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 IPR2021-00491

Patent 8,197,807

PRELIMINARY RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,197,807

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The Trustees of Dartmouth College ("Patent Owner") respectfully submit this Preliminary Response to the Petition seeking *inter partes* review of U.S. Patent No. 8,197,807 (Ex. 1001, "the '807 patent") filed by Thorne Research, Inc. ("Petitioner"). This Response is timely under 35 U.S.C. § 313 and 37 C.F.R. § 42.107 because it is within three months of the February 18, 2021 date of the Notice granting the Petition a filing date. Paper No. 3 (Notice of Filing Date) at 1.

I. INTRODUCTION

Patent Owner respectfully submits that *inter partes* review of the '807 patent should not be instituted because Petitioner has failed to demonstrate that it has a reasonable likelihood of prevailing with respect to the challenged claims of the '807 patent.

First, the primary reference in each of Petitioner's Grounds is not even prior art. The relied-upon portions of the '337 PCT Publication[1] and *Cell* article[2]

[1] International Publication No. WO 2005/077091 A2 ("the '337 PCT Publication") (Ex. 1007).

[2] Bieganowski & Brenner, "Discoveries of Nicotinamide Riboside as a Nutrient and Conserved *NRK* Genes Establish a Preiss-Handler Independent Route to NAD^+ in Fungi and Humans," 117 *Cell* 495 (May 14, 2004) ("the *Cell* article") (Ex. 1008).

regarding claims 1-3 of the '807 patent are not "by another," and thus these two references are not prior art under either pre-AIA § 102(a) or § 102(e).[3] Petitioner already had an opportunity to fully litigate the "by another" issue in a related IPR proceeding and submitted no evidence, much less evidence to establish a reasonable likelihood of prevailing, that the '337 PCT Publication or *Cell* article qualify as prior art under §§ 102(a) or 102(e).

In addition, Petitioner's priority argument is based entirely on an unsupported theory that the '807 patent priority claim is defective under the Paris Convention treaty. Tellingly, Petitioner cites no U.S. law or statute in support of its theory. The '807 patent makes a proper priority claim to the '701 Application under 35 U.S.C. § 120, the controlling U.S. statute, and Petitioner does not even attempt to argue otherwise. Thus, the *Cell* article is not prior art under pre-AIA § 102(b).

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[3] The Petition refers to the '337 PCT Publication and *Cell* article as "Brenner" (Ex. 1007) and "Bieganowski" (Ex. 1008), respectively. *See* Pet. at 32-35, 59. Because Patent Owner is submitting herewith declarations from both Dr. Brenner (Ex. 2002) and Dr. Bieganowski (Ex. 2003), Patent Owner will refer to the asserted references as the '337 PCT Publication (Ex. 1007) and *Cell* article (Ex. 1008) to avoid confusion with the eponymous declarations.

Second, the Board should exercise its discretion to deny institution because of the Petition's weak merits and because IPR of the challenged claims was previously denied institution, one of the two primary references was previously considered by the USPTO, and the patent is also at issue in multiple district court cases, including one at an advanced stage.

For at least these reasons, the institution of an *inter partes* review of the '807 patent should be denied.

II. RELATED IPR PROCEEDING

In IPR2021-00268, Petitioner challenged U.S. Patent No. 8,383,086 (Ex. 1024, "the '086 patent"), a continuation of the '807 patent. IPR2021-00268, Paper 2 at 1, 6. In IPR2021-00268, Petitioner advanced substantially the same alleged invalidity grounds against the '086 patent based on the *Cell* article and '337 PCT Publication as they do here against the '807 patent. *Id.* at 42-50.

In its Preliminary Response brief, Patent Owner explained that (1) the *Cell* article and '337 PCT Publication are not prior art under §§ 102(a) or 102(e) because the relied-upon portions of the references are the inventive work of Dr. Brenner alone (the named inventor of the '086 and '807 patents), IPR2021-00268, Paper 10 at 7-14, and (2) Petitioner's Paris Convention argument is unsupported and the *Cell* article is not prior art under § 102(b). IPR2021-00268, Paper 10 at 14-25.

With respect to the "by another" issue, Patent Owner submitted declarations from Drs. Brenner and Bieganowski (the only individuals listed as named inventors and authors on the '337 PCT Publication and *Cell* article, respectively) that unequivocally and consistently state that the relied-upon portions of the references are the inventive work of Dr. Brenner alone. *Id.* at 13. Petitioner sought the depositions of Drs. Brenner and Bieganowski. IPR2021-00268, Paper 16 at 6. After taking Dr. Bieganowski's deposition testimony, which unequivocally affirmed his declaration, Petitioner unilaterally elected to cancel the deposition of Dr. Brenner, leaving his declaration completely unrebutted and leaving the record with nothing but evidence that the relied-upon portions of the references are the inventive work of Dr. Brenner alone. *Id.* at 6-7. Thus, after an opportunity to fully litigate the "by another" issue, Petitioner was unable to present any evidence to support its theory that the *Cell* article and '337 PCT Publication qualify as prior art. IPR2021-00268, Paper 16 at 1-2, 6-10.

The arguments herein regarding the *Cell* article and '337 PCT Publication are substantially identical to those made in IPR2021-00268, and institution should be denied for the same reasons.

III. BACKGROUND

Charles M. Brenner, Ph.D. ("Dr. Brenner") is the sole named inventor of the '807 patent. Ex. 2002 ¶¶ 6, 11-15; '807 patent at (75). The claimed invention

stemmed from a nicotinamide riboside ("NR") research project ("NR research project") that Dr. Brenner led in late 2003 and early 2004 at Dartmouth Medical School. *See* Ex. 2002 ¶¶ 11-15. As part of the NR research project, Dr. Brenner established that NR is an unanticipated vitamin precursor of nicotinamide adenine dinucleotide ("NAD+"), and he identified and sequenced the gene that he ultimately named nicotinamide riboside kinase ("Nrk"). *Id.* ¶ 12. Dr. Brenner's laboratory research team included a postdoctoral fellow named Pawel Bieganowski Ph.D. ("Dr. Bieganowski"), who performed, at Dr. Brenner's direction, experiments and assays for identifying yeast and human genes that have Nrk activity. *Id.* ¶ 13; Ex. 2003 ¶ 7; Ex. 2004 at 16:18-17:3, 19:10-23, 21:22-22:14. Dr. Bieganowski has declared and testified under oath that he did not have any role in any aspect of Dr. Brenner's inventions regarding therapeutic uses or compositions of NR. Ex. 2002 ¶ 14; Ex. 2003 ¶ 8; *see also* Ex. 2004 at 10:10-20.

