UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

| | | |
|---|---|---|
| GEORGE D. PETITO, ANITA M. PETITO, CONNECTIVE LICENSING, LLC, | : | 13 Civ. 8040 (PAE) |
| | : | 13 Civ. 8074 (PAE) |
| Plaintiffs, | : | 13 Civ. 8077 (PAE) |
| | : | 13 Civ. 8128 (PAE) |
| -v- | : | |
| | : | OPINION & ORDER |
| PURITAN'S PRIDE, INC.; REXALL SUNDOWN, INC.; NATURE'S BOUNTY, INC.; PHYSIOLOGICS, LLC, | : | |
| Defendants. | : | |

PAUL A. ENGELMAYER, District Judge:

In these four related cases, George Petito, Anita Petito, and Connective Licensing, LLC allege that Puritan's Pride, Inc., Rexall Sundown, Inc., Nature's Bounty, Inc., and Physiologics, LLC, respectively, have each infringed U.S. Patent No. 6,645,948 ("the '948 patent"), entitled "Nutritional Composition for the Treatment of Connective Tissue." Defendants now move for summary judgment on two grounds. First, they argue that the '948 patent is invalid because it fails the utility and written description requirements of 35 U.S.C. § 112. Second, defendants argue that the '948 patent, if valid, is not entitled to an earlier filing date under 35 U.S.C. § 120 because it was not filed before the patenting of an earlier, related application. For the reasons that follow, the Court grants defendants' first motion for summary judgment, and finds the '948 patent invalid. The Court does not, therefore, have occasion to reach defendants' alternative motion for summary judgment.

## I. Background[1]

George and Anita Petito (the "Petitos") are the owners and inventors of the '948 patent. Def. 56.1 ¶ 1. Connective Licensing, LLC is the exclusive licensee of the '948 patent. *Id.* ¶ 2.

The '948 patent is the result of a series of patent applications by the Petitos. Because defendants' challenge turns on the sufficiency of the applications underlying and incorporated in the '948 patent, the Court reviews the facts concerning these successive patent applications in detail.

---

[1] Unless otherwise specified, all references to the docket refer to the docket in the lowest-numbered of these four related cases, *Petito et al. v. Puritan's Pride*, No. 13 Civ. 8040 (PAE) (S.D.N.Y. 2013).

The Court's account of the facts is derived from the parties' submissions in support of and in opposition to the instant motions, including: Defendants' Local Rule 56.1 Statement, Dkt. 31 ("Def. 56.1"); the Affidavit of Rachel M. Echols, Dkt. 32 ("Echols Aff."), and the exhibits attached thereto; the Affidavit of C. Nichole Gifford, Dkt. 36 ("Gifford Aff."), and the exhibits attached thereto; the Declaration of Daniel T. Johnston, M.D., Dkt. 45 ("Johnston Decl."); Plaintiffs' Counterstatement to Defendants' Local Rule 56.1 Statement, Dkt. 46 ("Pl. 56.1"); the Declaration of Darrell G. Dotson, Dkt. 48 ("Dotson Decl."), and the exhibits attached thereto; and Defendants' Response to Plaintiffs' Additional Statements of Material Facts, Dkt. 51 ("Def. Resp. 56.1").

Citations to a party's 56.1 Statement incorporate by reference the documents cited therein. Where facts stated in a party's 56.1 Statement are supported by testimonial or documentary evidence, and denied by a conclusory statement by the other party without citation to conflicting testimonial or documentary evidence, the Court finds such facts to be true. *See* S.D.N.Y. Local Rule 56.1(c) ("Each numbered paragraph in the statement of material facts set forth in the statement required to be served by the moving party will be deemed to be admitted for purposes of the motion unless specifically controverted by a correspondingly numbered paragraph in the statement required to be served by the opposing party."); *id.* at 56.1(d) ("Each statement by the movant or opponent . . . controverting any statement of material fact[ ] must be followed by citation to evidence which would be admissible, set forth as required by Fed. R. Civ. P. 56(c).").

