

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 IPR2024-00313
Patent RE47,045

Before SUSAN L. C. MITCHELL, ZHENYU YANG, and TAWEN
CHANG, *Administrative Patent Judges*.

CHANG, *Administrative Patent Judge*.

ORDER

Granting in Part and Denying Without Prejudice in Part
Patent Owner's Motion to Seal and for Entry of Protective Order
37 C.F.R. §§ 42.14, 42.54

I. INTRODUCTION

Patent Owner filed a Motion to Seal and for Entry of Protective Order (“Motion”) in this *inter partes* review. Paper 34. The proposed protective order is a modified version of the default protective order made available by the Board. *Id.* at 1. Patent Owner states that Petitioner does not oppose the entry of the modified default protective order. *Id.* However, Petitioner opposes the Motion to Seal. Paper 36.

II. MOTION FOR ENTRY OF PROTECTIVE ORDER

“The Board may, for good cause, issue an order to protect a party or person from disclosing confidential information.” 37 C.F.R. § 42.54(a). Because we grant in part Patent Owner’s Motion to Seal, and because Patent Owner represents that Petitioner does not oppose the entry of the modified protective order, Paper 34, 1, we find that good cause exists to enter the modified protective order attached as Appendix B to Patent Owner’s Motion. Patent Owner’s Motion is consequently granted with respect to the entry of the Protective Order.

III. MOTION TO SEAL

The Motion seeks to place under seal portions of the Deposition Transcript of Leonide Saad, Ph.D. (“Saad Deposition Transcript,” Ex. 1079) and Petitioner’s Reply (Paper 32).¹ Motion 1.

¹ Dr. Saad is the Chief Scientific Officer of Alkeus Pharmaceuticals, Inc. (“Alkeus”), which is the exclusive licensee of the ’045 patent and a real party-in-interest in this proceeding. Ex. 2191 ¶ 1; Paper 4, 2.

For the reasons discussed below, we find that the Motion does not provide a meaningful balancing of the public's interest in having a complete and understandable file history of the proceeding with Patent Owner's need to have all of the information sought to be sealed remain confidential. Accordingly, with a limited exception, the Motion is denied without prejudice.

A. Legal Standards

The Board recognizes “a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an inter partes review which determines the patentability of claims in an issued patent and therefore affects the rights of the public.” *Garmin International, Inc. v. Cuozzo Speed Technologies LLC*, IPR2012-00001, Paper 34, 1–2 (PTAB March 14, 2013). Under 35 U.S.C. § 316(a)(1), the default rule is that all papers filed in an inter partes review are open and available for access by the public.

Nevertheless, a party may file a motion to seal “truly sensitive information.” Trial Practice Guide,² 19; *see* 37 C.F.R. § 42.14. Under the rules governing this proceeding, confidential information is identified “in a manner consistent with Federal Rules of Civil Procedure 26(c)(1)(G), which provides for protective orders for trade secret or other confidential research, development, or commercial information.” Trial Practice Guide 19 (citing 37 C.F.R. § 42.54).

² Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 2019), *available at* <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

The standard for granting a motion to seal is “for good cause,” and the moving party has the burden of showing that it is entitled to the requested relief. 37 C.F.R. §§ 42.20(c), 42.54. Under the good cause standard,

a movant to seal must demonstrate adequately that (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, (3) there exists a genuine need to rely in the trial on the specific information sought to be sealed, and (4), on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record.

Argentum Pharms. LLC v. Alcon Res., Ltd., IPR2017-01053, Paper 27 (PTAB January 19, 2018) (informative), 4.

B. Analysis

1. Saad Deposition Transcript (Ex. 1079), 6:16

Patent Owner explains that line 16 of page 6 of the Saad Deposition Transcript “has . . . been redacted as it discloses the personal address of Dr. Leonide Saad, which is sensitive personal information.” Mot. 3. Patent Owner contends that Alkeus’s address is public information, and “[s]hielding [Dr. Saad’s] address from the public view will not impact the public’s interest in maintaining a complete and understandable file history.” Mot. 3–4, n.2.

We have reviewed this redacted line of the Saad Deposition Transcript, which appears to contain Dr. Saad’s personal address as Patent Owner alleges. We conclude that granting the Motion with respect to line 16 of page 6 of the Saad Deposition Transcript is appropriate as it contains personal information.

