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

PATENT OWNER RESPONSE

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Pursuant to 35 U.S.C. § 316(a)(8) and 37 C.F.R. § 42.120, Trustees of Dartmouth College ("Patent Owner") respectfully submit this Response to the Petition filed by Thorne Research, Inc. ("Petitioner") regarding U.S. Patent No. 8,197,807 (Ex. 1001, "the '807 patent").

I. INTRODUCTION

Petitioner bears "the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e). Petitioner has failed to meet that burden here.

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

[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).

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]

In addition, with respect to Petitioner's assertion of the *Cell* article as pre-AIA § 102(b) prior art, 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 earlier U.S. Patent Application No. 11/113,701 ("the '701 Application") under 35 U.S.C. § 120, the controlling U.S. statute, and Petitioner does not even argue otherwise. Indeed, the Board correctly found in its Institution Decision in a related IPR that a continuation of the '807 patent properly claims priority back to the '701 Application through the '807 patent.[4] 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. Patent Owner refers to the asserted references as the '337 PCT Publication (Ex. 1007) and *Cell* article (Ex. 1008) to avoid confusion with eponymous declarations in this IPR.

[4] *Thorne Research, Inc. v. Trustees of Dartmouth College*, IPR2021-00268, Paper 21, 15-17 (P.T.A.B. June 10, 2021) (regarding U.S. Patent No. 8,383,086 ("the '086 patent")).

For at least the reasons set forth herein, Petitioner has failed to meet its burden to establish that claims 1-3 of the '807 patent are unpatentable.

II. BACKGROUND OF DR. BRENNER'S INVENTION

Charles M. Brenner, Ph.D. ("Dr. Brenner") is the sole 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 id.* ¶¶ 11-15; Ex. 2015 ¶¶ 6-14.

For decades prior to Dr. Brenner's invention, scientists knew about the importance of nicotinamide adenine dinucleotide ("NAD+") to human health, *see* Ex. 2017 at 83 (explaining that NAD+ is of "immeasurable importance in cellular metabolism"), and that increasing NAD+ levels could aid in treating numerous diseases, *see* Ex. 2018 (filed 1988) at Abstract; Ex. 2019 (filed 1999) at 1:14-18. While scientists were aware that compounds such as nicotinic acid and nicotinamide were capable of increasing NAD+ levels, *see* Ex. 2018 at 2:33-43, prior to the invention of Dr. Brenner, the role of NR in increasing NAD+ levels was not understood. Ex. 2015 ¶ 8.

Dr. Brenner realized that there were unsolved problems in NAD+ metabolism and a potential opportunity for gene and pathway discovery related to NAD+, which led him to focus on NR. *Id.* ¶ 8. As part of the NR research project,

Dr. Brenner established that NR is an NAD+ precursor in a previously-unknown pathway. *Id.* ¶ 9. Dr. Brenner's research project also led to the identification of "yeast nicotinamide riboside kinase, Nrk1, and both human Nrk enzymes and [the demonstration of] their specific functions in NAD+ metabolism biochemically and genetically." *Id.* ¶ 10; Ex. 1008 at 495. Dr. Brenner's research led him to conclude that NR is a useful compound for elevation of NAD+ and that supplementation with NR may be beneficial. Ex. 2015 ¶ 10. It was Dr. Brenner alone who conceived of the invention of claims 1-3 of the '807 patent. *Id.* ¶¶ 5, 10, 12-13; Ex. 2002 ¶ 14.

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. Ex. 2002 ¶ 13; Ex. 2003 ¶ 7; Ex. 2015 ¶ 11; Ex. 2004 at 16:18-17:3, 19:10-14, 21:22-22:14. Dr. Bieganowski did not have an inventive role in any aspect of Dr. Brenner's inventions regarding therapeutic uses or compositions of NR. Ex. 2002 ¶ 14; Ex. 2003 ¶ 8; Ex. 2015 ¶ 12; *see also* Ex. 2004 at 21:22-22:14, 26:14-23, 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; Ex. 2015 ¶ 13. On August 25, 2005, the '337 PCT Application was published as the '337 PCT Publication, which Petitioner asserts in Ground 2 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 by the Petition are solely the invention of Dr. Brenner. *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; Ex. 2015 ¶¶ 14-28; *see also* Ex. 2004 at 19:10-14, 21:22-22:14, 26:14-23, 10:10-20.