As a result of the NR research project, Dartmouth filed U.S. Provisional Patent Application No. 60/543,347 ("the '347 Provisional") on February 10, 2004, and International Application No. PCT/US2005/004337 ("the '337 PCT Application") on February 9, 2005, which claimed priority to the '347 Provisional. *See* Ex. 1005; Ex. 1007; Ex. 2002 ¶¶ 7-8, 15. On August 25, 2005, the '337 PCT Application was published as the '337 PCT Publication, which Petitioner asserts in Ground 2 of this IPR as the "Brenner" reference. *See* Pet. at 34, 38; Ex. 1007; Ex.

2002 ¶ 8. The '347 Provisional and '337 PCT Publication both name Dr. Brenner and Dr. Bieganowski as co-inventors, but the portions of the '337 PCT Publication relied upon in the Petition are solely the invention of Dr. Brenner, the named inventor of the challenged '807 patent. *See* Ex. 1005 at 3; Ex. 1007 at (75); Pet. at 34-35, 51-56; Ex. 2002 ¶¶ 7-8, 16-17; Ex. 2003 ¶¶ 6, 8; *see also* Ex. 2004 at 10:10-20, 19:10-14, 21:22-22:14.

Certain aspects of the NR research project were also included in the *Cell* article, which was published on May 14, 2004, and which Petitioner asserts in Ground 1 of this IPR as the "Bieganowski" reference. *See* Pet. at 32, 38; Ex. 1008; Ex. 2002 ¶ 9. The *Cell* article names Dr. Brenner and Dr. Bieganowski as co-authors, but the portions of the *Cell* article relied upon by the Petition are solely the invention of Dr. Brenner, the named inventor of the challenged '807 patent. *See* Ex. 1008 at 495; Pet. at 40-50; Ex. 2002 ¶¶ 9, 18-19; Ex. 2003 ¶¶ 6, 8; *see also* Ex. 2004 at 10:10-20, 19:10-14, 21:22-22:14.

The '807 patent is directed to compositions comprising isolated NR in combination with one or more of tryptophan, nicotinic acid, or nicotinamide, wherein the composition is in admixture with a carrier and is formulated for oral administration and increases NAD+ biosynthesis upon oral administration. *See* '807 patent at claims 1-3. The '807 patent issued from U.S. Patent Application No. 11/912,400 ("the '400 Application"). The '400 Application is a national stage

entry of International Application No. PCT/US2006/015495 ("the '495 PCT"), which was published as International Publication No. WO 2006/116322 A2 and claims priority at least to U.S. Patent Application No. 11/113,701 ("the '701 Application"). The '807 patent thus claims priority at least back to the '701 Application. *See id.* at 1:11-13.

IV. PETITIONER HAS NOT DEMONSTRATED "A REASONABLE LIKELIHOOD OF PREVAILING" UNDER 35 U.S.C. § 314(a) ON GROUNDS 1-2 BECAUSE THE '337 PCT AND *CELL* ARTICLE ARE NOT PRIOR ART

Under 35 U.S.C. § 314(a), an IPR may only be instituted where "the information presented in the petition … and any response … shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition." *See also* 37 C.F.R. § 42.108(c). The burden of showing that this statutory threshold has been met belongs to Petitioner. *See, e.g.*, Office Patent Trial Practice Guide, 77 Fed. Reg. 48756, 48756 (Aug. 14, 2012) ("The Board … may institute a trial where the petitioner establishes that the standards for instituting the requested trial are met … .").

Each of Petitioner's asserted Grounds is based on the *Cell* article or the '337 PCT Publication, but neither of these two references is prior art. First, the relied-upon portions of the *Cell* article and '337 PCT Publication are the sole invention of the named inventor of the '807 patent (Dr. Brenner), meaning that the *Cell* article and '337 PCT Publication are not prior art under 35 U.S.C. § 102(a) or § 102(e).

Second, Petitioner's unsupported and inapplicable Paris Convention argument regarding the '807 patent's priority fails to establish the *Cell* article as prior art under 35 U.S.C. § 102(b).

Accordingly, Petitioner has failed to meet its burden of showing that there is a reasonable likelihood that it would prevail with respect to any Ground, and Petitioner's request for IPR should be denied.

A. The Asserted *Cell* Article and '337 PCT Publication Are Not Prior Art Under 35 U.S.C. § 102(a) or § 102(e)

All Grounds of the Petition are based on either the *Cell* article or '337 PCT Publication. *See* Pet. at 38, 40-56. Petitioner asserts that the '337 PCT Publication is allegedly prior art to the '807 patent under pre-AIA § 102(a) or § 102(e). *See id.* at 34 n.12, 38.

To qualify as prior art under either § 102(a) or § 102(e), the portions of the reference relied upon as prior art must be "by another." That is, the relied-upon portions of the reference must be the invention of someone other than the inventor of the challenged '807 patent, *i.e.*, Dr. Brenner. Here, however, Dr. Brenner is the sole inventor of the relied-upon portions of the *Cell* article and '337 PCT Publication asserted by Petitioner, as confirmed by declaration testimony from Dr. Brenner and both declaration and deposition testimony from Dr. Bieganowski, the only other co-author or co-inventor named for those two references. The *Cell*

article and the '337 PCT Publication are therefore not prior art under § 102(a) or § 102(e).

1. To Qualify as Prior Art Under § 102(a) or § 102(e), the Relied-Upon Portions Must Be "By Another"

Under Pre-AIA § 102, an inventor's own work is only prior art if it constitutes a statutory bar under § 102(b). *See Lacks Indus. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1346 (Fed. Cir. 2003) ("[I]t is 'well-settled' law that an inventor's own disclosure 'will not anticipate his later invention unless that prior work is such as to constitute a statutory bar under Section 102(b).'") (quoting Chisum on Patents § 3.08 [2][a] (1999)); *In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982) ("[C]ertainly one's own invention, whatever the form of disclosure to the public, may not be prior art against oneself, absent a statutory bar [under § 102(b)].") (internal quotation marks and citation omitted). An inventor's own work is thus not prior art under § 102(a) or § 102(e).

Under § 102(e), a claim is invalid only if "the invention was described in … an application for patent, published under section 122(b), ***by another*** filed in the United States before the invention by the applicant for patent." (Emphasis added). Thus, an applicant or patentee may "overcome a prior art reference under section 102(e)" by "establish[ing] that the relevant disclosure describes their own invention." *In re Costello*, 717 F.2d 1346, 1351 (Fed. Cir. 1983).

