

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENE COMPANY PTY LTD,

Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY
IN THE CITY OF NEW YORK,

Patent Owner.

Case No. IPR2024-00313

U.S. Patent No. RE47,045

Declaration of Kelley M. Hayes Greenhill

I. Introduction

1. I have prepared this Declaration in connection with the above referenced *Inter Partes* Review regarding U.S. Patent No. RE47,045. The Exhibits referenced in this Declaration are attached as Exhibits to this Declaration.

2. I am currently the Director of the Research & Information Services team at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP located at 901 New York Ave NW, Washington, District of Columbia, 20001-4413 (“Finnegan”).

3. I am over eighteen years of age, and I am competent to make this Declaration. I make this Declaration based on my own personal knowledge, and my professional knowledge of library science practices.

4. I earned a Master of Science in Library Science from the Catholic University of America in 1995, and a Bachelor of Arts in Political Science from Duquesne University in 1989. I have worked as a librarian for over twenty-five years. I have been employed at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP since 2019. Before that, from 1995 to 2015, I was employed in the Library Department of Sterne, Kessler, Goldstein & Fox, PLLC. And from 2015 to 2019, I was employed in the Knowledge and Research Service Group (formerly, Information Research Service) at Northrop Grumman Corporation.

5. I am a member of the American Association of Law Libraries.

II. Open Access Resources

6. Open Access (OA) refers to all electronic resources that are available online without any licensing or copyright restrictions. A publication is considered 'open access' when there are no financial, legal, or technical barriers to accessing it. This means anyone can read, download, copy, distribute, print, search for, and search within the information or use it for education or any other legal purpose. Examples of Open Access resources include articles, journals, books, conference proceedings, theses, videos, music, and more. Open Access has become increasingly popular in scholarly research and communication as academic resource prices have significantly increased over the past decade, and academic libraries' budgets have not kept pace with these new expenses.

III. EX2088 (*Scholl 2022*)

7. This attestation relates to the public accessibility the Abstract of Hendrik P Scholl, Gabrielle DeBartolomeo, Ilyas Washington, & Leonide Saad, ALK-001 (C20-D3-Vitamin A) slows the growth of atrophic lesions in ABCA4-related Stargardt Disease: Results of a Phase 2 placebo-controlled clinical trial (TEASE study), 63 Investigative Ophthalmology & Visual Science 38 (2022), (*Scholl 2022*). I understand that *Scholl 2022* has been submitted as Exhibit 2088 in this proceeding.

8. **Exhibit 2088** is a true and correct copy of the Abstract of Hendrik P Scholl, Gabrielle DeBartolomeo, Ilyas Washington, & Leonide Saad, *ALK-001 (C20-D3-Vitamin A) slows the growth of atrophic lesions in ABCA4-related Stargardt Disease: Results of a Phase 2 placebo-controlled clinical trial (TEASE study)*, 63 Investigative Ophthalmology & Visual Science 38 (2022), which was retrieved from the publicly available website <https://iovs.arvojournals.org/article.aspx?articleid=2779035>. I confirmed this on September 20, 2024. On September 20, 2024, I accessed the publicly available website, <https://iovs.arvojournals.org/>, Ex. B.1. From that webpage, I clicked on Issues on the top of the page with resulted in webpage, <https://iovs.arvojournals.org/issues.aspx>, Ex.B.2. From here I selected Past Issues tab which resulted in webpage, <https://iovs.arvojournals.org/issues.aspx#issueid=938685>, Ex. B.3. Then I clicked 2022 from the left scroll bar, from the center bar I selected June 2022 Volume 63 Issue 7 Pages 1-4310, which resulted in webpage, <https://iovs.arvojournals.org/issues.aspx#issueid=938596>, Ex. B. 4. I clicked the link for ALK-001 (C20-D3-Vitamin) slows the growth of atrophic lesions in ABCA4-related Stargardt Disease: Results of a Phase 2 placebo-controlled clinical trial (TEASE Study) which resulted in <https://iovs.arvojournals.org/article.aspx?articleid=2779035>, and downloaded the

webpage in PDF form. This resulted in the document downloaded and saved as **Exhibit 2088**.

