

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
MOTION TO EXCLUDE
37 C.F.R. §42.64(c)**

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I. INTRODUCTION

Petitioner (Forte) requests exclusion of patentee (University of Massachusetts) exhibit EX2005 (Damsky Declaration) for failure to comply with the Federal Rules of Evidence (FRE). 37 C.F.R. §§42.64(c), 42.65.

II. REASONS FOR EXCLUSION

Dr. Damsky's declaration (EX2005) should be excluded because he was unqualified as a person of ordinary skill at the time of the invention and he misrepresented his independence from this matter. Forte timely objected to EX2005 under FRE 401, FRE 402, FRE 403, FRE 602, FRE 701, FRE 702, and FRE 703. Paper 21, 3-4.

A. Dr. Damsky was not a POSA at the relevant time

Dr. Damsky's testimony is irrelevant and unreliable because he did not possess the knowledge of a POSA at the time of the invention. *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1376-77 (Fed. Cir. 2022) ("To offer expert testimony from the perspective of a skilled artisan in a patent case—like for claim construction, validity, or infringement—a witness must at least have ordinary skill in the art. Without that skill, the witness' opinions are neither relevant nor reliable."). Expert witness testimony is excludable where the proffered witness "was not one of ordinary skill in the art at the time of the invention." *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351, 1360 (Fed. Cir. 2006): FRE 402-403 and 702.

The parties agree that a POSA as of the critical date would have needed both: (1) an advanced degree (e.g., Ph.D., M.D., M.S., or equivalent), in a field related to medicine, immunology, molecular biology, cell biology, etc.; **and** (2) at least 3-5 years of experience in treating autoimmune diseases or researching cytokine signaling pathways relevant to treating autoimmune diseases. Pet., 18; Paper 6 (POPR), 16 (accepting Petition POSA definition and confirming the April 2017 critical date); *accord* Paper 19 (POR), 26-27 (“as of April 2017”). The critical date for the ’505 patent is April 24, 2017. Pet., 21; EX1001, (60), 1:6-13. Dr. Damsky recognized this to be the date of invention in both his deposition and declaration. EX2005, ¶¶94, 110-11, 141; EX1046, 12:7-9. But Dr. Damsky failed to satisfy the experience prong of this definition at the relevant time.

Dr. Damsky did not have the knowledge of a POSA at the time of the invention. In April 2017, Dr. Damsky was still a medical resident and was not board-certified. EX1046, 109:22-110:2, 112:18-22. He neither testifies that he is an immunologist himself nor testifies that he consulted one. EX1046, 128:14-129:6, 131:2-23; *id.*, 106:3-22, 108:7-14. His Ph.D. focus was cancer. EX1046, 108:16-23. Even his study of “basic immunology” during his fellowship completed in 2023 is all **post-critical date** experience. EX2005, ¶6; EX2006, 1; EX1046, 128:14-129:16. He has no publications providing direct research on vitiligo and no pre-critical date publications doing direct research on IL-15 or IL-2. EX1046,

134:4-10, 136:20-137:2, 137:13-15. As a very recent late-comer, Dr. Damsky lacked the requisite at least 3-5 years of experience in treating autoimmune diseases or researching cytokine signaling pathways relevant to treating autoimmune diseases that was needed to be a POSA in April 2017 **on top of** the advanced degree.

Because Dr. Damsky lacked the knowledge of a relevant POSA, he cannot reliably testify on matters of obviousness, written description, or enablement at the relevant time. *Kyocera*, 22 F.4th 1369, 1376-77. Evaluation of obviousness requires understanding the perspective of “a person of ordinary skill **at the time of the invention**[.]” *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (emphasis added). Similarly, “[w]ritten description is a question of fact, judged from the perspective of one of ordinary skill in the art **as of the relevant filing date**.” *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006) (emphasis added). Likewise, the enablement analysis involves underlying factual questions tied to “the time the application was filed.” *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000). Because PO failed to demonstrate Dr. Damsky had the knowledge of a POSA in April 2017, his testimony concerning the ’505 patent should be excluded.

B. Dr. Damsky misrepresented himself as an independent expert

Dr. Damsky’s declaration is not reliable because he purported to be an

independent witness without fully disclosing his relationship to the inventors and the real parties-in-interest. The testimony of an allegedly independent witness who fails to disclose his relationship to the inventors and real parties-in-interest not only raises a conflict of interest, but the witness's insider status also infects his testimony with access to inside information that does not reflect the knowledge of a POSA. *See Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1582 (Fed. Cir. 1996) (recognizing the materiality of "prior association with the inventors" as well as "knowledge of the invention"); *id.* at 1580 (material omission of inside information); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1188-89 (Fed. Cir. 2006) (failing to disclose in a declaration funding from an interested party is a material omission); *see also Sanders v. Mosaic Co.*, 418 F. App'x 914, 919 (Fed. Cir. 2011) ("Our cases indicate that the failure to disclose an expert's affiliation with" interested parties and concealing his connection, "thereby buttressing his credibility as an impartial witness," is a reliability problem). Dr. Damsky presented himself as an "independent expert" (EX2005, ¶1), but failed to disclose the breadth of his post-critical date relationship with both the inventors and the real parties-in-interest. Paper 4, 1 (identifying Incyte Corporation and Villarís Therapeutics, Inc. as real parties-in-interest). Accordingly, his testimony should be excluded as unreliable. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993) (reliability is the touchstone for expert testimony).

