

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SABINSA CORPORATION,
Petitioner,

v.

FRANCO CAVALERI,
Patent Owner.

PGR2022-00015
Patent 10,945,970 B2

Before SUSAN L. C. MITCHELL, CHRISTOPHER G. PAULRAJ, and
JAMIE T. WISZ, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

DECISION
Granting Institution of Post-Grant Review
35 U.S.C. § 324(a)

I. INTRODUCTION

On December 15, 2021, Sabinsa Corporation (“Petitioner”) filed a Petition for Post-Grant Review of claims 1–7 of U.S. Patent No. 10,945,970 B2 (Ex. 1001, “the ’970 patent”). Paper 1 (“Pet.”). Mr. Franco Cavaleri (“Patent Owner”) did not file a Preliminary Response.

Institution of post-grant review is authorized by statute only when “the information presented in the petition . . . demonstrate[s] 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; *see* 37 C.F.R. § 42.4. Upon considering the Petition and the cited evidence, we conclude that Petitioner has satisfied its burden under 35 U.S.C. § 324 to show that it is more likely than not that at least 1 of the claims challenged in the Petition is unpatentable.

A. Real Parties in Interest

Petitioner identifies itself as the real party in interest. Pet. 3. Patent Owner identifies itself as the real party in interest. Paper 5, 2.

B. Related Matters

Petitioner asserts that it “is unaware of any judicial matter or administrative matters that would affect, or be affected by, a decision in this proceeding,” and that “Patent Owner has not asserted the ’970 patent in any civil actions in the United States.” *See* Pet. 3. Patent Owner confirms these assertions. *See* Paper 5, 2.

Patent Owner identifies that the ’970 patent issued from Application Number 16/111,502, filed August 24, 2018, which is a continuation-in-part and “claims priority to PCT Patent Application PCT/CA2018/050275, filed on March 8, 2018, which in turn claims priority to Provisional Patent Application 62/469,554, filed on March 10, 2017. U.S. Patent Application

Serial Number 17/170,956, filed on February 9, 2021 [and currently pending before the Office], claims priority to U.S. Patent 10,945,970.” Paper 5, 2; Ex. 1001, codes (60), (63), (65).

C. The '970 Patent (Ex. 1001)

The '970 patent, titled “Curcumin-Based Compositions and Methods of Use Thereof,” issued March 16, 2021, identifying Patent Owner as the applicant and inventor. Ex. 1001, codes (71), (72). The '970 patent describes methods and compositions to increase low-density lipoprotein cholesterol (“LDL”) receptor levels on cells by providing to the cells a curcumin composition that is at least 15% curcumin II or at least 5% curcumin III. *Id.* at Abst., 1:15–19, 45–62, 3:46–62. Increasing LDL receptor expression levels in cells lowers LDL levels in a subject, thus ameliorating a variety of health conditions and imparting some health benefits. *Id.* at 3:56–62.

The '970 patent also describes administering a curcumin III-enriched composition to cells to decrease mitogen- and stress-activated protein kinase 1 (“MSK1”) levels, a nuclear kinase that plays a significant role in transcription regulation, which is known to have therapeutic and health benefits for such a decrease in MSK1 levels. *Id.* at 1:19–23, 2:34–40, 3:63–4:5.

The '970 patent states that curcumin III can be used to inhibit cytoplasmic and nuclear MSK1 production, MSK1 serine phosphorylation, and recruitment of MSK1 at inflammatory gene promoters. *Id.* at 4:1–4.

The '970 patent states:

The curcumin III compositions described herein—and related methods of using such composition—provide a major step in the transactivation regulation of downstream transcription

factors that are key to cell survival and recruitment of inflammatory and immune system events. . . . [T]he ability of the curcumin III compositions described herein to inhibit MSK1 production (or otherwise significantly reduce MSK1 levels) indicates that such compositions may also (indirectly) be used to modulate NFkB (nuclear factor kappa-light-chain-enhancer of activated B cells)—the aberrant expression and transactivation of which has been linked to cancer, inflammation, and autoimmune diseases.

Id. at 4:5–19.