IV. EX2090 (*Scholl 2024*)

9. This attestation relates to the public accessibility of the Abstract of Hendrik P. Scholl; Leonide Saad, Gabrielle DeBartolomeo, Neil M. Bressler, Stephen H. Tsang, Kimberly E. Stepien, Paul S. Bernstein, Byron L. Lam, Michael B. Gorin, Ilyas Washington, & Christine Nichols Kay, *Gildeuretinol Enables the Vitamin A Cycle*, 65 *Investigative Ophthalmology & Visual Science* 7 (2024) (*Scholl 2024*). I understand that *Scholl 2024* has been submitted as **Exhibit 2090** in this proceeding.

10. **Exhibit 2090** is a true and correct copy of the Abstract of Hendrik P. Scholl; Leonide Saad, Gabrielle DeBartolomeo, Neil M. Bressler, Stephen H. Tsang, Kimberly E. Stepien, Paul S. Bernstein, Byron L. Lam, Michael B. Gorin, Ilyas Washington, & Christine Nichols Kay, *Gildeuretinol Enables the Vitamin A Cycle*, 65 *Investigative Ophthalmology & Visual Science* 7 (2024), which was retrieved from the publicly available website, <https://iovs.arvojournals.org/>, Ex.B.1. From that webpage, I clicked Issues which resulted in the webpage, <https://iovs.arvojournals.org/issues.aspx>, Ex. B.2. From here I clicked, Past Issues, scrolled to June 2024 Volume Issue 7 Pages 1 – 6780 in the center bar, which resulted in the webpage, <https://iovs.arvojournals.org/issues.aspx#issueid=938678>,

Ex.B.5. From that webpage, I clicked the page links at the bottom until I found Gildeuretinol Enables the Vitamin A Cycle. I selected the link for Gildeuretinol Enables the Vitamin A Cycle, which resulted in webpage <https://iovs.arvojournals.org/article.aspx?articleid=2795499>, Ex. B. 6. From this page I downloaded the webpage in PDF form. This resulted in the document downloaded and saved as **Exhibit 2090**.

V. EX2096 (2021.07.14 Alkeus Press Release)

11. This attestation relates to the public accessibility of Alkeus Pharmaceuticals, *FDA Grants Alkeus Pharmaceuticals Breakthrough Therapy Designation for ALK-001 (C20-D3-vitamin A) for the Treatment of Stargardt Disease (2021) (2021.07.14 Alkeus Press Release)*. I understand that *2021.07.14 Alkeus Press Release 2021* has been submitted as **Exhibit 2096** in the proceeding.

12. **Exhibit 2096** is a true and correct copy of Alkeus Pharmaceuticals, *FDA Grants Alkeus Pharmaceuticals Breakthrough Therapy Designation for ALK-001 (C20-D3-vitamin A) for the Treatment of Stargardt Disease (2021)*, which was retrieved from the publicly available website <https://alkeuspharma.com/wp-content/uploads/2023/11/fda-grants-alkeus-pharmaceuticals-breakthrough.pdf>. I confirmed this on September 21, 2024. On September 21, 2024, I accessed the publicly available website, <https://alkeuspharma.com>, Ex. B. 7. From here I clicked News, from the resulting pull down menu, I clicked Press Releases, which resulted

