

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

THORNE RESEARCH, INC.,
Petitioner,

v.

TRUSTEES OF DARTMOUTH COLLEGE,
Patent Owner.

Case IPR2021-00268

Patent 8,383,086

**SUR-REPLY TO PETITIONER'S REPLY TO PATENT OWNER'S
PRELIMINARY RESPONSE**

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The Trustees of Dartmouth College (“Patent Owner”) submit this Sur-Reply to Thorne Research, Inc.’s (“Petitioner”) Reply to Patent Owner’s Preliminary Response to the Petition seeking *inter partes* review of U.S. Patent No. 8,383,086 (Ex. 1001, “the ’086 patent”). See Ex. 1024 at 23:20 (authorizing this Sur-Reply).

I. INTRODUCTION

Petitioner cannot establish that the relevant portions of the asserted ’337 PCT Publication and *Cell* article are “by another,” such that they would qualify as prior art under pre-AIA § 102(a) or (e). Patent Owner submitted unequivocal and entirely consistent declarations from Drs. Brenner and Bieganowski establishing that the portions of the references relied upon by Petitioner are the inventive work of Dr. Brenner alone. It was Petitioner’s burden to establish otherwise.

With the blessing of the Board, Petitioner sought and noticed the depositions of both declarants. During his deposition, Dr. Bieganowski confirmed his declaration testimony, and Petitioner did not obtain a single shred of testimony indicating that the relied-upon portions of the references were the inventive work of anyone other than Dr. Brenner. Petitioner then affirmatively cancelled the scheduled deposition of Dr. Brenner, leaving his declaration, which is corroborated by Dr. Bieganowski, completely un rebutted. Petitioner’s decision to abandon the deposition of Dr. Brenner effectively amounts to a concession that it cannot establish that the relied-upon portions of the references are the work of another.

After an opportunity to fully litigate the “by another” issue, Petitioner is left with no evidence—much less evidence to establish a reasonable likelihood of prevailing—that the ’337 PCT Publication or the *Cell* article qualify as prior art.

II. PETITIONER HAS NOT DEMONSTRATED “A REASONABLE LIKELIHOOD” OF ESTABLISHING THAT THE ’337 PCT PUBLICATION AND *CELL* ARTICLE ARE PRIOR ART

Petitioner has failed to meet its burden under § 314(a) to show “a reasonable likelihood” it would prevail in establishing that the ’337 PCT Publication and *Cell* article are “by another” and thus prior art. The central question is whether the relied-upon portions of the references represent the inventive work of Dr. Brenner alone. The undisputed evidence shows they do.

A. Patent Owner’s Declarations Establish that Dr. Brenner Is the Sole Inventor of the Relevant Subject Matter

Patent Owner submitted a declaration from Dr. Brenner, the sole inventor of the ’086 patent, and one from Dr. Bieganowski, who is not an inventor of the ’086 patent but is listed as a co-inventor and co-author in the ’337 PCT Publication and *Cell* article, respectively. Ex. 2002 ¶¶ 5-8; Ex. 2003 ¶ 5. These declarations establish that Dr. Brenner is the sole inventor of the ’086 patent claims, and that Dr. Bieganowski is not an inventor of any of the relied-upon portions of the asserted references. *See* Paper 10 at 11-13.

