

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

I. Introduction

Counsel for Petitioner and its RPI, Belite Bio, deposed Dr. Saad for nearly six hours with some 800 questions in response to a less-than-20-page declaration. Counsel knowingly and intentionally sought confidential information belonging not to Patent Owner but to Alkeus. Its defense for this overly invasive examination was that “[i]f there are concerns at any point about confidentiality, then the remedy for that is to designate the transcript confidential.” EX1079, 25:7-27:4, 40:17-21. Patent Owner has done just that: designated the transcript confidential and filed the present Motion to Seal to protect Alkeus’s confidential information. Petitioner nevertheless opposes (Opp., Paper 36) the Motion to Seal by misrepresenting that redacted information is public.

Petitioner fails to dispute, however, that Patent Owner’s redactions cover (1) “proprietary research methods, including clinical protocols for Alkeus’s Gildeuretinol drug product” and (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.”¹

¹ While the context of Patent Owner’s redactions of EX1079, 87:14-89:24 is expressly directed to confidential clinical trial information, Patent Owner withdraws its request to seal the testimony therein at 89:14-15 and 89:23-24 that relate to an

Mot., 4. Petitioner’s flood-the-zone strategy identifying *other* information that may be public does not make the redacted information any less confidential or commercially sensitive. The confidentiality concerns are amplified given that the redacted information could be used by Alkeus’s competitor—Petitioner’s RPI Belite Bio—in its own clinical trials. *See Dealer Computer Services, Inc. v. Muller*, No. CV 21-19811, 2024 WL 4252703, at *3 (D.N.J. Sept. 20, 2024) (“[A] non-party to litigation is afforded greater protection from discovery than a party.”).

Petitioner’s multi-page list asserting that Patent Owner has not justified its redactions is conclusory and inaccurate. *See* Opp. 3-6. The Motion specifically articulated the bases and good cause for its redactions. Mot. 4-6, 7-8. Patent Owner explained that the redactions “contain[] confidential information about the conduct of TEASE and SAGA clinical trials and [Alkeus’s] internal research and development operations.” *Id.* at 4. Patent Owner highlighted that this information is competitively sensitive, proprietary, and non-public, and it would give competitors an unfair competitive advantage. *Id.* at 4-6. Patent Owner further supported its Motion by relying on the Board’s routine practice of authorizing redactions of

employee’s title. Notably, Petitioner only now raises any issue with these redactions, notwithstanding all proposed redactions having been provided to Petitioner with Patent Owner’s proposed modified protective order in advance of filing.

confidential clinical trial information, *id.* at 7, which Petitioner neither responds to nor disputes.

Finally, Petitioner asserts that Patent Owner “redacts the Saad transcript broadly” (Opp. 12) and implies that redactions “from nearly fifty different question/answers” from the transcript are somehow overinclusive (Opp. 1, 3). To the contrary, given the invasive scope of the deposition—nearly 6 hours and 800 questions in response to a short declaration—redactions from less than fifty question/answers reflects a conservative, narrowly tailored, and wholly appropriate scope.

II. Patent Owner’s Redacted Materials Are Not Public and Do Not Mislead

Petitioner falsely and misleadingly represents that the redacted materials are public by pointing to *general* statements to improperly imply that *specific* information is public. *See* Opp. 6-10.

For example, Petitioner argues it was publicly known that “most of [Alkeus’s] actual science is done in-house” such that specific information redacted is not confidential. Opp, 6 (quoting EX2179, 3). Petitioner, however, crops the quoted sentence, the first half of which states: “Although Alkeus functions primarily as a lean biotech and *outsources many of its activities....*” EX2179, 3. (emphasis added). Regardless, nothing about “most” generally discloses the specific substance of the redacted information. Indeed, Petitioner does not and cannot argue so.

Petitioner further conflates Dr. Saad’s known position in managing Alkeus with public disclosure of its confidential clinical trials and internal operations. Opp. 7. The *general* statements in cited exhibits EX1081, EX1084, or EX1086 do not disclose the *specific* confidential information that is redacted. Petitioner’s suggestion that public disclosures that “Dr. Saad undertook [a] hands-on approach with essentially only a single employee” renders public such confidential details is, in Petitioner’s words, “perplexing and unsupported.” Opp., 7.

