

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HUMAN POWER OF N COMPANY,
Petitioner,

v.

HEARTBEET LTD,
Patent Owner.

PGR2021-00110
Patent 10,835,555 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 1–31 of U.S. Patent No. 10,835,555 B2 (Ex. 1001, “the ’555 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 ’555 patent is eligible for post-grant review. Accordingly, we do not institute a post-grant review of the challenged claims of the ’555 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 4, 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. 2; Paper 3, 1–2.

Petitioner identifies the following as related matters: U.S. Patent No. 10,555,968; U.S. Patent No. 9,180,140 (“the ’140 patent”); U.S. Patent No. 10,406,118; Reexamination No. 90/013,759, which is a reexamination of the ’140 patent; and PGR2021-00094¹.

Patent Owner listed the matters identified by Petitioner, but did not identify further potentially related matters. Paper 3, 1–2.

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

C. The '555 Patent

The '555 patent, titled “Compositions of Nitrates and Methods of Use Thereof,” issued November 17, 2020, from an application filed April 30, 2018. Ex. 1001, codes (54), (45), (22). It is a continuation-in-part of U.S. Application No. 14/830,937, filed on Aug. 20, 2015, and a continuation-in-part of application No. 12/528,794, filed as application No. PCT/SE2008/050212 on Feb. 26, 2008, application No. 14/830,937, which is a continuation of application No. 12/528,798, filed as application No. PCT/SE2008/050211 on Feb. 26, 2008. *Id.* at code (63). The '555 patent claims priority to U.S. Provisional application No. 60/919,709, filed March 22, 2007. *Id.* at code (60).

The '555 patent discloses “methods of increasing exercise endurance in a human subject.” *Id.* at 4:42–43. Among the methods disclosed is “[the] method comprising administering to a human subject prior to exercise a composition comprising an amount of inorganic nitrate (NO_3^-), wherein amount of inorganic nitrate provides a supplementary amount of the inorganic nitrate.” *Id.* at 4:43–47. The effects of the supplementary inorganic nitrate include that it “delays the onset of fatigue during exercise; reduces the subject’s oxygen consumption during exercise; and/or increases the available energy to the muscle.” *Id.* at 4:48–51.

With regard to dosing, the '555 patent discloses that the supplementary amount of the inorganic nitrate in the composition administers between 0.01 mmol nitrate ion and 10 mmol nitrate ion per kg body weight of the subject or between 0.1 mmol nitrate ion and 1 [60] mmol nitrate ion per kg body weight of the subject. For example, in one implementation, the supplementary amount of the inorganic acid in the composition administers 0.1 mmol nitrate ion per kg body weight of the subject.

Id. at 4:26–63. In “some implementations, the initial administration of the composition is at least three days prior to exercise” and administration can include “once a day” and by oral administration. *Id.* at 4:51–55.

The ’555 patent discloses an example titled “Oral Sodium Nitrate and Oxygen Consumption During Exercise,” detailing a study of “[n]ine healthy, well trained” male volunteers who “were trained cyclists or triathletes.” *Id.* at 23:61–27:14. The subjects were placed on a low-nitrate diet, and administered 0.1 mmol sodium nitrate/kg body weight/day, with the dosage being dissolved in water or an equal amount of sodium chloride (placebo) and divided into three equal portions administered throughout the day. *Id.* at 24:12–27. The treatment period was “two three-day periods, separated by a washout interval of ten days.” *Id.* at 24:10–11.

Following the testing period, the average resting systolic blood pressure of the treated group was lower following nitrate supplementation (112 +/- 8 mmHg) compared to placebo (120 +/- 5.9, $p < 0.01$), as was the diastolic blood pressure (68 +/- 5.5 mmHg) compared to placebo (74 +/- 6.8 mmHg, $p < 0.01$). *Id.* at 25:63–67. Oxygen uptake (VO_2) was lowered by $0.15 \text{ l} \cdot \text{min}^{-1}$ compared to placebo. *Id.* at 26:31–38.

The invention discloses use in a number of applications, including as a pre-surgical treatment for patients, a treatment for arterial insufficiency, and a treatment for “patients under metabolic stress.” *Id.* at 17:29–51.

