

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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GENE COMPANY PTY LTD,  
Petitioner,

v.

THE TRUSTEES OF COLUMBIA UNIVERSITY  
IN THE CITY OF NEW YORK,  
Patent Owner.

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Case IPR2024-00313  
Patent No. RE47,045

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**PETITIONER'S OPPOSITION TO  
PATENT OWNER'S MOTION TO SEAL**

## **I. INTRODUCTION**

Patent Owner (PO)'s Motion (Mot., Paper 34) to seal is conclusory, unsupported, and seeks to seal non-competitively-sensitive information that is already publicly available. PO seeks to redact information from nearly fifty different question/answers from the deposition transcript of Leonide Saad (EX1079), and portions of the Petitioner's Reply (Paper 32) citing the same, under enhanced protections for "Outside Counsel Only" confidential material. Mot., 1. PO offers only the vague, conclusory, and undifferentiated rationale that the redactions may discuss (1) the conduct of the TEASE and SAGA clinical trials; or (2) Alkeus's internal research and development operations. Mot., 3. But the Motion's non-specific, blanket characterization does not satisfy the standard for sealing, much less the "Outside Counsel Only" confidential designation threshold provided in its very own proposed protective order. PO does not demonstrate the information is competitively-sensitive. Moreover, much (if not all) of the redacted Q/A corresponds to publicly available information. Accordingly, PO's Motion to redact nearly fifty question/answers should be denied.

## **II. LEGAL STANDARD**

All papers filed in an IPR are presumptively made open to the public unless the party seeking to seal demonstrates good cause commensurate in scope with the confidential information the movant seeks to seal. 35 U.S.C. §316(a)(1), (7); 37

C.F.R. §42.54. Public policy favors public access to Board proceedings and motions to seal are only granted “for good cause.” *Garmin v. Cuozzo*, IPR2012-00001, Paper 34 at 1-3 (quoting 37 C.F.R. § 42.54); *see also Apple Inc. v. Samsung Electronics Co. Ltd.*, 727 F.3d 1214, 1221 (Fed. Cir. 2013) (courts have recognized a general right to inspect and copy public records and documents). The Board will only grant a motion to seal to protect “truly sensitive information” in a manner consistent with Fed. R. Civ. Pro. 26(c)(1)(G), “which provides for protective orders for trade secret or other confidential research, development, or commercial information.” Consolidated Trial Practice Guide, 19-20 (Nov. 2019) (citing 37 C.F.R. § 42.14). 42.54. By its own terms, PO’s proposed protective order applies the onerous “Outside Counsel Only” designation only to “confidential information that has not been made publicly available ***and*** that is competitively sensitive—i.e., if disclosed, could reasonably be used to inform or guide business decisions that would compete with or otherwise harm the designating party.”<sup>1</sup> Mot., Appendix A (¶3). Accordingly, non-confidential information, and information that is not ***competitively-sensitive***, will not be sealed.

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<sup>1</sup> All bold-italic emphases are added.

### III. OPPOSITION

PO's motion is conclusory, vague, and unsupported, and should therefore be denied. PO alleges the redactions for nearly fifty questions/answers contain no publicly available information and either relate to (1) "proprietary research methods, including clinical protocols for Alkeus's Gildeuretinol drug product"; or (2) "internal operations information [that] reveals proprietary analytical methods and training procedures that, if made public, would allow competitors to gain competitive insights into Alkeus's business practices." Mot., 4. But PO does not identify which redactions are allegedly for "proprietary research methods," nor does it provide any justification for alleging that any redactions cover "proprietary" information. Instead, PO's redactions correspond to information that is already publicly available. Moreover, PO does not come close to demonstrating any ***unfair competitive disadvantage*** from public disclosure of the redactions.

For the convenience of the Board, the chart below provides a list of questions/answers in the public version of EX1079 with redactions that PO has not justified.

|   | Redaction                    |  | Motion Justification |
|---|------------------------------|--|----------------------|
| 1 | EX1079 (Public), 36:21.      |  | None                 |
| 2 | EX1079 (Public), 83:18-24.   |  | None                 |
| 3 | EX1079 (Public), 83:25-84:3. |  | None                 |