"[T]he fact that [a challenged patent] has named a different inventive entity than a [prior application] does not necessarily make that [reference application] prior art." *Applied Materials, Inc. v. Gemini Research Corp.*, 835 F.2d 279, 281 (Fed. Cir. 1987). Rather, "the relevant question is not whether the references list different inventors, but 'whether the portions of the reference relied on as prior art, and the subject matter of the claims in question, represent the work of a common inventive entity.'" *EmeraChem Holdings, LLC v. Volkswagen Grp. of Am., Inc.*, 859 F.3d 1341, 1345 (Fed. Cir. 2017) (quoting *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1356 (Fed. Cir. 2003)). This analysis focuses on just "the portions of the reference relied on as prior art," not the reference as a whole. *Riverwood Int'l Corp.*, 324 F.3d at 1356.

As with § 102(e), one's own work is also not prior art under § 102(a). *Katz*, 687 F.2d at 454. Thus, a patentee may overcome a prior art reference under § 102(a) the same way as described above, *i.e.*, by establishing that the relied-upon portions of the reference describe their own invention. *See id.* at 455. Co-authoring an article does not make one an inventor of the subject matter disclosed therein. *See id.* ("[A]uthorship of an article by itself does not raise a presumption of inventorship with respect to the subject matter disclosed in the article.").

Where an inventor of a challenged patent is one of two co-inventors of an earlier application asserted under § 102(e), such as the '337 PCT Publication here,

either a declaration by the inventor of the challenged patent that he conceived the relied-upon portions or a disclaimer declaration by the other named co-inventor of the application is sufficient to establish that the application is not "by another" and is thus not prior art under § 102(e). *See, e.g.*, *In re DeBaun*, 687 F.2d 459, 463 (C.C.P.A. 1982) (finding inventor declaration sufficient); *In re Mathews*, 408 F.2d 1393, 1396 (C.C.P.A. 1969) (finding disclaimer declaration sufficient). Likewise, where an inventor of a challenged patent is one of two co-authors of a reference article asserted against the patent under § 102(a), such as the *Cell* article here, either a declaration by the inventor that he conceived the relied-upon portions of the article or a disclaimer declaration by the non-inventor co-author is sufficient to establish that the reference article is not by "others" and is thus not prior art under § 102(a). *See, e.g.*, *Katz*, 687 F.2d at 455-56 (finding an inventor declaration sufficient); *Ex Parte Hirschler*, 1952 Pat. App. LEXIS 55, at *7-10 (B.P.A.I. Jan. 31, 1952) (finding a disclaimer affidavit sufficient).

Unlike cases such as *Katz* though, where the burden is on an applicant "to establish that the subject disclosure was his original work, and his alone," 678 F.2d at 455, the burden here is on Petitioner to establish a reasonable likelihood that it would prevail in showing that the relied-upon portions of the *Cell* article and '337 PCT Publication were invented by Dr. Bieganowski rather than Dr. Brenner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir.

2015) (holding that, in an IPR, the burden of persuasion is on the petitioner and never shifts to the patentee).

2. Dr. Brenner Is the Sole Inventor of the Relied-Upon Subject Matter in the *Cell* Article and '337 PCT Publication

Dr. Brenner is the sole named inventor of the challenged '807 patent. '807 patent at (75); Ex. 2002 ¶¶ 1-4, 6. Dr. Brenner is also the sole inventor of the portions of the *Cell* article and '337 PCT Publication upon which Petitioner relies, and therefore neither of those two references is "by another" as required by pre-AIA § 102(a) and § 102(e).

a. Dr. Brenner's NR Research Project

Dr. Brenner worked from July 1, 2003 to June 30, 2009 as a professor and researcher at Dartmouth Medical School, where he was the project leader and principal investigator of the NR research project. Ex. 2002 ¶ 11. As a part of that project, in late 2003, Dr. Brenner directed members of his team to conduct experiments and assays related to NR, and as a result, Dr. Brenner identified and named an Nrk gene and discovered sequences of the Nrk1 and Nrk2 genes in humans. *Id.* ¶ 12. One member of Dr. Brenner's research team was Dr. Bieganowski, who was at the time a postdoctoral fellow in molecular biology who performed, at Dr. Brenner's direction, experiments and assays for identifying yeast and human genes that have Nrk activity. *Id.* ¶ 13; Ex. 2003 ¶ 7; Ex. 2004 at 16:18-17:3, 19:10-23, 21:22-22:14.

Dr. Brenner was solely responsible for all aspects of the NR research project related to therapeutic uses and compositions of NR, including the compositions recited in claims 1-3 of the '807 patent. Ex. 2002 ¶ 14; Ex. 2003 ¶ 8; *see also* Ex. 2004 at 10:10-20, 19:10-14, 21:22-22:14. Dr. Bieganowski did not contribute to the invention recited in claims 1-3 of the '807 patent or to any aspect of the NR research project regarding therapeutic uses or compositions of NR. Ex. 2002 ¶ 14; Ex. 2003 ¶ 8; *see also* Ex. 2004 at 10:10-20, 19:10-14, 21:22-22:14.

Certain aspects of the NR research project were disclosed in the '347 Provisional, which Dartmouth filed on February 10, 2004. Ex. 2002 ¶ 15; *see* Ex. 1005 at 2. Dartmouth later claimed priority to the '347 Provisional in the '337 PCT Application, which was later published as the '337 PCT Publication. *See* Ex. 1007; Pet. at 34; Ex. 2002 ¶¶ 7-8, 16; Ex. 2003 ¶¶ 6, 8. Certain results from the NR research project were also published in the *Cell* article. *See* Ex. 1008; Pet. at 32; Ex. 2002 ¶¶ 9, 15, 18; Ex. 2003 ¶¶ 6, 8.

The '347 Provisional and the '337 PCT Publication both name Dr. Brenner and Dr. Bieganowski as co-inventors. *See* Ex. 1005 at 3; Ex. 1007 at (75); Ex. 2002 ¶¶ 7-8; Ex. 2003 ¶ 6. However, the relied-upon portions of the '337 PCT Publication represent the invention of Dr. Brenner alone; Dr. Bieganowski was not the inventor of the subject matter in these relied-upon portions of the '337 PCT

Publication. *See* Pet. at 34-35, 51-56; Ex. 2002 ¶¶ 16-17; Ex. 2003 ¶ 8; *see also* Ex. 2004 at 10:10-20, 19:10-14, 21:22-22:14.