Dr. Damsky began collaborating with the inventors in 2019 and with Incyte beginning at least in 2021. EX1046, 39:7-41:4 (collaborations with inventors); EX1037 (publication co-authored with the inventors); EX1046, 76:4-10 (relationship with Incyte). In 2021, he started a lecture series with one inventor (Dr. Richmond) where they invited the second inventor (Dr. Harris) to speak. EX1046, 38:15-23 (founding Global Derm Talks with Dr. Richmond; Dr. Harris as presenter), 45:24-46:2 (Dr. Damsky and Dr. Richmond as founders of Global Derm Talks), 48:17-23 (attending the presentations). Dr. Damsky had social media interactions with Dr. Richmond promoting the lecture series. EX1046, 44:9-45:12 (discussing EX1038, Dr. Damsky's social media promoting Global Derm Talks with Dr. Richmond); EX1038. Dr. Damsky and Dr. Richmond also collaborated on a publication promoting the lecture series. EX1046, 49:7-23 (Dr. Damsky and Dr. Richmond co-authoring a publication (EX1039) promoting Global Dermatology Talks); EX1039. Drs. Damsky and Richmond hosted Dr. Harris' presentation. EX1046, 38:21-39:3 (Dr. Harris presenting), 52:1-53:19 (Dr. Damsky identifying himself, Dr. Richmond, and Dr. Harris at Dr. Harris' talk); EX1040.

In other forums where Dr. Damsky collaborated with the inventors, the inventors disclosed the patent-at-issue as a conflict of interest. Dr. Damsky admitted to collaborating with Dr. Richmond and Dr. Harris, and to knowing they were inventors of the challenged patent. EX1046, 29:3-30:11 (collaborating with

Dr. Richmond), 31:23-32:18 (publishing with Dr. Richmond; interacting with Dr. Harris); 35:22-36:3 (admitting knowledge that Dr. Richmond and Dr. Harris were inventors of the challenged patent). Dr. Damsky also had knowledge that Dr. Harris had been involved in starting a company (Villaris) concerning technology that is subject to the '505 patent. EX1046, 37:5-19; *see also id.*, 53:15-19 (Villaris logo at Dr. Harris' Global Dermatology Talk). Publications he co-authored with Dr. Richmond and Dr. Harris were clear in disclosing a conflict of interest relating to the '505 patent. EX1046, 41:5-23 (conflict of interest disclosed in EX1037); EX1046, 49:25-50:9 (conflict of interest disclosed in EX1039).

Likewise, Dr. Damsky elsewhere disclosed his conflict of interest regarding Incyte. In an interview with MedPage Today, Dr. Damsky admitted to his relationship with Incyte. EX1046, 74:11-23 (identifying Incyte), 76:7-10 (relationship began before November 2021); EX1042. At the 2022 Medical Dermatology Society Annual Meeting, Dr. Damsky admitted that he received both research support and consulting fees from Incyte. EX1046, 90:20-91:12; EX1043. Additionally, Dr. Damsky identified that he was a consultant for Incyte and received grant/research support from Incyte when being interviewed for a talk for Touch Immunology. EX1046, 105:14-22 (continued relationship with Incyte into 2023); EX1045.

But Dr. Damsky's declaration omitted the material aspects of his

relationship with the real party-in-interest in this case. EX2005, ¶1 (identifying himself as an “independent expert” without mentioning his connections with Incyte and the inventors); EX1046, 88:23-89:4 (admitting being aware of the relationship between Villarís and Incyte). The record reveals that Dr. Damsky’s focus on cytokine treatments for autoimmune diseases (JAK inhibition) took flight after the critical date in conjunction with his extensive and material connections to the inventors and Incyte. EX1046, 136:21-137:15 (Dr. Damsky unable to identify pre-critical date primary research into IL-15 or IL-2).

During his deposition, Dr. Damsky continued to obfuscate, downplaying his long-standing relationships rather than candidly acknowledging them. EX1046, 75:4-76:23 (not being forthcoming about Incyte or when his relationship with the company began), 77:5-81:4 (downplaying his \$200,000 funding agreement with Incyte). He obfuscated and tried to change the subject when asked for any other substantial entanglements with Incyte. EX1046, 81:6-82:23 (“it is possible that someone from Incyte may have come into my office to drop off a sample.

That is common. A lot of companies do it. Maybe I saw someone from Incyte in a dermatology meeting.”), 82:25-83:10 (“Q. So setting aside happenstance interactions and somebody dropping off a sample or meeting somebody at a cocktail party, do you have any other substantial entanglements with Incyte other than the clinical trial that you have been working on for the past two years?...THE

WITNESS: No, they didn't support any other clinical trials. Is that what you are asking?").

Dr. Damsky ultimately admitted to participating in "a prior case," but still tried to minimize the extent to which Incyte was involved. EX1046, 83:12-84:8 ("There was a prior case I was involved in that I believe involved Incyte to some extent."), 84:16-85:6 (Dr. Damsky still reluctant to acknowledge he was retained for Petitioner Incyte Corporation in prior case), 86:16-90:13 (Dr. Damsky still reluctant to admit Incyte was the prior petitioner for whom he testified and he could not identify anywhere in his declaration where he identified his prior expert witness work for Incyte). He was similarly reluctant to disclose whether Incyte is paying him for his testimony in this case. EX1046, 23:4-17 ("I don't remember.").

Dr. Damsky's failure to account for his post-critical date relationship with the inventors and real parties-in-interest demonstrates that his perspective is one of an insider rather than that of a POSA, and his declaration should thus be excluded as unreliable.

III. CONCLUSION

EX2005 should be excluded because Dr. Damsky was unqualified as a POSA at the time of the invention and he misrepresented his independence from the real parties-in-interest in this matter.

Respectfully submitted,

Dated: March 4, 2024

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CERTIFICATE OF SERVICE

I certify that today this paper was served by email on PO's counsel at:

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