D. Challenged Claims

Petitioner challenges claims 1–31 of the ’555 patent. Pet. 3–4. Claim 1 is the sole independent claim. Ex. 1001, 28:53–31:44. Claim 1 is illustrative and reproduced below:

1. A method of increasing exercise endurance in a human subject, the method comprising administering to a human subject prior to exercise a composition comprising an amount of inorganic nitrate (NO_3^-), wherein the amount of inorganic nitrate provides between 0.01 mmol nitrate ion and 10 mmol nitrate ion per kg body weight of the human subject.

Id. at 28:53–59.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–31 would have been unpatentable on the following grounds (Pet. 3–4):

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis ²
1	1–5, 11–13, 17–19	103(a) ³	NIH2 ⁴ (EX1056), which published in 2004 (EX1003 at ¶¶81–82; EX1069; EX1082 at ¶[0008], 1/15), Brunton ⁵ (EX1032), which published in 1909 (EX1003 at ¶84; EX1060; EX1061; EX1068 at ¶¶55–61).
2	11–12	103(a)	NIH2, Brunton, and Brunton2 ⁶ (EX1033), which published in 1906 . EX1003 at ¶125;

² This chart repeats the grounds as presented in Petitioner’s chart at Pet. 3–4.

³ Petitioner cites pre-AIA 35 U.S.C. § 103(a) because the ’555 patent claims priority to a patent application filed before March 16, 2013.

⁴ *The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure*, U.S. Dept. of Health and Human Services; National Institutes of Health; National Heart, Lung, and Blood Institute (2004) (Ex. 1056 “NIH2”).

⁵ 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”).

⁶ 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”).

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis ²
			EX1062; EX1063; EX1068 at ¶¶62–68.
3	6–10, 31	103(a)	NIH2, Brunton, and Shevach ⁷ (EX1027), which published in 2005.
4	6–10, 31	103(a)	NIH2, Brunton, Shevach, and Brunton2.
5	14–16, 25	103(a)	NIH2, Brunton, and Chevaux ⁸ (EX1043), which published in 1999.
6	16	103(a)	NIH2, Brunton, Chevaux, and Brunton2.
7	19–20	103(a)	NIH2, Brunton, and Prinkkilä ⁹ (EX1077), which published in 1989.
8	25–26	103(a)	NIH2, Brunton, Prinkkilä, Chevaux.
9	19, 21–24	103(a)	NIH2, Brunton, and Mäyrä-Mäkinen ¹⁰ (EX1080), which published in 2005.
10	25, 27–30	103(a)	NIH2, Brunton, Mäyrä-Mäkinen, Chevaux.
11	1–11, 13–21	112(a)	No written description.
12	1–11, 13–21	112(a)	Not enabled.

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

⁷ WO 2005/062713 A2, published July 14, 2005 (Ex. 1027 “Shevach”).

⁸ WO 99/45797, published Sept. 16, 1999 (Ex. 1043 “Chevaux”).

⁹ Helen M. Prinkkilä et al., U.S. Patent No. 4,853,237, issued August 1, 1989 (Ex. 1077 “Prinkkilä”).

¹⁰ Annika Mäyrä-Mäkinen et al., U.S. Patent No. 6,890,529 B1, issued May 10, 2005 (Ex. 1080 “Mäyrä-Mäkinen”).

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 post-doctoral research or clinical experience with physiology, biochemistry, exercise science, or dietary supplements and formulation.” Pet. 16 (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 ’555 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 construction of a single term, “inorganic nitrate.” Pet. 23–24. Patent Owner does not propose a construction for “inorganic nitrate.” Prelim Resp. 8–9. For purposes of determining whether to institute trial of the challenged claims, we determine it is not necessary to construe “inorganic nitrate.” *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.*, 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 ’555 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*.

The application that matured into the ’555 patent is a transition application, as it claims priority to an application filed before March 16, 2013. Specifically, the ’555 patent issued November 17, 2020, from U.S. Application No. 15/966,629 (“’629 application”), filed April 30, 2018.