The *Cell* article names Dr. Brenner and Dr. Bieganowski as co-authors. *See* Ex. 1008 at 495; Ex. 2002 ¶ 9; Ex. 2003 ¶ 6. However, the relied-upon portions of the *Cell* article represent the invention of Dr. Brenner alone; Dr. Bieganowski was not the inventor of the subject matter in these relied-upon portions of the *Cell* article. *See* Pet. at 40-50; Ex. 2002 ¶¶ 18-19; Ex. 2003 ¶ 8; *see also* Ex. 2004 at 10:10-20, 19:10-14, 21:22-22:14.

b. Declarations from Dr. Brenner and Dr. Bieganowski Confirm that Dr. Brenner is the Sole Inventor of the Relied-Upon Portions of the Asserted References

Patent Owner provides herewith unequivocal declarations from both Dr. Brenner and Dr. Bieganowski, who are the only two co-inventors of the ’337 PCT Publication and the only two co-authors of the *Cell* article. *See* Ex. 2002; Ex. 2003. The two declarations describe the NR research project that led to the disclosures in the ’337 PCT Publication and the *Cell* article, as well as each declarant’s role and contributions. *See* Ex. 2002 ¶¶ 11-15; Ex. 2003 ¶¶ 7-8. The two declarations are consistent and make clear that the subject matter in both the ’337 PCT Publication and the *Cell* article asserted in Grounds 1-2 is Dr. Brenner’s own invention and not the invention of Dr. Bieganowski. *See* Ex. 2002 ¶¶ 13-19; Ex. 2003 ¶¶ 7-8. Further, Dr. Brenner’s declaration is corroborated by the

disclaimer declaration of Dr. Bieganowski, who is not a named inventor of the '807 patent. *See* Ex. 2003 ¶¶ 7-8.[4]

c. Deposition Testimony from Dr. Bieganowski Further Confirms that Dr. Brenner is the Sole Inventor of the Relied-Upon Portions of the Asserted References

Patent Owner also provides herewith a copy of Dr. Bieganowski's deposition testimony from IPR2021-00268 involving U.S. Patent No. 8,383,086 (Ex. 1024, "the '086 patent"), which is a continuation of the '807 patent and also claims compositions of NR. Ex. 2004; *see* Ex. 2003 ¶ 5. In IPR2021-00268, Petitioner advanced nearly identical alleged invalidity grounds against the '086 patent based on the *Cell* article and '337 PCT Publication as they do here against the '807 patent. IPR2021-00268, Paper 2 at 42-50. In that proceeding, Patent Owner provided similar declarations from Drs. Brenner and Bieganowski with its Preliminary Response. IPR2021-00268, Paper 10 at 7, 11-13 (citing Exhibit Nos. 2002, 2003). In connection with Petitioner's request to file a Reply, Petitioner was afforded the opportunity to depose both declarants and to develop a full factual record on the question of whether the portions of the same references Petitioner

[4] *See Varian Med. Sys. v. William Beaumont Hospital*, IPR2016-00160, Paper 82 at 28-29 (P.T.A.B. May 4, 2017) (finding inventor's testimony corroborated by non-inventor who co-authored asserted reference).

asserts here are "by another." *See* IPR2021-00268, Ex. 1024 at 21:22-22:5, 23:20-25; *see generally* Ex. 2004. Despite noticing the depositions of both declarants, after deposing Dr. Bieganowski, Petitioner unilaterally elected to cancel Dr. Brenner's deposition. *See* IPR2021-00268, Ex. 2012.

Despite a full opportunity to question Dr. Bieganowski regarding his contributions to the '337 PCT Publication and *Cell* article, Petitioner obtained no evidence that Dr. Bieganowski is the inventor of subject matter regarding therapeutic uses and compositions of NR in those references. With respect to the work reflected in the *Cell* article and the '337 PCT Publication, Dr. Bieganowski's deposition testimony 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. 2004 at 16:18-17:16, 19:15-23. Just as he did in his declaration, Dr. Bieganowski testified that Dr. Brenner designed all of the relevant experiments reflected in the *Cell* article 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; *Sanofi-Aventis v. Immunex*, IPR2017-01879, Paper 88 at 22-24 (P.T.A.B. Feb. 14, 2019) (holding that "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 450, 455-56 (C.C.P.A. 1982)

(holding that a reference was not "by another" where co-authors were "working under the direction and supervision" of the inventor).

Therefore, based on consistent and unequivocal testimony from the only two individuals involved with the asserted '337 PCT Publication and *Cell* article, those two references are not "by another" and are thus not prior art under pre-AIA § 102(a) or § 102(e). Although either an inventor declaration or a disclaimer declaration can suffice, here, Patent Owner provides both, along with the disclaimer deposition testimony from Dr. Bieganowski.

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). Patent Owner presents two declarations and supporting deposition testimony (elicited by Petitioner) establishing that the relied-upon portions of the references were the inventive work of Dr. Brenner alone. Thus, the burden is on Petitioner to establish otherwise. *See Dynamic Drinkware*, 800 F.3d 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*, IPR2017-01879, Paper 88 at 10-11 (same). Because Petitioner has already been afforded the opportunity to develop a full factual record on the same "by another" issue and failed to identify any evidence to meet its burden, it necessarily follows that Petitioner could not meet its burden here.

The Board has denied institution in previous cases where patent owners made such clear showings that the relied-upon portions of an asserted reference were the sole work of the inventor of the challenged patent. *See, e.g.*, *IronRidge Inc. v. Rillito River Solar, LLC*, IPR2017-01681, Paper 11 at 10-12 (P.T.A.B. Jan. 9, 2018) (denying institution where inventor declaration supported position that an asserted reference described the inventor's own work and was not prior art). The same result should apply here, and the Petition should be denied.

B. The Asserted *Cell* Article Is Not Prior Art Under 35 U.S.C. § 102(b)

Ground 1 of the Petition is based on the *Cell* article, which Petitioner asserts is prior art under pre-AIA § 102(b). *See* Pet. at 32 n.10, 38, 40-50. But a printed publication is only prior art under § 102(b) if it describes the invention "more than one year prior to" the '807 patent's priority date. The *Cell* article was purportedly published on May 14, 2004. *See id.* at 32 n.10; Ex. 1008 at 495. Because the priority date for the '807 patent is no later than April 25, 2005, the *Cell* article is not prior art under § 102(b).

Petitioner challenges the '807 patent's priority claim based solely on a Paris Convention argument that is both unsupported and inapplicable. *See* Pet. at 8-18. Instead, the '807 patent's priority claim meets the requirements set forth in the applicable statute, 35 U.S.C. § 120, and the Petition does not argue otherwise.

