

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUMAN POWER OF N COMPANY,
Petitioner,

v.

HEARTBEET LTD,
Patent Owner.

PGR2022-00004
Patent 11,083,747 B2

Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324

I. INTRODUCTION

Human Power of N Company (“Petitioner”) filed a Petition requesting post-grant review of claims 1–7 of U.S. Patent No. 11,083,747 B2 (Ex. 1001, “the ’747 patent”). Paper 1 (“Pet.”). Heartbeet Ltd. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6 (“Prelim. Resp.”).

To institute a post-grant review, we must determine whether the information presented in the Petition, “if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a).

Upon consideration of the Petition and the Preliminary Response, for the reasons set forth below, we determine that Petitioner has not shown that the ’747 patent is eligible for post-grant review. Accordingly, we do not institute a post-grant review of the challenged claims of the ’747 patent.

A. Real Parties-in-Interest

Petitioner states it is the real party-in-interest. Pet. 1. Patent Owner identifies itself and an exclusive licensee, ThermoLife International, LLC, as real parties-in-interest. Paper 3, 1.

B. Related Matters

Both Petitioner and Patent Owner identify the following related case: *Thermolife International, LLC v. Human Power of N Company*, 6-21-CV-00144-ADA (W.D. Tex.). Pet. 1–2; Paper 3, 1–2.

Petitioner identifies the following as related matters: Pending U.S. Patent Application No. 17/308,007; U.S. Patent No. 10,842,813; Post Grant Review No. PGR2021-00094;¹ U.S. Patent No. 10,406,118; U.S. Patent No. 10,555,968; U.S. Patent No. 9,180,140; and Reexamination No. 90/013,759. Pet. 1–2.

Patent Owner identifies the same matters identified by Petitioner. Paper 3, 1–2.

¹ We declined to institute trial in PGR2021-00094. *See* PGR2021-00094, Papers 4, 10.

C. The '747 Patent

The '747 patent, titled “Compositions of Nitrates and Methods of Use Thereof,” issued August 10, 2021, from an application filed October 1, 2020. Ex. 1001, codes (54), (45), (22). It is a continuation-in-part of U.S. Application No. 15/966,508, filed on April 30, 2018, now U.S. Pat. No. 10,842,813 ('813 patent”), which is a continuation-in-part of application No. 14/830,937, filed on Aug. 20, 2015, now U.S. Pat. No. 10,555,968, which is a continuation of application No. 12/528,798, filed as application No. PCT/SE2008/050211 on Feb. 26, 2008, now U.S. Pat. No. 9,180,140. Application No. 15/966,508 is a continuation-in-part of application No. 12/528,794, filed as application No. PCT/SE2008/050212 on Feb. 26, 2008, now U.S. Pat. No. 10,406,118. *Id.* at code (63). The '747 patent claims priority to U.S. Provisional application No. 60/919,709, filed March 22, 2007. *Id.* at code (60).

Among the methods disclosed are “methods of decreasing systolic blood pressure in an adult human subject. The methods include administering inorganic nitrate (NO₃-) to a human or adult subject.” *Id.* at 4:48–51. In some embodiments, administration of the inorganic nitrate “reduces diastolic blood pressure” in the subject. *Id.* at 4:51–54.

The '747 patent discloses use of inorganic nitrates in the compositions used in the claimed methods obtained “from a natural nitrate source,” such as a “juice or dried concentrate from at least one of spinach, lettuce, fennel, cabbage, Chinese cabbage, and beetroot.” *Id.* at 5:41–49. Other embodiments disclose that inorganic nitrate sources can be nitrate salt such as “sodium nitrate, potassium nitrate, calcium nitrate,

zinc nitrate, ammonium nitrate, or arginine nitrate.” *Id.* at 5:29–45, 12:15–24.

The ’747 patent discloses an example titled “Effect of Ingestion of Beetroot on Blood Pressure,” detailing a study of “[a] 43-year old non-smoking subject with hypertension,” who “ingested fresh beetroot juice (300-400ml/day) for 14 days.” *Id.* at 27:58–60. The individual’s blood pressure when the experiment began (basal rate of systolic/diastolic pressure, in mmHg) was 142/99. *Id.* at 27:63–64. During the 14 days of the study, the subject experienced a mean reduction in systolic blood pressure of 15 mmHg and a mean reduction of 16 mmHg in diastolic pressure. *Id.* at 27:65–8:3. Six days after stopping administration of beetroot juice, the subjects blood pressure had increased to 140/100 mmHg. *Id.* at 28:3–5. The measurements of the subject’s blood pressure in mmHg over the experiment are depicted in Figure 9:

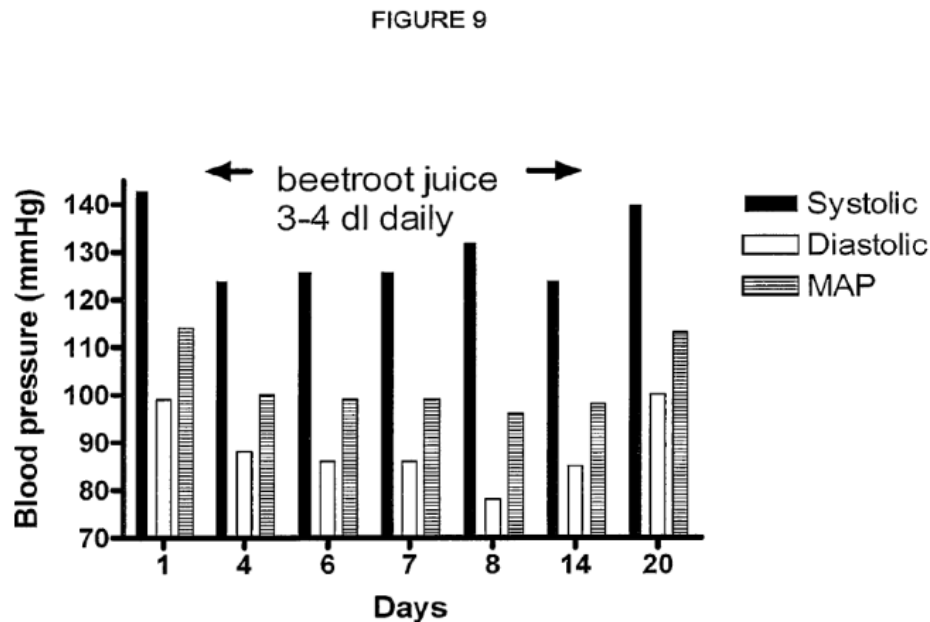


Figure 9 is a “graph showing the effect of a two-week intervention with [administration of] beetroot juice (fresh juice 3-4 dl/day) on systolic, diastolic, and mean arterial (MAP) blood pressure in a 43-year old male with hypertension.” *Id.* at 6:43–46. On day 20 of measurement (six days after administration of a source of inorganic nitrate had ceased), the systolic pressure measured 140 mmHg. *Id.* at 28:3–5, Fig. 9; *see also id.* at 6:43-46.

The ’747 patent discloses that nitrite/nitrate compositions can include additives that may enhance the bioactivity of the composition, such as polyphenols and/or non-pathogenic bacteria. *Id.* at 5:27–40, 12:43–61, 13:4–38. “The additive can be a natural flavor, an artificial flavor, a sweetener, a flavor enhancer, a color additive, an emulsifier, a stabilizer, a fat, or a preservative.” *Id.* at 5:24–27.

D. Challenged Claims

Petitioner challenges claims 1–7 of the ’747 patent. Pet. 3–4. Claim 1 is the sole independent claim. Ex. 1001, 29:1–23. Claim 1 is illustrative and reproduced below:

1. A method of decreasing systolic blood pressure, the method comprising administering inorganic nitrate (NO₃-) to an adult human subject. *Id.* at 29:2–4.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–7 would have been unpatentable on the following grounds (Pet. 3–4):

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis ²
1	1–3	102(a)(1)	Brunton ³ (Ex. 1032), which published in 1909. Ex. 1003 at ¶ 102; Ex. 1060; Ex. 1061; Ex. 1068 at ¶¶ 55–61).
2	1–4	103(a)	Brunton
3	4	103(a)	Brunton, and Brunton ² ⁴ (Ex. 1033), which published in 1906 . Ex. 1003 at ¶ 124; Ex. 1062; Ex. 1063; Ex. 1068 at ¶¶ 62–68.
4	5–7	103(a)	Brunton and Shevach (Ex. 1027), which published in 2005.
5	5–7	103(a)	Brunton, Shevach, and Brunton ² .
6	1–3, 5–7	112(a)	No written description
7	1–3, 5–7	112(a)	Not enabled

Petitioner relies on the declaration testimony of Jeff S. Volek, Ph.D. (Ex. 1003), in support of these grounds.

F. Person of Ordinary Skill in the Art

Petitioner proposes that one of ordinary skill in the art would have had “an M.D. degree or a Ph.D. degree in biochemistry, pharmacology, nutrition chemistry, exercise physiology, or kinesiology, and at least two years of

² This chart repeats the grounds as presented in Petitioner’s chart at Pet. 4.

³ Brunton, *An Address on Blood Pressure in Man: Its estimation and indications for treatment*, The British Medical Journal, pp. 64-67 (July 10, 1909) (Ex. 1032 “Brunton”).

⁴ Brunton et al., *An Address on Longevity and the Means of Attaining It*, The Lancet, Vol. 168, Issue 4342, pp. 1330–1355 (Nov. 17, 1906) (Ex. 1033 “Brunton 2”).

post-doctoral research or clinical experience with physiology, biochemistry, or dietary supplements and formulation.” Pet. 13 (citing Ex. 1003 ¶ 21).

Patent Owner does not challenge this definition at this time. Prelim. Resp. 7.

For purposes of this decision, we apply Petitioner’s proposed definition as it is consistent with the level of skill presented in the ’747 patent and applied art. We also note that the level of ordinary skill in the art at the time of the invention may be reflected in the prior art in this proceeding. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown”) (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).

G. Claim Construction

In a post-grant review, we apply the same claim construction standard as would be used by a district court to construe a claim in a civil action involving the validity or infringement of a patent. 37 C.F.R. § 42.200(b) (2020). Under that standard, claim terms are given their ordinary and customary meaning, as would have been understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history of record. *Id.*; *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc); *Thorner v. Sony Comput. Entm’t Am. LLC*, 669 F.3d 1362, 1365–66 (Fed. Cir. 2012).