in the webpage, <https://alkeuspharma.com/category/press-releases/>, Ex. B.8. From here I scrolled through the page linked on the bottom until I found FDA Grants Alkeus Pharmaceuticals Breakthrough Therapy Designation for ALK-001 (C20-D3-vitamin A) for the Treatment of Stargardt Disease on page 4, <https://alkeuspharma.com/category/press-releases/page/4/>, Ex B.9. I clicked Learn More under link for FDA Grants Alkeus Pharmaceuticals Breakthrough Therapy Designation for ALK-001 (C20-D3-vitamin A) for the Treatment of Stargardt Disease, which resulted in webpage, <https://alkeuspharma.com/fda-grants-alkeus-pharmaceuticals-breakthrough-therapy-designation-for-alk-001-c20-d3-vitamin-a-for-the-treatment-of-stargardt-disease-2/>, Ex. B.10. From this page I clicked Download Press Release, resulting in webpage, <https://alkeuspharma.com/wp-content/uploads/2023/11/fda-grants-alkeus-pharmaceuticals-breakthrough.pdf>, and downloaded a PDF form of the press release. This resulted in the document downloaded and saved as **Exhibit 2096**.

VI. EX2086 (*Scholl 2016*)

13. This attestation relates to the public accessibility of the Abstract of Hendrik P. Scholl, Syed Mahmood Shah, Christine Nichols Kay, Stephen H. Tsang, Kimberly E. Stepien, Paul S. Bernstein, Byron L. Lam, Michael B. Gorin, Ilyas Washington, & Leonide Saad, TEASE: a phase 2 clinical trial assessing the tolerability and effects of oral once-a-day ALK-001 on Stargardt disease, 57

Investigative Ophthalmology & Visual Science 12 (2016) (*Scholl 2016*). I understand that *Scholl 2016* has been submitted as **Exhibit 2086** in this proceeding.

14. **Exhibit 2086** is a true and correct copy of the Abstract of Hendrik P. Scholl, Syed Mahmood Shah, Christine Nichols Kay, Stephen H. Tsang, Kimberly E. Stepien, Paul S. Bernstein, Byron L. Lam, Michael B. Gorin, Ilyas Washington, & Leonide Saad, *TEASE: a phase 2 clinical trial assessing the tolerability and effects of oral once-a-day ALK-001 on Stargardt disease*, 57 Investigative Ophthalmology & Visual Science 12 (2016), which was retrieved from the publicly available website, <https://iovs.arvojournals.org/>, Ex. B.1. From that webpage, I clicked Issues which resulted in the webpage, <https://iovs.arvojournals.org/issues.aspx>, Ex. B.2. From here I clicked Past Issues, scrolled and click 2016 in the left scroll bar. Then I scrolled and clicked September 2016 Volume 57 Issue 12 Pages 10 -6601 in the center bar, which resulted in webpage, <https://iovs.arvojournals.org/issues.aspx#issueid=935755>, Ex. B.11. From here I clicked the page links at the bottom until I found *Scholl 2016*. I clicked the link for TEASE: a phase 2 clinical trial assessing the tolerability and effects of oral once-a-day ALK-001 on Stargardt disease, which resulted in webpage, <https://iovs.arvojournals.org/article.aspx?articleid=2557902>, Ex. B.12. I

downloaded the webpage in PDF form. This resulted in the document downloaded and saved as **Exhibit 2086**.

VII. EX2087 (*Scholl 2019*)

15. This attestation relates to the public accessibility of the Abstract of Hendrik P. Scholl, Stephen H. Tsang, Christine Nichols Kay, Thomas B. Connor, Michael B. Gorin, Paul S. Bernstein, Byron L. Lam, Zach Strecker, Justin Tyler Zaremba, Gabrielle DeBartolomeo, Ilyas Washington, & Leonide Saad, Stargardt disease ALK-001 phase 2 clinical trial: 12-month interim data, 60 Investigative Ophthalmology & Visual Science 9 (2019) (*Scholl 2019*). I understand that *Scholl 2019* has been submitted as **Exhibit 2087** in this proceeding.