1. The Declarations Explain the Context for the Laboratory Work that Led to the *Cell* Article and ’337 PCT Publication

Contrary to Petitioner’s assertion that there is “context missing” from the declarations (*see* Reply at 2-4), both declarations in fact provide background and context for the laboratory work that was reflected in the *Cell* article and the ’337 PCT Publication. Dr. Brenner’s declaration makes clear that he was “the project leader and principal investigator” of the NR research project and that he “directed members of [his] laboratory research team” to conduct experiments that he designed (Ex. 2002 ¶¶ 10-11); that Dr. Bieganowski was a postdoctoral fellow in the lab and that his specific role was to perform, at Dr. Brenner’s direction, “experiments and assays for identifying yeast and human genes that have [NR] kinase activity” (*Id.* ¶ 12); and that Dr. Brenner alone was responsible for “all aspects of the NR research project related to therapeutic uses and compositions of [NR]” (*i.e.*, claim 2 of the ’086 patent) (*Id.* ¶ 13). Similarly, Dr. Bieganowski’s declaration confirms that he simply performed, at Dr. Brenner’s direction, “the experiments and assays [Dr. Brenner] had designed for identifying yeast and human genes that have [NR] kinase activity.” Ex. 2003 ¶ 6. Dr. Bieganowski also confirmed that he did not contribute to “therapeutic uses or compositions of [NR]” (*i.e.*, claim 2 of the ’086 patent). *Id.* ¶ 7.

2. The Declarations Confirm that Dr. Bieganowski Is Not an Inventor of the Relied-Upon Portions of the References

Petitioner falsely asserts that the declarations do not address the “relevant portions of the references.” Reply at 3-4. On the contrary, after providing the

context for the NR research project, Dr. Brenner's declaration includes an analysis of each and every one of the relied-upon portions of the *Cell* article and '337 PCT Publication cited in the Petition. *See* Ex. 2002 ¶¶ 15-19.

Dr. Brenner's declaration unequivocally establishes the division of labor in his laboratory during the 2003-2004 timeframe, including work that was reflected in both the *Cell* article and the '337 PCT Publication. Against this backdrop, Dr. Brenner then explains that the specific relied-upon portions of those references were his inventive work alone. Although Petitioner would prefer to ignore those portions of Dr. Brenner's declaration because they defeat Petitioner's arguments that the references are prior art, Sections III and IV of Dr. Brenner's declaration provide unequivocal testimony that Dr. Brenner is the sole inventor of the relied-upon portions of those references. Ex. 2002 ¶¶ 15-19.

Dr. Bieganowski's declaration confirms and corroborates Dr. Brenner's statements. Dr. Bieganowski states unequivocally that he did not contribute to therapeutic uses or compositions of NR, and that any portions of the *Cell* article or '337 PCT Publication relied-upon by Petitioner directed to that subject matter (*i.e.*, all of the citations analyzed and discussed in Sections III and IV of Dr. Brenner's declaration) are the inventive work of Dr. Brenner alone. Ex. 2003 ¶¶ 6-7.

B. Petitioner Has the Burden of Persuasion and Production

Petitioner has the burden of persuasion on the "by another" issue. *See*

Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375, 1378 (Fed. Cir. 2015). On this issue, the Petition relied solely on the fact that Dr. Bieganowski is listed as an inventor on the '337 PCT Publication but not on the '086 patent. Pet. at 32 n. 7. Petitioner submitted no evidence, however, indicating that any of the relied-upon portions of the references were the inventive work of Dr. Bieganowski.

The two declarations unequivocally establish that the relied-upon portions of the references were the inventive work of Dr. Brenner alone. Thus, the burden shifted to Petitioner to establish otherwise. *See Dynamic Drinkware* at 1379-80 (holding that the burden of production returns to Petitioner after Patent Owner produces evidence disqualifying a prior art reference); *see also Sanofi-Aventis v. Immunex*, IPR2017-01879, Paper 88 at 10-11 (P.T.A.B. Feb. 14, 2019) (same).

Petitioner argues that the declarations did not shift the burden of production because they contain only “naked assertions.” Reply at 2. The declarations are neither conclusory nor naked assertions. *See supra* Section II.A. Moreover, the case that Petitioner relies on, *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, does not even discuss shifting the burden of production. 859 F.3d 1341, 1345-48 (Fed. Cir. 2017). Even according to *EmeraChem*, when an inventor declaration provides, for example, “explanation that [the inventor’s] co-authors [for an asserted reference] were students under his direction and supervision,” similar to Dr. Brenner’s declaration here, then it contains “more than a naked

assertion.” *Id.* (discussing *In re Katz*, 687 F.2d 450, 455-56 (C.C.P.A. 1982)). Additionally, *EmeraChem* involved only an inventor declaration, whereas here there is also a corroborating declaration. *See id.*; *cf. Varian Med. Sys. v. William Beaumont Hospital*, IPR2016-00160, Paper 82 at 21-22 (P.T.A.B. May 4, 2017) (inventor and disclaimer declarations sufficient to meet burden of production).

