

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FORTE BIOSCIENCES, INC.,
Petitioner,

v.

UNIVERSITY OF MASSACHUSETTES,
Patent Owner.

PGR2023-00014
Patent No. 11,278,505

**PATENT OWNER'S OPPOSITION TO PETITIONER'S
MOTION TO EXCLUDE**

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Patent Owner University of Massachusetts respectfully submits this Opposition to Petitioner's Motion to Exclude (Paper 34, "Mot.") the declaration of Professor William Damsky M.D., Ph.D. (EX2005). The motion is legally and factually baseless. Professor Damsky is an Assistant Professor of Dermatology and Pathology (Clinician-Scholar Track) at the Yale University School of Medicine. EX2006, 1. He is *twice* qualified as a person of ordinary skill—having received both his Ph.D. in Cell & Molecular Biology in 2011 and his M.D. in 2013, together with timely relevant experience in both cytokine research and treating vitiligo. Rather than lacking independence, Professor Damsky's professional activities demonstrate that he is a sought-after academic and expert, active in the research field.

I. Professor Damsky's Declaration Is Admissible

Petitioner's motion is a transparent and improper attempt to argue the merits of this case following a Reply that failed to resolve or even address the multitude of deficiencies in its Petition. It is not a proper motion to exclude. Indeed, Petitioner does not seek to exclude any of Patent Owner's underlying evidence relied upon by Professor Damsky reflecting, *inter alia*, hundreds of known IL-15/IL-15R inhibitors, references expressly incorporated in the '505 patent, evidence of the known research paradigm, or evidence that IL-15/IL-15R inhibitors had been effective in treating autoimmune diseases. *E.g.*, EX2005, §IV, §VI, Appendix A. Instead, Petitioner repeats its concocted challenges to Professor Damsky's qualifications and

credibility, repackaging them on purported evidentiary grounds. *See* Paper 25 (“Reply”), 25-27. While Petitioner’s challenges to Professor Damsky have already been shown to be substantively meritless (Paper 32 (“Sur-reply”), 23-26), as purported evidentiary bases they are further untimely, groundless, and in contravention of Board rules.

Contrary to Petitioner’s challenges to Professor Damsky’s credentials, he is uniquely and doubly qualified to provide expert testimony in this case. First, he holds a Ph.D. in Cell & Molecular Biology, an M.D., and has been a practicing dermatologist who is sought-after for his expertise in vitiligo. EX2005, ¶¶2-6; EX2006, 1. His academic credentials are beyond reproach.

Second, Professor Damsky has been researching cytokine signaling pathways and their role in treating autoimmune diseases for over a decade, beginning *prior to* earning his Ph.D. in 2011. *E.g.*, EX2005, ¶6. This included “intensively study[ing] intracellular signaling pathways” where several of which “are regulated by cytokine signaling.” *Id.*; EX1021; EX1046, 267:22-268:16. Professor Damsky also began treating vitiligo patients as medical student—that is prior to his 2013 M.D. degree—and prior to 2017 he was a Resident and Chief Resident in Dermatology. EX2006, 1; EX1046, 116:16-117:9, 267:22-268:16. His extensive work in the area of cytokine signaling and autoimmune diseases, specifically vitiligo, is confirmed through his prolific authorship in peer-reviewed journals, numerous invitations to speak in

industry, service as a principal investigator on clinical trials evaluating cytokine-targeted therapies, and leading various research teams. EX2005, ¶¶2-17; EX2006. Thus, his experience is likewise beyond reproach.

Third, in providing his opinions in this case, Professor Damsky applied his training and experience to scores of evidentiarily-unchallenged prior art references to provide testimony regarding, *inter alia*, the standard of care for treating vitiligo (EX2005, §IV.A), classic research paradigms in dermatological and autoimmune diseases (EX2005, §IV.B), and IL-15 signaling and its relevance to human disease (EX2005, §IV.C). His substantive testimony thus rests on evidence of unquestionable relevance and admissibility.