The '970 patent acknowledges that the health benefits of curcumin, especially from whole turmeric extract are known, but “the most common source of curcumin, the Indian spice turmeric (a member of Zingiberaceae), does not contain a sufficient amount of curcumin to provide an efficacious dose to a subject.” *Id.* at 1:32–35. Therefore, “the present invention includes certain compositions that contain elevated and concentrated levels of (1) curcumin II [or desmethoxycurcumin (“DMC”)] (relative to the amount of curcumin II found in natural curcumin extract); (2) curcumin III [or bisdemethoxycurcumin (“BDMC”)] (relative to the amount of curcumin III found in natural curcumin extract); or (3) a combination of curcumin II and curcumin III (relative to the amounts of curcumin II and curcumin III found in natural curcumin extract).” *Id.* at 3:46–54, 4:24–25. Such elevated and concentrated levels can be concentrated from curcumin II and curcumin III extracted from turmeric plant rhizomes or chemically synthesized. *Id.* at 5:1–8.

An effective amount of an LDL receptor-modulating curcumin composition is at least 15% curcumin II, at least 5% curcumin III or a combination of both. *Id.* at 5:15–20. Methods for inhibiting MSK1 serine phosphorylation includes providing to the cells “an effective amount of

curcumin composition that is at least 5% curcumin III.” *Id.* at 5:23–27. The ’970 patent provides five specific curcumin formulations that are formulated into capsules for oral administration and that may contain fillers and agents like vegetable capsule (hydroxypropyl methylcellulose), water, magnesium stearate, and silicon dioxide. *Id.* at 12:47–50, 65–67, 13:17–19, 36–38. The levels for curcumin I, II, and III for the first two formulations set forth in Examples 4 and 5 describe raw percentages, whereas the two formulations set forth in Examples 6 and 7 describe the percentages of curcumin I, II, and III as weight per volume percentages. *See id.* at 12:39–13:42.

D. Challenged Claims

Petitioner challenges all seven claims of the ’970 patent. Pet. 2. All seven claims for the ’970 patent are composition claims. Claims 1, 4, and 7 are independent. Claims 2 and 3 each depend directly from claim 1, and claims 5 and 6 each depend directly from claim 4.

Claim 4 is representative and reproduced below:

4. A composition that comprises:
 - (a) 45–55% curcumin I;
 - (b) 10–20% curcumin II;
 - (c) 20%–40% curcumin III, wherein the composition is formulated as a capsule, pill tablet, granule, solution or a suspension in an aqueous or non-aqueous liquid, oil-in-water or water-in-oil emulsion, elixir, syrup, paste, or dry powder.

Ex. 1001, 14:25–35.

E. The Asserted Ground of Unpatentability

Petitioner challenges the patentability of claims 1–7 of the '970 patent on the following grounds, *see* Pet. 5:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
4	§ 102(a)	Li ¹
5–6	§ 103	Li
5	§ 103	Li, Rhema, ² Grebow ³
6	§ 103	Li, Yang ⁴
1–3, 7	§ 103	Pushpakumari, ⁵ Hong, ⁶ Kim ⁷

¹ Rui Li et al., *Metabolic and pharmacokinetic studies of curcumin, demethoxycurcumin and bisdemethoxycurcumin in mice tumor after intragastric administration of nanoparticle formulations by liquid chromatography coupled with tandem mass spectrometry*, 879 J. CHROMATOGRAPHY B 2751–58 (2011) (Ex. 1006, “Li”).

² Rhema Group, *New Curcumin Extract Found to Counteract Inflammation at the Genetic Level*, Oct. 5, 2016 (Ex. 1015, “Rhema”).

³ Jennifer Grebow, *New Curcumin Ingredient Aims for High Level of One Specific Curcuminoid to Boost Anti-Inflammatory Activity*, Nutritional Outlook (Oct. 28, 2016) (Ex. 1016, “Grebow”).

⁴ Yi-Sun Yang, et al., *Lipid-Lowering Effects of Curcumin in Patients with Metabolic Syndrome: A Randomized, Double-Blind, Placebo-Controlled Trial*, 28 PHYTHOTHER. RES. 1770–1777 (2014) (Ex. 1010, “Yang”).