Petitioner proposes two terms for construction, “inorganic nitrate” and “nutritional supplement.” Pet. 27–30. Patent Owner does not propose a construction for either term. Prelim Resp. 7–8. For purposes of determining whether to institute trial of the challenged claims, we determine it is not necessary to construe either term proposed by Petitioner. *Vivid Techs., Inc.*

v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an AIA proceeding).

II. ELIGIBILITY FOR POST-GRANT REVIEW

As a threshold matter, we must determine whether the ’747 patent is eligible for post-grant review. The post-grant review provisions set forth in section 6(d) of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (September 16, 2011) (“AIA”), apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (stating that the provisions of section 6(d) “shall apply only to patents described in section 3(n)(1)”). Patents subject to the first-inventor-to-file provisions are those that issue from applications that contain or contained at any time—

(A) a claim to a claimed invention that has an effective filing date as defined in section 100(i) of title 35, United States Code, that is on or after [March 16, 2013]; or

(B) a specific reference under section 120, 121, or 365(c) of title 35, United States Code, to any patent or application that contains or contained at any time such a claim.

AIA § 3(n)(1).

Our rules require that each petitioner for post-grant review certify that the challenged patent is available for post-grant review. 37 C.F.R.

§ 42.204(a) (“The petitioner must certify that the patent for which review is sought is available for post-grant review . . .”). In addition, “[a] petition for a post-grant review may only be filed not later than the date that is 9 months

after the date of the grant of the patent or of the issuance of a reissue patent (as the case may be).” 35 U.S.C. § 321(c).

Determining whether a patent is subject to the first-inventor-to-file provisions of the AIA, and therefore eligible for post-grant review, is straightforward when the patentee filed the application from which the patent issued before March 16, 2013, or when the patentee filed the application on or after March 16, 2013, without any priority claim. The determination is more complex, however, for a patent that issues from a “transition application,” that is, an application filed on or after March 16, 2013, that claims the benefit of an earlier filing date. See MPEP § 2159.04 (9th ed. Rev. 10.2019, June 2020). Entitlement to the benefit of an earlier date under 35 U.S.C. §§ 119, 120, 121, or 365 is premised on disclosure of the claimed invention “in the manner provided by § 112(a) (other than the requirement to disclose the best mode)” in the earlier application. See 35 U.S.C. §§ 119(e), 120. Thus, a patent that issues from a transition application is not available for post-grant review if the claimed subject matter complies with the written description and enablement requirements of § 112(a) for an ancestor application *filed prior to March 16, 2013*.

A. Priority Claim of the '747 Patent

The application that matured into the '747 patent is a transition application, as it claims priority to an application filed before March 16, 2013. The '747 patent issued August 10, 2021, from U.S. Application No. 17/061,321 (“’321 application”), filed October 1, 2020. Ex. 1001, codes (45), (21), (22). Petitioner provides, and Patent Owner adopts, Chart 1 depicted below to represent the two patent chains to which the '747 patent claims priority:

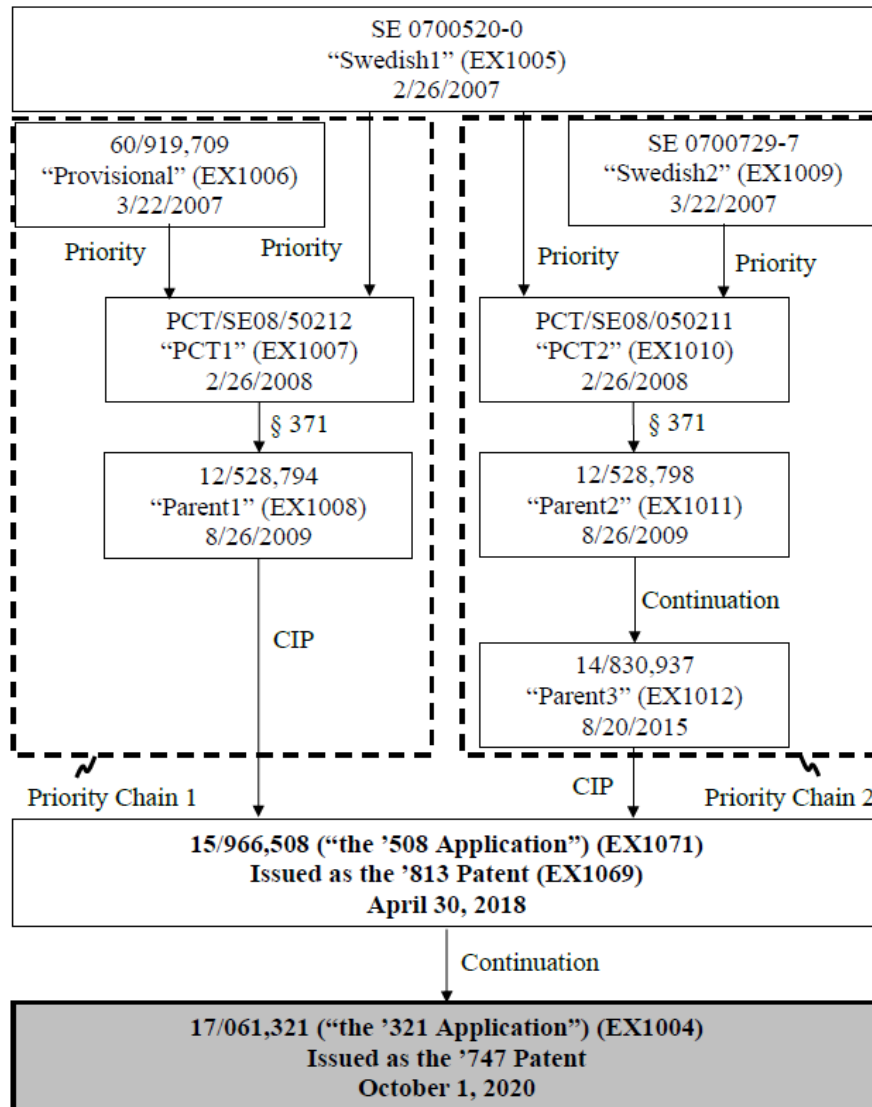


CHART 1

Chart 1 above is an excerpt from the Petition reflecting the familial relationships of the '555 patent's priority claim. Petition 32; Prelim Resp. 5. For ease of reference, we adopt the naming conventions shown in the chart and used by the parties. As Patent Owner states:

As shown in Chart 1, the '747 patent has two priority chains. In what Petitioner labels as "Priority Chain 1," the '747 patent claims priority to the '813 patent, which claims priority to U.S. Application No. 12/528,794 ("Parent1"), which issued

as U.S. Patent No. 10,406,118 and is the national stage application of PCT/SE08/50212 (“PCT1”). PCT1 in turn claims priority to both U.S. Provisional Application No. 60/919,709 (“Provisional”) and SE 0700520-0 (“Swedish1”).

And in what Petitioner labels as “Priority Chain 2,” the ’747 patent also claims priority to the ’813 patent, which in this chain claims priority to U.S. Application No. 14/830,937 (“Parent3”), which issued as U.S. Patent No. 10,555,968 and is a continuation of U.S. Application No. 12/528,798 (“Parent 2”), which issued as U.S. Patent No. 9,180,140. The latter is the national stage application of PCT/SE08/050211 (“PCT2”), which claims priority to both Swedish1 and SE 0700729-7 (“Swedish2”).

Prelim. Resp. 5–6. We collectively refer to the applications in the priority chain of the ’747 patent as the “Priority Applications.”

B. Legal Standard

The test for written description support is “whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date” based on an “objective inquiry into the four corners of the specification.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). If this test fails, the application is not entitled to the benefit of the earlier filing date.

The written description requirement is satisfied when the specification “set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed.” *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 928 (Fed. Cir. 2004). The specification does not have to provide exact or verbatim textual support for the claimed subject matter at issue. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). The Federal Circuit has

clarified that [a]lthough [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed The test for sufficiency of support . . . is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citations omitted). Moreover, “the written description requirement does not demand either examples or an actual reduction to practice.” *Capon v. Eshhar*, 418 F.3d 1349, 1352 (Fed. Cir. 2005). “An applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.” *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1365 (Fed. Cir. 2003). Furthermore, “[a] specification may . . . contain a written description of a broadly claimed invention without describing all species that [the] claim encompasses.” *Id.*

Finally, the written description inquiry is a question of fact, is context specific, and must be determined on a case-by-case basis. *Ariad Pharms., Inc.*, 598 F.3d at 1351 (citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985); *Capon*, 418 F.3d at 1357–1358); *see also Vas-Cath*, 935 F.2d at 1562 (“Precisely how close the original description must come to comply with the description requirement of § 112 must be determined on a case-by-case basis.”) (quoting *In re Smith*, 458 F.2d 1389, 1395 (CCPA 1972)). “[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Ariad Pharms., Inc.*, 598 F.3d at 1351 (citing *Capon*, 418 F.3d at 1357–1358). Factors used to evaluate the sufficiency of a disclosure include 1)

“the existing knowledge in the particular field”; 2) “the extent and content of the prior art”; 3) “the maturity of the science or technology”; and 4) “the predictability of the aspect at issue” (the “*Ariad* factors”). *Id.* (citing *Capon*, 418 F.3d at 1359).

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)). Undue experimentation is analyzed by applying the factors set forth in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).⁵ Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971); *see also In re Howarth*, 654 F.2d 103, 105 (CCPA 1981) (“An inventor need not, however, explain every detail since he is speaking to those skilled in the art.”).

“Patent claims are awarded priority on a claim-by-claim basis based on the disclosure in the priority applications.” *Lucent Techs., Inc. v. Gateway, Inc.*, 543 F.3d 710, 718 (Fed. Cir. 2008) (citations omitted).

C. Analysis

Petitioner asserts that the ’747 patent is eligible for post-grant review under AIA § 3(n)(1)(A) and (B) for two reasons: 1) the ’747’s immediate parent application, the ’813 patent, “contains claims [5–18 and 24] that are

⁵ The *Wands* factors are: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Wands*, 858 F.2d at 737.

not entitled to a pre-AIA priority date,” and 2) the ’747 patent “includes claims with a post-AIA priority date.” Pet. 30–31. Petitioner argues that certain limitations of claims 1–7 of the ’747 patent are unsupported in the ’813 priority application’s disclosure. Pet. 33–47.

Patent Owner disagrees and contends that Petitioner has failed to show that the ’747 patent is eligible for post-grant review. Prelim. Resp. 8–61. Patent Owner argues that claims 1–7 are each entitled an effective filing date “at least as early as February 26, 2008” and “find the requisite support under 35 U.S.C. § 112(a) in one or both of the PCT applications,” PCT1 and PCT2. *Id.* at 9–11.