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 '555 patent claims priority:

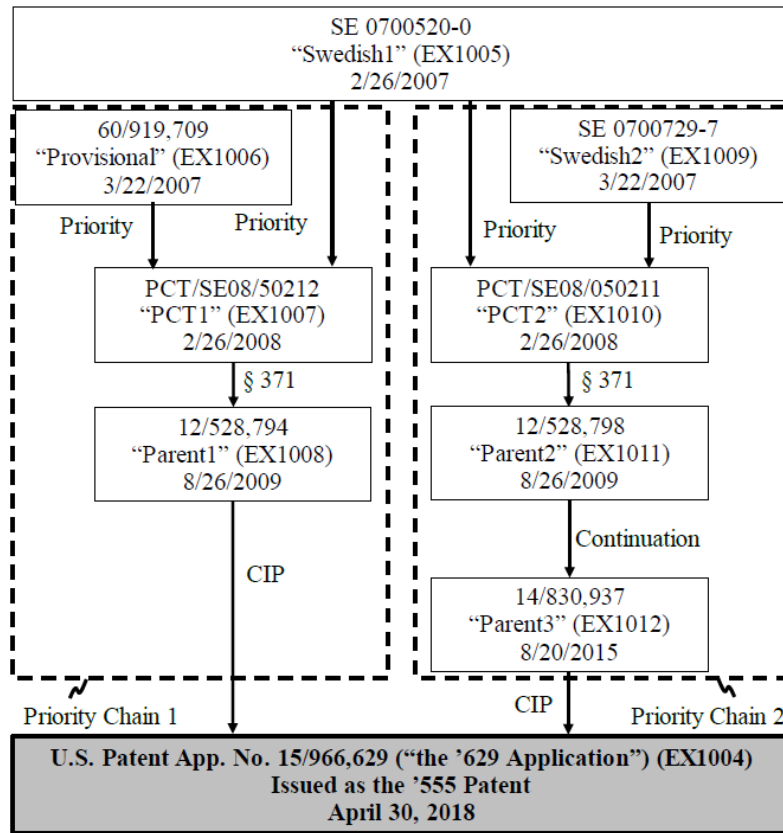


CHART 1

Chart 1 above is an excerpt from the Petition reflecting the familial relationships of the '555 patent's priority claim. Petition 25; Prelim Resp. 7. 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 '555 patent has two priority chains. In what Petitioner labels as "Priority Chain 1," the '555 patent 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 ’555 patent 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 (“Parent2”), 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. 7–8. We collectively refer to the applications in the priority chain of the ’555 patent as the “Priority Applications.”

Petitioner asserts that the ’555 patent is eligible for post-grant review under AIA § 3(n)(1)(B) because the Priority Applications “do not provide enabling written description support for claims 1–11 and 13–31, which thus have an effective filing date no earlier than that of the ’555 Patent: April 30, 2018.” Pet. 24–29.

Patent Owner disagrees and contends that Petitioner has failed to show that the ’555 patent is eligible for post-grant review. Prelim. Resp. 20–66. Patent Owner argues that claims 1–11 and 13–31 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 21–22.

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.

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., Inc.*, 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*, 258 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).¹¹ 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). We address the claims in the same groupings applied by the parties, and limit our discussion to the alleged lack of “enabling written description support” argued by Petitioner for each claim or group of 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.

A. Claims 1–11, 13–31

Petitioner alleges that the recitation of “[a] method of increasing exercise endurance’ that comprises ‘administering to a human subject ... between 0.01 mmol nitrate ion and 10 mmol nitrate ion per kg body weight,’ with claim 11 specifying 0.1-1 mmol nitrate ion per kg body weight” includes in the upper end of the range “**lethal** doses of potassium nitrate:

¹¹ 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.

‘about 40 to 300 mg NO₃- [per] kg’ (0.645-4.84 mmol/kg).” Pet. 25–26 (citing Ex. 1066 at 15/32; Ex. 1003 ¶ 7). Petitioner argues that “[e]ven for the better-tolerated sodium nitrate and ammonium nitrate, the claimed 10 mmol/kg dose” exceeds the “10 g NO₃” dose “generally associated” with “[d]eath and severe effects.” *Id.* at 26 (citing Ex. 1066 at 15/32; Ex. 1051 at 5; Ex. 1003 ¶ 76).