C. Petitioner Obtained No Evidence to Meet Its Burden

Aware of its burden, Petitioner requested depositions of Drs. Bieganowski and Brenner, which were scheduled for April 16 and 23, respectively. *See* Papers 12, 13. As explained below, Dr. Bieganowski’s deposition corroborates and confirms the declaration testimony, and nothing he said at his deposition supports Petitioner’s bald assertions on the “by another” issue. Apparently recognizing that it was wrong on the facts, Petitioner thereafter unilaterally elected to cancel Dr. Brenner’s deposition, leaving his declaration completely unrebutted. Ex. 2012.

1. Dr. Bieganowski’s Deposition Confirmed that He Did Not Invent the Relied-Upon Portions of the Asserted References

Dr. Bieganowski testified that he reviewed the claims of the ’086 patent and confirmed that he is “not an inventor of the claims of the ’086 patent.” Ex. 1025 at 10:10-20. When challenged on his understanding of the legal definition of an “inventor,” Dr. Bieganowski further confirmed that he is “not a patent lawyer” but that in science, the concept refers to a “new idea.” *Id.* at 26:8-12. He went on to explain that he understands the ’086 patent to claim, as its “new idea,” the “use of

NR as a drug or supplement,” which he unequivocally disowned as his invention in both his declaration and at his deposition. *Id.* at 26:14-23, 10:10-20; Ex. 2003 ¶ 7.

With respect to the work reflected in the *Cell* article and the '337 PCT Publication, again, Dr. Bieganowski's deposition testimony only confirmed the contents of his declaration. Dr. Bieganowski provided the context for the NR research project, including that it started when Dr. Brenner asked him to see if the NAD synthetase mutant could grow on a medium supplemented with NAD. Ex. 1025 at 16:18-17:16. Just as he did in his declaration, Dr. Bieganowski testified that Dr. Brenner designed all of the experiments reflected in the *Cell* paper and that Dr. Bieganowski performed those experiments at Dr. Brenner's direction using routine laboratory techniques. *Id.* at 19:10-14, 21:22-22:14.

2. Petitioner's Reply Fails to Refute the Record Evidence

Faced with a dearth of evidence on the “by another” issue, Petitioner's Reply instead focuses on irrelevant arguments that do not change the record evidence:

❖ Petitioner asserts that the declarations are uncorroborated (Reply at 2-3), but in fact, Dr. Brenner's declaration is corroborated by Dr. Bieganowski's consistent disclaimer declaration. *See Varian*, IPR2016-00160, Paper 82 at 28-29 (finding inventor's testimony corroborated by non-inventor who co-authored asserted reference); *Sanofi-Aventis*, IPR2017-01879, Paper 88 at 15-16.

❖ Petitioner asserts that Dr. Bieganowski's declaration is somehow deficient

because he allegedly did not review the references or know the legal definition of an “inventor.” Reply at 4-5. These arguments fail to rebut Dr. Bieganowski’s clear statements and testimony that he did not invent the relied-upon portions of the asserted references. In fact, Dr. Bieganowski testified that he was familiar with the contents of the references based on his contemporaneous laboratory work, that he reviewed the ’086 patent claims, and that he understood the scientific meaning of an invention. Ex. 1025 at 12:13-17, 10:10-20, 26:8-12.

❖ Petitioner asserts that “Dr. Bieganowski can also be a *co-inventor* to the subject matter” but provides *zero* evidence that Bieganowski co-invented anything. See Reply at 8 (emphasis in original). Indeed, Petitioner did not even question Dr. Bieganowski about the “composition” recited in the challenged claim or the specific relied-upon portions of the *Cell* article and ’337 PCT Publication.