As a preliminary issue, with respect to Petitioner’s argument that the ’747 patent cannot claim priority prior to March 16, 2013, because its “immediate parent—the ’813 Patent—contains claims that are not entitled to a pre-AIA priority date” (Pet. 30), we note that we addressed the issue of whether challenged claims 1–24 of the ’813 patent are entitled to claim priority to an application filed prior to March 16, 2013, in PGR2021-00094. In our Decision on Institution (Paper 7), which we modified in our Decision Denying Request for Rehearing (Paper 10), we confirmed that claims 1–24 have written descriptive support in PCT1 and PCT2, and thus, are entitled to claim priority to those applications under 35 U.S.C. §§ 119(e), 120, rendering them unavailable for challenge by post-grant review. Paper 7, 19–23; Paper 10, 3–22. For the reasons we explained at length in these papers, we are unpersuaded by Petitioner’s arguments in this proceeding (Pet. 33–47), which are identical in substance to the arguments in PGR2021-00094, that any of the claims in the ’813 patent lacks priority to PCT1 (Ex. 1007)

and/or PCT2 (Ex. 1010).⁶ We incorporate the fact finding and rationale from Paper 7 and Paper 10 of PGR2021-00094 in this proceeding, and will not revisit these arguments here independently of the allegations specifically relating to the '747 patent.

Below, we address Petitioner's allegations asserting that issued claims 1–3 and 5–7 of the '747 patent and originally-filed claims 1–10 and 12–17 lack written descriptive support in any pre-AIA priority application. Pet. 47–49. We address the claims in the groupings proposed by Petitioner and limit our discussion to the alleged lack of “enabling written description support” argued by Petitioner for these claims. Because Petitioner's allegation of a lack of “enabling written description support” appears to argue that the Priority Applications fail to both enable and provide sufficient written descriptive support for at least some the challenged claims, we address both challenges to the extent Petitioner's arguments are explained.

D. Issued Claims 5–7⁷ and Originally-Filed claims 4–10

Issued claims 5–7, with independent claim 1 included for reference, recite:

⁶ PCT1 (Ex. 1007) and PCT2 (Ex. 1010) both disclose uses of nitrate and nitrite supplementation. PCT1 focuses on the use of nitrate/nitrite supplementation to lower “metabolic rate, oxygen consumption and/or glucose homeostasis” in mammals. Ex. 1007 ¶ 1. PCT2 focuses on the use of nitrate/nitrite supplementation for performance enhancement in “nutritional foods and food supplements, liquid and solid edible products such as sport drinks, energy drinks and energy bars.” Ex. 1010 ¶ 1. Both PCT1 and PCT2 disclose the same experimental example comparing dietary supplementation with nitrate in volunteers to monitor their oxygen consumption. See Ex. 1007 ¶¶ 88–105; Ex. 1010 ¶¶ 79–93.

⁷ Petitioner does not allege that issued claim 4 has an effective filing date on or after March 16, 2013. See generally, Petition.

1. A method of decreasing systolic blood pressure, the method comprising administering inorganic nitrate (NO_3^-) to an adult human subject.

5. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in a composition consisting of the inorganic nitrate (NO_3^-) and at least one additive.

6. The method of claim 5, wherein the composition is a nutritional supplement.

7. The method of claim 5, wherein the inorganic nitrate (NO_3^-) is provided from a natural nitrate source.

Ex. 1001, 29:2–23.

Originally-filed claims 4–10, with originally-filed claim 1 included for reference, recite:

1. A method of promoting health in a human, the method comprising administering inorganic nitrate (NO_3^-) to the human, whereby administration of the inorganic nitrate (NO_3^-) reduces systolic blood pressure of the human.

4. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in a composition consisting of the inorganic nitrate (NO_3^-) and at least one additive.

5. The method of claim 4, wherein the composition is a nutritional supplement.

6. The method of claim 4, wherein the additive is selected from the group comprising: natural flavor, artificial flavor, sweetener, flavor enhancer, color additive, emulsifier, stabilizer, fat, and preservative.

7. The method of claim 4, wherein the inorganic nitrate (NO_3^-) is provided from a natural source.

8. The method of claim 7, wherein the natural nitrate source is juice or dried concentrate from at least one of spinach, lettuce, fennel, cabbage, Chinese cabbage, and beetroot.

9. The method of claim 4, wherein the source of the inorganic nitrate (NO_3^-) is in the form of a nitrate salt.

10. The method of claim 9, wherein the nitrate salt is selected from the group consisting of: sodium nitrate, potassium nitrate, calcium nitrate, zinc nitrate, ammonium nitrate, and arginine nitrate.

'321 application (Ex. 1004), 41.

