

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC.,
Petitioner,

v.

UNIVERSITY OF MASSACHUSETTS,
Patent Owner.

Case No. PGR2023-00014
Patent No. 11,278,505

**PETITIONER FORTE BIOSCIENCES, INC.'S
REPLY IN SUPPORT OF MOTION TO EXCLUDE
37 C.F.R. §42.64(c)**

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I. INTRODUCTION

Patentee (the University) erects a strawman about Dr. Damsky's current qualifications rather than address the argument petitioner (Forte) actually made about the unreliability of Dr. Damsky's testimony (EX2005). Forte carried its burden on its unrebutted argument. EX2005 should be excluded.

II. REASONS FOR EXCLUSION

Dr. Damsky's declaration (EX2005) is doubly unreliable. Not only was he not a person of ordinary skill at the time of the invention but he also has post-filing insider knowledge that directly undercuts his ability to testify reliably and objectively on questions of support. Forte did not challenge his current qualifications to be an expert in some other proceeding, but instead showed why his testimony was inherently doubly unreliable on the issues *in this proceeding*. The University's counterargument that Dr. Damsky is *currently* qualified is thus a strawman.

A. Strawman argument is improper opposition

The University argues Forte "challenges...Professor Damsky's credentials" without citation to Forte's motion. Paper 37, 2. The University's argument attempts to change the subject from the real problems. First, Forte argued that Dr. Damsky was not a POSA *at the relevant time*—a critical requirement for establishing the relevance and *reliability* of the testimony. *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022)

(explaining that without POSA qualifications, “the witness’ opinions are neither relevant nor reliable.”). Second, Dr. Damsky had undisclosed and unacknowledged insider knowledge from working with the inventors **after** the critical date that materially infect the relevance, reliability, and objectivity of his testimony about what a POSA would have known **by** the critical date. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1190, 1195 (Fed. Cir. 2006) (identifying lack of objectivity as a key concern with a non-independent witness);¹ *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1360 (Fed. Cir. 2006) (affirming **exclusion** of proffered expert who “was not one of ordinary skill in the art **at the time of invention.**”) (emphasis added). None of this detracts from Dr. Damsky’s qualifications to testify as an expert in some other case, but it directly impeaches the reliability and objectivity of his ability to testify in **this** case, which is what Forte actually argued.

Although the University contends it **did** disclose Dr. Damsky’s entanglement

¹ The University complains that some of the cases Forte cited involve inequitable conduct. Paper 37, 13. The focus of the cited cases is the **materiality** of an expert’s relationship to the inventors so the factfinder can assess the reliability and objectivity of the expert’s testimony. Hence, the cases are directly on point for the issues Forte actually argued—reliability and objectivity—and highlight its importance to a threshold **evidentiary** assessment.

with the inventors, its argument is telling: the University cites, without explanation, a page from Dr. Damsky's curriculum vitae. Paper 37, 3, citing EX2006, 3. It is not apparent what this single page is purporting to tell the Board and Forte, nor is it our burden to make the University's argument for it. Nevertheless, if we speculate that the University is referring to a single entry on page 3 (of an 18-page CV) mentioning "Incyte", it remains unclear how that entry ties to the subject matter of this proceeding. That obscure buried reference falls well short of identifying the full scope of Dr. Damsky's relationship with Incyte that undercuts Dr. Damsky's testimony. Cf. Paper 34, 5-8.

Similarly, the University fleetingly mentions *Kyocera* and *Flex-Rest*, but only by addressing qualifications generally rather than these cases' requirement for POSA-specific requirements. The University did not discuss, much less distinguish, for example, *Flex-Rest's exclusion* of the expert for lacking POSA-qualifications ***at the time of invention***. Reframing an argument into a strawman is inapposite and forfeits any proper response to the actual argument. Cf. *Rembrandt Diagnostics v. Alere, Inc.*, 76 F.4th 1376, 1382-83 (Fed. Cir. 2023) (non-argument forfeits proper argument).

The University also attacks Forte's "bias" arguments, again without citation to Forte's motion. Paper 37, 4. While Dr. Damsky's post-critical date entanglement with the inventors suggests bias as well, more pertinent to the motion is the fact

that it necessarily undercuts his reliability and objectivity because he—unlike a POSA or an independent expert—has in his mind what the inventors actually did (after the critical date), which colors his view of the relevant art at the relevant time. *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1581 (Fed. Cir. 1996) (recognizing the materiality of “pre-existing knowledge of the invention when he prepared his affidavit” on sufficiency of disclosure). Once again, the University tries to change the subject rather than engaging Forte’s actual argument.

The University provides no opposition on point to Forte’s actual arguments because it has none. Forte carried its burden as specified by controlling precedent, and the University forfeited any relevant response, so the motion to exclude Dr. Damsky’s testimony as irrelevant and ***unreliable*** in this case should be granted.

B. Strawman argument about motion propriety is misdirected

Lacking an argument on the merits, the University instead shoots the messenger. Paper 37, 4 (arguing Forte’s motion is “an improper attempt to argue the weight of the evidence”). Again, the University misses the point. Forte established that case law treats both lack of qualification at the critical date and undisclosed relationships with the inventors as relevance and ***reliability*** issues, not mere weight issues. *Kyocera*, 22 F.4th at 1376-77 (identifying non-POSA expert as a reliability issue); *Ferring*, 437 F.3d at 1190, 1195 (identifying non-independence as a reliability issue); *see also Sanders v. Mosaic Co.*, 418 F. App’x 914, 919 (Fed.

Cir. 2011) (“failure to disclose an expert’s affiliation” is a reliability problem). Hence, consistent with the controlling case law, in its motion to exclude, Forte properly challenged the relevance and **reliability** of Dr. Damsky as a witness in this case rather than the weight of any particular statement he made. Once again, the University changes the subject rather than engaging with the actual argument.

Indeed, the University’s error is shown in its argument about Forte’s “blanket” challenge to Dr. Damsky’s testimony. Paper 37, 8. Because Dr. Damsky’s lack of POSA-qualifications at the relevant time, and his subsequent insider knowledge, infect his ability to testify reliably and objectively at all, a “blanket” challenge is precisely the appropriate challenge in this case. The actually-argued challenge is specific to the witness’ ability to testify objectively and reliably at all, not merely to a particular statement.

III. CONCLUSION

EX2005 should be excluded in its entirety as irrelevant and unreliable because the University failed to proffer an expert witness who is reliable and objective for the contested subject matter in this proceeding.

Respectfully submitted,

Dated: March 13, 2024

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