16. **Exhibit 2087** is a true and correct copy of the Abstract of Hendrik P. Scholl, Stephen H. Tsang, Christine Nichols Kay, Thomas B. Connor, Michael B. Gorin, Paul S. Bernstein, Byron L. Lam, Zach Strecker, Justin Tyler Zaremba, Gabrielle DeBartolomeo, Ilyas Washington, & Leonide Saad, *Stargardt disease ALK-001 phase 2 clinical trial: 12-month interim data*, 60 Investigative Ophthalmology & Visual Science 9 (2019), which was retrieved from the publicly available website, <https://iovs.arvojournals.org/>, Ex.B.1. From that webpage, I clicked Issues which resulted in the webpage, <https://iovs.arvojournals.org/issues.aspx>, Ex. B.2. From here I clicked, Past Issues, scrolled and click 2019, in the left bar. Then I scrolled and clicked July 2019

Volume 60 Issue 9 Pages 1 – 6835 in the center bar, which resulted in webpage, <https://iovs.arvojournals.org/issues.aspx#issueid=938143>, Ex B.13. From that webpage, I clicked the page links at the bottom until I found *Scholl 2019*. I clicked the link for Stargardt disease ALK-001 phase 2 clinical trial: 12-month interim data, which resulted in webpage, <https://iovs.arvojournals.org/article.aspx?articleid=2746412>, Ex B.14. I downloaded the webpage in PDF form. This resulted in the document downloaded and saved as **Exhibit 2087**.

VIII. EX2190 (*Belite Bio Company Presentation_202409*)

17. This attestation relates to the public accessibility of Belite Bio, Early Intervention with an Oral Treatment for Macular Degeneration (2024) (*Belite Bio Company Presentation_202409*). I understand that Belite Bio Company Presentation_202409 has been submitted as **Exhibit 2190** in this proceeding.

18. **Exhibit 2190** is a true and correct copy of Belite Bio, Early Intervention with an Oral Treatment for Macular Degeneration (2024), which was retrieved from the publicly available website, <https://belitebio.com/>, Ex.B.15. From that webpage, I clicked INVESTORS which resulted in the webpage, <https://investors.belitebio.com/>, Ex.B.16. From here I clicked PRESENTATIONS & EVENTS, which resulted in webpage, <https://investors.belitebio.com/presentations-events/presentations>, Ex.B.17. From

that webpage, I clicked Company Presentation, which resulted in the webpage, <https://investors.belitebio.com/static-files/837a64fe-a778-4209-9239-313d77a3aa0f>. I downloaded the webpage in PDF form. This resulted in the document downloaded and saved as **Exhibit 2190**.

IX. EX2165 (*Sherman 2013*)

19. This attestation relates to the public accessibility of Jerome Sherman, *A Novel Biomarker for Stargardt Disease?* (2013) (*Sherman 2013*). I understand that *Sherman 2013* has been submitted as **Exhibit 2165** in the proceeding.

20. **Exhibit 2165** is a true and correct copy of Jerome Sherman, *A Novel Biomarker for Stargardt Disease?* (2013), which was retrieved from the publicly available website <https://www.reviewofoptometry.com/article/a-novel-biomarker-for-stargardt-disease>. I confirmed this on September 22, 2024. On September 22, 2024, I accessed the publicly available website, <https://www.reviewofoptometry.com/>, Ex. B.19. From here I typed “A Novel Biomarker for Stargardt Disease” into the search bar on the top right corner of the webpage and clicked the search button, which resulted in the webpage, <https://www.reviewofoptometry.com/search?q=A+Novel+Biomarker+for+Stargardt+Disease>, Ex. B.20. From here I clicked A Novel Biomarker for Stargardt Disease?, resulting in the webpage <https://www.reviewofoptometry.com/article/a->

novel-biomarker-for-stargardt-disease, and downloaded a PDF form of the website.

This resulted in the document downloaded and saved as **Exhibit 2165**.