Petitioner further argues that, despite disclosing administration of “up to ‘10 mmol/kg/day’ of nitrate,” none of the Priority Applications disclose how to “increase exercise endurance—or ‘delay[] the onset of fatigue,’ ‘reduce[] the subject’s oxygen consumption,’ or ‘increase[] the available energy to the muscle . . . with a composition containing such a deadly dose of nitrate.”” *Id.* at 26 (citing Ex. 1003 ¶ 77; Ex. 1005 at 4 (“0.01-100 mmol/kg/day” and “0.1-10 mmol/kg/day”); Ex. 1006 ¶ 36). Petitioner argues that the single example disclosed in the Priority Applications – a dose of 0.1 mmol/kg/day – is “insufficient to show the usability of a lethal 10 mmol/kg dose of nitrate for any non-lethal application, let alone for increasing endurance, delaying fatigue, reducing oxygen consumption, or increasing energy availability.” *Id.* at 26–27 (citing Ex. 1003 ¶ 77; Ex. 1005 at 3; Ex. 1006 ¶¶ 59–60). Petitioner alleges the Priority Applications show “no more than a mere hope that inorganic nitrate doses as high as 1 mmol/kg or 10 mmol/kg” are able to provide the claimed benefits and are thus “insufficient to show possession of the full scope of claims 1–11 and 13–31” and do not enable the claimed administration, meaning these claims are not entitled to claim priority to the Priority Applications. *Id.* at 27–28 (citing Ex. 1003 ¶ 78). Petitioner cites *Nuvo Pharms. (Ir.) Designated Activity Co. v. Dr. Reddy’s Labs. Inc.*, 923 F.3d 1368, 1380–81 (Fed. Cir. 2019) and

LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) in support of its arguments. *Id.*

Patent Owner responds that PCT1 and PCT2 provide support for all elements of independent claim 1, including the disputed claim limitations. *Id.* at 22–33. Patent Owner argues that PCT1 and PCT2 disclose the same working example disclosed in the ’555 patent specification described above (*see* I.C., *supra*), with demonstrated increases in exercise endurance as claimed. *Id.* at 24–26 (citing Ex. 1008¹² ¶¶ 82, 85, 88, 103; Ex. 1010 ¶¶ 24, 25, 47, 79–93). Patent Owner further argues that PCT1 and PCT2 disclose the claimed treatment range for inorganic nitrate. *Id.* at 27–28 (citing, e.g., Ex. 1008 ¶¶ 9, 44, 69; Ex. 1010 ¶¶ 16, 62, 63, 76).

Patent Owner argues that written descriptive support for the disclosed range is undisputed, and that Petitioner’s sole theory that the claim lacks support is based on its allegation that the maximum dose of the range is lethal. *Id.* at 29 (referring to Pet. 26 (“the claimed maximum doses of 10 mmol/kg and 1 mmol/kg exceed and fall within, respectively, the range for **lethal** doses of potassium nitrate: ‘about 40 to 300 mg NO₃- [per] kg’ (0.645-4.84 mmol/kg)” (citing Ex. 1066)). Patent Owner argues that Exhibit 1066¹³ is inadmissible because Petitioner has not presented evidence

¹² Although Patent Owner asserts that the challenged claims are entitled to claim priority to PCT1 (Prelim. Resp. 22), Patent Owner’s references in the discussion cite to Ex. 1008, which Petitioner identified as “Parent 1” (Pet. iv). Because the referenced paragraphs of these two documents are identical, our analysis here applies to both references.

¹³ Exhibit 1066 is described in the Petition as “Wayback Machine Archive of INCHEM Webpage entitled Nitrates and nitrites (archived Dec. 15, 2006).” Pet. x.

to authenticate the exhibit, and because it contains hearsay evidence offered “for the truth of the matter asserted—that certain doses of certain nitrates are, in fact, lethal to humans.” *Id.* at 29–30. Patent Owner argues that, to the extent Ex. 1066 is considered, it does not establish the lethality of inorganic nitrate in the context of its use within the claimed invention because PCT1 “discloses a working example in which three test subjects were given one of the doses that Petitioner alleges are ‘lethal’” with no observed lethality. *Id.* at 30 (citing Ex. 1008 ¶ 106). In addition, Patent Owner argues that Ex. 1066 states that “the ‘main toxicological concern’ with ingestion of nitrates ‘is development of methaemoglobinaemia, a condition where more than 10% of the haemoglobin is transformed into methaemoglobin. When the conversion exceeds 70% the condition can be fatal.’” *Id.* (quoting Ex. 1066 at 14–15). Patent Owner argues that the inventors of PCT1 “recognized this concern, and explained in PCT1 that administration of inorganic nitrate according to the claimed methods ‘does not cause any significant increase of the methemoglobin level in said mammal.’” *Id.* (citing Ex. 1008 ¶¶ 6, 9, 37, 40, 45, 47, 82; Ex. 1010 ¶¶ 45, 55).