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; Ex. 2015 ¶ 13. 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. *See* Ex. 1008 at 495; Pet. at 40-50; Ex. 2002 ¶¶ 9, 18-19; Ex. 2003 ¶¶ 6, 8; Ex. 2015 ¶¶ 14-15, 29-34; *see also* Ex. 2004 at 19:10-14, 21:22-22:14, 26:14-23, 10:10-20.

The '807 patent is directed to compositions of 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 claims priority to the '701 Application. The '807 patent thus claims priority at least back to the '701 Application. *See id.* at 1:11-13.

III. PETITIONER HAS NOT MET ITS BURDEN OF SHOWING THAT EITHER THE *CELL* ARTICLE (GROUND 1) OR THE '337 PCT PUBLICATION (GROUND 2) IS PRIOR ART

Petitioner asserts Ground 1 based on the *Cell* article and Ground 2 based on the '337 PCT Publication, but neither of these references is prior art. First, the portions of the *Cell* article and '337 PCT Publication that Petitioner relies upon for the alleged unpatentability of claims 1-3 were conceived by the named inventor of the '807 patent (Dr. Brenner), not "by another" (Dr. Bieganowski), meaning that the *Cell* article and '337 PCT Publication are not prior art under 35 U.S.C. § 102(a) or § 102(e). Second, as the Board correctly found in its Institution Decision in a related IPR with respect to a continuation of the '807 patent,[5] Petitioner's unsupported and inapplicable Paris Convention argument regarding the '807

[5] *Thorne Research*, IPR2021-00268, Paper 21, 15-17.

patent's priority fails to establish the *Cell* article as prior art under 35 U.S.C. § 102(b).

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

Both Grounds of the Petition are based on either the *Cell* article or '337 PCT Publication. *See* Pet. at 38, 40-56. To qualify as § 102(a) or § 102(e) prior art, these references must be "by another," *i.e.*, the relied-upon subject matter thereof must have been invented by someone other than the inventor of the challenged '807 patent (Dr. Brenner). The relied-upon subject matter, however, was invented solely by Dr. Brenner, as confirmed by declaration testimony from Dr. Brenner,[6] corroborating disclaimer testimony from Dr. Bieganowski's declaration and deposition, the superior-subordinate relationship between Drs. Brenner and Bieganowski, and Dr. Brenner's review of documentation. The *Cell* article and the '337 PCT Publication are therefore not "by another" and not prior art under § 102(a) or § 102(e).

[6] A first declaration of Dr. Brenner was submitted in connection with Patent Owner's Preliminary Response. Ex. 2002. Patent Owner also submits a second declaration of Dr. Brenner in connection with this Patent Owner Response. Ex. 2015.

1. To Qualify as Prior Art Under § 102(a) or § 102(e), Relied-Upon Subject Matter in the Reference Must Be Invented "By Another," *i.e.*, by Dr. Bieganowski

Under Pre-AIA § 102, an inventor's own work is prior art *only if* it constitutes a statutory bar under § 102(b). *See In re Katz*, 687 F.2d 450, 454 (C.C.P.A. 1982). An inventor's own work is thus not prior art under § 102(a) or § 102(e). *See id.*; § 102(e).

A 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). For this, "the relevant question is … 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) (internal quotation omitted). A patentee may overcome a prior art reference under § 102(a) the same way, *i.e.*, by establishing that the relied-upon portions of the reference describe their own invention. *See Katz*, 687 F.2d at 455.

The Federal Circuit set forth the following test "to decide whether a reference … is 'by another'":

> [T]he Board must (1) determine what portions of the reference … were relied on as prior art to anticipate the claim limitations at issue, (2) evaluate the degree to which those portions were conceived "by another," and (3) decide whether that other person's contribution is significant enough, when measured against the full anticipating disclosure, to render him a joint inventor of the applied portions of the reference … .

Duncan Parking Techs., Inc. v. IPS Grp., Inc., 914 F.3d 1347, 1358 (Fed. Cir. 2019); *see, e.g.*, *Ethicon LLC v. Intuitive Surgical, Inc.*, 847 F. App'x 901, 908-09 (Fed. Cir. 2021) (applying the *Duncan Parking* test and reversing the Board).