❖ Petitioner also complains that the declarations are unreliable because they reflect events from “eighteen years ago.” Reply at 5-6. But, Dr. Bieganowski testified in both his declaration and deposition that he recalled his role in Dr. Brenner’s lab (Ex. 2003 ¶ 6; Ex. 1025 at 16:18-19:23), which is consistent with his testimony that he did not contribute to therapeutic uses or compositions of NR (Ex. 2003 ¶ 7). Moreover, Petitioner’s argument on this point rings particularly hollow in light of its decision to forgo the deposition of the inventor of the ’086 patent.

❖ Petitioner’s argument that the declarants are allegedly “interested” is also

contrary to both the record and the law. Dr. Bieganowski testified that he is not being compensated for his testimony and that he has no interest in ChromaDex or Dartmouth. Ex. 1025 at 6:15-7:13. The fact that he has a consulting agreement also does not diminish the reliability of his testimony, particularly given that he was subject to cross-examination under oath and has no interest in the patent or this proceeding. *See Trans Ova Genetics, LC v. XY, LLC*, IPR2018-00250, Paper 35 at 10 n.9 (P.T.A.B. June 26, 2019) (holding that testimony from a compensated witness, who, as a former board member, may have had an interest in the outcome, was credible because it “was under oath and subject to cross-examination”).

❖ Petitioner incorrectly asserts that because Dr. Bieganowski performed experiments disclosed in the references, they cannot represent Dr. Brenner’s inventive work. Reply at 10. But this completely ignores Dr. Bieganowski’s unequivocal testimony that his work was routine and done at Dr. Brenner’s direction. *See, e.g., Sanofi-Aventis*, IPR2017-01879, Paper 88 at 22-24 (“conduct[ing] routine experiments” at the “direction of [the inventor] according to known techniques” does not constitute inventorship “by another”); *In re Katz*, 687 F.2d at 455-56 (reference was not “by another” where co-authors were “working under the direction and supervision” of the inventor).

❖ Petitioner also asserts that the relevant subject matter is not Brenner’s “inventive work” because it purportedly “represent[s] the work of those in the prior

art.” Reply at 8-10. But this argument relies on the false premise that the invention of claim 2 of the ’086 patent is simply isolated NR. *Id.* at 9-10 (asserting that “NR and its isolation was already known”). Petitioner’s assertion ignores that claim 2 includes the limitations of claim 1 and is another attempt at its faulty collateral estoppel argument. *See* Pet. at 22. But as previously explained, claim 2 includes the limitations of claim 1 and its validity is determined with respect to all claim elements. Paper 10 at 31-34. Indeed, a patentee’s “by another” argument surely does not require that the inventor show that he invented the subject matter of each relied-upon element of a reference separately and independently.

III. CONCLUSION

After a full opportunity to develop a factual record and litigate the “by another” issue, Petitioner fails to present evidence that Dr. Bieganowski is the inventor of anything, much less the subject matter of the relied-upon portions of the asserted references. Because Petitioner cancelled Dr. Brenner’s deposition, the deposition testimony of Dr. Bieganowski is the only potential evidence that Petitioner has to rely upon to meet its burden. But Petitioner has identified *zero* evidence that anyone other than Dr. Brenner invented the relied-upon portions of the *Cell* article and ’337 PCT Publication. These two references are therefore not “by another” and cannot be prior art. Accordingly, there is not a reasonable likelihood of Petitioner prevailing and the Petition should be denied.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned hereby certifies that a copy of the foregoing SUR-REPLY PETITIONER'S REPLY TO PATENT OWNER'S PRELIMINARY RESPONSE was served on May 7, 2021 by filing this document through the Patent Trial and Appeal Board End to End as well as by delivering a copy via the delivery method indicated to the attorneys of record for the Petitioner as follows:

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