The following abbreviations are used herein for the parties' memoranda of law: Defendants' Memorandum of Law in Support of Their Motion for Summary Judgment on Patent Invalidity, Dkt. 30 ("Def. Br."); Plaintiff's Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment on Patent Invalidity, Dkt. 47 ("Pl. Br."); Defendants' Reply Memorandum of Law in Further Support of Their Motion for Summary Judgment on Patent Invalidity, Dkt. 49 ("Def. Reply Br.").

**A. The '710 Application**

On March 24, 1998, the Petitos filed U.S. Patent Application No. 09/046,710. Dotson Decl. Ex. A (the "'710 application" or the "grandparent application"). The '710 application claimed a nutritional composition to support "the creation of new body tissue and cartilage growth in humans and animals," which could be administered orally or by injection. *Id.* at 6. It also promised other benefits: "the enhancement of chondrocyte synthesis, the maintenance of healthy muscle and tissue, increasing the desirable concentration of hyaluronic acid, and being anti-inflammatory." *Id.*

The claimed composition contained six ingredients: (1) glucosamine hydrochloride, (2) chondroitin sulfate, (3) hydrolyzed or native collagen, (4) sodium hyaluronate, (5) a manganese salt, and, optionally (6) L-malic acid. *Id.* at 1, 8. For each ingredient, the application listed a preferred concentration and two ranges of concentrations (an "optional range" and a "broad range"), with the dosage amounts described in terms of milligrams per kilogram of bodyweight. *Id.* at 9. For example, for the first ingredient, glucosamine hydrocholoride, the application stated that the preferred concentration was 5 mg, the optional range was 3 to 8 mg, and the broad range was 2 to 10 mg. *Id.*

On June 23, 1998, the examiner rejected the claims in the '710 application, on two grounds. Echols Aff. Ex. D. First, he found the claims were indefinite within the meaning of 35 U.S.C. § 112, because they "fail[ed] to particularly point out and distinctly claim the subject matter which applicant regards as the invention" and because, although certain claims referred to "effective amounts," they did not "recite for what purpose the effective amounts are to be directed against." *Id.* at 2. Second, the examiner concluded, the claimed composition was obvious over the prior art. *Id.* at 2–6. The examiner explained:

> The composition claims appear to be a combination of previously known compositions (with the exception of the addition of malic acid) which were successful for a particular purpose *i.e.* healing and/or maintenance of connective tissue. However, it has previously been held that it is obvious to combine ingredients which have been separately employed for a particular purpose in order to obtain the expected combination of benefits. *See In re Greenfield*, 571 F.2d 1185, 197 USPQ 227 (CCPA 1978).[2] With regard to the addition of malic acid, one of ordinary skill in the art would have found obvious to add a flavor enhancer to a food/drink product for the purpose of making the composition more palatable for the user.

*Id.* at 4.

On August 21, 1998, the Petitos filed an Amendment and Response. Echols Aff. Ex. G ("'710 amendment"). In their response, the Petitos attempted to refute the examiner's reasons for rejecting the '710 application. *Id.* at 2–7. They also submitted a letter dated August 14, 1998 from David C. Polen, President of DP Nutritionals, to George Petito, describing three patients who benefited from the administration of the composition.[3] '710 amendment Ex. A. The body of Polen's letter is as follows:

> The cases below are people who have benefited from the use of the composition:
>
> R.R. is a 78-year-old white female widow that has a part time job on weekends working in [a] supermarket. She states that she needs the job because she needs to be in contact with people. In November of 1997, she was afraid that she was going to have to give up her job due to the pain that she would experience in her hips and knees when she was on her feet for over a half hour and the pain was getting increasingly more difficult for her to live with. She was put on Osteocaps in September of 1997 and at her visit in November, she stated that all of her pain was gone and was looking forward to keeping her part time job. She was taken off Osteocaps in April of 1998 and at her last appointment on June 27, 1998 she was still pain free.

[2] The U.S. Court of Customs and Patent Appeals ("CCPA") is the Federal Circuit's predecessor. Its decisions are binding precedent on the Federal Circuit and therefore, as to patent matters, on this Court. *See S. Corp. v. United States*, 690 F.2d 1368, 1369 (Fed. Cir. 1982).

