁷⁹ EX 2024 (Jarosz Declaration, par. 50).

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.”⁸⁰

The Jarosz Declaration thus claims that the behavior and decisions of Slayback, Eye Therapies, and Bausch strongly suggest that these companies regarded and continue to regard Lumify[®] as a marketplace success.⁸¹ For the reasons listed below, the discussion in the Jarosz Declaration is misleading and unreliable.

59. 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.⁸² Similarly, the Jarosz Declaration claims that Petitioner’s costs associated with the submission of its ANDA and the costs Petitioner will incur in this IPR are evidence that Slayback

⁸⁰ EX 2024 (Jarosz Declaration, par. 51).

⁸¹ EX 2024 (Jarosz Declaration, par. 52).

⁸² EX 2024 (Jarosz Declaration, pars. 58 and 65).

believes Lumify[®] is a marketplace success.⁸³ The Jarosz Declaration is overly simplistic and misleading.

60. 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 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.

61. Furthermore, the decision by a company to file 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

⁸³ EX 2024 (Jarosz Declaration, pars. 53-55).

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.

62. 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.

63. 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.

64. Therefore, the decision by Slayback to pursue selling a generic alternative to Lumify[®] fails to provide evidence of purported marketplace success of Lumify[®].

C. The Jarosz Declaration Fails to Address the Profitability (or Lack Thereof) of Lumify®

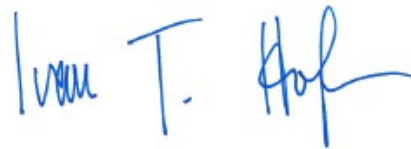
65. The Jarosz Declaration fails to address the profitability (or lack thereof) of Lumify®. From an economic perspective, an analysis of profitability (or lack thereof) of a product can be an important metric in the evaluation of the marketplace success of a product.

66. Based on my review of the limited financial data available for Lumify®, I have not seen evidence and the Jarosz Declaration fails to discuss that Lumify® has achieved a cumulative profit (taking into account discounts and coupons; cost of goods sold; marketing and promotional expenses; research and development expenses; and other allocable operating costs). This renders the Jarosz Declaration flawed and incomplete.

* * * * *

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,

A handwritten signature in blue ink, reading "Ivan T. Hofmann". The signature is written in a cursive style with a horizontal line underneath.

Ivan T. Hofmann

Dated: December 16, 2022

Appendix

Appendix 1

Exhibit/ Paper No.	Document
Paper 2	Petition for IPR U.S. Patent 8,293,742
Paper 7	Patent Owner's Preliminary Response (IPR2022-00142)
Paper 13	Decision Granting Institution of <i>Inter Partes</i> Review 35 U.S.C. 314, 37 C.F.R. 42.4
1001	U.S. Patent No. 8,293,742
1002	Declaration of Neal A. Sher, M.D., dated November 4, 2021
1003	Declaration of Paul A. Laskar, Ph.D., dated November 4, 2021
1004	U.S. Patent No. 6,294,553
1049	Declaration of Neal A. Sher, M.D. in Support of Petitioner's Reply dated December 16, 2022
1051	Transcript of John Ferris, dated November 2, 2022
1052	Transcript of John C. Jarosz, dated November 11, 2022
1067	https://assignment.uspto.gov/patent/index.html#/patent/search/resultFilter?searchInput=8293742 , accessed December 2, 2022
1068	Ivan T. Hofmann CV and Testimony
1069	Bausch SEC Form 10-Q, for the period ended June 30, 2022, available at https://otp.tools.investis.com/clients/us/bausch_health_companies/SEC/sec-show.aspx?FilingId=16064281&Cik=0000885590&Type=PDF&hasPdf=1 , accessed November 17, 2022
1070	Bausch Fourth Quarter 2018 Earnings Call Transcript, dated February 20, 2019, available at https://seekingalpha.com/article/4242568-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2018-results-earnings-call-transcript , accessed November 17, 2022
1071	Bausch Second Quarter 2019 Earnings Call Transcript, dated August 6, 2019, available at https://seekingalpha.com/article/4282236-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q2-2019-results-earnings-call-transcript , accessed November 17, 2022