Therefore, the Petition fails to raise a legitimate challenge to the '807 patent's priority claim and establish the *Cell* article as prior art under § 102(b).[5]

1. Petitioner's Position on Priority Is Based on an Unsupported and Inapplicable Paris Convention Argument

The '807 patent claims priority through the '495 PCT to at least the '701 Application, filed April 25, 2005. *See* '807 patent at 1:11-13. Petitioner asserts, based on its unsupported Paris Convention argument, that the '807 patent cannot claim priority further back than the '495 PCT, filed April 20, 2006. *See* Pet. at 8-9. Petitioner's priority argument fails for several independent reasons: (1) it is premised entirely on non-self-executing treaties and is not supported by any controlling U.S. statute or case law, (2) the Paris Convention rule that Petitioner relies upon is enacted in 35 U.S.C. § 119 and is thus inapposite because the '807 patent's priority claim is governed instead by § 120, and (3) the Patent Cooperation Treaty ("PCT") provision that incorporates the Paris Convention rule relied upon

[5] Petitioner's Ground 1 also relies upon the Rosenbloom reference (Ex. 1015) but only as a secondary reference in combination with the *Cell* article. Pet. at 38, 40-50. Indeed, Rosenbloom does not even disclose NR, and Ground 1 relies upon Rosenbloom only for the limited purpose of "teaching conventional carriers and dosage forms for an oral supplement formulation." *See id.* at 42, 34, 47, 50. Therefore, without the *Cell* article as prior art, Ground 1 fails.

by Petitioner also includes a relevant exception that applies here. The Petition's priority argument is therefore neither supported nor applicable to the '807 patent's priority claim.

a. Petitioner Relies Entirely on Treaties That Are Not Self-Executing and Fails to Cite Any U.S. Law

The Petition's argument regarding the '807 patent's priority claim is premised entirely on Article 4 of the Paris Convention for the Protection of Industrial Property[6] ("Paris Convention"), as incorporated by Article 8 Section (2)(a) of the PCT.[7] *See* Pet. at 9-18. Specifically, Petitioner relies upon the rule in Paris Convention Article 4 Sections (C)(1)-(2) and (C)(4) stating that "[t]he periods of priority … shall be twelve months" "from the date of filing of the first application" and further setting forth the conditions under which "[a] subsequent application … shall be considered as the first application." Based on these treaty provisions, Petitioner asserts (i) that the '347 Provisional was allegedly the "first application," and (ii) because the '495 PCT was filed more than twelve months after the '347 Provisional, the '495 PCT allegedly cannot claim priority back to the '347 Provisional. *See* Pet. at 10, 16. Petitioner then asserts, without citation to any

[6] Available at: https://wipolex.wipo.int/en/text/287556.

[7] Available at: https://wipolex.wipo.int/en/text/288637.

authority, that this alleged defect somehow infects claims of priority to subsequently-filed applications, such as the '701 Application. *See id.* at 17.

However, neither the Paris Convention nor the PCT is self-executing, and both treaties are thus only given effect to the extent they are implemented by U.S. statute. *See In re Rath*, 402 F.3d 1207, 1209-10 (Fed. Cir. 2005) ("[T]he Paris Convention is not a self-executing treaty and requires congressional implementation."); *Yasuko Kawai v. Metlestics*, 480 F.2d 880, 884 (C.C.P.A. 1973); *Actelion Pharm., Ltd. v. Matal*, 881 F.3d 1339, 1341 (Fed. Cir. 2018) (noting that "the [PCT] … was implemented in 35 U.S.C. § 351 *et seq*."). The Petition's priority argument fails for this reason alone, as it cites no support other than the Paris Convention treaty, as incorporated by the PCT, and neither of these two treaties is binding on the Board. Indeed, the Petition cites ***no U.S. statute or case law*** to support its priority argument. *See* Pet. at 8-18.[8]

[8] Petitioner asserts that its alleged "understanding" of the '807 patent's priority based on the Paris Convention is "consistent with" a corrected filing receipt, but Petitioner cites no proof that the priority listed in the filing receipt is due to the Paris Convention. Pet. at 18. Moreover, Petitioner cites no authority that says a filing receipt somehow overrides the fact that the '807 patent's priority claim satisfies the relevant statutory requirements. *Id.*; *see infra* Section IV.B.2.

b. The Paris Convention Rule Relied Upon by Petitioner Is Enacted in 35 U.S.C. § 119, but the '807 Patent's Priority Claim Is Governed Instead by § 120

To the extent that Article 4 of the Paris Convention is implemented by U.S. statute, that U.S. statute is not applicable to the priority claim of the '807 patent. Article 4 of the Paris Convention, on which Petitioner's entire priority argument is predicated, was enacted by Congress in 35 U.S.C. § 119. *See Scimed Life Sys. v. Medtronic Vascular, Inc.*, 468 F. Supp. 2d 60, 67 n.6 (D.D.C. 2006) (recognizing that "Section 119 … [was] enacted in order to implement Article 4 of the Paris Convention" (citing *Vogel v. Jones*, 486 F.2d 1068, 1072 (C.C.P.A. 1973))). More specifically, Petitioner's priority argument relies on Paris Convention Article 4 Sections (C)(1)-(2) and (C)(4), and these provisions correspond with § 119 subsections (a) and (c), respectively.

As discussed above, Petitioner fails to cite or rely upon § 119 or any other U.S. statute. Regardless, Petitioner ***cannot*** rely upon § 119 because the portions of that statute that correspond with Article 4 of the Paris Convention govern claims of ***foreign*** priority. *See* § 119(a), (c).

The Supreme Court and Federal Circuit make clear that § 119 applies only to claims of ***foreign*** priority. *See Return Mail, Inc. v. U.S. Postal Serv.*, 139 S. Ct. 1853, 1864 n.5 (2019) ("Section 119 discusses the effect of a patent application filed in a foreign country … on the patent-application process in the United

States."); *In re Gosteli*, 872 F.2d 1008, 1010-11 (Fed. Cir. 1989). The actual language of the Paris Convention itself also shows that its Article 4 provisions apply only to claims of priority to ***foreign*** applications. *See, e.g.*, Paris Convention Art. 4(A)(1) ("Any person who has duly filed an application for a patent … *in one of the countries* of the Union … shall enjoy, for the purpose of filing *in the other countries*, a right of priority during the periods hereinafter fixed." (emphasis added)).

Here, however, the '807 patent's priority claim involves only ***domestic*** priority to United States applications. That is, each of the applications in the '807 patent's priority claim—including the '495 PCT and '701 Application—is either a U.S. patent application or an international (PCT) application designating the United States. None of those applications is a foreign application,[9] and the Paris Convention rule enacted in § 119 thus does not apply to the '807 patent's priority claim.

Domestic priority, and therefore the '807 patent's priority claim, is instead governed by 35 U.S.C. § 120. *See* § 120 (providing conditions for priority to "an application previously filed in the United States, or as provided by section 363"); § 363 ("An international application designating the United States [*e.g.*, the '495

[9] The '337 PCT Application and '347 Provisional are also not foreign applications.

PCT] shall have the effect … of a national application for patent regularly filed in the [USPTO].”); § 365(c) (providing that “an international application designating the United States [*e.g.*, the ’495 PCT] shall be entitled to the benefit of the filing date of a prior national application [*e.g.*, the ’701 Application]” “[i]n accordance with the conditions and requirements of *section 120*” (emphasis added)). The distinction between § 119’s application to foreign priority and § 120’s application to domestic priority is clear. *See, e.g.*, *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1324 n.5 (Fed. Cir. 2008) (recognizing that “when a patent application is entitled to the benefit of the filing date of an earlier United States patent application,” “[t]he statute that provides for that entitlement is 35 U.S.C. § 120,” whereas “§ 119 … provides that an application is entitled to the benefit of the filing date of an earlier foreign application”).