[3] Specifically, the patients were administered a product, Osteocaps, which a second letter explained "contains the ingredients in the ['710] application, within the ranges recited." '710 Amendment Ex. A; *see also* '710 Amendment at 7 (describing the letters).

> M.S. is a 61-year-old housewife from Brooks[,] Kentucky. Her complaints were digestive disorders, Arthritis, Back aches and headaches. She was tested and found to have food allergies so she was put on the appropriate diet and nutritional supplements for this condition. As the food allergies started to clear up she still complained about arthritic pain and was put on Osteocaps on her next visit. One month later she stated that her pain started to clear up in about four days and was completely gone in a week. She also stated that she does not want to be without them.
>
> L.G. is a 62-year-old patient who resides in West Point, Kentucky. She came into the office stating that she was bitten by a spider about 18 months ago and still had a lot of joint pain from the bite. The patient was put on Osteocaps and Vitamin C. At her second appointment in thirty day[s] she stated that her pains in her joints had gotten much better, and at her third visit she was totally pain free. She has been taking Osteocaps for six months and has not had any pain in her joints since.

'710 amendment Ex. A.

On November 24, 1998, the examiner concluded that the Petitos' arguments were "not persuasive" and reaffirmed his rejection of the claims on the grounds of indefiniteness and obviousness. Echols Aff. Ex. I. He explained that "[i]nvention can reside in a composition of matter formed by the intermixture of two or more ingredients which result in a product possessing characteristics of utility that are new, additional and materially different from the property or properties which the individual ingredients do not possess in common," but that "there is nothing patentable unless the applica[nt] by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected, and useful function." *Id.* at 3–4 (citing *In re Levin*, 178 F.2d 945 (CCPA 1949)). The examiner determined that the Polen letter did not show that the results were "unexpected and significant." *Id.* at 4 (citing Manual of Patent Examining Procedure § 716.02(b)).

On May 24, 1999, the Petitos filed a notice of appeal. *See* Echols Aff. Ex. H. They did not, however, file an appeal brief. *See id.* On January 3, 2000, the Patent and Trademark Office sent the Petitos a notice stating that the '710 application had been abandoned. *Id.*

**B. The '169 Application and the '005 Patent**

On July 26, 1999, the Petitos filed U.S. Patent Application No. 09/360,169 as a continuation-in-part of the '710 application. Dotson Decl. Ex. B (the "'169 application" or the "parent application").

The '169 application was nearly identical to the '710 application. It sought to patent a nutritional composition containing the same six ingredients as the '710 application, which could be administered to humans and animals, orally or by injection, to support "the creation of new body tissue and cartilage growth" and to provide the benefits claimed in the '710 application. *See* '169 application at 6–9; *see also* Pl. 56.1 ¶¶ 60–61, 69–70; Def. Resp. 56.1 ¶¶ 60–61, 69–70. For each ingredient, the '169 application listed a preferred concentration, an optional range, and a "broad range," in the same amounts recited in the '710 application. *See* '169 application at 10; *see also* Pl. 56.1 ¶¶ 72–73; Def. Resp. 56.1 ¶¶ 72–73. The '169 application did not include the Polen letter describing the three patients who had benefited from the use of the composition.

The '169 application, however, differed from the '710 application in several ways. Most relevant here, the '169 application added a new paragraph, in which it sought to distinguish the prior art:

> Unlike the compositions disclosed in the prior art, it is believed that the present composition provides an enhanced chondroprotective effect by providing foundational support for the creation of new body tissue and cartilage growth in mammals because it comprises hydrolyzed Type 1 collagen having a preferred molecular weight average no greater than 2,000 Daltons, more preferably the hydrolyzed Type 1 collagen has a molecular weight average of about 1,000 to 1,500. It is believed that the hydrolyzed Type 1 Collagen having a preferred molecular weight average no greater than about 2,000 Daltons, acts as a transporter or carrier for the larger molecules of sodium hyaluronate and/or chondroitin sulfate by aiding in the absorption process of these large molecules, thereby increasing the bio-availability of each.

*Id.* at 11.