⁵ K. N. Pushpakumari, et al., *Purification and Separation of Individual Curcuminoids from Spent Turmeric Oleoresin, a By-Product from Curcumin Production Industry*, 5 INT’L J. PHARM. SCI. & RES. 3246–54 (Aug. 2014) (Ex. 1012, “Pushpakumari”).

⁶ Xingqui Hong, et al., *Effects of bisdemethoxycurcumin in reducing lipids and fighting lipid peroxidation*, 4 CHIN. J. NAT. MED. 121–24 (Mar. 2006) (Ex. 1017, “Hong”).

⁷ Sung-Bae Kim, et al., *Hepatoprotective Effect and Synergism of Bisdemethoxycurcumin against MCD Diet-Induced Nonalcoholic Fatty Liver Disease in Mice*, PLoS ONE (Feb. 16,

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
3	§ 103	Pushpakumari, Hong, Kim, Yang
7	§ 103	Antony, ⁸ Pushpakumari
1, 2, 4, 5, 7	§ 112(a)	Lack of written description and lack of enablement
1–7	§ 112(b)	Indefiniteness

Petitioner submits the Declaration of Mansoor M. Amiji, Ph.D. (Ex. 1019) in support of institution of post-grant review.

II. ANALYSIS

A. *Eligibility for Post-Grant Review*

The post-grant review provisions set forth in Section 6(d) of the AIA⁹ apply only to patents subject to the first-inventor-to-file provisions of the AIA. *See* AIA § 6(f)(2)(A) (“The amendments made by subsection (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 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. *Id.* § 3(n)(1). Our rules require that each petitioner for post-grant review certify that the challenged patent has an effective filing date that renders the patent 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

2016) (Ex. 1009, “Kim”).

⁸ Benny Antony, U.S. Patent Application No. 2014/0193533, published July 10, 2014 (Ex. 1011, “Antony”).

⁹ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”).

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); *see also* 37 C.F.R. § 42.202(a) (accord).

Petitioner states that “the earliest date to which the ’970 patent can claim priority is after March 16, 2013.” Pet. 1. Petitioner also states that the ’970 patent issued on March 16, 2021, which is less than nine months prior to the filing of the Petition. *Id.*

On this record, we determine that the ’970 patent is eligible for post-grant review. Specifically, the application leading to the ’970 patent was filed on August 24, 2018, and claims priority to a series of provisional applications, the first of which was filed on March 10, 2018. Ex. 1001, codes (22), (60). All of these dates fall after March 16, 2013. Also, this Petition was filed on December 15, 2021, which is within nine months after the March 16, 2021, issue date of the ’970 patent. *Id.* at code (45).

B. Person of Ordinary Skill in the Art

Factual indicators of the level of ordinary skill in the art include “the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field.” *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*).

According to Petitioner, a person of ordinary skill in the relevant art (“POSA”) “would comprise an individual with a Ph.D in pharmaceutical sciences, pharmaceuticals, chemical engineering, or a related field, or an M.S.

or B.S. degree in pharmaceutical sciences, pharmaceuticals, chemical engineering, or a related field, with an additional 3–5 years of practical experience in pharmaceutical or nutraceutical product development of characterization.” Pet. 17 (citing Ex. 1019 ¶ 94 (Dr. Amiji Declaration)).

Because Petitioner’s definition of a person of skill in the art appears commensurate with the level of skill reflected in the asserted art in this case as well as the ’970 patent itself, we apply Petitioner’s proposed level of ordinary skill in the art to determine whether it is more likely than not that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (stating prior art itself can reflect the appropriate level of ordinary skill in the art).

