

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PACIFIC BIOSCIENCES OF CALIFORNIA, INC,
Petitioner

v.

THE CHINESE UNIVERSITY OF HONG KONG,
Patent Owner

Case **IPR2024-00028**
Patent No. **11,091,794 B2**

**PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO
EXCLUDE (PAPER 24)**

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I. INTRODUCTION

Petitioner's Motion to Exclude ("MTE") the Declaration and Supplemental Declaration of Patent Owner's expert Dr. Koo (Exhibits 2002 and 2041, respectively) should be denied because Petitioner's objections were not timely identified and are meritless. If Dr. Koo's testimony were so unqualified and contrary to documentary evidence, surely Petitioner would have filed reply testimony from its own expert, Dr. Dessimoz, supporting its assertions. That Dr. Dessimoz did not do so, and that Petitioner does not dispute the many admissions in Dr. Dessimoz's testimony that support Patent Owner's positions and corroborates Dr. Koo's testimony as explained in Patent Owner's Response (Paper 15) and Sur-Reply (Paper 21) shows that Petitioner's attorney allegations in the MTE are baseless. In fact, Petitioner's mischaracterizations in the MTE are no more than a transparent attempt to circumvent the word-count limits of its merits briefing by injecting merits arguments in its evidentiary motion.

Petitioner's misrepresentations begin with the burden on a motion to exclude. Contrary to Petitioner's assertion, "the party moving to exclude evidence 'bears the burden of proof to establish that it is entitled to the requested relief,' *i.e.*, that the material sought to be excluded is inadmissible under the Federal Rules of Evidence." *Kiosoft Techs., LLC v. Payrange Inc.*, PGR2021-00077, Paper 32, 53–55, 2022 WL 15525624 at *23–24 (P.T.A.B. Oct. 26, 2022) (quoting 37 C.F.R. § 42.20(c) and

denying motion to exclude expert testimony). But as explained herein, Petitioner's mischaracterizations and transparent attempt to improperly argue the merits fall far short of meeting Petitioner's burden to demonstrate that Dr. Koo's testimony should be excluded. Accordingly, Patent Owner requests that the MTE be denied.

II. PETITIONER'S OBJECTIONS WERE NOT TIMELY IDENTIFIED

Rule 42.64(b)(1) requires that "[o]nce a trial has been instituted, any objection [to evidence] must be filed within five business days of service of evidence to which the objection is directed." Further, "[t]he objection must identify the grounds for the objection with sufficient particularity to allow correction in the form of supplemental evidence." 37 C.F.R. § 42.64(b)(1). Accordingly, the Board has found that "[t]he lack of an effective objection is sufficient basis to deny a Motion to Exclude." *Hunter's Mfg. Co. v. Ravin Crossbows, LLC*, IPR2023-00407, Paper 53, 41, 2024 WL 3347293 at *17 (P.T.A.B. Jul. 9, 2024) (citing *B/E Aerospace, Inc. v. MAG Aerospace Indus., LLC*, IPR2014-01511, Paper 104, 8, 2016 WL 1082741 at *3 (P.T.A.B. Mar. 18, 2016)). In *Hunter's Mfg. Co.*, the Board denied Petitioner's motion to exclude an expert declaration in part because "[i]n this instance, Patent Owner's Objections (Paper 33) ran afoul of Rule 42.64(b)(1), leaving Petitioner without any meaningful sense of the alleged evidentiary flaws in [the] Reply Declaration — until Patent Owner filed its Motion to Exclude." *Id.* Similarly, in *Abbott Diabetes Care, Inc. v. Dexcom, Inc.*, the Board denied a motion to exclude,

explaining that a “boilerplate objection is woefully insufficient to show that Petitioner objected with sufficiently particularity to allow correction in the form of supplemental information, as our Rule requires.” IPR2022-00914, Paper 45, 57, 2023 WL 7226315 at *25 (P.T.A.B. Nov. 2, 2023).

Just like in *Hunter’s Mfg. Co.* and *Abbott Diabetes Care*, here Petitioner’s generic objections fail to provide any meaningful sense of the objection. While the MTE alleges that “Dr. Koo’s testimony disregards both the broad scope of the challenged claims and more than half the evidentiary record, and his opinions are predicated on various legal and factual errors,” not a single one of those issues is identified in Petitioner’s generic objections, let alone with respect to any particular paragraph or portion of Dr. Koo’s testimony. Petitioner’s generic objections to the entirety of Dr. Koo’s testimony provide no “meaningful sense of the alleged evidentiary flaws.” *Hunter’s Mfg. Co.*, IPR2023-00407, Paper 53, 41, 2024 WL 3347293 at *17.