Petitioner argues that, for the reasons given in Section VIII.A.3. of the Petition, the priority applications “preceding the ’508 Application that issued as the ’813 Patent do not provide written description support for administering a nitrate-and-additive-only composition to reduce systolic blood pressure, and especially not with the additives recited in original claim 6.” Pet. 48. Petitioner argues that the lack of written description supporting the ’813 patent results in issued claims 5–7 and originally-filed claims 4–10 having “an effective filing date no earlier than that of the ’508 Application: April 30, 2018.” *Id.*

In Section VIII.A.3., Petitioner argues that “none of the priority applications provide written description support for a nitrate-and-additive-only composition for a subject requiring a systolic blood pressure reduction.” Pet. 40 (citing Ex. 1003 ¶¶ 107–109). Petitioner argues that the ’813 patent contrasts additives from polyphenols and discloses their use in separate embodiments. *Id.* at 40–41 (citing Ex. 1069, 5:5–12; 11:25–61, Fig. 1; Ex. 1003 ¶ 107). Petitioner further argues that the priority applications either do not mention additives, or disclose them only in the context of “functional food.” *Id.* at 41 (citing Ex. 1007 ¶ 39 as example of additive in functional food, other paragraphs to show no additive use). Petitioner argues that although polyphenols are added to nitrate, they are not an additive in that composition). *Id.* (citing Ex. 1003 ¶ 109).

Petitioner argues that the nitrite administration disclosed with “non-pathogenic live bacteria” that “enhance the generation of bioactive

compounds” are not additives, but comprise part of “‘nitrate-containing food or drink’ not nitrate-and-additive-only compounds.” *Id.* at 41–42 (citing Ex. 1007 ¶¶ 54, 57; Ex. 1008 ¶¶ 54, 57 (same); Ex. 1003 ¶ 110). Petitioner also argues that PCT1 and Parent1 priority applications do not disclose “additives like sweeteners, emulsifiers, and stabilizers.” *Id.* (citing Ex. 1003 ¶ 111). Petitioner argues the additives disclosed in the second priority chain (e.g., PCT2) are only in the context of “functional food,” are not “in a composition consisting of nitrate and one or more additives,” and “do not describe giving nitrate-and-additive compositions to reduce systolic blood pressure or to a subject requiring a systolic blood pressure reduction.” *Id.* (citing Ex. 1009 ¶¶ 30–32; Ex. 1010 ¶¶ 23, 38–44; Ex. 1012 (¶¶ 23, 38–44); Ex. 1012 (same); Ex. 1003 ¶ 108).

Patent Owner notes that we held in PGR2021-00094 that PCT1 discloses the limitation “at least one additive” and that PCT1 “discloses that numerous additives, and combinations of additives, may be administered with inorganic nitrate.” Prelim. Resp. 23 (citing Decision Denying ’813 PGR Institution, 20). Patent Owner reiterates that PCT1 discloses mixing a nitrate-rich composition with an antibacterial compound to prevent degradation of the inorganic nitrate, and argues that the antibacterial is thus an additive contemplated by the PCT1 inventors. *Id.* (citing Ex. 1007 ¶ 57). Patent Owner also reiterates that PCT1 discloses the use of nitrate and/or nitrite with polyphenols and optionally also live non-pathogenic bacteria, disclosing the “one or more additive” limitation. *Id.* at 24–25 (citing Ex. 1007 ¶¶ 52, 54. Finally, Patent Owner argues that PCT2, which is also a priority application of the ’747 and ’813 patents, also discloses nitrate/nitrite compositions with additives including antibacterial compounds such as

acidifying agents (e.g., fruit juices or pH altering substances), “natural and artificial flavours, sweeteners, salt, flavour enhancers, colour additives, emulsifiers, stabilizers, fats, preservatives, and the like.” *Id.* at 27–28 (citing Ex. 1010 ¶¶ 23, 29, 37, 45, 54–55, 61).

Patent Owner is correct: we addressed each of Petitioner’s arguments at length in PGR2021-00094. Compare issues raised at Pet. 40–42 (Section VIII.A.3) with issues addressed in PGR2021-00094 Paper 7 (Decision) at 19–21 and Paper 10 (Denial of Request for Rehearing) at 12–16. For the reasons stated in those Papers and for the reasons stated by Patent Owner summarized above, we are not persuaded that one of skill in the art would not have understood the specifications of PCT1 and PCT2 to encompass the method of administering a composition comprising inorganic nitrate and one or more additives, which may have included the various types of additive examples recited in claim 6 of the ’747 patent.

*E. Issued Claims 1–3 and 5–7 and
Originally-Filed Claims 1–10 and 12–17.*

Issued claims 1–3 recite:

1. A method of decreasing systolic blood pressure, the method comprising administering inorganic nitrate (NO_3^-) to an adult human subject.
2. The method of claim 1, whereby administration of the inorganic nitrate (NO_3^-) reduces diastolic blood pressure of the adult human subject.
3. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in a composition in the form of a liquid, a paste, a gel, a bar, a cake, a powder, a granulate, an effervescent tablet, a chewing gum, a tablet, a capsule, a lozenge, a fast melting tablet or wafer, a sublingual tablet, or a spray.

Ex. 1001, 29:2–13.