Unlike § 119, § 120 does not include the rule that Petitioner relies upon from Article 4 of the Paris Convention. *See generally* § 120 (imposing no requirement of filing within 12 months of a “first” application). The Paris Convention rule is thus not imposed upon the ’807 patent’s priority claim under the applicable statute. Rather, § 120 only requires co-pendency between links of a priority chain. *See id.*

Therefore, Petitioner’s priority argument fails because its argument is based entirely upon the Paris Convention rule, and that Paris Convention rule, as enacted in § 119, is wholly inapplicable to the ’807 patent’s priority claim.

c. The Paris Convention Rule Relied Upon by Petitioner Is Further Inapplicable Because the PCT Provides an Exception

Even if the Paris Convention treaty and PCT were self-executing and constituted sufficient support before the Board, Petitioner's argument nonetheless fails because the PCT provision that incorporates Article 4 of the Paris Convention also includes a relevant exception that applies to the '495 PCT's priority claim to the '701 application. Article 8 Sections (1) and (2)(a) of the PCT incorporate Article 4 of the Paris Convention:

> (1) The international application may … claim[] the priority of one or more earlier applications filed in or for any country party to the Paris Convention … .
> (2)(a) Subject to the provisions of subparagraph (b), *the conditions for, and the effect of, any priority claim* declared under paragraph (1) *shall be as provided in Article 4 of the … Paris Convention … .*

(Emphasis added). The Petition cites the emphasized portion of the above-quoted PCT provision to support Petitioner's assertion that "Article 4 of the Paris Convention governs priority claims made in applications filed under the [PCT]." Pet. at 9.

However, Petitioner's argument ignores that PCT Article 8 Section (2)(b) includes a relevant exception to the application of Paris Convention Article 4. *See* PCT Art. 8(2)(a) (stating that Article 4 of the Paris Convention provides conditions for PCT applications' priority claims "[s]ubject to the provisions of subparagraph [2](b)"). Specifically, PCT Article 8 Section (2)(b) provides that if "an

international application" (*e.g.*, the '495 PCT) claims priority to a "national application[] filed in … a designated State" (*e.g.*, the '701 application), then "the conditions for, and the effect of, the priority claim in that State shall be governed by the national law of that State." Thus, U.S. law—not Article 4 of the Paris Convention—applies to the '495 PCT's claim of priority to the '701 application. And as discussed above, Petitioner's priority argument does not cite any U.S. law.

Therefore, even if the Board were to consider and apply only the Paris Convention treaty and PCT, Petitioner's priority argument nonetheless fails because Article 8 of the PCT includes a relevant exception under which the '495 PCT's priority claim to the '701 Application is exempted from the rule that Petitioner relies upon in Article 4 of the Paris Convention.

2. The '807 Patent's Priority Claim to the '701 Application Meets the Requirements of 35 U.S.C. § 120

As discussed above, the '807 patent's priority claim to the '701 Application is governed by 35 U.S.C. § 120. *See* '807 patent at 1:11-13; 35 U.S.C. §§ 120, 363, 365(c). "Under § 120, a patent is entitled to the priority date of an earlier filed application if (1) the written description of the earlier filed application discloses the invention claimed in the later filed application sufficient to satisfy the requirements of § 112; (2) the applications have at least one common inventor; (3) the later application is filed before the issuance or abandonment of the earlier filed application; and (4) the later application contains a reference to the earlier

filed application." *In re NTP, Inc.*, 654 F.3d 1268, 1277 (Fed. Cir. 2011); *see also* 35 U.S.C. § 120. The '807 patent's priority claim, through the '495 PCT's priority claim, satisfies each of these requirements of § 120 back to at least the '701 Application.

First, each application in the priority chain from the '807 patent back to the '701 Application satisfies the requirements of § 112 regarding claims 1-3 of the '807 patent. The specifications of the '495 PCT and '701 Application are both the same as the specification of the '807 patent with respect to disclosure of the invention in claims 1-3 of the '807 patent. For example, the Petition itself asserts that the subject matter of claims 1-3 of the '807 patent is supported by the following disclosures in the '807 patent's specification: 3:3-11, 4:8-9, 4:21-36, 9:9-14, 9:23-33, 27:7-12, 27:39-46, 28:41-45, 29:24-30:12, 30:19-56, 33:30-45. *See* Pet. at 10-16. Those same exact disclosures are contained in the '495 PCT and '701 Application. *See* Ex. 2005 (international publication of the '495 PCT) at 3:23-31, 6:1-3, 6:15-32, 15:31-16:4, 16:12-22, 53:25-30, 54:26-55:1, 57:1-5, 58:19-60:12, 60:18-61:23, 66:31-67:11; Ex. 1019 (file history of the '701 Application) at 241-309 (specification, see specifically native pages thereof at 3:23-31, 6:1-3, 6:15-32, 15:31-16:4, 16:12-22, 53:17-22, 54:19-27, 56:28-57:1, 58:17-60:11, 60:17-61:22, 66:29-67:9). Thus, the '701 Application and the '495 PCT both satisfy § 112 for purposes of § 120.

Second, the ’807 patent, ’495 PCT, and ’701 Application all name the same common inventor: Dr. Brenner. *See* ’807 patent at (75); Ex. 2005 at (75); Ex. 1019 at 1.

Third, there was co-pendency among applications in the priority chain. That is, the ’400 Application that issued as the ’807 patent is a national stage entry of the ’495 PCT, which was filed on April 20, 2006, before the abandonment of the ’701 Application on December 28, 2006. *See* ’807 patent at (22), (86); Ex. 2005 at (22); Ex. 1019 at 1-2; 35 U.S.C. § 363; MPEP § 1893.03(c) (noting that “[a] prior filed nonprovisional application [*i.e.*, ’701 Application] is copending with the national stage application [*i.e.*, ’807 patent] if the prior U.S. national application [*i.e.*, ’701 Application] was pending on the international filing date of the national stage application [*i.e.*, the filing date of the ’495 PCT]”).

Fourth, all applications in the chain back to the ’701 Application specifically identify the earlier-filed applications in the chain. That is, the ’807 patent contains a reference to the ’701 Application and to the earlier-filed ’495 PCT in the chain, and the ’495 PCT also contains a reference to the ’701 Application. *See* ’807 patent at 1:11-13; Ex. 2005 at 1:7-9.