Moreover, the burden of production and the ultimate burden of persuasion are on Petitioner to establish that the *Cell* article and '337 PCT Publication are "by another" and therefore prior art. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); 35 U.S.C. § 316(e); *Varian Med. Sys. v. William Beaumont Hospital*, IPR2016-00160, Paper 82, 21-22 (P.T.A.B. May 4, 2017).

Under the *Duncan Parking* test, for the *Cell* article or the '337 PCT Publication to be prior art to claims 1-3, someone other than Dr. Brenner, the sole inventor of the '807 patent, must have "conceived" some "significant" contribution to the relied-upon portions of the reference and thus be a "joint inventor" of the relied-upon portions. Dr. Bieganowski is the only potential "other person[]," as he

is the only other individual named in the *Cell* article and '337 PCT Publication besides Dr. Brenner. *See* Ex. 1007 at (75); Ex. 1008 at 495. Therefore, Petitioner has the burden of establishing that Dr. Bieganowski conceived of—and thus invented—some significant contribution to the relied-upon portions of those two references.

Petitioner's Reply to Patent Owner's Preliminary Response argues that a reference may alternatively be "by another" if the "[relied-upon] portions do not represent the *inventive* work of Dr. Brenner, but instead represent the work of those in the prior art." Paper 17 at 8-10 (emphasis in original). That is, Petitioner argues that the references are "by another" because certain relied-upon portions were allegedly in the prior art and thus not invented by either Dr. Brenner or Dr. Bieganowski. But Petitioner is wrong on multiple levels.[7]

[7] This argument in Petitioner's Reply to Patent Owner's Preliminary Response is premised specifically on the limitation in claim 2 of the '086 patent—*i.e.*, "the nicotinamide riboside is isolated from a natural or synthetic source"—which appears in the '807 patent in only claim 2, not claims 1 or 3. *See* Paper 17 at 10 (relying on the fact that "the Board previously found … the subject matter recited in claim 1 of the '086 patent" to be unpatentable); '807 patent at claims 1-3.

Foundationally, if the relied-upon portions were already in the prior art, then Petitioner could just assert the underlying prior art reference. But instead, Petitioner attempts to obfuscate and back-door a way around the proper "by another" analysis. The law is clear that the "by another" analysis asks who *invented* the relied-upon portions and does not, as Petitioner argues, ask whether the relied-upon portions constitute an invention as opposed to merely "the work of those in the prior art."

Indeed, the "by another" test in *Duncan Parking* presumes that the relied-upon portions are inventive by asking whether those applied portions were "conceived" and "joint[ly] invent[ed]" by some other person. 914 F.3d at 1358; *see also CSL Behring LLC v. Bioverativ Therapeutics Inc.*, IPR2018-01313, Paper 10, 11 (P.T.A.B. Jan. 9, 2019) ("As to what inquiry is relevant, in *Katz* the Federal Circuit determined that a reference by an inventor co-authored with non-inventors was not § 102(a) prior art on the basis that the co-authors contribution fails to rise to joint inventorship … ." (citing 687 F.2d at 455-56)). Moreover, the *Duncan Parking* test requires an identifiable "other person[]" in order for a reference to be "by another," and does not contemplate, as Petitioner suggests, that relied-upon portions of a reference can be contributed generally by "those in the prior art." *Compare* 914 F.3d at 1358 *with* Paper 17 at 8-10.

2. The Invention of the '807 Patent and Relied-Upon Subject Matter in the *Cell* Article and '337 PCT Publication

Dr. Brenner worked from 2003 to 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 experiments and assays related to NR, and as a result, Dr. Brenner discovered that NR is an NAD+ precursor in a previously-unknown pathway, identified and named an Nrk gene and discovered sequences of the Nrk1 and Nrk2 genes in humans, and ultimately conceived of therapeutic uses and compositions of NR. *Id.* ¶ 12; Ex. 2015 ¶¶ 9-10, 12. One member of Dr. Brenner's research team was Dr. Bieganowski, 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. Ex. 2002 ¶ 13; Ex. 2003 ¶ 7; Ex. 2015 ¶¶ 11-12; Ex. 2004 at 16:18-17:3, 19:10-23, 21:22-22:14.