C. Claim Construction

We construe claims “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b).” 37 C.F.R. § 42.200 (2019). Therefore, we construe the challenged claims under the framework set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–19 (Fed. Cir. 2005) (en banc). Under this framework, claim terms are given their ordinary and customary meaning, as would be 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.* Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*,

Matal, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner asserts that the term “about” in relation to the percentages of curcumin I, II, and III in claims 2 and 5 of the '970 patent “should be given its ordinary meaning of ‘approximately’ rather than a particular numerical range.” Pet. 18. On this record, we agree with Petitioner that “about” generally means “approximately,” but how much this term numerically affects the express boundaries for ranges set forth in the claims that the term “about” modifies is not clarified by the proposed construction. *See Ortho-McNeil Pharmas., Inc. v. Caraco Pharma.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007) (“Although both parties and the district court seem to agree that the term “about” means “approximately,” the parties and the district court disagree over the numerical limits that that term imparts to the limitation “1:5” in this case.”).

The United States Court of Appeals for the Federal Circuit (“Federal Circuit”) states:

The use of the word “about,” avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technological and stylistic context. We thus consider how the term . . . was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor’s intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter.

Id. (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) (citations omitted)).

We note that the term “about” is used several times throughout the Specification of the '970 patent usually in reference to amounts of

components in a composition or the total amount of a composition. *See, e.g.,* Ex. 1001, 11:39–40 (stating “typical natural curcumin extract contains low levels of curcumin III, often *about* 0.2%-1% curcumin III”), 12:42–45 (describing Curcumin Formulation One as including “30-40% curcumin I (such as *about* 35% curcumin I); 9-11% curcumin II (such as *about* 10% curcumin II); and 45%-55% curcumin III (such as *about* 50% curcumin III)”), 12:50–54 (stating each capsule of Curcumin Formulation One may include “*about* 1131 mg of the total composition”). We also note that the claims of the ’970 patent claim ranges for Curcumin I, II, and III, *see id.* at 14:11–13 (claim 1), 14:26–28 (claim 4), 14:40–45 (claiming “at least 50% curcumin II or III” for claim 7), as well as particular percentages, *see id.* at 14:18–20 (claim 2—“about” certain percentages for curcumin I, II, and III), 14:33–35 (claim 5—same). The Federal Circuit in *Ortho-McNeil* pointed out that a claim to a single weight ratio and a claim to a range of weight ratios “leads to a conclusion that one of ordinary skill in the art would understand the inventors intended a range when they claimed one and something more precise when they did not.” 476 F.3d at 1327.

We do not need to determine at this stage of the proceeding the precise meaning of the term “about” as used in claims 2 and 5. *See Nidec Motor Corp.*, 868 F.3d at 1017. To the extent a more precise construction of the term “about” is necessary to resolve any issues in this proceeding, however, we invite the parties during trial to provide further analysis in light of the Specification and any other evidence that sheds light on such meaning, taking into account our above discussion.

D. Indefiniteness

We begin with the indefiniteness ground because it informs our analysis for the anticipation and obviousness grounds. In Ground 9, Petitioner contends that claims 1–7 are

indefinite because they fail to convey, with reasonable certainty, how the percentages of curcumin I, II, and III in each claim are measured. As . . . Dr. Amiji explains, there are two reasons why: first, because the claims fail to recite, and the specification does not indicate, on what basis the percentages of curcuminoids are measured; and second, because the claims and specification both fail to indicate whether the percentages of curcuminoids in the composition are relative to the percentages of the total curcuminoids, or of the entire composition as formulated.

Pet. 69.

For the reasons explained below, we determine that Petitioner demonstrates that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable as indefinite.

1. Principles of Law

“In an [inter partes review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)) *see* 35 U.S.C. § 322(a)(3) (stating same for post grant reviews). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

“The specification [of a patent] shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” 35 U.S.C. § 112(b) (2018). A patent “is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014); *see* USPTO Memorandum on the Approach to Indefiniteness Under 35 U.S.C. § 112 in AIA Post-Grant Proceedings (Jan. 6, 2021).

2. Analysis

First, we begin with the language of the claims. Each challenged claim of the '970 patent describes either a particular percentage or a range of percentages for each of curcumin I, II, and III. *See* Ex. 1001, 14:10–49.