Petitioner's challenge to Professor Damsky's independence also fails. Mot., 3-8. Not only did Professor Damsky disclose his prior relationship in his CV (EX2006, 3), the professional interactions on which Petitioner relies only confirm that he is a sought-after and credible expert, *not* an allegedly biased insider. This is also reflected in support, honors and recognitions disclosed in Professor Damsky's CV, including funding grants from Dermatology Foundation, Skin Cancer Foundation, and Centers for Disease Control as well as the following awards: Young Physician Scientist Award, American Society for Clinical Investigation; Robert E. Leet and Clara Guthrie Patterson Trust Mentored Research Award; and

Dermatologist Investigator Research Fellowship, Dermatology Foundation.
EX2006, 2-5.

In view of the above, and as explained further below, Professor Damsky's testimony is relevant and admissible evidence.

A. Petitioner's Motion Is Improper

Petitioner challenges Professor Damsky's testimony on two grounds—as allegedly not meeting the standard of a POSA and as being biased. Both challenges should be denied as contravening Board rules as (1) improperly arguing weight and (2) failing to have timely objected with sufficient specificity.

1. Petitioner Improperly Argues Weight, Repeating its Reply

Petitioner's challenges to Professor Damsky's declaration are an improper attempt to argue the weight of the evidence, prohibited by Board rules. "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." Consolidated Trial Practice Guide, November 2019 ("TPG") at 79; *see also* 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012); *EIS GmbH v. Novoluto GmbH*, IPR2019-01444, Paper 45, 47 (PTAB Aug. 5, 2021) (denying motion to exclude where expert allegedly failed to disclose prior work with Patent Owner, explaining "[a]lthough the testimony regarding Dr. Herbenick's work for Patent Owner may be relevant, it goes to the issue of credibility, not admissibility").

Reflecting the impropriety of its arguments, Petitioner cites to no PTAB support for its position and merely repeats the arguments against Professor Damsky made in Petitioner's Reply (Reply, 25-27), which Patent Owner has already refuted (Sur-reply, 23-26). Petitioner's re-arguing of these same baseless attacks is an improper attempt to subvert Board rules and have the last word on this already-briefed issue. TPG at 73-74, 79.

2. Petitioner Failed to Object with Sufficient Particularity

Petitioner did not timely object to EX2005 based on Professor Damsky's qualifications as a person of ordinary skill at the time of the invention or independence. Its motion thus also fails for this reason. 37 C.F.R. § 42.64(b)(1). Underscoring this violation of the Board's rules, Petitioner's Motion does not set forth which Rules of Evidence or law it previously invoked or is now invoking regarding Professor Damsky's independence.

Petitioner's evidentiary objections were based on a blanket invocation of "F.R.E. 401-403, 602, 701-703," for "any portion of EX2005." Paper 21, 3-4. They included only generic objections "to the extent" Professor Damsky's testimony is not based on his personal knowledge (citing "F.R.E. 602, 701"), not based on his knowledge, skill, experience, training or education and not based on sufficient data (citing "F.R.E. 702-703; 37 C.F.R. §42.65"), and as potentially outweighed by unfair prejudice and confusion of the issues (citing "F.R.E. 401-403"). Paper 21, 3. By

contrast, Petitioner's motion, premised on Dr. Damsky's meeting the level of skill in the art and alleged bias, is not based on any of these grounds.

Nowhere did Petitioner's objections allege that Professor Damsky was not a person of ordinary skill at the time of the invention or not an independent expert. *See* Paper 21, 3-4; *cf.* Mot., 1. Thus, Petitioner did not "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) (emphasis added). This precluded Patent Owner from submitting supplemental evidence under 37 C.F.R. § 42.64(b)(2) addressing the bases on which Petitioner now relies. "The lack of an effective objection is sufficient basis to deny Petitioner's Motion." *B/E Aerospace, Inc. v. MAG Aerospace Indus., LLC*, IPR2014-01511, Paper 104, 6-8 (PTAB Mar. 18, 2016) (denying motion to exclude where served objections used "boilerplate language" and did not assert objections later raised in a motion to exclude); 37 C.F.R. §§ 42.20(c), 42.64(c).