X. EX2186 (*Sternberg 2010*)

21. This attestation relates to the public accessibility of the abstract of P. Sternberg, P. J. Rosenfeld, J. S. Slakter, J. M. Koester, & A. Reaves, *Topical OT-551 for Treating Geographic Atrophy: Phase II Results*, 51 Investigative Ophthalmology & Visual Science 13 (2010) (*Sternberg 2010*). I understand that *Sternberg 2010* has been submitted as **Exhibit 2186** in the proceeding.

22. **Exhibit 2186** is a true and correct copy of the abstract of P. Sternberg, P. J. Rosenfeld, J. S. Slakter, J. M. Koester, & A. Reaves, *Topical OT-551 for Treating Geographic Atrophy: Phase II Results*, 51 Investigative Ophthalmology & Visual Science 13 (2010), which was retrieved from the publicly available webpage <https://iovs.arvojournals.org/article.aspx?articleid=2375018>. I confirmed this on September 22, 2024. On September 22, 2024, I accessed the publicly available website, <https://iovs.arvojournals.org/>, Ex. B.1. From here I typed “Topical OT-551 for Treating Geographic Atrophy: Phase II Results” into the search bar and clicked the search button, which resulted in the webpage, <https://arvojournals.org/solr/searchresults.aspx?q=Topical%20OT-551%20for%20Treating%20Geographic%20Atrophy%3A%20Phase%20II%20Results&restypeid=1>, Ex. B.26. From here I clicked Phase II Results, resulting in the

webpage

<https://iovs.arvojournals.org/article.aspx?articleid=2375018&resultClick=1> and downloaded a PDF form of the website. This resulted in the document downloaded and saved as **Exhibit 2186**.

XI. EX2187 (*Stokkermans 2009*)

23. This attestation relates to the public accessibility of Thomas J. Stokkermans, *What's New in Clinical Trials for Treatment of Dry AMD* (2009) (*Stokkermans 2009*). I understand that *Stokkermans 2009* has been submitted as **Exhibit 2187** in the proceeding.

24. **Exhibit 2187** is a true and correct copy of Thomas J. Stokkermans, *What's New in Clinical Trials for Treatment of Dry AMD* (2009), which was retrieved from the publicly available webpage <https://www.reviewofoptometry.com/article/whats-new-in-clinical-trials-for-treatment-of-dry-amd>. I confirmed this on September 22, 2024. On September 22, 2024, I accessed the publicly available website, <https://www.reviewofoptometry.com> Ex. B.27. From here I clicked View More Publications, which resulted in the webpage, <https://www.reviewofoptometry.com/publications/archive>, Ex B.28. From here I clicked 2008, which resulted in the webpage, <https://www.reviewofoptometry.com/publications/archive/all/2008>, Ex. B.29. From

here I clicked Fifth Annual Guide to Retinal Disease, which resulted in the webpage, <https://www.reviewofoptometry.com/publications/fifth-annual-guide-to-retinal-disease>, Ex. B.30. From here I clicked What's New in Clinical Trials for Treatment of Dry AMD, resulting in the webpage <https://www.reviewofoptometry.com/article/whats-new-in-clinical-trials-for-treatment-of-dry-amd>, and downloaded a PDF form of the website. This resulted in the document downloaded and saved as **Exhibit 2187**.

XII. EX2070 (*Travis 2007*)

25. This attestation relates to the public accessibility of the abstract of G. H. Travis, J. H. Peng, J. Hu; D. Bok, S. Nusinowitz, & R. A. Radu, *Is the Vitamin A Treatment Safe for Retinal Degeneration Caused by Mutations in ABCA4 Gene?*, 48 Investigative Ophthalmology & Visual Science 13 (2007) (*Travis 2007*). I understand that *Travis 2007* has been submitted as **Exhibit 2070** in the proceeding.