As Petitioner points out, there is no indication, however, in any of these claims as to how these percentages of curcumin I, II, or III are to be measured such as weight by weight (“w/w”) or weight by volume (“w/v”). Pet. 70 (citing Ex. 1019 ¶ 274). As Dr. Amiji explains, “[w]eight-to-volume percentages are typically calculated by dividing the weight of a solute, in grams, by the volume of the solution, in mL,” or alternatively, as the weight of the solute to the volume of the solvent. Ex. 1019 ¶ 275. Dr. Amiji also explains that:

A weight-to-weight percentage is typically calculated by dividing the weight of a single component by the weight of the entire composition. . . . Weight-to-weight percentages are commonly used in the pharmaceutical industry when preparing solid compositions, as it is generally easier to calculate weight-to-weight percentages when mixing defined weights of solid

components, while calculating weight-to-volume concentrations would require measuring the total volume of the solid mixture or calculating it using the density of each individual component.

Id. ¶ 277. We find on this record that Dr. Amiji provides a reasonable explanation as to how one of skill in the art would determine whether to use w/w or w/v measurements in making a composition of the challenged claims.

Petitioner asserts that not only do the claims fail to indicate how the different curcumins are measured, but “a POSA would not be able to determine from the specification of the ’970 patent on what basis these percentages are measured.” Pet. 70 (citing Ex. 1019 ¶ 274). In reviewing the Specification for the ’970 patent, Dr. Amiji points out that Examples 4 and 5 respectively describe Curcumin Formulations One and Two, which he asserts correspond to claims 1–6 of the ’970 patent, but those Examples do not indicate the basis on which the percentages of curcumin I, II, or III are measured. *Id.* (citing Ex. 1019 ¶ 275, Ex. 1001, 5:8–10). By contrast, in other places in the Specification of the ’970 patent, such as in Examples 6, 7, and 8 that respectively describe Curcumin Formulations Three, Four, and Five, the Specification expressly states that the measurement for percentages of curcumins is w/v. *See id.* (citing Ex. 1019 ¶ 276); Ex. 1001, 13:5–47.

Dr. Amiji explains why the Specification of the ’970 patent as described above does not inform one of skill in the art about how the percentages of curcumin I, II, and III are to be measured. Dr. Amiji explains that the compositions of claim 1–3 correspond to the curcumin formulation disclosed in Example 4, and the compositions of claims 4–7 correspond to the curcumin formulation disclosed in Example 5. *See* Ex. 1019 ¶ 276. Both Examples 4 and 5 disclose that the curcumin compositions are

formulated as a capsule, which Dr. Amiji testifies is a solid oral dosage form that includes the solids curcumin I, II, and III. *Id.*

Based on these teachings, Dr. Amiji concludes:

Because these compositions are mixtures of solids, a POSA would be confused if the percentages referred to (w/v), as the '970 patent does not identify what makes up the “volume” of the mixture, nor does it offer any guidance to a POSA as to what the “volume” component of these (w/v) percentages refers. And even though Examples 6 and 7 both disclose that curcumin II and III may be present in at least 50% (w/v), neither provides any guidance as to what makes up the “volume” component of these percentages.

A POSA, in fact, would expect the solid compositions disclosed and claimed in the '970 patent to have the percentage concentrations of the curcuminoids expressed as weight-to-weight, or (w/w), percentages. . . .

Because a POSA would reasonably expect the percentages recited in claims 1–7 to refer to (w/w), and because the only reference in the specification is (w/v), the claims read in light of the specification, would fail to provide a POSA with reasonable certainty regarding the scope of claims 1–7.

Ex. 1019 ¶¶ 276–278.

We agree with Dr. Amiji’s analysis and determine, based on the present record, that Petitioner has established that it is more likely than not that claims 1–7 are indefinite. Claims 1–7 are unclear because these claims do not specify how the percentages of curcumin I, II, or III, are to be measured, but instead only provide raw percentages for each curcumin species. *See* Ex. 1001, 14:10–49. The Specification of the '970 patent mentions a weight-by-volume measure for curcumin species for only Examples 6 through 8, but as Dr. Amiji testifies, these Examples are formulated as capsules with *optional* fillers that may be liquid including water. *See id.* at 13:15–19, 34–38. The remaining Examples 4 and 5 setting

forth alternative curcumin formulations are also formulated as capsules with the optional fillers, but provide no indication as to how the percentages for the curcumin species should be measured. *See id.* at 12:42–50, 58–67.