B. Professor Damsky Was a POSA at the Critical Date

Petitioner's argument that Professor Damsky "did not possess the knowledge of a POSA at the time of invention," (Mot. 1) is demonstrably false. Professor Damsky is an expert who exceeded the qualifications of a POSA as of April 2017. Notably, Petitioner does not object that Professor Damsky is an expert in this field today. *See* Mot.

Petitioner's only challenge to Professor Damsky's qualifications is that he allegedly "lacked the requisite 3-5 years of experience in treating autoimmune diseases or researching relevant cytokine signaling pathways relevant to treating autoimmune diseases," as of April 2017. Mot. 3. Petitioner, however, narrowly focuses on Professor Damsky's Ph.D. thesis and board certification, while ignoring Professor Damsky's extensive experience. Mot., 2-3.

Professor Damsky was awarded his Ph.D. in Cell & Molecular Biology in 2011, six years before the critical date. EX2006, 1. During his Ph.D. training, he "intensively studied intracellular signaling pathways" and the effects of alerting signaling to those pathways, such as cytokines. EX2005, ¶6. Professor Damsky additionally obtained his medical degree four years before the critical date in 2013, and testified that he began treating patients, including those with the autoimmune disease vitiligo, even earlier during his time as a medical student, i.e., *prior to* 2013. EX2005, ¶¶2-6, EX2006, 1; EX1046, 116:16-117:9. Professor Damsky further explained that between 2011 and 2017 his research group "was active in researching cytokines in dermatology and beyond dermatology in a number of different settings using translational approaches, invasive approaches in clinical trials," confirming that he had ***more than*** "3-5 years of experience in treating autoimmune diseases or researching relevant cytokine signaling pathways relevant to treating autoimmune diseases" by April 2017. EX1046, 267:22-268:16.

Petitioner also ignores Professor Damsky's multiple publications prior to April 2017 regarding treatment and research of autoimmune diseases, including cytokine pathway and vitiligo, confirming his experience in the relevant field at the relevant time. EX2005, 14 (reference no. 74 (EX1021)), 16 (reference nos. 80 and 82).¹ Reflecting his relevant experience, Professor Damsky was awarded a Dermatologist Investigator Research Fellowship in 2017. EX2006, 2.

Petitioner's challenge to Professor Damsky's expertise is further belied by its own reliance on one of his publications addressing cytokine pathways and multiple autoimmune diseases, including vitiligo. Paper 2, 9 (citing EX1021). Petitioner relies on this pre-April 2017 publication from Professor Damsky that reviews the role of JAK inhibitors in dermatology (EX1021) and cites this article as describing the pathology of autoimmune disease pathway, precisely the expertise it alleges Professor Damsky does not have. Paper 2, 9. In relevant part, the article describes

¹ Ref. No. 80: Damsky, W. and King, BA, "STATing the obvious: it's time for new treatments in atopic dermatitis," *Br. J. Dermatol.* 175(5): 861-862 (2016).
Ref. No. 82: Damsky W. and King, BA, "Idiopathic erythema multiforme: evidence of underlying janus kinase-signal transducer and activator of transcription activation and successful treatment with tofacitinib," *J. Am. Acad. Dermatol. Case Rep.* 2(6): 502-504 (2016).

the JAK-STAT signaling pathway and its potential in the autoimmune disease pathway with the following figure:

