

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

**PATENT OWNER'S MOTION TO SEAL AND
FOR ENTRY OF PROTECTIVE ORDER
UNDER 37 C.F.R. §§ 42.14 & 42.54**

Pursuant to 37 C.F.R. §§ 42.14 and 42.54, Patent Owner moves for entry of the attached Protective Order and to seal portions of the Deposition Transcript of Leonide Saad, Ph.D (EX1079) and Petitioner's Reply (Paper 32; "Pet. Reply").

I. Introduction

Patent Owner previously moved for entry of the Board's Default Protective Order and to seal EX2094. *See* Paper 22. As indicated in the previous motion, the embargo requiring EX2094 to be confidential has been lifted, and the information is now public. *Id.* at 2. Patent Owner has filed an unsealed copy of the exhibit.

Patent Owner now seeks to seal portions of the Deposition Transcript of Leonide Saad, Ph.D. (EX1079) and Petitioner's Reply. As explained below, the Deposition Transcript contains highly confidential information that requires a modified protective order. Petitioner's Reply cites to portions of EX1079 that contain highly confidential information. Pet. Reply, 20-21. Good cause exists to seal portions of EX1079 and Petitioner's Reply. Petitioner was contacted and does not oppose the entry of the modified default protective order, but did not take a position on this motion to seal.

II. Request to Seal

Patent Owner asks the Board to seal portions of EX1079 and Petitioner's Reply. The portions which Patent Owner seeks to seal have been redacted from the publicly-filed version of EX1079 and Petitioner's Reply.

A. Governing Rules and PTAB Guidance

Under 35 U.S.C. § 316(a)(1), the default rule is that all papers and documents filed in an *inter partes* review are open and publicly available. A party’s paper or document may be accompanied by a motion to seal, and the information at issue is treated as sealed pending the outcome of the motion. 35 U.S.C. § 316(a)(1). Only “confidential information,” is protected from disclosure. 35 U.S.C. § 316(a)(7) (“The Director shall prescribe regulations . . . providing for protective orders governing the exchange and submission of confidential information”). In that regard, the Consolidated Trial Practice Guide provides:

The rules aim to strike a balance between the public’s interest in maintaining a complete and understandable file history and the parties’ interest in protecting truly sensitive information.

* * *

Confidential Information: The rules identify confidential information in a manner consistent with Federal Rule of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information. 37 C.F.R § 42.54.

Consolidated Trial Practice Guide November 2019 at 19. Ultimately, “[t]he standard for granting a motion to seal is ‘good cause,’” which “includes showing the

information addressed in the motion is truly confidential, and that such confidentiality outweighs the strong public interest in having an open record.” *See Grimco, Inc. v. Principal Lighting Grp., LLC*, IPR2021-00968, Paper 46 at 3 (PTAB Nov. 18, 2022); 37 C.F.R. § 42.54.

B. The Confidential Information

Exhibit 1079 contains competitively sensitive, non-public, and confidential research, development, or commercial information. For example, the Deposition Transcript contains confidential information about the conduct of TEASE and SAGA clinical trials and Alkeus Pharmaceuticals, Inc.’s (“Alkeus’s”) internal research and development operations.¹ (EX1079 at 36:21, 83:18-19, 83:21-84:3, 84:6-8, 84:10-12, 87:14-88:3, 88:7-89:24, 91:13-16, 92:21-93:5, 93:9-94:8, 94:10-16, 213:8-9, 213:11-15, 214:2-3, 214:5-8, 216:1-4, 216:8-15, 216:25-217:3, 217:15-218:1, 218:5-9, 226:25-227:10, 231:11-15, 234:9-13, 234:20-24, 235:1-3, 235:9-11, 235:16-21, 235:23-24, 236:13-17, 236:20-237:2)². Petitioner relies on the information in the italicized citations in its Reply. Pet. Reply, 20-21.