Exhibit/ Paper No.	Document
1072	Bausch Fourth Quarter 2020 Earnings Call Transcript, dated February 24, 2021, available at https://seekingalpha.com/article/4408646-bausch-health-companies-inc-bhc-ceo-joe-papa-on-q4-2020-results-earnings-call-transcript , accessed November 17, 2022
1073	Bausch Fourth Quarter 2021 Earnings Call Transcript, dated February 23, 2022, available at https://seekingalpha.com/article/4489552-bausch-health-companies-inc-bhc-ceo-joseph-papa-on-q4-2021-results-earnings-call-transcript , accessed November 17, 2022
1074	https://www.hg.agency/news/muse-awards , accessed November 17, 2022
1075	https://museaward.com/ , accessed November 17, 2022
1076	https://www.hg.agency/ , accessed November 17, 2022
1077	https://museaward.com/winner-info.php?id=2187 , accessed November 17, 2022
1078	https://museaward.com/winner-info.php?id=2186 , accessed November 17, 2022
1079	https://wavemakerglobal.com/usa/news-wavemaker-us-wins-two-gold-effie-awards , accessed November 17, 2022
1080	https://wavemakerglobal.com/our-work , accessed November 17, 2022
1081	https://www.fiercepharma.com/marketing/bausch-lomb-kickstarts-tiktok-campaign-lumify-it-asks-consumers-dance-their-eyes , accessed November 17, 2022
1082	https://www.prnewswire.com/news-releases/bausch--lomb-launches-the-lumifyeyedance-challenge-on-tiktok-301594922.html , accessed November 17, 2022
1083	https://www.tiktok.com/tag/lumifyeyedance?lang=en , accessed November 17, 2022
1084	https://www.ftc.gov/system/files/documents/plain-language/1001a-influencer-guide-508_1.pdf , accessed November 17, 2022
1085	https://www.tiktok.com/@allanface/video/7129967072628657454?is_copy_url=1&is_from_webapp=v1&lang=en , accessed November 17, 2022

Exhibit/ Paper No.	Document
1086	https://www.tiktok.com/@orionsisters/video/7124396970558459179?is_copy_url=1&is_from_webapp=v1&lang=en , accessed November 17, 2022
1087	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 November 17, 2022
2020	Declaration of Dr. Robert Noecker, dated August 24, 2022
2021	Declaration of Dr. Robert Williams, dated August 26, 2022
2023	Declaration of John Ferris, dated August 26, 2022
2024	Declaration of John C. Jarosz, dated August 26, 2022
2052	LUM.0205.USA.21
2057	IRI Panel Data
2058	IRI Point-of Sale Data
2065	Lumify® NDA Approval, December 22, 2017
2068	Bausch + Lomb Corporation Q1 2022 Financial Results
2075	Bausch 2021 FY Presentation
2079	https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm , accessed November 17, 2022
2097	https://www.businesswire.com/news/home/20220729005454/en/Dr.-Reddys-Laboratories-enters-into-a-licensing-agreement-with-Slayback-Pharma-to-%E2%80%A6 , accessed November 17, 2022
2103	https://ir.bauschhealth.com/news-releases/2018/05-07-2018-130249958 , accessed November 17, 2022
2124	https://www.prnewswire.com/news-releases/bausch--lomb-licenses-new-technology-with-potential-to-treat-millions-affected-by-ocular-redness-185856742.html , accessed November 17, 2022
2156	Lumify® ECP A&U Report 2020
2159	Q2 2022 Bausch + Lomb Financial Results
2162	Deposition Transcript of Dr. Neal Sher, dated August 10, 2022
2191	Lumify® Label, December 2017, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208144Orig1s000lbl.pdf , accessed November 17, 2022
2198	Deposition Transcript of Dr. Paul Laskar, dated August 4, 2022