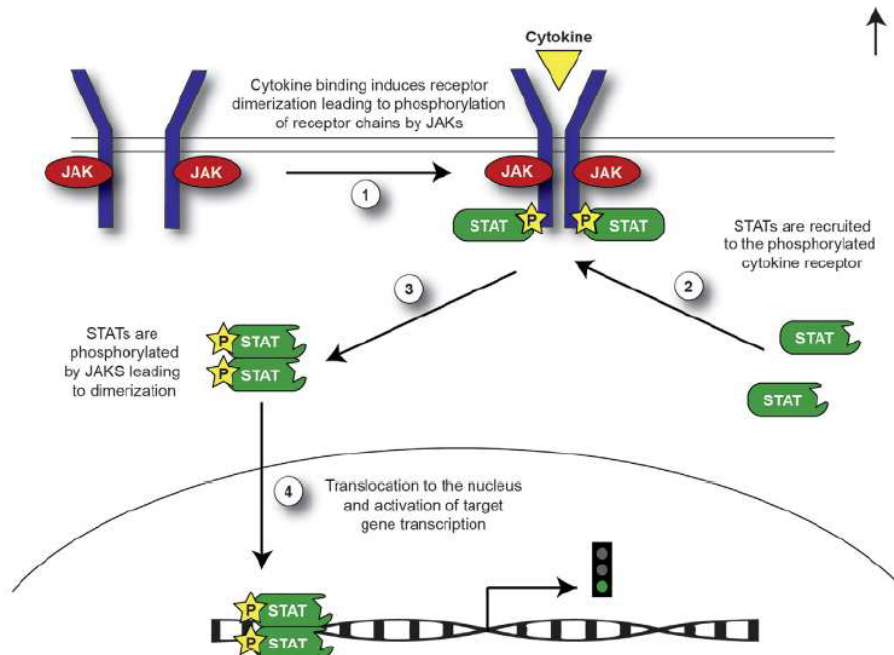


Fig 1. Janus kinase—signal transducer and activator of transcription (JAK-STAT) signaling pathway. JAK inhibitors antagonize JAK protein function and prevent activation of the pathway.

EX1021, Fig 1. In fact, this reference is “[o]ne of the most highly cited [Journal of the American Academy of Dermatology] articles” (EX2006, 14), further underscoring Professor Damsky’s experience—indeed expertise—in this field as of April 2017. It is specious, at best, to suggest that the author of this detailed and heavily relied upon prior art article lacked the qualifications of a POSA.

Thus, based on his educational experience and years of work in both “treating autoimmune diseases” *and* “researching cytokine signaling pathways relevant to treating autoimmune diseases,” Professor Damsky thus exceeded the qualifications of a POSA as of April 2017.

Petitioner's cited cases also fail to support its position that Professor Damsky lacks credibility and should be excluded. Many of Petitioner's cited cases simply state a POSA must provide testimony as of the time of invention, but do not address admissibility of expert testimony, let alone in Post Grant Reviews. Mot., 3. And while *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369 (Fed. Cir. 2022) and *Flex-Rest, LLC v. Steelcase, Inc.*, 455 F.3d 1351 (Fed. Cir. 2006), address admissibility in the ITC or district court (Mot., 1), the purported experts there were not found to meet the standard of a POSA in stark contrast with Professor Damsky's extensive relevant credentials here.

C. Professor Damsky Is an Independent Expert

Petitioner also manufactures attacks on Professor Damsky's independence. Mot., 3-8. Not only are such challenges untimely and improper for a motion to exclude (*supra*, § I.A), but they also rely on mischaracterizations of Professor Damsky's testimony. And, again, while Petitioner cloaks its arguments in the context of admissibility, it made the same arguments in its Reply (Reply, 25-27). Patent Owner responded to those arguments (Sur-Reply 23-26) and Petitioner's attempt to bolster its previous arguments should be rejected. *See* TPG at 73-74, 79.

Petitioner attempts to portray Professor Damsky as not independent. It ignores, however, that Professor Damsky testified unambiguously under oath that he did not consult with any of the inventors or parties regarding this case (EX1046,

38:4-11, 131:20-132:24) and signed a declaration confirming his role as an independent expert (EX2005, ¶1; EX1046, 24:8-25:22).