Petitioner’s objections to both EX2002 and EX2041 are essentially the same. Both objections simply list various rules of evidence and generically assert noncompliance with those rules without identifying a single issue or portion of either

declaration.¹ Just like in *Abbott Diabetes Care*, Petitioner objects to the entirety of Dr. Koo's declarations with a generic recitation of the rule. *Compare* Paper 16 at 1 and Paper 11 at 1 (each reciting "Dr. Koo fails to provide a reasoned basis for his opinions. Moreover, Dr. Koo's opinions are not the product of reliable principles and methods, and they rely on data from tests without an affidavit providing the explanations required by 37 C.F.R. § 42.65(b)") with *Abbott Diabetes Care*, IPR2022-00914, Paper 45, 57, 2023 WL 7226315 at *25 (finding objections "woefully insufficient" that object to hundreds of paragraphs with the generic statement that the "testimony is based on insufficient facts or data, is not the product of reliable principles and methods, and does not reliably apply the appropriate principles and methods to the fact of the case."). Here, Petitioner's woefully insufficient objections do not assert the bases for the MTE or identify any portion of Dr. Koo's declarations related to any of those purported deficiencies. Paper 16, at 1–2; Paper 11 at 1–2.

Petitioner's Motion should be denied for that reason alone.

¹ The objections to EX2041 identify a series of paragraphs as not relevant on the basis that those paragraphs are not expressly recited in Patent Owner's Response. Paper 16 at 2. The MTE does not assert, and Petitioner has thus waived, that argument.

III. DR. KOO'S DECLARATIONS SATISFY THE FRE

“A motion to exclude ... may not be used to challenge the sufficiency of the evidence to prove a particular fact.” PTAB Consolidated Trial Practice Guide (Nov. 2019), 79. “A motion to exclude is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents.” *Id.* So in *Abbott Diabetes Care*, the Board explained that “arguments [that] go to the weight to be afforded [an expert’s] testimony, not to its admissibility [are] an improper basis for seeking the exclusion of [that testimony].” IPR2022-00914, Paper 45, 57, 2023 WL 7226315 at *25. And as the Board explained in *Machinex Indus., Inc. v. JJG IP Holdings, LLC*, “the Board is capable of assessing the weight to be given [expert] testimony without excluding it.” IPR2020-00899, Paper 45, 103–104, 2021 WL 4876262 at *42 (P.T.A.B. Oct. 4, 2021) (denying motion to exclude expert testimony explaining that “[a]s to reliability, the policy considerations for excluding expert testimony, ... by the gatekeeping framework established by the Supreme Court in *Daubert*, are less compelling in bench proceedings such as *inter partes* reviews”).

Petitioner’s transparent attempt to circumvent the word-count limits of its merits briefing by injecting merits arguments for the first time in its evidentiary motion should be rejected. Dr. Koo’s declarations meticulously analyzed the

arguments made in the Petition and Petitioner's expert's declaration in support of the Petition and explained at length why claim 1 is patentable over Ground 1.

First, the fundamental basis for Petitioner's motion is false. Petitioner accuses Patent Owner of "withholding" twenty-five exhibits from Dr. Koo. MTE at 7. In fact, the undersigned counsel provided all of the exhibits filed with the Petition to Dr. Koo at the outset of this case. And at deposition, Dr. Koo confirmed that he "considered a lot of documents – read a lot of documents when drafting his declaration[,]” that he did not “remember all of them off the top of [his] head,” but “if it was heavily focused on, if it was focused on, then [he] included that in this list of considered – materials considered.” EX1049 at 58:2-8. At deposition, Petitioner did not ask Dr. Koo if any document was withheld from him. Petitioner's mischaracterization of Dr. Koo's testimony to argue otherwise should be disregarded.

And of the documents identified in the MTE, for eighteen of those Exhibits, the MTE does not assert any reason why those exhibits required any particular focus from Dr. Koo. Specifically, other than identifying the exhibits by title and number, the MTE provides no reason why those exhibits are relevant to any portion of Dr. Koo's declarations. Not one reason.

For the remaining seven exhibits, the Petition and Reply do not cite any of those exhibits for any issue addressed by Dr. Koo in the declarations. First, four of

the exhibits (Exhibits 1018, 1019, and 1020, and 1024) are cited for Grounds 2-4 that relate to dependent claims. Paper 2 at 58, 65, 68; Paper 24 at 9. The Petition does not rely upon those exhibits with respect to Ground 1, the sole ground asserted against the sole independent claim at issue and addressed by Dr. Koo. In responding to Ground 1, Dr. Koo addressed the arguments and assertions that Petitioner actually made in this proceeding. Petitioner's complaint that Dr. Koo did not "grapple" with "the content of those references" when Petitioner itself did not cite or rely on those references for any portion of Ground 1 is nonsense.