Originally-filed claims 1–10 and 12–17 recite:

1. A method of promoting health in a human, the method comprising administering inorganic nitrate (NO_3^-) to the human, whereby administration of the inorganic nitrate (NO_3^-) reduces systolic blood pressure of the human.
2. The method of claim 1, whereby administration of the inorganic nitrate (NO_3^-) reduces diastolic blood pressure of the human.
3. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in the form of beetroot juice.
4. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in a composition consisting of the inorganic nitrate (NO_3^-) and at least one additive.
5. The method of claim 4, wherein the composition is a nutritional supplement.
6. The method of claim 4, wherein the additive is selected from the group comprising: natural flavor, artificial flavor, sweetener, flavor enhancer, color additive, emulsifier, stabilizer, fat, and preservative.
7. The method of claim 4, wherein the inorganic nitrate (NO_3^-) is provided from a natural nitrate source.
8. The method of claim 7, wherein the natural nitrate source is juice or dried concentrate from at least one of spinach, lettuce, fennel, cabbage, Chinese cabbage, and beetroot.
9. The method of claim 4, wherein the source of the inorganic nitrate (NO_3^-) is in the form of a nitrate salt.
10. The method of claim 9, wherein the nitrate salt is selected from the group consisting of: sodium nitrate, potassium nitrate, calcium nitrate, zinc nitrate, ammonium nitrate, and arginine nitrate.
12. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered orally.
13. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in a composition in the form of a liquid, a paste, a gel, a bar, a cake, a powder, a granulate, an effervescent tablet, a chewing

gum, a tablet, a capsule, a lozenge, a fast melting tablet or wafer, a sublingual tablet, or a spray.

14. The method of claim 1, wherein the inorganic nitrate (NO_3^-) is administered in a composition comprising the inorganic nitrate (NO_3^-) and a polyphenol.

15. The method of claim 14, wherein the polyphenol provided is from at least one natural source selected from the group consisting of: apple, pear, grapes, lemon, orange, lime, peach, pomegranate, grapefruit, kiwi, ginger, pineapple, blackberries, black raspberries, blueberries, cranberries, red raspberries, cherries, bog wortleberry, lingonberries, black elderberry, black chokeberry, black currant, cloudberry, strawberries, carrots, chili, rhubarb, onions, cacao products, green tea, black tea, nuts, Yerba mate, and coffee.

16. The method of claim 15, wherein the amount of the inorganic nitrate (NO_3^-) in the composition is at least 50% by weight or by volume.

17. The method of claim 14, wherein the composition is a functional food.

'321 application (Ex. 1004), 41–42.

Petitioner argues that, for the reasons given in Section VIII.A.4. of the Petition, the priority applications preceding the '508 application that issued as the '813 patent did not “show the usability of nitrate doses as high as 100 mmol/kg (which would have been lethal) or as low as 0.01 mmol/kg (which would have been ineffective) for reducing systolic blood pressure.” Pet. 49. Petitioner argues that the '508 application likewise does not support these claim limitations, and has “only including working examples recording systolic blood pressure reductions with 0.10 mmol/kg of nitrate salt or beetroot juice.” *Id.* (citing Ex. 1071 ¶¶ 109–110, 119, 128, (second); Ex. 1003 ¶ 128).

In Section VIII.A.4., Petitioner argues that the priority applications “do not disclose these doses for a person requiring a blood pressure

reduction, much less a systolic blood pressure reduction.” Pet. 43 (citing Ex. 1003 ¶ 114; Ex. 1005, 4; Ex. 1006 ¶¶ 8, 33–36, 60; Ex. 1007 ¶¶ 9, 40, 44, 69; Ex. 1008 (same); Ex. 1009 ¶¶ 40, 53; Ex. 1010 ¶ 63; Ex. 1011 (same); Ex. 1012 (same)). Petitioner argues that the purposes for the nitrate/nitrite dosing of the recited levels was for lowering the metabolic rate or for preoperative drinks, not the treatment of systolic blood pressure. *Id.* at 43–44 (citing Ex. 1007 ¶¶ 9, 40, 44, 69, 108–109; Ex. 1008 (same)). Petitioner claims where diastolic blood pressure reduction is discussed, nitrate doses are not disclosed. *Id.* at 44 (citing Ex. 1007 ¶¶ 108–109; Ex. 1008 (same); Ex. 1003 ¶¶ 114–115).

Petitioner argues that the priority applications do not “show possession of” or “enable a method of decreasing systolic blood pressure using the full range of claimed doses” because a systolic blood pressure reduction in healthy subjects is shown only at a dose of 0.10 mmol/kg/day of sodium nitrate while claims 14–16 of the ’747 patent are “significantly broader.” Pet. 44 (citing Ex. 1007 ¶ 89; Ex. 1008 (same); Ex. 1003 ¶ 117). Petitioner argues that the maximum doses recited in claims 14–16, of “100 mmol/kg, 10 mmol/kg, and 1 mmol/kg—exceed or fall within the range for **lethal** doses of potassium nitrate: ‘about 40 to 300 mg NO₃- [per] kg’ (0.645–4.84 mmol/kg).” *Id.* at 44 (citing Ex. 1066, 15/32, Ex. 1003 ¶ 117, Ex. 1069 claim 12).

Petitioner argues the dose range is insufficiently described for use in decreasing systolic blood pressure. *Id.* at 45. Petitioner also argues that the details of the beetroot juice example “showing a reduction in systolic blood pressure does not include sufficient details to calculate a nitrate dose.” *Id.* (citing Ex. 1007 ¶¶ 108–109). Petitioner’s expert calculates a dose using reference materials that is “**at least** 4.5 times greater than the recited 0.01

mmol/kg. *Id.* (citing Ex. 1003 ¶¶ 118–119). Based on this information, Petitioner asserts that the inventors of the priority application had insufficient information to support their claimed invention and thus the priority applications, “show no more than a mere hope that inorganic nitrate doses (a) as high as 1 mmol/kg, 10 mmol/kg, or 100 mmol/kg or (b) as low as 0.01 mmol/kg are usable to reduce systolic blood pressure,” and that such information is insufficient to show possession of or enable the full scope of claims 14–16. *Id.* at 45–46 (citing Ex. 1003 ¶ 117). Petitioner argues that the scope of claims 17–18 includes “any inorganic nitrate” source, and is thus broader and not supported by the teachings regarding sodium nitrate. *Id.* at 47 (citing Ex. 1003 ¶ 122).