The '169 application also: (1) added, to its discussion of prior art, two patents not discussed in the '710 application, one of which had been issued after the submission of the '710 application, *id.* at 3 (referring to U.S. Patent Nos. 5,840,715 and 4,837,024); (2) specified that the third ingredient, hydrolyzed Type I collagen, should preferably have an average molecular weight of no greater than 2000 Daltons, *id.* at 9; (3) noted that the sixth ingredient, L-malic acid, "acts as a detoxifying agent by ridding the body of lactic acid often found in connective tissue," *id.*; and (4) reordered and reconfigured certain claims, without appearing to make any changes of substance, other than as to the average molecular weight of the hydrologized Type I collagen, *id.* at 12–15. Otherwise, the '169 application appeared nearly identical in substance and wording to the '710 application.

On November 5, 2002, the Patent and Trademark Office granted the '169 application and issued to the Petitos U.S. Patent No. 6,476,005, entitled "Oral and Injectable Nutritional Composition."[4] Gifford Aff. Ex. B (the "'005 patent" or the "parent patent").

**C. The '590 Application and the '948 Patent**

On November 5, 2002, the same day that the Patent and Trademark Office issued the '005 patent, plaintiffs filed U.S. Patent Application No. 10/287,590 as a continuation-in-part of the prior '169 application, which was a continuation-in-part of the '710 application. Dotson Decl. Ex. D (the "'590 application"). On November 11, 2003, the Patent and Trademark Office granted the '590 application and issued to the Petitos the '948 patent, the patent at issue in this case. Dotson Decl. Ex. C (the "'948 patent").

[4] The examiner for the '710 application was Howard C. Lee. *See* Echols Aff. Ex. D at 7. The examiner for the '169 application was James O. Wilson. *See* '005 patent (cover page).

The '948 patent incorporates the '169 application's disclosures (also contained in the '005 patent) in their entirety, but is styled as an improvement over the '169 application (and therefore the '005 patent). *Id.* at col. 3 ll. 12–15.

The '948 patent is directed to "[a] nutritional composition for the treatment of connective tissue in mammals comprising: a therapeutically effective amount of [1] a glucosamine salt, [2] chondroitin sulfate, [3] collagen, and [4] sodium hyaluronate." *Id.* at col. 4 ll. 54–58 (Claim 1). These are the first four ingredients listed in both the '005 patent and the '710 application. The '948 patent claims that these ingredients "synergistically act as the chondroprotective agent" and that the resulting compositions "effectively provide foundational support for the creation of new body tissue and cartilage growth, facilitate chondrocyte synthesis, protect and maintain healthy muscle and tissue, increase hyaluronic acid concentrations, and reduce inflammation." *Id.* at col. 3 ll. 23–24, 29–33. It also explains that "[t]he collagen component acts as a transporter or carrier for the larger molecules of sodium hyaluronate and/or chondroitin sulfate by aiding in the absorption process of these large molecules, thereby increasing the bio-availability of these therapeutic effective components." *Id.* at col. 4 ll. 43–48.

The '948 patent's dependent claims add optional ingredients, including the latter two ingredients in the parent and grandparent applications, *i.e.*, manganese salt and L-malic acid; and three new categories of optional ingredients, *i.e.*, an anti-inflammatory agent, an analgesic such as aspirin, and either Vitamin C or Vitamin $B_{12}$. *Id.* at col. 5 ll. 1–21 (Claims 5–13).

Whereas the '710 application and '005 patent listed, for each ingredient, a preferred concentration, an optional range, and a "broad range," the '948 patent sets out a single range for each ingredient. *Id.* at col. 6 ll. 10–15 ("[T]he composition comprises, based on mg/kg of bodyweight, about 1–30 mg/kg of a glucosamine salt; about 1–15 mg/kg of a chondroitin sulfate;

about 1–30 mg/kg of collagen; and about 1–15 mg/kg of sodium hyaluronate."). In each case, that range is broader than the "broad range" listed in the predecessor applications.

As for prior art, the '948 patent begins by stating that "[t]he related art of interest discloses numerous pharmaceutical compositions and methods for the treatment of connective tissue in humans and animals." *Id.* at col. 1 ll. 20–22. The '948 patent then discusses a number of prior patents and products, some of which used two or three of the ingredients in the '948 patent.[5] *Id.* at col. 1–2. Significantly, although no prior art used all four of the '948 patent's ingredients, each ingredient was used with one or more of the others in at least one prior patent or product disclosed in the prior art section.