26. **Exhibit 2070** is a true and correct copy of the abstract of . H. Travis, J. H. Peng, J. Hu; D. Bok, S. Nusinowitz, & R. A. Radu, *Is the Vitamin A Treatment Safe for Retinal Degeneration Caused by Mutations in ABCA4 Gene?*, 48 Investigative Ophthalmology & Visual Science 13 (2007), which was retrieved from the publicly available website <https://iovs.arvojournals.org/article.aspx?articleid=2388309&resultClick=1>. I confirmed this on September 22, 2024. On September 22, 2024, I accessed the

publicly available website, <https://iovs.arvojournals.org/>, Ex. B.1. From here I typed “Is the Vitamin A Treatment Safe for Retinal Degeneration Caused by Mutations in ABCA4 Gene?” into the search bar and clicked the search button, which resulted in the webpage, <https://arvojournals.org/solr/searchresults.aspx?q=Is%20the%20Vitamin%20A%20Treatment%20Safe%20for%20Retinal%20Degeneration%20Caused%20by%20Mutations%20in%20ABCA4%20Gene%3F&restypeid=1>, Ex. B.34. From here I clicked Is the Vitamin A Treatment Safe for Retinal Degeneration Caused by Mutations in ABCA4 Gene?, resulting in the webpage <https://iovs.arvojournals.org/article.aspx?articleid=2388309&resultClick=1> and downloaded a PDF form of the website. This resulted in the document downloaded and saved as **Exhibit 2070**.

XIII. EX2177 (*Caruso 2008*)

27. This attestation relates to the public accessibility of the abstract of R. C. Caruso, E. Agron, P. Lopez, L. M. Reuter, J. Bacik, P. A. Sieving, & I. M. MacDonald, *Docosahexaenoic Acid Does Not Improve Visual Function in Patients With Autosomal Recessive Stargardt Disease*, 49 Investigative Ophthalmology & Visual Science 13 (2008) (*Caruso 2008*). I understand that *Caruso 2008* has been submitted as **Exhibit 2177** in the proceeding.

28. **Exhibit 2177** is a true and correct copy of the abstract of R. C. Caruso, E. Agron, P. Lopez, L. M. Reuter, J. Bacik, P. A. Sieving, & I. M. MacDonald, *Docosahexaenoic Acid Does Not Improve Visual Function in Patients With Autosomal Recessive Stargardt Disease*, 49 Investigative Ophthalmology & Visual Science 13 (2008), which was retrieved from the publicly available website <https://iovs.arvojournals.org/article.aspx?articleid=2380070&resultClick=1>. I confirmed this on September 22, 2024. On September 22, 2024, I accessed the publicly available website, <https://iovs.arvojournals.org/>, Ex. B.1. From here I typed “Docosahexaenoic Acid Does Not Improve Visual Function in Patients With Autosomal Recessive Stargardt Disease” into the search bar and clicked the search button, which resulted in the webpage, <https://arvojournals.org/solr/searchresults.aspx?q=Docosahexaenoic%20Acid%20Does%20Not%20Improve%20Visual%20Function%20in%20Patients%20With%200Autosomal%20Recessive%20Stargardt%20Disease&restypeid=1>, Ex. B.35. From here I clicked Docosahexaenoic Acid Does Not Improve Visual Function in Patients With Autosomal Recessive Stargardt Disease, resulting in the webpage <https://iovs.arvojournals.org/article.aspx?articleid=2380070&resultClick=1> and downloaded a PDF form of the website. This resulted in the document downloaded and saved as **Exhibit 2177**.

XIV. EX2091 (*Gorin 2024*)

29. This attestation relates to the public accessibility of the abstract of Michael B. Gorin, Leonide Saad, Gabrielle DeBartolomeo, Ilyas Washington, Hendrik P. Scholl, Marc T. Mathias, Philip Ferrone, & Christine Nichols Kay, *Gildeuretinol Arrested Stargardt Disease, The TEASE-3 Study*, 65 Investigative Ophthalmology & Visual Science 7 (2024) (*Gorin 2024*). I understand that *Gorin 2024* has been submitted as **Exhibit 2091** in the proceeding.