Dr. Amiji persuasively explains on the record before us that how a POSA interprets the method for measuring claimed percentages of the curcumin species makes a significant difference in assessing the metes and bounds of the claims. *See* Ex. 1019 ¶ 278. For instance, Dr. Amiji explains:

By way of example, a curcumin composition comprising 35 g curcumin I, 10 g curcumin II, and 50 g curcumin III, with 5 g of other components, would meet the curcuminoid content limitations of claims 1 and 2 if the percentages referred to (w/w) percentages. But, if the recited percentages were measured as (w/v), such a composition would only infringe if they were present in a volume of 100 mL of solution or suspension (as weight-per-volume percentages are typically used), and the specification offers no guidance on what solvent to use to make such a solution or suspension to achieve the specific percentages recited as (w/v). Further, the same remains true for the percentages recited in 4–7.

Id.

We also find on this record that not only does the '970 patent fail to teach how to measure the claimed percentages for curcumin I, II, or III, but it also fails to indicate whether these percentages are based on the total amount of curcuminoids *or* whether such total amount includes any additional excipients or carriers that make up the entire composition. Pet. 73–74; Ex. 1019 ¶¶ 283–287. For instance, each independent claim requires that the claimed composition be “formulated as a capsule, pill, tablet, granule, solution or a suspension in an aqueous or non-aqueous liquid, oil-in-water or water-in-oil emulsion, elixir, syrup, paste, or dry

powder.” *See* Ex. 1001, 14:13–17 (claim 1), 14:28–32 (claim 4), 14:46–49 (claim 7).

Dr. Amiji testifies that many of these dosage forms would require introducing other components in addition to curcumin I, II, and III. *See* Ex. 1019 ¶ 284. Dr. Amiji concludes that “[t]hus, by writing the claims in this manner, the patentee has created ambiguity as to whether the percentages of curcuminoids in the composition are relative to the percentages of the total curcuminoids, or of the entire composition as formulated.” *Id.*

Dr. Amiji also provides an example to show how including only the curcumin species in the total for the composition versus including any ingredient in the composition makes a significant difference in assessing the metes and bounds of the claims. Dr. Amiji testifies:

[A] composition containing 35 mg curcumin I, 15 mg curcumin II, and 50 mg curcumin III (along with 5 mg of other curcuminoids), formulated as a capsule that also included 85 mg of microcrystalline cellulose, 5 mg magnesium stearate, and 10 mg silicon dioxide, would meet the limitation of claims 1 and 2 if (a) the percentages in the composition were (w/w) percentages, and (b) the percentages were measured relative to the total curcuminoid content. But if the “composition” also includes the microcrystalline cellulose, magnesium stearate, and silicon dioxide, then the percentages of each curcuminoid would fall *well below* the ranges recited in, e.g., claims 1 and 2. The same is true for claim 3 (which depends from claim 1, and thus incorporates those limitations), as well as claims 4–7. The addition of any other excipients would also lead to a dilution of the (w/w) concentrations of the curcuminoids.

Ex. 1019 ¶ 285.

We find this example persuasive on this record to show that how one of skill in the art interprets what to include in the total amount of ingredients

to determine the percentage of curcumin I, II, and III, makes a significant difference and that the '970 patent does not teach which way is encompassed by the challenged claims. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344 (Fed. Cir. 2015) (holding claim indefinite where molecular weight could be measured three different ways and would yield different results and the patent and prosecution history did not provide guidance as to which measure to use).

3. Conclusion

As Petitioner notes, “[t]he percentages of curcumin I, II and III could be calculated as (1) weight-to-weight based on the total amount of curcuminoids; (2) weight-to-volume based on the total amount of curcuminoids in a solvent; or (3) weight-to-weight based on the total amount of all components in the composition.” Pet. 75. Dr. Amiji has convincingly demonstrated on the record before us that each of these calculations results in different percentages of curcumin I, II, and III for the same product. Therefore, we agree with Petitioner that a person of ordinary skill in the art would have no certainty from the Specification or the claims as to which method should be used. *See Dow Chem. Co. v. Nova Chems. Corp.*, 803 F.3d 620, 630 (Fed. Cir. 2015) (stating “the patent and prosecution history must disclose a single known approach or establish that, where multiple known approaches exist, a person having ordinary skill in the art would

know which approach to select”) (citing *Teva Pharm. USA, Inc.*, 789 F.3d at 1341, 1344–45).