¹ Alkeus is the exclusive licensee of Patent No. RE47,045 and a real party in interest in these proceedings. Paper 4 at 2.

² EX1079 at 6:16 has also been redacted as it discloses the personal address of Dr. Leonide Saad, which is sensitive personal information. Shielding his address from the public view will not impact the public’s interest in maintaining a complete and understandable file history. The address of Alkeus is public information. Thus, good cause exists to seal this information. *See Dong Guan Leafy Windoware Co. LTD. v.*

C. Good Cause Exists for Sealing the Confidential Information

There is good cause to seal EX1079 and Petitioner's Reply.

Exhibit 1079 includes confidential and highly sensitive business information of Patent Owner's RPI, Alkeus. In particular, EX1079 includes highly sensitive information regarding the conduct of clinical trials and internal operations at Alkeus that have been maintained as confidential and are not publicly available.

Alkeus faces concrete harm if the confidential information is released to the public. The confidential information related to the clinical trials includes proprietary research methods, including clinical protocols for Alkeus's Gildeuretinol drug product. If disclosed, competitors and other third parties could gain unfair competitive advantages by accessing Alkeus's trial design and analytical methods. Similarly, the internal operations information reveals proprietary analytical methods and training procedures that, if made public, would allow competitors to gain competitive insights into Alkeus's business practices. Petitioner relies on portions of this information in its Reply. Pet. Reply, 20-21.

The potential harm to Alkeus from public disclosure outweighs any public interest in accessing this information. The public record will reflect the general substance and significance of these documents, and the requested redactions are

Anli Spring Co. LTD, PGR2020-00001, Paper 15 at 3-5 (May 22, 2020) (sealing personal information including personal addresses).

narrowly tailored to protect only specific confidential details about Alkeus's clinical trials and internal operations. The public's interest in accessing these details is minimal compared to the competitive harm Alkeus would suffer from their disclosure.

Accordingly, good cause exists for sealing EX1079 and Petitioner's Reply, and Patent Owner respectfully moves to file these documents under seal.

III. CERTIFICATION OF NON-PUBLICATION

The undersigned counsel certifies the information sought to be sealed by this Motion to Seal has not, to their knowledge, been published or otherwise made public.

IV. Protective Order

Patent Owner respectfully requests that the Board enter the revised Protective Order, attached as Appendix A, to protect the highly sensitive and confidential information in EX1079 and Petitioner's Reply. The Parties agreed to a modified version of the Default Protective Order (Consolidated Trial Practice Guide November 2019 at 117-22). Compared to the Default Protective Order, the revised Protective Order in Appendix A contains an additional designation "PROTECTIVE ORDER MATERIAL – OUTSIDE ATTORNEYS' EYES ONLY" for confidential material and restricts the material to Outside Counsel, Experts, Office Staff and Support Personnel. In addition, the revised Protective Order provides that Support Personnel shall also include support personnel of outside counsel of record for a

party in the proceeding. *See* Appendix B (redline version showing changes to the Default Protective Order).

Good cause exists for these restrictions as the Board has recognized a necessity for similar designations on confidential material in other IPR proceedings. *See, e.g., Mylan Lab 'ys Ltd. v. Aventis Pharm. S.A.*, IPR2016-00712, Paper 35 at 3 (granting motion to seal exhibits disclosing “confidential clinical research information”); *Celltrion, Inc. v. Genentech, Inc.*, IPR2016-01667, Paper 20 at 3 (granting motion to seal exhibits including “non-public research and development information in the form of proprietary clinical and scientific data concerning [the drug product], and confidential information about drug development and regulatory approval strategies.”). Here, the parties are competitors, and the more limited access provided by the “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY” designation is necessary to protect Patent Owner’s confidential information from potential use by other companies and/or potential exposure to the public. Moreover, the PTAB Consolidated Trial Practice Guide states that “the parties may agree to modify the Default Protective Order to provide additional tiers or categories of confidential information, such as ‘Attorneys’ Eyes Only,’” and that “[t]he Board will presumptively accept agreed-to changes that provide additional categories of confidentiality as long as they are reasonable and adequately define what types of materials are to be included in the additional categories.” Consolidated Trial Practice

Guide November 2019 at 115-116. The Parties in this proceeding have agreed to the additional designation “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY,” and the proposed revised Protective Order reasonably limits its applicability 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.” *See* Appendix A, ¶3.