Certain aspects of the NR research project were disclosed in the '347 Provisional, which Dartmouth filed on February 20, 2004. Ex. 2002 ¶ 15; *see* Ex. 1005 at 2. Dartmouth later claimed priority to the '347 Provisional in the '337 PCT Application, which was 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 name both Dr. Brenner and Dr. Bieganowski as co-inventors. *See* Ex. 1005 at 3; Ex. 1007 at (75); Ex. 2002 ¶¶ 7-8; Ex. 2003 ¶ 6. Likewise, the *Cell* article names both Dr. Brenner and Dr. Bieganowski as co-authors. *See* Ex. 1008 at 495; Ex. 2002 ¶ 9; Ex. 2003 ¶ 6. Petitioner’s initial assertion of these references as prior art under § 102(a) and § 102(e) is based merely on the fact that these references name both Dr. Brenner and Dr. Bieganowski. Pet. at 34 n.12.

However, under *Duncan Parking*, to determine whether these two references are actually “by another,” the Board must determine specifically “what portions of the reference … [are] relied on as prior art to [invalidate] the claim limitations at issue.” 914 F.3d at 1358; *see Ethicon*, 847 F. App’x at 908-09 (reversing the Board because it “did not correctly identify the portions of [the reference] relied on”).

Here, the invention that is recited in claims 1-3 of the ’807 patent is a composition of NR formulated for therapeutic use, with certain additional attributes.[8] Thus, while some relied-upon portions of the *Cell* article and ’337 PCT

[8] The certain additional attributes include, for example, that the NR is isolated and in combination with certain other components, that the composition is in admixture with a certain carrier, that the composition is formulated for and increases NAD+ biosynthesis upon oral administration, that the NR is isolated from a natural or

Publication mention isolation techniques and other routine or previously-known methods and technologies as background, all are specifically applied to, and relied upon in the context of, therapeutic uses and compositions of NR. Ex. 2015 ¶¶ 15-34; *see also* Ex. 2016 at 83:3-13, 84:23-86:8, 87:1-7, 87:23-88:25 (acknowledging that cited portions of the *Cell* article and '337 PCT Publication are relied upon by Petitioner for a therapeutic "composition" as claimed).

3. The Relied-Upon Subject Matter in the *Cell* Article and '337 PCT Publication Was Invented Only by Dr. Brenner And Not Dr. Bieganowski

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 subject matter of the *Cell* article and '337 PCT Publication upon which Petitioner relies, and therefore neither of those references is "by another."

The relied-upon portions of the *Cell* article and '337 PCT Publication are relied upon by Petitioner in relation to therapeutic oral compositions of NR, which is the subject of challenged claims 1-3. And Dr. Brenner was solely responsible for all aspects of the NR research project related to therapeutic uses and compositions of NR and all inventions regarding the same. Ex. 2002 ¶ 14; Ex.

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synthetic source (claim 2), and/or that the composition is formulated into a certain form (claim 3). *See* '087 patent at claims 1-3.

2015 ¶¶ 12, 15-34; *see also* Ex. 2003 ¶ 8. Dr. Bieganowski did not contribute to or conceive of any aspect of the NR research project regarding therapeutic uses or compositions of NR, much less make a contribution "significant enough, when measured against the full anticipating disclosure, to render him a joint inventor" under *Duncan Parking*. 914 F.3d at 1358; Ex. 2002 ¶ 14; Ex. 2003 ¶ 8; Ex. 2015 ¶¶ 4, 11-12; *see also* Ex. 2004 at 19:10-14, 21:22-22:14, 26:14-23, 10:10-20.

a. Dr. Brenner Invented the Relied-Upon Subject Matter in the Cell Article

The relied-upon portions of the *Cell* article represent the invention of Dr. Brenner alone, as Dr. Bieganowski did not invent any subject matter in these relied-upon portions of the *Cell* article. *See* Pet. at 40-50; Ex. 2002 ¶¶ 18-19; Ex. 2003 ¶ 8; Ex. 2015 ¶¶ 15, 29-34. In his declarations, Dr. Brenner identifies each portion of the *Cell* article cited by Petitioner, identifies specifically the subject matter that Petitioner relies upon in each of these cited portions, and then explains how the relied-upon subject matter of each individual cited portion constitutes his invention alone. Ex. 2002 ¶¶ 18-19; Ex. 2015 ¶¶ 15, 29-34. More specifically, Dr. Brenner's second declaration (Ex. 2015) explains that the relied-upon portions of the '337 PCT Publication relate to aspects of his invention of a therapeutic composition of NR such as discovery that NR is an NAD+ precursor in a previously-unknown pathway (¶¶ 30, 33-34), identification of sources of NR for use in therapeutic compositions (¶¶ 30-31, 33), and use of NR as a therapeutic (¶¶