For example, a prior patent, issued to Dov Michaeli, described a topical composition for wound healing that combined ingredient #3, collagen, with a variant of ingredient #4, glycosaminoglycan. *Id.* at col. 1 ll. 20–28 (citing U.S. Patent No. 4,837,024). Two prior patents sought to treat connective tissue in mammals through compositions that combined ingredient #1, glucosamine salt, with ingredient #2, chondroitin sulfate. *Id.* at col. 2 ll. 4–15 (citing U.S. Pat. Nos. 5,364,845 and 5,587,363). A product named Body Ammo Nutraceuticals sought to treat connective tissue with capsules that combined a variant of ingredient #1, glucosamine, with ingredient #2, chondroitin sulfate, and a variant of ingredient #4, hyaluronic acid. *Id.* at col. 2 ll. 16–20. And Richardson Labs, Inc., created a dietary supplement to reconstitute bone cartilage which combined a variant of ingredient #1, glucosamine, with ingredient #2, chondroitin sulfate, and ingredient #3, collagen. *Id.* at col. 2 ll. 20–25.

[5] The '948 patent's discussion of prior art is substantially similar to that of the '005 patent, except that the '948 patent (1) mentions one patent issued to George Petito, U.S. Patent No. 5,929,050 on July 27, 1999 for treating open wounds, which the '005 patent did not mention; (2) mentions two unpatented but publicly disclosed products, Body Ammo Nutraceuticals and an unnamed product disclosed by Richardson Labs, Inc., which the '005 patent did not mention; and (3) does not mention certain patents referenced in the '005 patent. *See id.* at col. 1–2.

The '948 patent closes its discussion of the prior art with the following statement, apparently intended to distinguish the prior art:

> While all the above references have been describe[d] as being effective for their intended use, there remains a need in the art for a therapeutic composition which demonstrates enhanced effectiveness in the treatment of connective tissues, exhibit[s] other improved beneficial properties, and provide[s] even wider applications in the modes of administration. The present invention meets these needs.

*Id.* at col. 2 ll. 33–39. In effect, the '948 patent was directed not at the four ingredients themselves, but at the synergistic interaction.

The '948 patent does not include the Polen letter, contained in the '710 amendment application, regarding the three patients who used the composition, or any other reports concerning patients who were administered the composition.

**D. Procedural History**

On November 12–14, 2013, plaintiffs filed these four related lawsuits alleging infringement of the '948 patent. *See Petito et al. v. Puritan's Pride, Inc.*, No. 13 Civ. 8040 (PAE) (S.D.N.Y.), Dkt. 1; *Petito et al. v. Rexall Sundown, Inc.*, No. 13 Civ. 8074 (PAE) (S.D.N.Y.), Dkt. 1; *Petito et al. v. Nature's Bounty, Inc.*, No. 13 Civ. 8077 (PAE) (S.D.N.Y.), Dkt. 1; *Petito et al. v. Physiologics, LLC*, No. 13 Civ. 8128 (PAE) (S.D.N.Y.), Dkt. 1. Initially, only the *Puritan's Pride* case, No. 13 Civ. 8040, was assigned to this Court. *See* Dkt. 10. On January 2, 2014, the parties jointly requested that the four cases be heard by the same judge. *Id.* Pursuant to that request, on January 10 and 17, 2014, the remaining three cases were reassigned to this Court as related to *Petito et al. v. Puritan's Pride, Inc.*, No. 13 Civ. 8040.

On January 30, 2014, at the initial pretrial conference, the Court permitted defendants to take expedited discovery on and file early summary judgment motions as to certain discrete issues. Dkt. 26. On April 4, 2014, defendants filed the instant motions for summary judgment.

The first asserts that the '948 patent is invalid because it fails to meet the written description and enablement requirements of 35 U.S.C. § 112. Dkt. 29–32. The second asserts that the '948 patent is not entitled to claim the benefit, under 35 U.S.C. § 120, of the filing date of the '005 patent and the '710 application. Dkt. 33–36. On April 23 and 24, 2014, plaintiffs filed their oppositions. Dkt. 40–48. On May 5, 2014, defendants replied. Dkt. 49–54. On June 5, 2014, the Court heard argument. Dkt. 56 ("Tr.").