Thus, the ’807 patent and other application in the priority chain back to the ’701 Application meet the requirements under § 120 for disclosure, common inventorship, co-pendency, and referencing. Indeed, Petitioner’s priority argument

relies entirely upon the Paris Convention, as discussed above, and does not even assert that the '807 patent's priority claim fails to meet any of the requirements under § 120. Therefore, because § 120 is satisfied, the '807 patent is entitled to the benefit of at least the '701 Application's filing date.

3. The *Cell* Article Is Not Prior Art Under § 102(b)

Because the '807 patent's priority claim meets the requirements set forth in the applicable statute, § 120, at least back to the '701 Application, the proper priority date is at least as early as the filing date of the '701 Application, *i.e.*, April 25, 2005. Therefore, the *Cell* article, which was purportedly published on May 14, 2004, was not published more than one year prior to this priority date and is not prior art under pre-AIA § 102(b). *See* Pet. at 32 n.10; Ex. 1008 at 495.

V. THE BOARD SHOULD EXERCISE ITS DISCRETION UNDER 35 U.S.C. § 314(a) TO DECLINE TO INSTITUTE REVIEW

The Board has discretion to deny institution of an IPR based on a holistic view of several non-exclusive sets of considerations related to the treatment of a challenged patent in previous IPR proceedings and parallel district court cases, as well as consideration of a petition's merit. Here, based on a balanced assessment of all relevant circumstances, the Board should exercise its discretion to deny institution based on the weakness of the Petition's merits and based on a prior IPR and multiple co-pending district court cases, including one at an advanced stage.

A. The Board Has Discretion to Deny Institution Based on a Prior IPR Proceeding, Art and Arguments Previously Before the Office, a Parallel District Court Case, and a Petition's Weak Merits

The Board has discretion to deny institution of an IPR under 35 U.S.C. § 314(a). *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1351 (2018) (holding that "§ 314(a) invests the Director with discretion on the question *whether* to institute review" (emphasis in original)); *Mylan Labs. Ltd. v. Janssen Pharm., N.V.*, 989 F.3d 1375, 1382 (Fed. Cir. 2021) ("The Director is permitted, but never compelled, to institute an IPR. And no petitioner has a right to such institution. For example, the Director is free … to determine that for reasons of administrative efficiency an IPR will not be instituted … ."); *see also* 37 C.F.R. § 42.4(a). This discretion is informed by § 316(b), which requires consideration of "the efficient administration of the Office, and the ability of the Office to timely complete [instituted] proceedings." *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide November 2019 ("TPG")[10] at 56.

In deciding whether to institute, the Board takes into account various considerations. *See* TPG at 55-63. Such considerations include whether a petition is a "'follow-on' petition[] challenging the same patent as challenged previously in an IPR." TPB at 56. For this, the Board may consider the non-exclusive *General*

[10] Available at: https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf.

Plastic factors, including the finite resources of the Board and whether a subsequent petition was filed after the patent owner's preliminary response and the Board's decision on whether to institute review in a prior IPR. *Id.* at 56-57 (citing *General Plastic Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 15-16 (P.T.A.B. Sept. 6, 2017) (precedential)).

The Board will also consider a two-part framework under 35 U.S.C. § 325(d), which first looks at "whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office" and second, if either of those conditions is met, considers "whether the petitioner has demonstrated that the office erred in a manner material to the patentability of challenged claims." *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). This analysis applies to situations where similar art or arguments were before the Office during a previous IPR. *See id.* at 10 (precedential). For the first part of the test, the Board may consider non-exclusive *Becton Dickinson* factors regarding "the similarities" between and "cumulative nature of" the asserted art and the previously-presented prior art, and "the extent of the overlap between the arguments made [previously] and the manner in which petitioner relies on the prior art [or patent owner distinguishes the prior art]." *See id.* at 9-10 (precedential) (citing *Becton*

Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17-18 (P.T.A.B. Dec. 15, 2017) (precedential in relevant part)).

The *General Plastic* factors and *Becton Dickinson* factors are not exclusive though, and the Board may also deny institution based on "the advanced state of a parallel district court proceeding" that involves the same patent. *See* TPG at 58, 62 (citing *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (P.T.A.B. Sept. 12, 2018) (precedential)). In deciding whether "efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in [a] parallel proceeding," the Board's "holistic view" may include consideration of the *Fintiv* factors. *Apple, Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5-6 (P.T.A.B. Mar. 20, 2020) (precedential). These *Fintiv* factors include "whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted," "proximity of the court's trial date to the Board's projected statutory deadline for a final written decision," "investment in the parallel proceeding by the court and the parties," "overlap between issues raised in the petition and in the parallel proceeding," and "other circumstances that impact the Board's exercise of discretion, including the merits." *Id.*

Notably, the considerations described above are not limited to subsequent petitions by the same petitioner or parallel district court cases involving the at-issue petitioner. *See* TPG at 57 n.1, 58; *NetApp Inc. v. Realtime Data LLC*,

IPR2017-01195, Paper 9 at 10 (P.T.A.B. Oct. 12, 2017) (denying institution where "a different petitioner filed a petition challenging a patent that had been challenged already by previous petitions," as the Board's discretion under § 314(a) "is not limited to situations where the same party files multiple petitions"); *Unified Patents, Inc. v. PersonalWeb Techs., LLC*, IPR2014-00702, Paper 13 at 6-9 (P.T.A.B. July 24, 2014) (precedential) (denying institution under § 325(d) based on previous IPRs by different petitioners); *Mylan Labs. Ltd. v. Janssen Pharm. NV*, IPR2020-00440, Paper 17 at 13-25 (P.T.A.B. Sept. 16, 2020) (denying institution based in part on parallel litigation that did not involve the petitioner).

Additionally, the Board may exercise its discretion to deny institution based on a petition's weak merits. *See* TPG at 58 (stating that exercising discretion to deny institution is "part of a balanced assessment of all relevant circumstances in the case, *including the merits*" (emphasis added)). "[W]eaker merits may favor exercising discretion to deny institution." *TCO AS v. NCS Multistage Inc.*, PGR2020-00077, Paper 16 at 18 (P.T.A.B. Feb. 18, 2021) (citing *Fintiv*, IPR2020-00019, Paper 11 at 15 (precedential)). For example, in *TCO AS*, the Board held that "the weakness of the merits of Petitioner's petition," along with an overlap of parallel proceedings, "outweigh[ed] the factors in favor of exercising discretion to institute." PGR2020-00077, Paper 16 at 23.

B. Institution Should Be Denied Based on the Prior IPR of the '807 Patent, Multiple District Court Cases, and the Petition's Weak Merits

The Board should exercise its discretion to deny institution of the Petition based on the considerations below for purposes of efficiency, fairness, and timing.