30-34). Dr. Brenner also explains that he alone designed the experiments and assays described in the *Cell* article and that Dr. Bieganowski's role was to perform the assays and experiments at his direction. *Id.* ¶¶ 30-31, 33.

b. Dr. Brenner Invented the Relied-Upon Subject Matter in the'337 PCT Publication

The relied-upon portions of the '337 PCT Publication represent the invention of Dr. Brenner alone, as Dr. Bieganowski did not invent any 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; Ex. 2015 ¶¶ 15-28. In his declarations, Dr. Brenner identifies each portion of the '337 PCT Publication cited by Petitioner, identifies specifically the subject matter that Petitioner relies upon in each of these cited portions, and then explains how the relied-upon subject matter of each individual cited portion constitutes his invention alone. Ex. 2002 ¶¶ 16-17; Ex. 2015 ¶¶ 15-28. More specifically, Dr. Brenner's second declaration (Ex. 2015) explains that the relied-upon portions of the '337 PCT Publication relate to aspects of his invention of a therapeutic composition of NR such as discovery that NR is an NAD+ precursor in a previously-unknown pathway (¶¶ 18, 24), identification of sources of NR for use in therapeutics (¶¶ 19, 24-26, 28), use of NR as a therapeutic (¶¶ 20-24), and carriers, forms of administration, and other components for a therapeutic composition of NR (¶¶ 22, 27). Again, Dr. Brenner also explains that he alone designed the experiments and assays described in the '337 PCT

Publication and that Dr. Bieganowski's role was to perform the assays and experiments at his direction. *Id.* ¶¶ 17, 19, 25-26, 28.

c. Dr. Bieganowski Disclaimed Any Inventive Contribution to the Relied-Upon Subject Matter

Dr. Bieganowski, in his sworn declaration, disclaims any inventive contribution to the relied-upon portions of the *Cell* article and '337 PCT Publication. Ex. 2003 ¶ 8. He also confirms that Dr. Brenner designed the experiments related to the NR research project, and that his role was to perform the experiments at Dr. Brenner's direction. *Id.* ¶ 7.

In IPR2021-00268, where Petitioner challenges the related '086 patent by relying upon essentially the same portions of the *Cell* article and '337 PCT Publication as relied upon here, Petitioner was afforded the opportunity to depose Dr. Bieganowski regarding whether those relied-upon portions are "by another."[9] *See* IPR2021-00268, Paper 2 at 42-50; IPR2021-00268, Ex. 1024 at 21:22-22:5, 23:20-25; *see generally* Ex. 2004. Despite having the opportunity to depose Dr.

[9] Given Petitioner's deposition of Dr. Bieganowski in IPR2021-00268, and due to the substantial similarity of Dr. Bieganowski's declarations in the two proceedings, Petitioner elected to forgo a separate comparable deposition in the present IPR, thus acknowledging that Dr. Bieganowski's deposition testimony in IPR2021-00268 is also relevant to the "by another" issue in the present IPR. Ex. 2012.

Bieganowski regarding his contributions to the *Cell* article and '337 PCT Publication, Petitioner obtained ***zero*** evidence that Dr. Bieganowski conceived any aspect of the relied-upon portions. *See generally* Paper 17 (failing to even argue, much less cite deposition evidence, that Dr. Bieganowski conceived or invented any aspect of the relied-upon subject matter). Instead, Dr. Bieganowski's deposition testimony confirmed that he did not invent any aspect of the relied-upon portions of the asserted references. *See* Ex. 2004 at 19:10-14, 21:22-22:14 (testifying that Dr. Brenner designed the experiments reflected in the *Cell* paper and that Dr. Bieganowski performed those experiments at Dr. Brenner's direction using routine techniques); *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"); *Katz*, 687 F.2d at 455-56 (holding that a reference was not "by another" where co-authors were "working under the direction and supervision" of the inventor); *see also* Ex. 2004 at 26:14-23, 10:10-20 (disowning any inventive contribution related to the "use of NR as a drug or supplement").