Petitioner's citation to Exhibit 1045 is also inapposite. Neither the Petition nor Petitioner's expert's declaration include a single citation to Exhibit 1045. Not one. Instead Petitioner references Exhibit 1045 with attorney argument in its Reply, to which Dr. Koo has no opportunity to respond. *See* 37 C.F.R. § 42.23 ("A sur-reply ... may not be accompanied by new evidence other than deposition transcripts of the cross-examination of any reply witness."). And, Petitioner could have, but presented no testimony from its own expert regarding any relevance of Exhibit 1045.

In fact, Exhibit 1045 is not relevant at all. Exhibit 1045 is a continuation of the '338 patent, one of the primary references for Ground 1. Without explanation and based solely on attorney argument, Petitioner asserts that the *ex parte* allowance of a claim in Exhibit 1045 is relevant to evaluating the '338 patent's application to a completely different claim, claim 1 of the '794 patent. Simply put, the allowance of

a different claim that is unrelated to the claims at issue here is not relevant to the patentability of claim 1 of the '794 patent. Dr. Koo extensively evaluated the disclosure of the '338 patent itself and addressed the arguments that Petitioner and its expert actually made regarding that disclosure.

Moreover, if any prior consideration of the disclosure in the '338 patent by the Office is relevant to this proceeding, it is the Office's prior evaluation of what the '338 patent discloses with respect to claim 1 of the '794 patent actually at issue here and the Office's subsequent allowance of *that* claim 1 over both Flusberg and the '338 patent. As set forth in Patent Owner's Response (Paper 15) at 7–9 and just like as Dr. Koo has testified here, during prosecution of the '794 patent and following an interview discussing proposed claim amendments and both Flusberg and the '338 patent, the examiner determined that while “Flusberg displays various widths of pulses in their sequence data in a window,” Flusberg does not appear to “measure the widths as a data point to be combined with interpulse duration, nucleotide identity and position in determining the presence of mutations.” EX1004 at 217. The Examiner referred to that same reasoning for nonobviousness with respect to the '338 patent. *Id.* In other words, the Office has expressly found that neither Flusberg nor the '338 patent disclose the claimed “input data structure” having the recited combination of features including nucleotide identity, which is the primary issue addressed in Dr. Koo's declarations. Accordingly, Petitioner's

belated and unsupported attorney arguments about *ex parte* allowance of unrelated claims required no “grappling” by Dr. Koo, particularly in advance of Petitioner making those unsupported and irrelevant arguments. The Office got it right the first time when it expressly considered the ’338 patent and Flusberg and allowed claim 1 over those references.

Regarding Exhibits 1032 and 1036, the Petition includes a single string citation to several references including Exhibits 1032 and 1036 for the proposition that “[w]hile machine learning was known for decades, more widespread implementation of such technologies in genomic applications paralleled the increased availability of open-source resources.” Petition at 10–11. Even after both of Dr. Koo’s declarations were served, Petitioner does not cite Exhibit 1036 for any purpose until the MTE and only cites Exhibit 1032 to complain that Dr. Koo did not consider it. Paper 19 at 24, n. 2.

Similarly, Petitioner complains that Dr. Koo did not “grapple with” Exhibit 1035. Exhibit 1035 is not asserted in any ground. Without any explanation and again based solely on attorney argument, Petitioner asserts for the first time in Reply, *i.e.*, after both of Dr. Koo’s declarations were served, that Exhibit 1035 discloses using “nucleotide identity as the input matrix to a convolutional neural network (CNN) for the purpose of detecting methylation sites.” Paper 24 at 8. Both the Petition and Petitioner’s expert never make such an assertion and instead cite Exhibit 1035 in a

string of citations with other references for the non-controversial propositions that there was an interest in modification detection using third general sequencing and that convolutional neural networks (CNNs) have been used in modification detection. *See* Petition at 1, 11, 32; EX1002 at ¶¶ 26, 43, 44, 88, 89, 138, 155. Petitioner's belated and unsupported attorney argument cannot serve as a basis to exclude Dr. Koo's testimony.