Although Petitioner goes to great pains to argue against discretionary denial, a closer evaluation reveals that Petitioner's arguments are nothing more than conclusory assertions that certain factors weigh in its favor, while conveniently ignoring the weakness of its grounds. *See* TPG at 58 (stating that exercising discretion to deny institution is "part of a balanced assessment of all relevant circumstances in the case, including the merits"). At the outset, Petitioner incorrectly states that *Fintiv* does not apply (*see* Pet. at 23 n.9) in the face of clear precedent that discretionary denial considerations, including the *Fintiv* factors, are not limited to instances where Petitioner is the same party involved in a prior IPR or parallel district court proceeding. *See, e.g.*, TPG at 57 n.1, 58; *NetApp*, IPR2017-01195, Paper 9 at 10; *Unified Patents*, IPR2014-00702, Paper 13 at 6-9 (precedential); *Mylan Labs.*, IPR2020-00440, Paper 17 at 13-25.

There is no dispute that the Petition is a follow-on challenge of claims 1-3 of the '807 patent. This same patent and claims were previously challenged in a petition in *Elysium Health, Inc. v. Trustees of Dartmouth College*, IPR2017-01796 ("the '1796 IPR"), where the Board denied institution. *See* Ex. 1027 at 1-2; Ex.

1004 at 9-10. The Board's decision denying institution was issued in January 2018, years before the present Petition was filed in February 2021, so the Petitioner has the benefit of Patent Owner's preliminary response and the Board's decision in the prior '1796 IPR. *See* Ex. 1027 at 1; Ex. 1004 at 9; Ex. 1026 at 37; Pet. at 61.

Notwithstanding the availability of the record from the '1796 IPR, the prior art and arguments in the Petition here are substantially the same as those considered and rejected by the Board in the previous '1796 IPR. Given that the *Cell* article and '337 PCT Publication are not prior art to the '807 patent, the only "new" prior art asserted in the Petition here is the Rosenbloom reference (Ex. 1015). *See* Pet. at 32-35, 38; *supra* Section IV. In the previous '1796 IPR, the Board found that the asserted prior art did not disclose NR that is "isolated" as required by claim 1. *See* Ex. 1027 at 10, 11. Just like the references asserted in the '1796 IPR, Rosenbloom also does not disclose NR that is "isolated" as recited in claim 1. Indeed, Rosenbloom fails to even disclose NR in the first place. *See generally* Ex. 1015. Rather, Petitioner relies upon Rosenbloom only in combination with the *Cell* article, which is not prior art, and only for "teaching conventional carriers and dosage forms for an oral supplement formulation." *See* Pet. at 38, 42, 47, 50. The Rosenbloom reference asserted here is thus no better, and is in fact worse, than the references asserted in the earlier '1796 IPR.

Petitioner's discretionary denial arguments also fail to properly apply the Board's two-part framework under *Advanced Bionics*. With respect to the *Cell* article, although it is not prior art, Petitioner's argument that "the first part of the Board's two-part framework is not satisfied" is demonstrably false. Pet. at 24. Petitioner omitted the fact that the *Cell* article was submitted to the Office in an IDS and marked as considered by the Examiner, as well as discussed in a Response to an Office Action, thereby satisfying the first part of the framework. Ex. 1004 at 35, 103-04; *Advanced Bionics*, IPR2019-01469, Paper 6 at 7-8 (precedential). Petitioner's discretionary denial argument then does not address the second part of the Board's framework and is thus facially defective, and the Board should deny institution. *See* Pet. at 24 (stating "the second part need not be reached"); *Advanced Bionics*, IPR2019-01469, Paper 6 at 8-9 (precedential) ("If a condition in the first part of the framework is satisfied and the petitioner fails to make a showing of material error, the Director generally will exercise discretion not to institute *inter partes* review").

The Board should also deny institution because the '807 patent is being challenged in a parallel district court case—*i.e.*, *ChromaDex, Inc., et al. v. Elysium Health, Inc.*, Case No. 18-cv-01434 (D. Del.) ("the Delaware District Court case") —that has a trial scheduled prior to the Board's statutory deadline for a final written decision. The Delaware District Court case includes a challenge to the

validity of the same patent and claims challenged in the present Petition. *See* Ex. 2011 ¶ 5. Trial is scheduled to begin in the Delaware District Court case on September 27, 2021. *See id.* ¶¶ 6-7; Ex. 2009 at PO_DART807_2009-0003; Ex. 2010.[11] In contrast, if an IPR were instituted here, the projected statutory deadline for a final written decision would be August 18, 2022, over ten months after the Delaware District Court's trial date. *See* 35 U.S.C. §§ 314(b), 316(a)(11). The Delaware District Court case is not stayed. *See* Ex. 2011 ¶ 8. Also, Petitioner provides no evidence of a potential stay, and a stay is unlikely due to the advanced stage of the Delaware District Court case and the long delay between its scheduled trial and the projected statutory deadline for the Petition. In addition, the '807 patent is being asserted in *ChromaDex, Inc., et al. v. Thorne Research, Inc.*, Case No. 21-cv-04241 (S.D.N.Y.) (filed May 12, 2021) ("the New York District Court case").[12] Thus, in the event the Board denies institution, Petitioner will still have the opportunity to raise defenses in the New York District Court case.

[11] Claim construction was already completed in the Delaware District Court case in January 2021, before Petitioner filed the Petition that began this proceeding in February 2021. *See* Ex. 2011 ¶ 4; Ex. 2007; Pet. at 64.

[12] In the New York District Court case, Patent Owner is a plaintiff and Petitioner is the defendant.

Conducting a parallel review of a patent where one of the primary references was previously before the PTO, the Board has already reviewed and denied institution of an IPR for the patent, and the patent is also at issue in multiple district court litigations, including one at an advanced stage, would be an inefficient use of the Board's resources, and the Board would be justified in exercising its discretion to deny institution.

The Petition's weak merits also support denial. The primary references for both Grounds in the Petition are not even prior art. *See supra* Section IV. And in an attempt to qualify one of those references as prior art, the Petition sets forth a priority argument based entirely on an unsupported and inapplicable Paris Convention theory that ignores U.S. law. *Id.*

For each of these reasons, Patent Owner respectfully requests that the Board exercise its discretion and deny institution.

VI. CONCLUSION

For the foregoing reasons, there is not a reasonable likelihood of Petitioner prevailing with respect to the challenged claim of the '807 patent. Accordingly, the Petition should be denied under 35 U.S.C. § 314(a).

Respectfully submitted,

Date: May 18, 2021

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CERTIFICATION UNDER 37 C.F.R. §42.24

Under the provisions of 37 C.F.R. §42.24, the undersigned hereby certifies that the foregoing document contains 9,094 words, and thus complies with the word-count limits of 37 C.F.R. § 42.24.

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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 PRELIMINARY RESPONSE TO PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,197,807 was served on May 18, 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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