Patent Owner concludes that Petitioner’s arguments fail to establish that the Priority Applications do not enable the challenged claims because they do not identify any “undue experimentation” that would have been required “to practice the invention of claim 1 at any dosage falling within the claimed range.” *Id.* at 31. Rather, Patent Owner argues, the only difference needed would be to “simply administer a different dosage to the human for which increased exercise endurance is desired.” *Id.* Patent Owner distinguishes Petitioner’s cited cases as inapposite on these facts. *Id.* at 31–33.

We agree with Patent Owner's arguments that PCT1 and PCT2 contain the referenced disclosures and, on this record, conclude Petitioner has not shown sufficiently that the features of claims 1–11 and 13–31 are not disclosed in PCT1 and PCT2. *See* Ex. 1008 ¶¶ 6, 9, 37, 40, 45, 47, 82; Ex. 1010 ¶¶ 45, 55.¹⁴ Accordingly, we do not find that these claims are eligible for post-grant review for failure of the Priority Applications to provide sufficient written description of the challenged features of these claims.

With regard to enablement, as Patent Owner has stated (Prelim. Resp. 29), Petitioner's sole argument is that certain portions of the claimed range would require delivery of a lethal dose of inorganic nitrate per statements made in Ex. 1066. *See* Pet. 26. We begin with Patent Owner's challenges to Exhibit 1066.

We agree with Patent Owner that Exhibit 1066 is inadmissible as it has not been authenticated, which could be done, for example, by verification as a business record under FRE 901(b)(1) with sufficient testimony. *See U.S. v. Bansal*, 663 F.3d 634, 667–668 (3d Cir. 2011). Petitioner has offered no such testimony to authenticate the exhibit, despite having done so for other exhibits. *See, e.g.*, Ex. 1068, Declaration of Sylvia Hall-Ellis testifying to the authenticity of, *e.g.*, Exhibit 1026.

However, because an expert witness can rely upon inadmissible evidence in forming an opinion (FRE 703), we consider the statements made by Dr. Volek as informed by his review of Exhibit 1066 among other sources reviewed in forming his opinion. To establish that claims 1–11 and

¹⁴ The same disclosures are provided in the intervening priority applications Parent1, the application following PCT1, and Parent2 and Parent3, the applications following PCT2. *See* Ex. 1008, ¶¶ 6, 9, 37, 40, 45, 47, 82; Ex. 1011 ¶¶ 45, 55; Ex. 1012 ¶¶ 45, 55.

13–31 are eligible for post-grant review for failure of the Priority Applications to enable these claims, Dr. Volek’s testimony must show that it is more likely than not, for instance by examining the *Wands* factors, that a person of ordinary skill in the art could not practice the claimed method without undue experimentation. The *Wands* factors require an analysis that is focused on the guidance and working examples presented in the disclosure of the patent application at issue.

Dr. Volek’s testimony on this issue is at Exhibit 1003 ¶¶ 76–78. Dr. Volek opines that claims 1–11 and 13–31 recite a method of increasing endurance comprising administering a dose of nitrate ion within a claimed range that includes lethal doses of potassium nitrate: “the claimed maximum doses of 10 mmol/kg and 1 mmol/kg exceed and fall within, respectively, the range for *lethal* doses of potassium nitrate: ‘about 40 to 300 mg NO₃⁻ [per] kg’ (0.645-4.84 mmol/kg²),” and that for “sodium nitrate and ammonium nitrate, the claimed 10 mmol/kg dose was 54.7 g and 46.8 g of NO₃⁻ for an average-weight (88.2 kg) male and average-weight (75.4 kg) female, respectively, which exceed the ‘10 g NO₃⁻’ that is ‘generally associated’ with ‘[d]eath and severe effects.’” *Id.* ¶ 76. Dr. Volek also relies on Exhibit 1066 for his calculation of the molar mass of NO₃⁻ in inorganic nitrate dosing. *Id.* at n2. Dr. Volek states that, although all but one of the Priority Applications disclose the entire dosing range, “none disclose how to increase exercise endurance—or ‘delay[] the onset of fatigue,’ ‘reduce[] the subject’s oxygen consumption,’ or ‘increase[] the available energy to the muscle’ as dependent claims 3–5 recite and as claim 1 thus encompasses—with a composition containing such a deadly dose of nitrate.” *Id.* ¶ 77. Dr. Volek states that each application contains an example in which subjects consumed a dose of 0.1 mmol/kg/day, but that

this example “is insufficient to show the usability of a lethal 10 mmol/kg dose of nitrate for any non-lethal application, let alone for increasing endurance delaying fatigue, reducing oxygen consumption, or increasing energy availability.” *Id.* Dr. Volek concludes:

The applications in the '555 Patent's priority chain thus show no more than a mere hope that inorganic nitrate doses as high as 1 mmol/kg or 10 mmol/kg are usable to increase endurance, delay fatigue, reduce oxygen consumption, or increase energy availability—which a[n ordinarily skilled artisan] would understand to be insufficient to show possession of the full scope of claim 1—and do not enable such an administration, which would have been fatal to its recipient.

Id. ¶ 78. Dr. Volek cites no other reference or authority for his conclusions.

We are unpersuaded that Dr. Volek's reliance on Exhibit 1066 as the sole source of his conclusion that certain doses of inorganic nitrate would have been lethal in the context of the claimed methods is sufficient to establish undue experimentation under the *Wands* factors. As Patent Owner argues, the working example disclosed in PCT1 discloses administration of a dose Dr. Volek states would have been lethal, but was not. Rather, the result of that experiment was a demonstrated decrease in glucose consumption by the participants, a benefit of increased endurance. Ex. 1008 ¶ 106. We agree with Patent Owner that this case is distinguishable from those cited by Petitioner for the reasons explained by Patent Owner (Prelim. Resp. 31–33), and also from the recent case by our reviewing court, *Amgen, Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021). In *Amgen*, the court found the claims lacked enablement because the claims recited dual functional limitations, and potentially millions of antibody candidates could be found to fall within those limitations. *Id.* at 1088. The court found the examples provided in the specification insufficient to enable the full scope of the claims given the

limited examples as compared to the large potential antibody field and the high effort required to screen and identify all such antibodies. *Id.*

Here, as Patent Owner has observed, the only effort required to practice claims within the range in light of the working example is to “simply administer a different dosage to the human for which increased exercise endurance is desired,” which would have been within the scope of the ordinarily skilled artisan. Prelim. Resp. 31. Moreover, Patent Owner correctly notes that methaemoglobinaemia¹⁵, the source of the lethality cited in Exhibit 1066, does not result via the claimed method. Prelim. Resp. 30, citing Ex. 1066 at 14–15. As Patent Owner explains, Petitioner’s sole cited Exhibit, 1066, discloses a risk of development of methaemoglobinaemia, a condition where more than 10% of the haemoglobin is transformed into methaemoglobin.” *Id.* When the conversion to haemoglobin exceeds 70% the condition can be fatal.” Ex. 1066 at 14–15. Patent Owner explains that the inventors discussed the risk of development of methaemoglobinaemia, and explained in PCT1 that their methods do not cause a significant rise in the methemoglobin level in the test subjects. Prelim. Resp. 30. Moreover, PCT1 discloses a working example where three test subjects were given a dose in the range Petitioner alleges would be lethal, with no ill result. *Id.*, citing Ex. 1008 ¶ 106. Dr. Volek’s failure to address this discrepancy, or to provide alternate sources to explain why his conclusion is nonetheless correct, merits his brief testimony on this issue be assigned little probative

¹⁵ PCT1 explains that “Methemoglobin is a form of hemoglobin in which the iron in the heme group is in the Fe³⁺ state, not the Fe²⁺ of normal hemoglobin. Methemoglobin is unable to carry oxygen. Methemoglobinemia is defined as a blood disorder characterized by the presence of a higher than normal level of methemoglobin in the blood.” Ex. 1007 ¶ 37. Ex. 1066

value. *See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 294 (Fed. Cir. 1985) (“Lack of factual support for expert opinion going to factual determinations” is sufficient to “render the testimony of little probative value in a validity determination.”).