30. **Exhibit 2091** is a true and correct copy of the abstract of Michael B. Gorin, Leonide Saad, Gabrielle DeBartolomeo, Ilyas Washington, Hendrik P. Scholl, Marc T. Mathias, Philip Ferrone, & Christine Nichols Kay, *Gildeuretinol Arrested Stargardt Disease, The TEASE-3 Study*, 65 Investigative Ophthalmology & Visual Science 7 (2024), which was retrieved from the publicly available website SITE. I confirmed this on September 22, 2024. On September 22, 2024, I accessed the publicly available website, <https://iovs.arvojournals.org/>, Ex. B.1. From here I typed “Gildeuretinol Arrested Stargardt Disease, The TEASE-3 Study” into the search bar and clicked the search button, which resulted in the webpage, <https://arvojournals.org/solr/searchresults.aspx?q=Gildeuretinol%20Arrested%20Stargardt%20Disease%2C%20The%20TEASE-3%20Study&restypeid=1>, Ex. B.36. From here I clicked the first result titled Gildeuretinol Arrested Stargardt Disease, The TEASE-3 Study, resulting in the webpage <https://iovs.arvojournals.org/article.aspx?articleid=2795594&resultClick=1>. On

this webpage, I clicked Author Affiliations & Notes to expand that section and downloaded a PDF form of the webpage. This resulted in the document downloaded and saved as **Exhibit 2091**.

XV. EX2097 (2023.06.05 Alkeus Press Release)

31. This attestation relates to the public accessibility of Alkeus Pharmaceuticals, *Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol (ALK-001) in the Treatment of Stargardt Disease (2023)* (2023.06.05 Alkeus Press Release). I understand that 2023.06.05 Alkeus Press Release has been submitted as **Exhibit 2097** in the proceeding.

Exhibit 2097 is a true and correct copy of Alkeus Pharmaceuticals, *Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol (ALK-001) in the Treatment of Stargardt Disease (2023)*, which was retrieved from the publicly available website <https://alkeuspharma.com/wp-content/uploads/2023/10/Alkeus-June-5-2023-Press-Release.pdf>. I confirmed this on September 21, 2024. On September 21, 2024, I accessed the publicly available website, <https://alkeuspharma.com>, Ex. B. 7. From here I clicked News, from the resulting pull down menu, I clicked Press Releases, which resulted in the webpage, <https://alkeuspharma.com/category/press-releases/>, Ex. B.8. From here I scrolled through the page linked on the bottom until I found Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol

(ALK-001) in the Treatment of Stargardt Disease on page 3, <https://alkeuspharma.com/category/press-releases/page/3/>, Ex B.37. I clicked Learn More under link for Alkeus Announces \$150 Million Series B Financing, Supporting Rapid Registration Path for gildeuretinol (ALK-001) in the Treatment of Stargardt Disease, which resulted in webpage, <https://alkeuspharma.com/alkeus-announces-150-million-series-b-financing-supporting-rapid-registration-path-for-gildeuretinol-alk-001-in-the-treatment-of-stargardt-disease/>, Ex. B.38. From this page I clicked Download Press Release, resulting in webpage, <https://alkeuspharma.com/wp-content/uploads/2023/10/Alkeus-June-5-2023-Press-Release.pdf>, and downloaded a PDF form of the press release. This resulted in the document downloaded and saved as **Exhibit 2097**.

XVI. EX 2107 (*Breakthrough Therapy 2018*)

32. This attestation relates to the public accessibility of FDA, *FDA Breakthrough Therapy, 2018 (Breakthrough Therapy 2018)*. I understand that *Breakthrough Therapy 2018* has been submitted as Exhibit 2017 in this proceeding.