For the reasons explained above, we are persuaded that the claims, Specification, and prosecution history¹⁰ fail to inform a person of ordinary skill in the art with reasonable certainty of the scope of the claims. We therefore conclude that Petitioner has demonstrated that is more likely than not that Petitioner will prevail in showing that claims 1–7 of the ’970 patent are unpatentable as indefinite under Ground 9.

E. Lack of Written Description and Enablement

In Ground 8, Petitioner asserts that claims 1, 2, 4, 5, and 7 lack written description because a person of ordinary skill in the art “reading the specification of the ’970 patent would not understand that the inventor possessed solution, syrup, elixir, or water-in-oil emulsion dosage forms.” Pet. 61–62; Ex. 1019 ¶¶ 256, 261. Petitioner also asserts that these claims also are not enabled because the ’970 patent does not teach a person of ordinary skill in the art how to make or use the claimed solution, syrup, elixir, or water-in-oil emulsion dosage forms without undue experimentation. Pet. 61–62.

Dr. Amiji testifies that other than formulations for capsules, the Specification of the ’970 patent provides only general disclosure regarding other formulating compositions. Ex. 1019 ¶ 262 (quoting Ex. 1001, 6:62–65 (stating “the compositions described herein may be administered in any *desired and effective* manner, e.g., as pharmaceutical compositions or

¹⁰ We do not discern any clarity to be gained concerning the appropriate measure for the claimed percentages of curcumin I, II, or III from our review of the prosecution history. See Ex. 1002.

nutritional supplements for oral ingestion”)). Dr. Amiji further explains that to form solutions, emulsions, syrups, and elixirs requires dissolving the solid curcuminoids in an acceptable solvent or carrier. *Id.* ¶ 263.

Dr. Amiji also states that the Specification of the '970 patent does not provide any guidance on which particular carriers would work, only that the carrier “***must*** be ‘acceptable’ in the sense of being compatible with the other ingredients of the formulation and ***not injurious to the subject***,” *see id.*

¶ 264 (quoting Ex. 1001, 7:20–24), and that suitable carriers are “well known in the art” and “can be determined using ordinary skill in the art, *see id.* (quoting Ex. 1001, 7:24–28). Dr. Amiji points out other generalizations in the Specification of the '970 patent that in his view provide insufficient guidance to one of ordinary skill in the art in how to make the solution, syrup, elixir, or water-in-oil emulsion dosage forms without undue experimentation especially in light of curcumin’s insolubility in water. *See id.* ¶¶ 265–270.

As we have found on the record before us that Petitioner has established that it is more likely than not that claims 1–7 are indefinite, we need not reach here whether Petitioner has met this same burden for establishing lack of written description and enablement for claims 1, 2, 4, 5, and 7. We do encourage the parties to provide further evidence during trial as to what one of skill in the art would have known concerning formulations of curcumin I, II, and III, in solution, syrup, elixir, or water-in-oil emulsion dosage forms.

F. Anticipation by Li

Petitioner asserts that claims 4 is anticipated by Li, and sets forth how each limitation is met by Li. As support, Petitioner cites the Declaration of Dr. Amiji. *See* Pet. 42–46; Ex. 1019 ¶¶ 134–139.

1. Principles of Law

To show anticipation under § 102, each and every claim element, arranged as in the claim, must be found in a single prior art reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008). The prior art need not, however, use the same words as the claims in order to find anticipation. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). It is also permissible to consider not only the literal teachings of the prior art reference, but also the inferences an ordinarily skilled person would draw from the reference. *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017); *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). A reference may also anticipate a claim even if it does not expressly teach all the limitations arranged or combined as in the claim, “if a person of skill in the art, reading the reference, would ‘at once envisage’ the claimed arrangement or combination.” *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068 (Fed. Cir. 2017) (quoting *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)).