## II. Applicable Legal Standards

### A. Summary Judgment

To prevail on a motion for summary judgment, the movant must "show[] that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Federal Rule of Civil Procedure 56(a). The movant bears the burden of demonstrating the absence of a question of material fact. In making this determination, the Court must view all facts "in the light most favorable" to the non-moving party. *Holcomb v. Iona Coll.*, 521 F.3d 130, 132 (2d Cir. 2008); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

To survive a summary judgment motion, the opposing party must establish a genuine issue of fact by "citing to particular parts of materials in the record." Fed. R. Civ. P. 56(c)(1); *see also Wright v. Goord*, 554 F.3d 255, 266 (2d Cir. 2009). "A party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment." *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (citation omitted). Only disputes over "facts that might affect the outcome of the suit under the governing law" will preclude a grant of summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining whether there are genuine issues of material fact, the Court is "required to resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom

summary judgment is sought." *Johnson v. Killian*, 680 F.3d 234, 236 (2d Cir. 2012) (citation omitted).

**B. Patent Invalidity**

"An issued patent enjoys a presumption of validity, 35 U.S.C. § 282, that can be overcome only through clear and convincing evidence." *Univ. Of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 920 (Fed. Cir. 2004). The "clear and convincing evidence" standard "has been described as 'evidence which produces in the mind of the trier of fact an abiding conviction that the truth of the factual contentions are highly probable.'" *Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 718 F. Supp. 2d 382, 391 (S.D.N.Y. 2010) *aff'd*, 435 F. App'x 927 (Fed. Cir. 2011) (quoting *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988)).

## III. Discussion

Defendants argue that the '948 patent is invalid because it does not provide sufficient evidence of its usefulness. As a result, defendants argue, the '948 patent fails the utility and written description requirements of § 112.[6] For the reasons that follow, the Court agrees as to both points.

**A. Utility**

The utility requirement arises under §§ 101 and 112 of the Patent Act.

Section 101 requires that a patent be "new and useful." 35 U.S.C. § 101; *see also Aristocrat Technologies Australia PTY Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir.

[6] Defendants primarily frame this argument as regarding written description. The leading cases in this area, however, treat this issue as principally one of utility. *See In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1323–27 (Fed. Cir. 2009); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322–25 (Fed. Cir. 2005). Accordingly, the Court does the same.

2008). It therefore requires "that the specification disclose as a matter of fact a practical utility for the invention." *In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993).

Section 112 sets out the requirements for patent specifications. It requires that a patent specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to *enable any person* skilled in the art to which it pertains, or with which it is most nearly connected, *to make and use* the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." 35 U.S.C. § 112 (emphasis added). Section 112 therefore creates the "enablement" requirement, which "incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005); *see also id.* ("In explaining what constitutes a sufficient showing of utility in the context of the enablement requirement, this court has stated that an applicant's failure to disclose how to use an invention may support a rejection under either section 112, paragraph 1 for lack of enablement, or section 101 for lack of utility when there is a complete absence of data supporting the statements which set forth the desired results of the claimed invention.") (citations omitted).

"Whether a disclosure is enabling under 35 U.S.C. § 112(a) is a question of law based on underlying factual inquiries." *CreAgri, Inc. v. Pinnaclife, Inc.*, Case No. 11-CV-6635-LHK, 2013 WL 6673676, at *17 (N.D. Cal. Dec. 18, 2013) (citing *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed. Cir. 1999)). "Whether an invention is operative, and hence has utility within the meaning of § 101, appears to be one of those factual inquiries." *Id.* (citing *In re Dash*, 118 Fed. App'x 488, 490 (Fed. Cir. 2004)).

"When utility as a drug, medicant, and the like in human therapy is alleged, it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct." *In re Jolles*, 628 F.2d 1322, 1327 (CCPA 1980); *accord Rasmusson*, 413 F.3d at 1323. The burden of proving utility applies with equal force "when an inventor tries to distinguish his claims from the prior art by introducing evidence of unexpected 'synergistic' properties." *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 808 (Fed. Cir. 1989). "In such cases, the evidence should at least demonstrate 'an effect greater than the sum of the several effects taken separately.'" *Id.* (quoting *Sakraida v. Ag Pro, Inc*., 425 U.S. 273, 282 (1976)).