Finally, Petitioner argues that claim 18 “lacks support for the recited once-a-day administration” for reasons discussed in Section VIII.A.2., in which Petitioner alleges that no examples exist in any priority application showing dosing of “at least 3 deciliters fresh beetroot juice” once a day. *Id.* at 36. According to Petitioner, the doses administered were divided across multiple doses and a skilled artisan would not have given nitrate/nitrite in a single dose. *Id.* at 38–39 (citing Ex. 1003 ¶¶ 100–102, 105; Ex. 1007 ¶¶ 40–43, 89, 108, 115; Ex. 1008 ¶¶ 89, 108).

Patent Owner notes that we held in PGR2021-00094 that PCT1 discloses administering the inorganic nitrate as at least 3 deciliters of fresh beetroot juice once a day in the example of the 43-year-old subject with hypertension, and that the skilled artisan would have understood that administration as a single bolus as detailed by the application was possible. Prelim. Resp. 18 (citing Ex. 1007 ¶ 108; Ex. 1003 ¶ 100).

Patent Owner argues that PCT1 discloses that “administering inorganic nitrate in the form of a nitrate salt reduces systolic blood pressure

in an adult human subject requiring reduction in systolic blood pressure” and provides an example “demonstrating reduction in systolic blood pressure via administration of inorganic nitrates in the form of a nitrate salt” in “nine subjects [who] ingested ‘0.1 mmol **sodium nitrate**/kg/ bodyweight/day.’” *Id.* at 21–22 (citing Ex. 1009 ¶ 89). Patent Owner argues “PCT1 indicates that the same effect would occur in a person requiring a reduction in systolic blood pressure for health reasons, such as to reduce cardiovascular disease risk.” *Id.* at 22 (citing Ex. 1007 ¶ 51). In addition, Patent Owner argues that both PCT1 and PCT2 provide support for the dosage ranges recited in claims: “For use of a nitrate salt perorally, a dose of about **0.01-100 mmol/kg/24 h** is currently preferred or more preferably a dose of about **0.01-10 mmol/kg/24h**, and even more preferably **0.1 – 1 mmol/kg/24h**” and a working example using 0.1 mmol/kg. *Id.* at 33–34 (citing Ex. 1007 ¶¶ 9, 21, 44, 69, 89; Ex. 1008 ¶¶ 16, 62–63, 80). Patent Owner notes that we were not persuaded by Petitioner’s arguments against support for the entire range of doses in the priority applications or the suggestion of lethality in PGR2021-00094, including because PCT1 “discloses a *working example* in which three test subjects were given one of the doses that Petitioner alleges are ‘lethal.’” *Id.* at 36, 40 (citing Ex. 1007 ¶ 106). Patent Owner also argues that PCT1 and PCT2 both “make clear that the active ingredient in all inorganic nitrates is the nitrate anion (NO₃-), and that nitrate salts such as sodium nitrate, as well as natural sources of nitrate such as vegetables, can serve as an NO₃-source.” *Id.* at 35–36 (citing Ex. 1007 ¶ 89; Ex. 1010 ¶ 80).

Patent Owner is correct: we addressed each of Petitioner’s arguments at length in PGR2021-00094. Compare issues raised at Pet. 36–40 (Section VIII.2. with issues addressed in PGR2021-00094 Paper 7 (Decision) at 16–18 and Paper 10 (Denial of Request for Rehearing) at 3–12; compare issues

raised at Pet. 43–47 (Section VIII.A.4) with issues addressed in PGR2021-00094 Paper 7 (Decision) at 21–22 and Paper 10 (Denial of Request for Rehearing) at 16–22. For the reasons stated in those Papers and for the reasons stated by Patent Owner summarized above, we are not persuaded that one of skill in the art would not have understood the specifications of the priority applications to possess and disclose the subject matter of claims 1–3 and 5–7 and originally-filed claims 1–10 and 12–17 of the ’747 patent.

In addition, we find herein that PCT1 and PCT2 provide sufficient written descriptive support to have informed the skilled artisan at the time of the invention that inorganic nitrate and nitrate sources from numerous sources existed and could serve as components for use in the method of the challenged claims. See Ex. 1007 ¶¶ 25, 49, 51, 53, 57, 67, 89, 108, 109; Ex. 1010 ¶¶ 30, 32, 34, 45, 50, 53, 55, 57, 69, 80.

Accordingly, we find that Petitioner has not identified any challenged claim reciting subject matter that is only entitled to an effective filing date after March 16, 2013. For this reason, we find that Petitioner has not shown sufficiently that the ’747 patent is eligible for post-grant review.

III. CONCLUSION

After considering the evidence and arguments presently before us, we determine Petitioner has not identified any challenged claim reciting subject matter that is only entitled to an effective filing date after March 16, 2013. For this reason, we find that Petitioner has not shown sufficiently that the ’747 patent is eligible for post-grant review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(d), the Petition is *denied*.

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Patent 11,083,747 B2

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