With regard to claimed ranges, “[w]hen a patent claims a range . . . that range is anticipated by a prior art reference if the reference discloses a point within the range.” *Ineos USA LLC v. Berry Plastics Corp.*, 783 F.3d 865, 869 (Fed. Cir. 2015). If the prior art discloses a range and not a specific point, however, “then the prior art is only anticipatory if it describes

the claimed range with sufficient specificity such that a reasonable fact finder could conclude that there is no reasonable difference in how the invention operates over the ranges.” *Id.* (citing *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006)).

2. Analysis

Petitioner asserts that Li discloses a composition—containing 55.3% curcumin, 17.7% DMC, and 27.0% BDMC (w/w)—that is a point within the ranges of claim 4 when the margin of error for HPLC measurements is considered, and formulated as an oil-in-water emulsion as claimed in claim 4. Pet. 43–46 (citing Ex. 1006, 2753; Ex. 1019 ¶¶ 135–139).

In arriving at this conclusion, Petitioner and Dr. Amiji have assumed “that the percentages recited in claim 4 are weight-to-weight (w/w) percentages of the curcuminoid content, and not of the total formulation.” Pet. 44, n.1. As Petitioner notes, and as we have discussed in Section II.D., the claims, when read in light of the Specification and the prosecution history, lack sufficient clarity for us to determine that Petitioner’s interpretation that the claimed percentages are weight-to-weight of the curcuminoid content is the correct one. Therefore, because the scope of the claims cannot be determined without speculation, any differences between the claimed invention and the asserted prior art cannot be ascertained based on the present record. *See Oticon Medical AB v. Cochlear Bone Anchored Solutions AB*, IPR2017-01018, Paper 52, 15 (PTAB Aug. 21, 2018).

We invite the parties to address further during trial whether claims 1–7 are amenable to construction and application of the asserted art.

G. Obviousness Grounds

In Grounds 2–4, Petitioner again relies on Li with the continued assumption that the percentages recited in claim 4 are weight-to-weight (w/w) percentages of the curcuminoid content, and not of the total formulation. *See* Pet. 47, n.2 (Ground 2), 49 (Ground 3), 51 (Ground 4). Again, because the scope of the claims cannot be determined without speculation, any differences between the claimed invention and the asserted prior art cannot be ascertained based on the present record.

With respect to Grounds 5–7, Petitioner relies on Pushpakumari as disclosing the levels of curcumin I, II, and III in most commercially available curcumin extracts that may be enriched with curcumin III based on the teachings of Hong to arrive at the compositions of claims 1, 2, and 7. *See* Pet. 52–55. Petitioner states that it again assumes “that the percentages recited in claims 1 and 7 are weight-to-weight (w/w) percentages of the curcuminoid content, and not of the total formulation.” Pet. 53, n.3.

Claims 1 and 7 are the only independent claims at issue in Grounds 5–7, and Petitioner relies on the above-stated teaching in Pushpakumari and assumption concerning the scope of claims 1 and 7. *See* Pet. 55–61, *see also* Pet. 60, n.4 (stating “Dr. Amiji and Petitioners have assumed that the percentages recited in claim 7 are weight-to-weight (w/w) percentages of the curcuminoid content, and not of the total formulation.”).

Again, because the scope of the claims cannot be determined without speculation, any differences between the claimed invention and the asserted prior art cannot be ascertained based on the present record. We again invite the parties to address further during trial whether claims 1–7 are amenable to construction and application of the asserted art.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition establishes that it is more likely than not that Petitioner will prevail in showing that challenged claims 1–7 of the '970 patent are unpatentable based on at least the indefiniteness ground presented in the Petition. Accordingly, we institute a post-grant review of claims 1–7 of the '970 patent based on all the grounds set forth in the Petition. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); 37 C.F.R. § 42.208(a) (“When instituting post-grant review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.”).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 324(a), a post grant review of claims 1–7 of the '970 patent is hereby instituted on the grounds set forth in the Petition; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 324(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial, which commences on the entry date of this decision.

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