4. Patent Owner's Evidence For the "By Another" Issue Is Corroborated and Sufficient

Patent Owner presents unequivocal declarations regarding who invented the relied-upon subject matter of the *Cell* article and '337 PCT Publication, including two declarations from the only inventor of the '807 patent, Dr. Brenner (Ex. 2002,

Ex. 2015), and a corroborating disclaimer declaration from an uninterested person, Dr. Bieganowski (Ex. 2003), who is the only other individual named in the references. Dr. Brenner's declarations and Dr. Bieganowski's corroborating declaration are all further corroborated by Dr. Bieganowski's deposition testimony that he did not invent the relied-upon portions (Ex. 2004). Moreover, the declaration testimony is further corroborated by the professor-subordinate relationship between Drs. Brenner and Bieganowski, the declarants' respective roles in the NR research project, and Dr. Brenner's review of contemporaneous documentation in the form of the first public description (Ex. 1008) and early patent filings (Ex. 1005, Ex. 1007) describing the NR research project. This evidence is more than sufficient to corroborate Dr. Brenner's testimony and to establish that the relied-upon portions of the two references are not "by another."

Where an inventor of a challenged patent is one of two co-authors or co-inventors of an earlier reference, 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-author or co-inventor of the reference can be sufficient to establish that the reference is not "by another" and is thus not prior art. *See, e.g.*, *Katz*, 687 F.2d at 455-56 (finding inventor declaration sufficient for § 102(a) reference); *In re DeBaun*, 687 F.2d 459, 463 (C.C.P.A. 1982) (finding inventor declaration sufficient for § 102(e) reference); *Ex Parte Hirschler*, 1952

Pat. App. LEXIS 55, at *7-10 (B.P.A.I. Jan. 31, 1952) (finding disclaimer affidavit sufficient for § 102(a) reference); *In re Mathews*, 408 F.2d 1393, 1396 (C.C.P.A. 1969) (finding disclaimer declaration sufficient for § 102(e) reference). Although either an inventor declaration or a disclaimer declaration can suffice, here, Patent Owner provides both and thus leaves no doubt. *See* Ex. 2002; Ex. 2003; Ex. 2015.

Also, Dr. Brenner's declaration testimony is not a "naked assertion" as Petitioner alleges. *See* Paper 17 at 2-4 (citing *EmeraChem*, 859 F.3d at 1345-47). *EmeraChem* found that a "declaration amounts to a naked assertion by an inventor" when "[n]othing in the declaration itself, or in addition to the declaration, provides any context, explanation, or evidence to lend credence to the inventor's bare assertion." 859 F.3d at 1345. Here, however, Dr. Brenner's declarations provide background and context for the laboratory work and inventions that led to and are reflected in the at-issue references, including the respective roles of Drs. Brenner and Bieganowski. *See* Ex. 2002 ¶¶ 11-15; Ex. 2015 ¶¶ 6-14. Dr. Brenner also individually discusses each relied-upon portion of the at-issue references and explains how the relied-upon subject matter in each portion relates to his work and constitutes his invention alone. *See* Ex. 2015 ¶¶ 15-34.

Additionally, Dr. Brenner's declarations are corroborated by Dr. Bieganowski's uninterested disclaimer declaration, which confirms that he did not contribute to "therapeutic uses or compositions of [NR]" and instead 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 ¶¶ 7-8; *see Varian*, IPR2016-00160, Paper 82, 21-22; *Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1351 (Fed. Cir. 2001) ("[T]estimony of someone other than the alleged inventor may corroborate an inventor's testimony." (citation omitted)). Dr. Brenner's declarations, as well as Dr. Bieganowski's own declaration, are further corroborated by Dr. Bieganowski's deposition, where he again confirmed that he is not an inventor of the subject matter at issue. *See* Ex. 2004 at 21:22-22:14, 26:14-23, 10:10-20 (disowning any inventive contribution related to the "use of NR as a drug or supplement"). Dr. Bieganowski's deposition testimony also confirmed the context of the NR research project, including that Dr. Brenner designed all of the experiments reflected in the *Cell* article and that Dr. Bieganowski performed those experiments at Dr. Brenner's direction using routine techniques. *Id.* at 16:18-17:16, 19:10-14, 21:22-22:14.