|    |                             |  |      |
|----|-----------------------------|--|------|
| 4  | EX1079 (Public), 84:6-12.   |  | None |
| 5  | EX1079 (Public), 87:14-88:3 |  | None |
| 6  | EX1079 (Public), 88:7-8.    |  | None |
| 7  | EX1079 (Public), 88:9-14.   |  | None |
| 8  | EX1079 (Public), 88:14-18.  |  | None |
| 9  | EX1079 (Public), 88:19-22.  |  | None |
| 10 | EX1079 (Public), 88:23-25.  |  | None |
| 11 | EX1079 (Public), 89:1-4.    |  | None |
| 12 | EX1079 (Public), 89:5-8.    |  | None |
| 13 | EX1079 (Public), 89:9-11.   |  | None |
| 14 | EX1079 (Public), 89:12-13.  |  | None |
| 15 | EX1079 (Public), 89:14-15.  |  | None |
| 16 | EX1079 (Public), 89:16-19.  |  | None |
| 17 | EX1079 (Public), 89:20-24.  |  | None |
| 18 | EX1079 (Public), 91:13-16.  |  | None |
| 19 | EX1079 (Public), 92:21-25.  |  | None |
| 20 | EX1079 (Public), 93:1-3.    |  | None |
| 21 | EX1079 (Public), 93:4-5, 9. |  | None |
| 22 | EX1079 (Public), 93:10-13.  |  | None |

|    |                                 |  |      |
|----|---------------------------------|--|------|
| 23 | EX1079 (Public), 93:14-17.      |  | None |
| 24 | EX1079 (Public), 93:18-21.      |  | None |
| 25 | EX1079 (Public), 93:22-24.      |  | None |
| 26 | EX1079 (Public), 93:25-94:2.    |  | None |
| 27 | EX1079 (Public), 94:3-8.        |  | None |
| 28 | EX1079 (Public), 94:10-12.      |  | None |
| 29 | EX1079 (Public), 94:13-16.      |  | None |
| 30 | EX1079 (Public), 213:8-15.      |  | None |
| 31 | EX1079 (Public), 214:2-8.       |  | None |
| 32 | EX1079 (Public), 216:1-8.       |  | None |
| 33 | EX1079 (Public), 216:9-12.      |  | None |
| 34 | EX1079 (Public), 216:13-15.     |  | None |
| 35 | EX1079 (Public), 216:25-217:3.  |  | None |
| 36 | EX1079 (Public), 217:15-24.     |  | None |
| 37 | EX1079 (Public), 217:25-218:1.  |  | None |
| 38 | EX1079 (Public), 218:5-9.       |  | None |
| 39 | EX1079 (Public), 226:25-227:10. |  | None |
| 40 | EX1079 (Public), 231:11-15.     |  | None |
| 41 | EX1079 (Public), 234:9-13.      |  | None |

|    |                                |  |      |
|----|--------------------------------|--|------|
| 42 | EX1079 (Public), 234:20-235:3. |  | None |
| 43 | EX1079 (Public), 235:9-11.     |  | None |
| 44 | EX1079 (Public), 235:16-24.    |  | None |
| 45 | EX1079 (Public), 236:13-24.    |  | None |
| 46 | EX1079 (Public), 236:25-237:2. |  | None |

**A. PO Fails To Demonstrate Confidentiality and Competitive-Sensitivity of the Redactions Despite Public Information**

PO's conclusory assertion that the redactions disclose clinical trial research methods, or internal analytical methods or training procedures (Mot., 4), are facially insufficient to establish either confidentiality or competitive-sensitivity in light of the publicly-available information.

Alkeus long ago publicized its decision to conduct the science *in-house*, using a limited number of Alkeus personnel. For example, PO publicly submitted publicity based on an interview Dr. Saad gave in 2015. EX2179, 3. The publicity piece explained for Alkeus that “most of its actual science is done in-house” and that expert contract development critical to “the required Good practice umbrella” would be delayed until “[a]fter scientific milestones have been achieved.” EX2179, 3. Dr. Washington thus applied “great attention to scientific details, while [Dr. Saad] focused on...day-to-day operation” and “value-adding activities instead of employee management.” EX2179, 3.

Eight years later, Alkeus went back to the media, publicly claiming that Dr. Saad undertook this hands-on approach with essentially only a single employee. EX1081, 2 (“Unlike most biotech startups, Alkeus has been run by one person for most of its existence.”), 3 (“Saad ran Alkeus himself”), 3 (Saad was “reluctant to relinquish control”); EX1084, 2-3 (“from 2010 until 2018, Alkeus was a one-man show” because Dr. Saad wanted “to do it myself”), 3 (“Saad hired a second employee in 2018 to oversee clinical operations” but decided to wait to expand the company further “to await clinical results”), 4 (“Alkeus is slated to go from a two-person enterprise”); EX1086, 03 (“a company that only had one employee for most of its history”), 04 (“[Saad] went so far as to travel personally to all of the clinical sites to make sure the protocol was understood and followed correctly—normally the work of an expensive Contract Research Organization.”). In the face of these public disclosures and claims by Alkeus to the press, PO’s redactions to the Saad deposition transcript are perplexing and unsupported.