33. Exhibit 2107 is a true and correct copy FDA, *FDA Breakthrough Therapy*, Retrieved from <https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/breakthrough-therapy> (2018). I confirmed this on September 23, 2024. On September 23, 2024, I accessed the publicly available website, <https://www.fda.gov/>, EX 2107.39. From that webpage,

I typed Breakthrough therapy accelerated approval priority in the search box and clicked the magnifying glass, which resulted in the webpage, <https://www.fda.gov/search?s=Breakthrough+therapy+accelerated+approval+priority>, EX 2107.40. I clicked the link for Fast Track Breakthrough Therapy Accelerated Approval Priority Review, which resulted in the webpage, <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>, EX2107.41. From here I clicked Breakthrough Therapy and downloaded the document PDF format as **Exhibit 2107**.

XVII. EX 2108 (*Alkeus Pharmaceuticals 2024*)

34. This attestation relates to the public accessibility of *Alkeus Pharmaceuticals (Alkeus Pharmaceuticals 2024)*. I understand that *Alkeus Pharmaceuticals 2024* has been submitted as **Exhibit 2108** in this proceeding.

35. Exhibit 2108 is a true and correct copy Alkeus Pharmaceuticals, Retrieved from <https://alkeuspharma.com/>, (2024). I confirmed this on September 23, 2024. On September 23, 2024, I accessed the publicly available website, <https://alkeuspharma.com/>, EX2108.42. I downloaded this webpage as, using the image as EX 2108.

XVIII. EX 2188 (FDA 2017)

36. This attestation relates to the public accessibility of FDA, FDA awards 15 grants to fund new clinical trials to advance the development of medical products for the treatment of rare diseases (2017). I understand that FDA 2017 has been submitted as **Exhibit 2188** in this proceeding.

37. **Exhibit 2188** is a true and correct copy FDA, FDA awards 15 grants to fund new clinical trials to advance the development of medical products for the treatment of rare diseases (2017). Retrieved from <https://www.fda.gov/news-events/press-announcements/fda-awards-15-grants-clinical-trials-stimulate-product-development-rare-diseases>). I confirmed this on September 23, 2024. On September 23, 2024, I accessed from the publicly available website, <https://www.fda.gov/>, EX 2107.39. In the search bar I entered FDA awards 15 grants fund new clinical and click the magnifying glass, which resulted in webpage, <https://www.fda.gov/search?s=FDA+awards+15+grants+to+fund+new+clinical+trials+to+advance+the+development+of+medical+products+for+the+treatment+of+rare+diseases+>, EX 2188.43. From there, I click the link for FDA awards 15 grants for clinical trials to stimulate product development for rare diseases and downloaded the page in PDF format as **EX 2188**.

XIX. EX 2189 (FDA 2018)

38. This attestation relates to the public accessibility of FDA, FDA awards 12 grants to fund new clinical trials to advance the development of medical products for the treatment of rare diseases (2018). I understand that FDA 2018 has been submitted as **Exhibit 2189** in this proceeding.

39. **Exhibit 2189** is a true and correct copy FDA, FDA awards 12 grants to fund new clinical trials to advance the development of medical products for the treatment of rare diseases, (2018). Retrieved from <https://www.fda.gov/news-events/press-announcements/fda-awards-12-grants-fund-new-clinical-trials-advance-development-medical-products-treatment-rare>. I confirmed this on September 23, 2024. On September 23, 2024, I accessed the publicly available website, <https://www.fda.gov/>, EX 2107.39. In the search bar I entered FDA awards 15 grants fund new clinical and click the magnifying glass, which resulted in webpage, <https://www.fda.gov/search?s=FDA+awards+12+grants+to+fund+new+clinical+trials+to+advance+the+development+of+medical+products+for+the+treatment+of+rare+diseases>, EX 2189.44. From there, I click the link for FDA awards 12 grants for clinical trials to stimulate product development for rare diseases and downloaded the page in PDF format as EX 2189.

XX. Conclusion

40. In signing this Declaration, I understand it will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I understand I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

41. I declare that all statements made herein of my knowledge are true, that all statements made on information and belief are believed to be true, and 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.

Executed on __September 23, 2024__, in the District of Columbia.



Kelley M. Hayes Greenhill