Additionally, Dr. Brenner's testimony is corroborated by the superior-subordinate relationship between him and Dr. Bieganowski in relation to the NR research project that resulted in the *Cell* article and '337 PCT Publication. For example, when an inventor declaration provides "explanation that [the inventor's] co-authors [for an asserted reference] were students under his direction and

supervision," then it contains "more than a naked assertion." *EmeraChem*, 859 F.3d at 1347-48. That is true here because Dr. Brenner's declarations, together with the corroborating declaration and deposition testimony by Dr. Bieganowski, explain that Dr. Brenner designed the relevant experiments and that Dr. Bieganowski, as a postdoctoral fellow in Dr. Brenner's laboratory, performed experiments under Dr. Brenner's direction and supervision. *See* Ex. 2002 ¶¶ 11-13; Ex. 2015 ¶¶ 11-12; Ex. 2003 ¶ 7; Ex. 2004 at 16:18-17:16, 19:10-14, 21:22-22:14. The *Cell* article itself further corroborates this relationship by listing Dr. Brenner as the senior author and only providing correspondence information for Dr. Brenner. Ex. 1008 at 495.

Additionally, while an inventor is not required to rely upon contemporaneous documentary evidence, *see EmeraChem*, 859 F.3d at 1347, Dr. Brenner's testimony is supported by his review of contemporaneous documentation of his NR research project. This documentation includes the *Cell* article itself, which was the first, contemporaneous, public description of Dr. Brenner's work on the subject matter at issue, as well as the '347 Provisional, which was the contemporaneous patent filing regarding the same. Ex. 2015 ¶¶ 3, 13; Ex. 2002 ¶ 10. Dr. Brenner also bases his declaration testimony on his review of an intervening declaration regarding therapeutic NR formulations that he submitted to the USPTO in 2012 as an inventor of the '400 Application that issued

as the ’807 patent. Ex. 2015 ¶ 14, Exhibit A. This documentation confirmed Dr. Brenner’s memory that he conceived the inventions in the relied-upon portions of the at-issue references. *Id.* ¶¶ 13-14.

Additionally, the claims and inventorship of the ’807 patent and ’086 patent on the one hand versus the ’337 PCT on the other support the declarants’ testimony that therapeutic compositions of NR were conceived by only Dr. Brenner. Specifically, the ’807 patent and ’086 patent, which name only Dr. Brenner as an inventor, only include claims directed to therapeutic compositions of NR, whereas the ’337 PCT, which also names Dr. Bieganowski as an inventor, includes claims not limited to therapeutic compositions of NR. *See* ’807 patent at claims 1-3; Ex. 1024 (’086 patent) at claims 1-5; Ex. 1007 at 68-72.

In sum, the totality of the evidence is consistent and makes clear that the relied-upon subject matter in both the *Cell* article and ’337 PCT Publication asserted in the Petition is Dr. Brenner’s own invention and not the invention of Dr. Bieganowski.

5. The Board’s Institution Decision

Prior to Institution of this IPR, Patent Owner sought to establish that the *Cell* article and ’337 PCT Publication are not “by another” by submitting Dr. Brenner’s first declaration (Ex. 2002) and Dr. Bieganowski’s declaration (Ex. 2003) and deposition testimony (Ex. 2004). However, the “by another” analysis in the

Board's Institution Decision did not consider the layers of corroboration and the full scope of all pertinent evidence here.

The Board's analysis found that Dr. Brenner's testimony was "conclusory," that he did not use any contemporaneous documentation to confirm his memory, and that his testimony was not supported by any corroborating evidence. Paper 18, 17-20. At the outset, a second declaration from Dr. Brenner that individually addresses each relied-upon portion of the at-issue references, as discussed above in Section III.A.3, is submitted herewith, and this declaration was not previously submitted in this IPR. Second, the Board did not consider that the *Cell* article and '347 Provisional constitute contemporaneous documentation that Dr. Brenner reviewed to affirm his memory, as discussed above in Section III.A.4. For example, the Board, without explanation, did not consider Dr. Brenner's consideration of the *Cell* article because it is an asserted reference. But the *Cell* article is documentary evidence of the experiments and work Drs. Brenner and Bieganowski were undertaking at that time. Moreover, for his second declaration, submitted herewith, Dr. Brenner relied upon an intervening 2012 declaration submitted to the USPTO to affirm his memory. Ex. 2015 ¶ 14, Exhibit A. Additionally, the Board did not acknowledge that Dr. Brenner's testimony is corroborated by both Dr. Bieganowski's uninterested disclaimer declaration and

deposition testimony, as well as the superior-subordinate relationship between Drs. Brenner and Bieganowski, as discussed above in Sections III.A.3-4.