We further note that patent claims that contain some inoperative embodiments do not necessarily lack enablement, provided a person of ordinary skill in the art field would know how to identify, without undue experimentation, that those embodiments that would work. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984); *see also In re Cook*, 439 F.2d 730 (CCPA 1971) (holding that claims covering lenses with specified parameters were not invalid for lack of enablement despite encompassing “inoperative embodiments” of lenses with parameters within the recited ranges, but that were not useful as zoom lenses as intended, because “it would be obvious to those skilled in lens design whether a given embodiment within the indicated ranges, once conceived, would or would not be useful as a zoom lens”); MPEP 2164.08(b) (“the standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art”). On this record, we do not find that the evidence shows that the ordinarily skilled artisan would have been unable to practice the method of claims 1–11 and 13–31 based on the disclosures in PCT1 and PCT2 without undue experimentation.

B. Claim 2

Petitioner argues that claim 2 recites that the initial administration of the inorganic nitrate composition is “‘at least three days prior to exercise,’ but none of the ’555 Patent’s priority applications mention such timing, with

their exercise-focused example instead focused on the effect of nitrate administration within three days of exercise.” Pet. 28 (citing, e.g., Ex. 1007 ¶¶ 20, 89; Ex. 1008 ¶¶ 20, 89). Petitioner makes no separate argument alleging lack of enablement for claim 2.

Patent Owner responds that the example in PCT1 (Ex. 1008 ¶ 89) discloses two three-day periods of nitrate administration separated by “a washout interval of ten days.” Prelim Resp. 33. Patent Owner argues that the claim does not require administration be continuous for the days prior to exercise and thus, this example, with the initial administration being sixteen days prior to the second three-day period of exercise, meets the limitation. *Id.* at 33–34. Patent Owner additionally argues that the second three-day period alone meets the claim limitation as the subjects were instructed not to exercise during the days of administration and thus, day one of administration was at least three days prior to exercise. *Id.* at 34.

We agree with Patent Owner’s arguments that PCT1¹⁶ contains the referenced disclosure¹⁷ and, on this record, conclude Petitioner has not shown sufficiently that the features of claim 2 are not disclosed in PCT1. On this record, we are not persuaded that one of skill in the art would not have believed that the specification of PCT1 discloses administration of inorganic nitrate at least three days prior to exercise. We are thus

¹⁶ Patent Owner additionally argues that PCT2 provides similar and additional disclosures providing written description support for the challenged claims. Prelim. Resp. 34–35. As we conclude PCT1 provides sufficient independent disclosure, we do not reach these arguments here.

¹⁷ The same disclosures are provided in the intervening priority applications Parent1, the application following PCT1, and Parent2 and Parent3, the applications following PCT2. *See* Ex. 1008, ¶¶ 88–105; Ex. 1011 ¶¶ 75–94; Ex. 1012 ¶¶ 79–94.

unpersuaded that the ordinarily skilled artisan would not have believed the inventor had possession of the subject matter of claim 2 as of the filing date of PCT1. *Vas-Cath*, 935 F.2d at 1563.

C. Claim 13

Petitioner argues that claim 13 further recites that “the composition is ‘administered ... **once a day**[,]’” but the “’555 Patent’s priority applications lack any description of once-daily administration of an inorganic nitrate composition to a subject prior to exercise.” Pet. 28 (citing, generally, Ex. 1005). Petitioner argues that although the Priority Applications “may disclose sodium nitrate administration for a three-day period prior to exercise, the exercise-focused example in each makes clear that the daily doses described therein are not achieved through a single administration,” and thus, claim 13 lacks written descriptive support for single daily dose administration. *Id.* at 28–29 (citing Ex. 1006 ¶ 60, as stating “‘The **daily dose was divided** and ingested **three times** daily.’”; Ex. 1007 ¶ 89; Ex. 1008 ¶ 89; Ex. 1009 ¶ 53; Ex. 1010 ¶ 80; Ex. 1003 ¶ 79). Petitioner makes no separate argument alleging lack of enablement for claim 13.

Patent Owner responds that the once daily dosing limitation of claim 13 is entitled to priority based on the disclosure in PCT1 that “[f]or 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**.” Prelim. Resp. 51–52 (citing Ex. 1008 ¶ 44). Patent Owner argues that the skilled artisan would have understood this statement to teach that administration “per day” is daily dosing, which would include a daily dose administered on a once a day basis. *Id.* at 52. In addition, Patent Owner notes that PCT1 discloses administration of inorganic nitrate as a single “bolus” dose: “[t]he

nitrate and/or nitrate comprising composition and possible further combinations described herein can be administered continuously *or as single bolus doses.*” *Id.* at 52 (citing Ex. 1008 ¶ 41).