The unredacted portions of the Saad deposition transcript only deepen the mystery of how PO can hope to justify its redactions. Dr. Saad testified publicly that this single employee he hired in the 2017-2018 time-frame was named Gabrielle, that she was a pre-med student at the time with no advanced degree, no prior experience grading retinal images, and no training as an ophthalmologist. EX1079 (Public), 89:25-91:12. Dr. Saad disclosed in the public record that he had

never graded retinal images prior to his work at Alkeus, that Dr. Washington (who is not an ophthalmologist) trained Dr. Saad to grade retinal images, and that Dr. Saad then trained Gabrielle to delineate multiple images, verify the accuracy, and verify the test-retest variability. EX1079 (Public), 92:1-3, 92:4-7, 91:17-21. Dr. Saad disclosed publicly that Dr. Washington's involvement in the "scientific part" included "looking at an image" for "the database grading" and "provid[ing] some opinions," but that Dr. Washington did not perform the database grading systematically "over time." EX1079 (Public), 92:8-20. Dr. Saad testified publicly that "Doing it in-house allows you to do it at your own pace, allows you to have high-quality results, allows you to—and has no cost associated with it except that as of your own employees' time." EX1079 (Public), 94:18-22. He also publicly disclosed that he and Gabrielle DeBartolomeo were the ones who personally visited the clinical sites in the TEASE-1 study to oversee the physicians and to "verify the data." EX1079 (Public), 121:14-123:23 ("Q. Did you visit all of the clinical sites? A. I did...Performing the oversight."). PO's assertions that the redactions are either confidential or proprietary thus fail to pass even the most basic scrutiny.

PO's inability to distinguish between confidential and public information is well illustrated by its baseless assertions that the Alkeus practice of relying extensively on unqualified interns to perform its clinical trials was an Alkeus trade

secret. EX1079 (Public), 190:3-5 (“The next intern. There’s going to be a lot.”), 181:7-183:3 (PO counsel incorrectly asserting Alkeus’s use of interns to perform its clinical studies was “commercially sensitive” and “misappropriated confidential information” before Dr. Saad admitted in the face of public documents from the internet his practice of hiring “interns over the years”). These interns included undergraduate students and others who lacked appropriate qualifications. EX1079 (Public), 183:3-190:2 (Dr. Saad hired an undergraduate pre-dental student as a “Clinical operations intern” who “reviewed ocular imagery” and performed “data entry and verification” and organized the “TEASE” study data); EX1074 (LinkedIn: Same); EX1079 (Public), 190:8-193:17 (Dr. Saad hired a “Clinical trial associate intern” who performed “source document review” and “statistical analyses on trial data to assist in planning future trials”); EX1075 (LinkedIn: Same); EX1076 (pre-med student’s LinkedIn recording she was employed by Alkeus May 2017-2019 to coordinate the “Phase 2 Tolerability and Effects of ALK-001 on Stargardt Disease (TEASE), NCT02402660,” was tasked with “acquiring all endpoints for patients enrolled at Columbia Harkness Eye Institute,” and served as liaison between trial participants and Alkeus’s “CEO”); EX1079 (Public), 193:20-197:7 (authenticating the individual but disputing her employment status); EX1079 (Public), 197:8-200:18 (“Clinical operations intern, Alkeus Pharmaceuticals Inc.” engaged in “management of ongoing clinical trials” and in

clinical “data collection and analysis”); EX1077 (LinkedIn: Same); EX1079 (Public), 200:19-204:3 (Alkeus intern was an undergraduate student who assisted in “clinical data collection and analysis”); EX1078 (LinkedIn: Same). PO’s Motion thus appears to be nothing more than a tactic to hide from the public the deficient manner in which it performed its clinical trials.

To the extent PO argues these deficiencies are proprietary, competitively-sensitive trade secrets, this argument is baseless. PO’s own clinician already testified that clinical trials should be conducted using qualified readers at independent reading centers, reading fully-masked images to prevent bias. EX1069, 224:7-225:20 (“It prevents somebody from saying oh, yeah, this drug appears to be working because they know that picture A actually came two years before picture B.”). Image scoring should be adjudicated independently before results are known or reported, and a sponsoring-company executive should never be adjudicating the images. EX1069, 225:21-227:18 (“In my opinion, that would not have been appropriate.”). In the face of the admitted safeguards that should be followed, PO has not explained how the material it redacted could conceivably qualify as proprietary, competitively-sensitive business information.