The Board's analysis also found Dr. Bieganowski's declaration to be uncorroborated and conclusory. Paper 18, 18-20. This finding appears to evaluate Dr. Bieganowski's declaration as that of an interested inventor requiring corroboration. But Dr. Bieganowski submitted a *disclaimer* declaration, was deposed by the Petitioner, and his involvement "does not rise to the level of self-interest required to justify triggering application of the corroboration rule." *See Thomson, S.A. v. Quixote Corp.*, 166 F.3d 1172, 1176 (Fed. Cir. 1999). Dr. Bieganowski's disclaimer declaration is one form of corroborating evidence for Dr. Brenner's inventor declaration. The Board points to no authority requiring or explaining why corroborating testimony, like that provided by Dr. Bieganowski here, also needs to be separately corroborated by even more evidence. Additionally, Dr. Bieganowski's testimony is also reliable and credible because it was under oath and subject to cross-examination. *See Trans Ova Genetics, LC v. XY, LLC*, No. IPR2018-00250, Paper 35, 10 n.9 (P.T.A.B. June 26, 2019).

The Board's analysis also found that Dr. Brenner claimed to have invented the work of another. Paper 18, 19-20. However, Dr. Brenner's second declaration submitted herewith clarifies that the portion of the '337 PCT Publication at issue (at 3:31-4:6) is relied upon by Petitioner for its teaching that NR is an NAD+

precursor in a previously-unknown pathway, which Dr. Brenner discovered, and not for its disclosure of others' work regarding NR being an NAD+ precursor in bacteria. Ex. 2015 ¶ 18. The Board's analysis also focused on the wrong subject matter regarding the *Cell* article, as Petitioner does not rely upon the *Cell* article for just teaching NR isolation techniques, but instead for allegedly teaching the use of isolated NR in a therapeutic composition, as discussed in Section III.A.2. *See also* Ex. 2015 ¶¶ 29-34.

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. However, as the Board correctly found in its Institution Decision in IPR2021-00268 with respect to a continuation of the '807 patent, the *Cell* article does not qualify as prior art under § 102(b). IPR2021-00268, Paper 21 at 15-17. This is because the '807 patent properly claims priority to at least the '701 Application filed April 25, 2005 (*see* '807 patent at 1:11-13), and the *Cell* article—which was not purportedly published until May 14, 2004 (*see* Pet. at 32 n.10; Ex. 1008 at 495)—therefore was not published "more than one year prior to" the '807 patent's priority date as required by § 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.

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 or establish the *Cell* article as prior art under § 102(b).[10]

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

[10] Petitioner’s Ground 1 also relies upon the Rosenbloom reference (Ex. 1015, “Rosenbloom”) 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.

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 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[11] ("Paris Convention"), as incorporated by Article 8 Section (2)(a) of the PCT.[12] *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

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

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

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 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.[13]

[13] 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

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).

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filing receipt somehow overrides the fact that the '807 patent's priority claim satisfies the relevant statutory requirements. *Id.*; *see infra* Section III.B.2.

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,[14] and the Paris

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

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 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. Indeed, in IPR2021-00268, where Petitioner challenges the priority date of a continuation of the '807 patent using the same Paris Convention argument, the Board correctly found that "the relevant portions of the Paris Convention and the PCT are found in 35 U.S.C. § 119" and that "Section 119 relates to claims to foreign priority and ***is not applicable to the instant case***." IPR2021-00268, Paper 21 at 15-16; *compare* Pet. at 8-18 *with* IPR2021-00268, Paper 2 at 6-14.

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 and the *Cell* Article Is Thus Not Prior Art Under § 102(b)

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. *See* IPR2021-00268, Paper 21 at 16-17 (finding that a continuation of the '807 patent properly claims priority back to the '701 Application through the '807 patent).

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, *i.e.*, April 25, 2005. And thus, 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.

IV. CONCLUSION

For the foregoing reasons, the Board should reject both grounds in the Petition and find that claims 1-3 of the '807 patent are patentable.

Respectfully submitted,

Date: November 9, 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 8,687 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 PATENT OWNER RESPONSE was served on November 9, 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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