2. Remaining excerpts of Saad Deposition Transcript (Ex. 1079) and Petitioner's Reply (Paper 32)

Patent Owner asserts the remaining redacted portions of Exhibit 1079 contain Alkeus's "competitively sensitive, non-public, and confidential research, development, or commercial information," in particular "the conduct of TEASE and SAGA clinical trials" and its "internal research and development operations." Mot. 4. Patent Owner further asserts that Petitioner relies on the alleged confidential information in Exhibit 1079 in the portions of the Reply Patent Owner seeks to place under seal. *Id.*

Patent Owner asserts that there is good cause to seal portions of Ex. 1079 and Petitioner's Reply because "[t]he confidential information . . . includes proprietary research methods, including clinical protocols for Alkeus's Gildeuretinol drug product," which, if disclosed, could allow "competitors and other third parties [to] gain unfair competitive advantages by accessing Alkeus's trial design and analytical methods." Mot. 4. Patent Owner asserts that, in addition, "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." *Id.*

Patent Owner asserts that the potential harm to Alkeus from public disclosure outweighs any public interest in accessing the information because "[t]he public record will reflect the general substance and significance of these documents, and the requested redactions are narrowly tailored to protect only specific confidential details about Alkeus's clinical

trials and internal operations,” in which the public has “minimal” interest. Mot. 4–5.

Patent Owner’s justifications fail to satisfy the good cause requirement of 37 C.F.R. § 42.54(a). The majority of the redactions in the Saad Deposition Transcripts appear to be focused on the specifics of image reading for the clinical trials conducted by Alkeus, including, for instance, the identity, affiliation, qualifications, and/or training of the individuals who performed such image reading (*see, e.g.*, Ex. 1079, 36:16–21, 91:13–16), as well as subsequent analysis of the image data (*see, e.g.*, Ex. 1079, 216:1–218:9).

Patent Owner does not provide a particularized showing as to why the specific types of redacted details of the clinical trials are confidential. For instance, identities of individuals who may have performed image reading for Alkeus’s clinical trials do not appear to be confidential. *See, e.g.*, Ex. 1074. Likewise, some of the redacted details of the clinical trial protocols appear to have been publicly disclosed. *Compare* Ex. 1087, 8 *with* Ex. 1079, 83:18–84:12; Paper 36, 12–13. Neither has Patent Owner provided particularized explanations of how knowledge of such details would allow third parties to gain competitive advantage.

Finally, Petitioner relies on the redacted portions for its arguments regarding secondary considerations. Reply 20–21. Thus, public policy supports making information in the redacted portions available to the public for purposes of understanding the full record.

Nevertheless, counsel for Patent Owner has certified that information sought to be sealed by the motion has not, to their knowledge, been

published or otherwise made public. Mot. 5. Moreover, some of the redactions relate to analysis of the data in the clinical trials, which may be of the type of research and development documents that businesses typically keep confidential to avoid competitive harm. Patent Owner also asserts that the confidential information belongs to Alkeus, a non-party, and thus should receive heightened protection.³ Paper 43, 2. Accordingly, we deny Patent Owner's Motion to Seal without prejudice so that Patent Owner may renew its motion to provide more particularized justifications for the redactions it seeks.

We note that any renewed motion to seal should include a showing that (1) the information sought to be sealed is truly confidential, (2) a concrete harm would result upon public disclosure, and (3) on balance, an interest in maintaining confidentiality outweighs the strong public interest in having an open record. *See Argentum Pharms. LLC*, IPR2017-01053, Paper 27, at 3–4. The mere fact that a document is non-public is not sufficient to demonstrate that it should be sealed.

The materials that are the subject of the motions to seal shall continue to be provisionally sealed until the Board rules on any renewed motion to seal these materials. *See* 37 C.F.R. § 42.14 (discussing Board's authority to provisionally seal information). Should Patent Owner not file a motion to

³ We understand that Patent Owner has standing to assert Alkeus's interest with respect to the information sought to be sealed. If this is not the case, the parties shall contact the Board by e-mail, within 10 days of this order, to request a conference call for purposes of discussing how to address Alkeus's information.

seal within the timeframe provided below, the Board will unseal the materials that are the subject of the motions to seal.

Accordingly, it is ORDERED that:

Patent Owner's Motion is granted with respect to the entry of the Protective Order;

FURTHER ORDERED that the Protective Order provided as Appendix B of Patent Owner's Motion is entered in this *inter partes* review;

FURTHER ORDERED that Patent Owner's Motion to Seal is granted with respect to Ex. 1079, 6:16 but otherwise denied without prejudice;

FURTHER ORDERED that Patent Owner may, within 10 days of the date of this Order, file a renewed motion to seal;

FURTHER ORDERED that, should Patent Owner timely file a renewed motion to seal as authorized above, Petitioner is authorized to file a response within 10 days of the renewed motion to seal, and Patent Owner is authorized to file a reply within 5 days of Petitioner's response; and

FURTHER ORDERED that, should Patent Owner not timely file a motion to seal as authorized above, the Board will unseal the materials sought to be sealed in Exhibit 1079 and Paper 32.

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