Petitioner's other transparent merits arguments are equally irrelevant and do not warrant excluding Dr. Koo's testimony. First, Petitioner's arguments regarding Dr. Koo's purported failure to address nexus are false. Dr. Koo expressly explained the technical reasons why the nexus requirement is satisfied. Specifically and as explained in Patent Owner's Sur-Reply (Paper 21) at 15-16, Dr. Koo testified that claim 1 of the '794 patent provided a significantly improved method to detect DNA modifications because of the claim's specific "input data structure" as follows: "[t]he reason the method of claim 1 has such a high AUC is because the inventors discovered, by systematically probing the predictive power of features, an optimal feature set to construct an input data structure that could accurately detect base modification." EX2041, ¶39. Dr. Koo continued, "[t]hose features are a window, and the properties of each nucleotide in the window, namely, the nucleotide identity, the position of the nucleotide with respect to a target position within the window, the PW, and the IPD." *Id.* That testimony is un rebutted and establishes a nexus to why

claim 1's method achieved unexpected results, received praise, was copied by others, and why others, including Petitioner, tried but failed. Further and contrary to Petitioner's assertion, even Petitioner's expert agrees that Tse is the method of claim 1. EX2037, 213:19-21 ("I believe that the patent -- '794 patent, claim 1, is -- corresponds to the model, this clause in that paper."). That Dr. Koo's declarations do not articulate the legal standard for nexus is not relevant and cannot be a basis to exclude his meticulous and unrebutted evaluation of the technical reasons confirming that the objective indicia strongly favor nonobviousness.

Next, Petitioner's criticism of Dr. Koo's interpretation of Figures 11 and 14 mischaracterizes Dr. Koo's testimony. Dr. Koo did not disregard or dismiss the figures and simply explained that Figures 11 and 14 are "not realistic," "toy," and "cartoon" because the figures are a "depiction of the artist" and an "idealized version of what data could potentially look like." EX1049, 98:15–101:2. Regardless, Figures 11 and 14 simply confirm that the Flusberg publications had the same data as the PacBio-BAM, yet disclosed a method that avoids including nucleotide identity in an input data structure as claimed. And, as explained in Patent Owner's Sur-Reply (Paper 21) at 9–10, while the '338 patent identifies a long list of properties that could be included in an input data structure, the '338 patent does not identify nucleotide identity as one of them because the Flusberg publications' method accounts for nucleotide identity in a different way—by keeping it constant. *See also* EX1007,

67:64–67 reciting that “it will be clear to one of ordinary skill that the approach can be extended to pulse metrics other than IPD, such as pulse width, branch rate, mismatch rate, deletion rate, etc.,” but omitting any mention of nucleotide identity.

Similarly, Petitioner’s complaints regarding Dr. Koo’s consideration of sequence alignment are meritless. As explained in Patent Owner’s Sur-Reply at 12, Petitioner’s own expert recognized that the use of nucleotide identity in sequence alignment does not disclose including nucleotide identity as a property in an input data structure. EX2037, 193:11–13. Petitioner’s belated attorney argument otherwise is both meritless and goes to credibility, not admissibility.

Regarding Petitioner’s allegation regarding Dr. Koo’s purported misquoting of Dr. Dessimoz (Paper 24 at 12), at deposition Petitioner’s attorney represented that it was a misquote, but when Dr. Koo asked to see the transcript and explain it, Petitioner’s attorney would not show it to him and did not ask any questions regarding its substance. EX1049 at 147:21–148:5.

Petitioner’s case law is also inapposite or supports that Dr. Koo’s testimony should not be excluded. For example, in *SAS Inst., Inc. v. World Programming Ltd.*, the district court declined to exclude an expert’s testimony explaining that “even if the complete universe of evidence could have impacted [the expert’s] opinion, the court cannot substitute its judgment for that of the expert as to what is sufficient

evidence to inform his experiential conclusion.” 125 F. Supp. 3d 579, 590 (E.D.N.C. 2015).

IV. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board Deny Petitioner’s motion to exclude Exhibits 2002 and 2041.

Respectfully submitted,

Date: January 9, 2025

By: / Joseph P. Hamilton /
Joseph P. Hamilton, Reg. No. 51,440
Perkins Coie LLP
1888 Century Park East, Suite 1700
Los Angeles, CA 90067
Phone: 310-788-3271

Counsel for Patent Owner

CERTIFICATE OF SERVICE

The undersigned hereby certifies that service on Petitioner was made as follows, in accordance with 37 C.F.R. § 42.6(e):

Date of service: January 9, 2025

Manner of service: 1. Electronic submission through the USPTO Patent Trial and Appeal Board P-TACTS System
2. Electronic mail

Document(s) served: **PATENT OWNER'S OPPOSITION TO PETITIONER'S MOTION TO EXCLUDE (PAPER 24)**

Persons served: Michael T. Rosato (Reg. No. 52,182)
mrosato@wsgr.com

Sonja R. Gerrard (Reg. No. 72,802)
sgerrard@wsgr.com

Patrick M. Medley (Reg. No. 74,735)
pmedley@wsgr.com

/ Amy Candeloro /

Paralegal
Perkins Coie LLP