#### **B. PO’s Selective Redactions Mislead the Public**

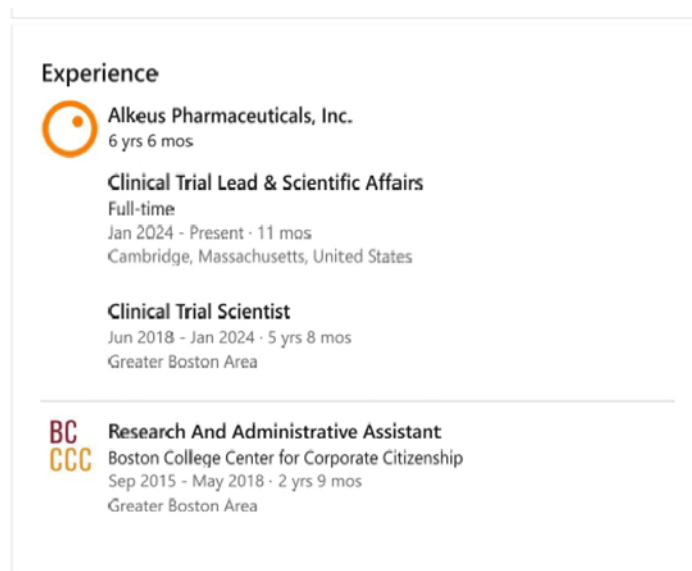
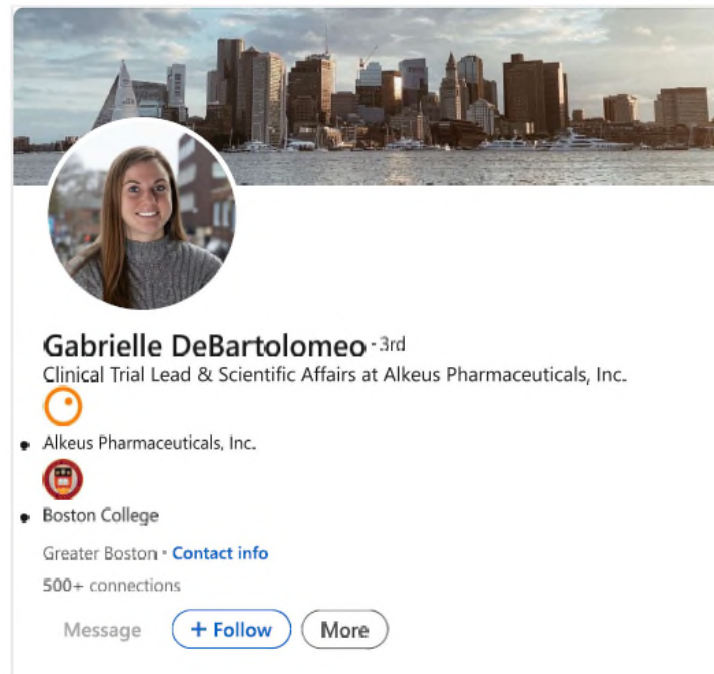
PO’s selective redactions are particularly problematic because they risk misleading the public regarding PO’s clinical trial procedures. PO touts interim

study results while hiding from the public how they were obtained. Petitioner cannot explain more in this brief without discussing the redacted material. But the Board's sealing procedures do not exist to facilitate a patent owner's misrepresentations to the public. Nor do the Board's sealing procedures exist to spare the patent owner from embarrassment resulting from publicly disclosing how it carried out the very trials it is relying on to try to support the patentability of the patent at issue.

### **C. PO's Confidentiality Certification Deserves No Weight**

PO has a pattern of designating materials as confidential when they are not—and failing to justify the confidentiality burdens it imposes on the Board and the parties. PO previously filed a motion to seal material that it concurrently filed in the public record, unnecessarily shifting to Petitioner and the Board the costs of dealing with PO's confidentiality designations. *See* Paper 26.

PO's present Motion and non-publication certification (Mot., 5) fare no better. For example, Gabrielle DeBartomoleo's public LinkedIn profile openly declares her job titles at Alkeus:



<https://www.linkedin.com/in/gabrielle-debartolomeo/>

Yet PO redacts the Saad transcript broadly and without justification. EX1079 (Public), 89:14-24 (redacted).

As another example, PO presented its clinical protocols publicly on the

internet *months before* filing this Motion. EX1087, 08 (apples-to-oranges measurement of siblings vs. study participants in TEASE 3). Yet PO again redacts the Saad transcript broadly and without justification EX1079 (Public), 83:18-24, 83:25-84:3, 84:6-12 (redacted). These are just a few examples demonstrating the baselessness of PO's confidentiality certification. PO's conclusory and incorrect assertions of confidentiality and competitive-sensitivity should be afforded no deference.

#### IV. CONCLUSION

In light of PO's failure to support its requested relief and the impending final hearing in this case, PO's request to seal the redactions (other than Dr. Saad's private address) should be promptly *denied*.

Respectfully submitted,

Date: February 3, 2025

/ Jad A. Mills /  
Jad A. Mills, Lead Counsel  
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**CERTIFICATE OF SERVICE**

I certify that the foregoing Petitioner's Opposition to Patent Owner's Motion to Seal was served on this 3rd day of February, 2025, on the Patent Owner at the electronic service addresses as follows:

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