We agree with Patent Owner’s arguments that PCT1¹⁸ contains the referenced disclosure¹⁹ and, on this record, conclude Petitioner has not shown sufficiently that the features of claim 13 are not disclosed in PCT1. The written description requirement does not require the specification to provide an example for each embodiment of the invention. *Capon*, 418 F.3d at 1352. On this record, we are not persuaded that one of skill in the art would not have believed that the specification of PCT1 discloses administration of inorganic nitrate in the claimed dosing range and in dose quantities that could include once a day to a subject for the purpose of improving metabolic efficiency and improved athletic performance. We are thus unpersuaded that the ordinarily skilled artisan would not have believed the inventor had possession of the subject matter of claim 13 as of the filing date of PCT1. *Vas-Cath*, 935 F.2d at 1563.

D. Claims 6–10, 31

Petitioner argues that claims 6–10 and 31 recite the use of inorganic nitrate and “at least one additive,” but there is no disclosure “for a nitrate-and-additive-only composition.” Pet. 29 (citing Ex. 1003 ¶ 80). Petitioner argues that certain of the Priority Applications “mention additives only in

¹⁸ Patent Owner additionally argues that PCT2 provides similar and additional disclosures providing written description support for the challenged claims. Prelim. Resp. 52–53. As we conclude PCT1 provides sufficient independent disclosure, we do not reach these arguments here.

¹⁹ The same disclosure is provided in the intervening priority applications Parent1, the application following PCT1. *See* Ex. 1008, ¶ 44.

the context of multi-component products like ‘functional food’ or energy bars, not in a composition consisting of nitrate and one or more additives.” *Id.* (citing Ex. 1007 ¶ 39, Ex. 1008 ¶ 39, Ex. 1009 ¶¶ 30–32; Ex. 1010 ¶¶ 23, 38–44; Ex. 1011 ¶¶ 23, 38–44; Ex. 1012 ¶¶ 23, 38–44; Ex. 1003 ¶ 80). Petitioner makes no separate argument alleging lack of enablement for claims 6–10 and 31.

Patent Owner argues that PCT1 discloses using additives, including combinations of additives, with inorganic nitrate. Prelim. Resp. 41–43. Patent Owner argues the additives disclosed are antimicrobials, pH stabilizers, or health-promoting substances disclosed for use with inorganic nitrate. *Id.* at 41–42 (citing Ex. 1008 ¶¶ 39, 57). Patent Owner also argues that PCT1 discloses combinations of inorganic nitrate or nitrate with polyphenols and, optionally, live non-pathogenic bacteria as synergists that contribute to effectiveness of the active ingredient. *Id.* at 42–43 (citing Ex. 1008 ¶¶ 10, 17, 50–51, 69; Ex. 2001 at v). Patent Owner argues that PCT2 provides support for the additional limitations of claim 31, reciting an additive that is one of a “natural flavor, artificial flavor, sweetener, flavor enhancer, color additive, emulsifier, stabilizer, fat, and preservative.” *Id.* at 65 (citing Ex. 1010 ¶¶ 2, 3, 34–44).

We agree with Patent Owner’s arguments that PCT1²⁰ contain the referenced disclosures²¹ and, on this record, conclude Petitioner has not

²⁰ Patent Owner additionally argues that PCT2 provides similar and additional disclosures providing written description support for claim 6–10. Prelim. Resp. 43–46. As we conclude PCT1 provides sufficient independent disclosure, we need not address these arguments herein.

²¹ The same disclosures are provided in the intervening priority application Parent1, the application following PCT1. *See* Ex. 1008, ¶¶ 10, 17, 50–51, 69.

shown sufficiently that the features of claims 6–10 and 31 are not disclosed in PCT1 and PCT2. On this record, we are not persuaded that one of skill in the art would not have believed that the specifications of PCT1 and PCT2 disclose administration of inorganic nitrate and an additive in the composition claims 6–10 and 31. We are thus unpersuaded that the ordinarily skilled artisan would not have believed the inventor had possession of the subject matter of claims 6–10 and 31 as of the filing date of PCT1 and PCT2.

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 '555 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 '555 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 No. 10,835,555 B2

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