V. CONCLUSION

For the reasons set forth above, Patent Owner respectfully requests the Board grant this motion to seal and enter the revised Protective Order.

Respectfully submitted,

Dated: January 3, 2025

/Mark J. Feldstein/

Mark J. Feldstein, Reg. No. 46,693

Counsel for Patent Owner

The Trustees of Columbia University in the
City of New York

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing PATENT OWNER'S MOTION TO SEAL AND FOR ENTRY OF PROTECTIVE ORDER UNDER 37 C.F.R. §§ 42.14 & 42.54 was served electronically via email on January 3, 2025, in its entirety on the following:

Jad A. Mills
Michael T. Rosato
Matthew Bresnahan
WILSON SONSINI GOODRICH & ROSATI
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mbresnahan@wsgr.com

Petitioner has consented to electronic service.

Dated: January 3, 2025

/William Esper/
William Esper
Legal Assistant and PTAB Coordinator
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.

APPENDIX A

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PROTECTIVE ORDER

PROTECTIVE ORDER

The following Protective Order will govern the filing and treatment of confidential information in IPR2024-00313.

Protective Order

This protective order governs the treatment and filing of confidential information, including documents and testimony.

1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL” or “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY.”

2. Access to confidential information marked “PROTECTIVE ORDER MATERIAL” is limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Parties. Persons who are owners of a patent involved in the proceeding and other persons who are named parties to the proceeding.

(B) Party Representatives. Representatives of record for a party in the proceeding who are not also in-house counsel for a party.

(C) Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding, provided that:

- i. such experts are not presently employed by the Parties or of an affiliate of a Party hereto for purposes other than this Action;
- ii. before access is given, the expert's signed Acknowledgment is served upon the producing Party with a current curriculum vitae of the expert, including a list of other cases in which the expert has provided a report or testified (at trial or deposition) and a list of companies that the expert has been employed by or provided consulting services pertaining to the field of the invention of the challenged patents or the products accused of infringement within the last four years and a brief description of the subject matter of the consultancy or employment, at least seven (7) days before access to material designated pursuant to Section 1 is to be given to that expert, to allow the producing Party to object to and notify the receiving Party in writing that it objects to disclosure of such material to the expert. The Parties agree to promptly confer and use good faith to resolve any such objection. If the Parties are unable to resolve any objection, either Party may—within seven (7) days of receipt of the notice, or within such other time as the Parties may agree— request authorization from the Board to file a motion with

the Board seeking a protective order with respect to the proposed disclosure. No disclosure shall occur until all such objections are resolved by agreement or Board order.

(D) In-House Counsel. In-house counsel of a party.

(E) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

(F) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

3. Access to confidential information marked “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY” is limited to the individuals in Section 2(F), and those individuals in Section 2(B)-(C) and (E) who have executed

the acknowledgment appended to this order, provided that for purposes of this Section 3, individuals permitted access pursuant to Section 2(E) shall be limited to only those individuals directly assisting individuals in Section 2(B)-(C). For clarity, the omission of individuals in Section 2(D) is intended to preclude in-house counsel for the non-disclosing party from accessing the disclosing party's confidential information; it is not intended to preclude in-house counsel for a disclosing party from accessing the disclosing party's own confidential information. The "PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY" designation shall be applied 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.

4. Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than those persons identified above in Section 2(A)–(E), shall be extended access to confidential information only upon agreement of the parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the burden of proving that such person should be restricted from access to confidential information.

5. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

(A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;

(B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient uses to maintain the confidentiality of information not received from the disclosing party;

(C) Ensuring that support personnel of the recipient who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and

(D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

6. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

(A) Documents and Information Filed with the Board.

i. A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-

confidential description of the nature of the confidential information that is under seal and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The documents or information shall remain under seal unless the Board determines that some or all of it does not qualify for confidential treatment.

- ii. Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain

under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties.

- i. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to another party during discovery or other proceedings before the Board shall be clearly marked as “PROTECTIVE ORDER MATERIAL” or “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY” and shall be produced in a manner that maintains its confidentiality.

7. Within 60 days after the final disposition of this action, including the exhaustion of all appeals and motions, each party receiving confidential information must return, or certify the destruction of, all copies of the confidential information to the producing party.

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Standard Acknowledgment for Access to Protective Order Material

I _____, affirm that I have read the Protective Order; that I will abide by its terms; that I will use the confidential information only in connection with this proceeding and for no other purpose; that I will only allow access to support staff who are reasonably necessary to assist me in this proceeding; that prior to any disclosure to such support staff I informed or will inform them of the requirements of the Protective Order; that I am personally responsible for the requirements of the terms of the Protective Order and I agree to submit to the jurisdiction of the Office and the United States District Court for the Eastern District of Virginia for purposes of enforcing the terms of the Protective Order and providing remedies for its breach.

[Signature]

APPENDIX B

UNITED STATES PATENT AND TRADEMARK OFFICE

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~~DEFAULT~~ PROTECTIVE ORDER

~~DEFAULT~~ PROTECTIVE ORDER

The following ~~Default~~ Protective Order will govern the filing and treatment of confidential information in IPR2024-00313 ~~the proceeding~~.

~~Default~~ Protective Order

This protective order governs the treatment and filing of confidential information, including documents and testimony.

1. Confidential information shall be clearly marked “PROTECTIVE ORDER MATERIAL” or “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY.””

2. Access to confidential information ~~is~~ marked “PROTECTIVE ORDER MATERIAL” ~~is~~ limited to the following individuals who have executed the acknowledgment appended to this order:

(A) Parties. Persons who are owners of a patent involved in the proceeding and other persons who are named parties to the proceeding.

(B) Party Representatives. Representatives of record for a party in the proceeding who are not also in-house counsel for a party.

(C) Experts. Retained experts of a party in the proceeding who further certify in the Acknowledgement that they are not a competitor to any party, or a consultant for, or employed by, such a competitor with respect to the subject matter of the proceeding, provided that:

i. such experts are not presently employed by the Parties or of an affiliate of a Party hereto for purposes other than this Action;

~~i.~~ii. before access is given, the expert's signed Acknowledgment is served upon the producing Party with a current curriculum vitae of the expert, including a list of other cases in which the expert has provided a report or testified (at trial or deposition) and a list of companies that the expert has been employed by or provided consulting services pertaining to the field of the invention of the challenged patents or the products accused of infringement within the last four years and a brief description of the subject matter of the consultancy or employment, at least seven (7) days before access to material designated pursuant to Section 1 is to be given to that expert, to allow the producing Party to object to and notify the receiving Party in writing that it objects to disclosure of such material to the expert. The Parties agree to promptly confer and use good faith to resolve any such objection. If the Parties are unable to resolve any objection, either Party may—within seven (7) days of receipt of the notice, or within such other time as the Parties may agree— request authorization from the Board to file a motion with

the Board seeking a protective order with respect to the proposed disclosure. No disclosure shall occur until all such objections are resolved by agreement or Board order.

(D) In-House Counsel. In-house counsel of a party.

(E) Support Personnel. Administrative assistants, clerical staff, court reporters and other support personnel of the foregoing persons who are reasonably necessary to assist those persons in the proceeding shall not be required to sign an Acknowledgement, but shall be informed of the terms and requirements of the Protective Order by the person they are supporting who receives confidential information.