Petitioner’s hyperbolic rhetoric that unredacted portions of Dr. Saad’s testimony “only deepen the mystery of how PO can hope to justify its redactions” (Opp. 7-8) further undermines its opposition. While citing extensively to unredacted materials—EX1079, 89:25-91:12, 91:17-21, 92:1-3, 92:4-7, 92:8-20, 94:18-22, 121:14-123:23—Petitioner does not and cannot show this unredacted testimony discloses the redacted information. For example, 89:25-91:12 relates to an employee’s background; 91:17-21 relates to general training provided to an employee; 92:1-20 describes Dr. Saad’s experience prior to forming Alkeus in 2010 (204:9-11) and Dr. Washington’s lack of role in grading; 94:18-22 is a general statement about image grading cost; and 121:14-123:23 relates to general clinical trial oversight. Once again, these citations do not describe the specific confidential information redacted. Nor should Patent Owner’s efforts to maximize public

disclosure by not redacting additional testimony be turned against it to argue that redacted material must be disclosed.

Petitioner further ties itself in knots, arguing that Patent Owner’s “redactions mislead the public” (Opp. 10-11) after having previously argued “publicly-available information” precludes any claim to confidentiality (Opp. 6). Both cannot be true. In fact, neither are true. Notably, rather than misleading, Alkeus clinical trial results have been validated, were conducted and published by the Chief Medical Officer of *Petitioner’s RPI (Belite Bio)*, and have been relied upon by the FDA to award Breakthrough Therapy Designation. POR, 51-52; Sur-Reply, 21-24; EX1079, 216:1-218:9 (results validated). EX2086-EX2091 (all coauthored by Dr. Scholl); EX2190, 3 (showing Dr. Scholl as Belite’s CMO); EX2096, EX2107 (Breakthrough Therapy Designation).

The rest of Petitioner’s arguments are unrelated to any issue of public availability and instead attempt to expand Petitioner’s Reply arguments. *Compare* Reply, 19-21 *with* Opp. 7-13; *but see* EX1079, 217:16-218:9. Arguments that Alkeus provided opportunism to interns from Harvard, Boston University, Tufts, etc. are irrelevant—especially given Dr. Saad’s testimony at, *inter alia*, 214:2-8, 216:1-218:9. Petitioner’s argument relying on Dr. Del Priore’s testimony is likewise unrelated as Petitioner pointedly was not seeking opinions about Alkeus’s clinical

trials. Opp. 10. Petitioner should, moreover, be prohibited from relying on its new arguments—at oral argument or otherwise—in support of its Petition.

III. Patent Owner’s Redacted Materials Are Proprietary, Competitively Sensitive Business Information

As argued in the Motion to Seal, the redacted information relates to information that is confidential, not public, and concerns research and development of ALK-001. Mot. 4-8. The Board has routinely found it appropriate to redact this type of information. *Id.*; *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.”). For the same reasons, Patent Owner’s Motion to Seal sufficiently justified why the redacted information is propriety, competitively sensitive business information.

The “Outside Counsel Only” restriction is particularly necessary and appropriate where Petitioner still fails to properly identify—as required under 35 U.S.C. §§ 312(a)(2)—its RPIs, including Alkeus’s competitor Belite Bio that is co-represented by Petitioner’s counsel, and attempts to elicit confidential Alkeus

information that could benefit Belite Bio. EX1079, 25:7-27:4, 209:15-22; POR, 63-64; POPR, 73-75; Paper 11, 5.

IV. Patent Owner's Confidentially Certification Support Redaction

Petitioner further opposes the Motion by falsely arguing that Patent Owner had previously sought to designate as confidential material that was already public. Opp. 11-13. Patent Owner's prior motion was related to material under embargo from public disclosure at time of filing, and Patent Owner de-designated the material after the embargo lifted. Paper 26, EX2094. Here, by contrast, Patent Owner's redactions at 83:18-24, 83:25-84:3, and 84:6-12 relate to certain information that remains confidential. Petitioner's argument that EX1087 at 8 discloses the redacted information also false. Opp. 12-13. The public statement regarding unexpected efficacy in preventing "[p]rogression of Stargardt disease from baseline to 24 months, as well as in comparison to age matched historical imaging of siblings" (EX1087, 8) does not disclose the redacted information. Therefore, Petitioner does not provide any reason for the Board to doubt Patent Owner's confidentiality certification.

V. Conclusion

Despite its assertions otherwise, Petitioner does not demonstrate that the redacted information is public. Patent Owner's redactions and justification of the redactions are in line with information and arguments that the Board has routinely

found sufficient to seal information about clinical trials. Accordingly, Patent Owner requests that the Board grant its Motion to Seal.

Respectfully submitted,

Dated: February 28, 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
REPLY TO PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION
TO SEAL was served electronically via email on February 28, 2025, in its entirety
on the following:

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Petitioner has consented to electronic service.

Dated: February 28, 2025

/William Esper/
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