Petitioner embellishes Professor Damsky's relationship with the inventors to suggest that Professor Damsky had an extensive preexisting relationship. Mot., 5. Petitioner, for example, points to the Global Derm Talks, overlapping speaking engagements with the inventors, and discrete social media interactions as evidencing a close relationship, while ignoring the existence of another unrelated co-founder of the Global Derm Talks (EX1046, 45:13-46:2) and Professor Damsky's testimony that it is "very common to give talks and organize talks in dermatology" (EX1046, 45:13-22; *see also id.* 101:21-102:11). Petitioner additionally attempts to convert Professor Damsky's general practice of congratulating those in his field via social media (EX1046, 68:7-12; 69:18-70:1, 102:23-103:19) into something nefarious.

Petitioner's argument that Professor Damsky concealed his prior relationship also falls flat. Mot., 5-8. As an initial matter, it is contradicted by Professor Damsky's CV, which lists his prior consulting. EX2006, 3; *see also* EX2005, ¶18. Professor Damsky further confirmed under oath that the prior work was identified in his CV and explained that it related to one clinical trial that has not begun. EX1046, 76:11-78:81:4; 89:12-21.

Petitioner, however, ignores these disclosures and mischaracterizes portions of Professor Damsky's deposition testimony to argue that he "obfuscate[d]" his prior

relationships. Mot., 7-8. As reflected in the transcript, Petitioner’s counsel was trying to play memory games, refusing to provide documents to which he was referring. EX1046, 81:6-12-87:17. When it became clear that the questioner was asking about Professor Damsky’s litigation consulting work, he testified candidly about his previous work with the law firm he was retained by and stated repeatedly that he was not sure of the extent of Incyte’s involvement in that matter and “wouldn’t characterize ... my relationship [in that matter] as a collaborative one with Incyte.” EX1046, 82:25-87:17. And Petitioner’s suggestion that because Professor Damsky is biased because he is being compensated (Mot., 8) obviously has no merit. *NuVasive, Inc. v. Iancu*, 752 F. App’x 985 at 996 (Fed. Cir. 2018).

Petitioner’s statement that “[p]ublications [Professor Damsky] co-authored with [the ’505 patent inventors] were clear in disclosing a conflict of interest relating to the ’505 patent,” has no bearing on whether Professor Damsky, who is not an inventor, has any conflict due to the ’505 patent or the parties in this case. Mot. 6 (citing EX1037; EX1039). To the contrary, the conflicts statements in EX1037 and EX1039 expressly disclose that Professor Damsky does not share conflicts only separately identified for other co-authors. In this regard, contrary to Petitioner’s suggestion, those publications clearly state only that the inventors, *not* Professor

Damsky, have an interest in the provisional application that resulted in the '505 patent (not the '505 patent itself)² and Villarís. EX1037, 1; EX1039, 118.

In support of its manufactured prejudice argument, Petitioner relies on a series of cases from district courts in the context of claims for inequitable conduct. Mot., 4. No such claim has been brought here, and Petitioner makes no attempt to analogize the facts of these cited cases to this case or to Post Grant Reviews generally. In any case, Petitioner's allegation of bias at most "goes to the issue of credibility, not admissibility," *Eis GmbH*, IPR2019-01444, Paper 45 at 47, and as described above, is unfounded and should be denied.

II. Conclusion

For the foregoing reasons, Patent Owner respectfully requests that Petitioner's Motion be denied.

Date: March 8, 2024

Respectfully submitted,

/Mark J. Feldstein/

Mark J. Feldstein

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² In fact, Professor Damsky testified that when co-publishing with the inventors, he did not know whether he would have reviewed their conflict disclosures or known that they had an interest in the provisional application that resulted in the '505 patent. EX1046, 41:5-42:8, 50:4-51:6; *see also* EX1046, 33:24-35:20.

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing **Patent Owner's Opposition to Petitioner's Motion to Exclude** was served electronically via email on March 8, 2024, in its entirety on the following:

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Dated: March 8, 2024

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