(F) The Office. Employees and representatives of the United States Patent and Trademark Office who have a need for access to the confidential information shall have such access without the requirement to sign an Acknowledgement. Such employees and representatives shall include the Director, members of the Board and their clerical staff, other support personnel, court reporters, and other persons acting on behalf of the Office.

3. Access to confidential information is marked “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY” is limited to the individuals in Section 2(F), and those individuals in Section 2(B)-(C) and (E) who have executed

the acknowledgment appended to this order, provided that for purposes of this Section 3, individuals permitted access pursuant to Section 2(E) shall be limited to only those individuals directly assisting individuals in Section 2(B)-(C). For clarity, the omission of individuals in Section 2(D) is intended to preclude in-house counsel for the non-disclosing party from accessing the disclosing party's confidential information; it is not intended to preclude in-house counsel for a disclosing party from accessing the disclosing party's own confidential information. The "PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY" designation shall be applied 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.

3.4. Employees (e.g., corporate officers), consultants, or other persons performing work for a party, other than ~~in-house counsel and in-house counsel's support staff, who sign the Acknowledgement~~ those persons identified above in Section 2(A)–(E), shall be extended access to confidential information only upon agreement of the parties or by order of the Board upon a motion brought by the party seeking to disclose confidential information to that person and after signing the Acknowledgment. The party opposing disclosure to that person shall have the

burden of proving that such person should be restricted from access to confidential information.

4.5. Persons receiving confidential information shall use reasonable efforts to maintain the confidentiality of the information, including:

- (A) Maintaining such information in a secure location to which persons not authorized to receive the information shall not have access;
- (B) Otherwise using reasonable efforts to maintain the confidentiality of the information, which efforts shall be no less rigorous than those the recipient uses to maintain the confidentiality of information not received from the disclosing party;
- (C) Ensuring that support personnel of the recipient who have access to the confidential information understand and abide by the obligation to maintain the confidentiality of information received that is designated as confidential; and
- (D) Limiting the copying of confidential information to a reasonable number of copies needed for conduct of the proceeding and maintaining a record of the locations of such copies.

5.6. Persons receiving confidential information shall use the following procedures to maintain the confidentiality of the information:

- (A) Documents and Information Filed with the Board.

- i. A party may file documents or information with the Board along with a Motion to Seal. The Motion to Seal should provide a non-confidential description of the nature of the confidential information that is under seal and set forth the reasons why the information is confidential and should not be made available to the public. A party may challenge the confidentiality of the information by opposing the Motion to Seal. ~~The The submission shall be treated as confidential and remain under seal, unless the Board determines that the documents or information do not to qualify for confidential treatment. The information~~ shall remain under seal unless the Board determines that some or all of ~~the information~~it does not qualify for confidential treatment.
- ii. Where confidentiality is alleged as to some but not all of the information submitted to the Board, the submitting party shall file confidential and non-confidential versions of its submission, together with a Motion to Seal the confidential version setting forth the reasons why the information redacted from the non-confidential version is confidential and should not be made available to the public. A party may challenge the confidentiality of the information

by opposing the Motion to Seal. The non-confidential version of the submission shall clearly indicate the locations of information that has been redacted. The confidential version of the submission shall be filed under seal. The redacted information shall remain under seal unless the Board determines that some or all of the redacted information does not qualify for confidential treatment.

(B) Documents and Information Exchanged Among the Parties.

- i. Documents (including deposition transcripts) and other information designated as confidential that are disclosed to another party during discovery or other proceedings before the Board shall be clearly marked as “PROTECTIVE ORDER MATERIAL” or “PROTECTIVE ORDER MATERIAL – OUTSIDE COUNSEL ONLY” and shall be produced in a manner that maintains its confidentiality.

6.7. Within 60 days after the final disposition of this action, including the exhaustion of all appeals and motions, each party receiving confidential information must return, or certify the destruction of, all copies of the confidential information to the producing party.

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[Signature]