"Typically, patent applications claiming new methods of treatment are supported by test results." *In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009). Human trials are not the only acceptable tests; "results from animal tests or in vitro experiments[7] may also suffice to satisfy the utility requirement." *Id.* at 1324–25.

The '948 patent, however, is not supported by any experimental results—whether human, animal, or in vitro. Instead, the '948 patent's entire explanation of its utility is that its ingredients "synergistically act as [a] chondroprotective agent" and that "[t]he collagen component acts as a transporter or carrier for the larger molecules of sodium hyaluronate and/or chondroitin sulfate by aiding in the absorption process of these large molecules, thereby increasing the bio-availability of these therapeutic effective components." '948 patent at col. 3 ll. 23–24, col. 4 ll. 43–48. The '948 patent also incorporates the '169 patent's conclusory statement, on which the plaintiffs place substantial weight, that "[i]t has been *found* that the following composition has

[7] "'In vitro' experiments are performed in artificial environments outside living organisms (such as in a test tube or culture media), while 'in vivo' experiments are performed within living organisms." *Id.* at 1325 n.7.

provided the above-mentioned benefits in both humans and animals." '005 patent at col. 4 ll. 12–14 (emphasis added). Significantly, none of these statements describes test results or other substantiating evidence.[8]

Indeed, plaintiffs do not seriously attempt to argue that the '948 patent meets the utility requirement as articulated in the above cases. Instead, plaintiffs seek to distinguish these cases. Accordingly, the Court reviews in depth the two most recent and important cases addressing that requirement, *In re '318 Patent Infringement Litig.*, 583 F.3d 1317 (Fed. Cir. 2009) and *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005). The Court then considers plaintiffs' attempts to distinguish these cases.

In *In re '318 Patent*, the patent at issue was directed at treating Alzheimer's disease with galanthamine (also spelled "galantamine"). 583 F.3d at 1320. The Federal Circuit affirmed the district court's decision, rendered after a bench trial, that the patent was invalid because it failed the enablement requirement. The Federal Circuit explained that "the specification for the '318 patent was only just over one page in length, and it provided almost no basis for its stated conclusion that it was possible to administer 'an effective Alzheimer's disease cognitively-enhancing amount of galanthamine.'" *Id.* at 1321 (quoting the '318 patent).

[8] The closest thing to substantiating evidence in this chain of patents is the letter from David Polen, included in the '710 amendment, which described three patients who benefited from taking Osteocaps, a product which contained the ingredients disclosed in the '710 application, the '005 patent, and in a version of the '948 patent as stated in the dependent claims. Plaintiffs rightly do not argue that the patent should be upheld on the basis of this letter. The methodology is so lacking in any scientific rigor (*e.g.*, the sample size is so small, there is no control group), and the description is so sparse (*e.g.*, as to dosages, concentrations, frequency, other medications taken, and, most importantly, as to the number of patients who were treated with Osteocaps but whose symptoms did not improve), that the letter cannot qualify as an experiment within the meaning of *In re '318* and *Rasmusson*. *See also* Echols Aff. Ex. I at 4 (examiner's conclusion that the Polen letter did not show that the results were "unexpected and significant").

Notably, the '318 patent was grounded in the scientific research of the time. At the time of the early 1986 application for the '318 patent, researchers had observed that the presence of Alzheimer's symptoms was correlated with reduced levels of acetylcholine, a neurotransmitter, in the brain. *Id.* at 1320. Galanthamine was also known to increase the amount of acetylcholine available for neurotransmission, by inhibiting the work of an enzyme that breaks down acetylcholine. *Id.* at 1320–21. In early 1986, many Alzheimer's researchers were investigating treatments related to one of the two main types of receptors that acetylcholine binds to during neurotransmission in the brain. *Id.* at 1320.

The specification for the '318 patent accordingly provided "short summaries of six scientific papers in which galantamine had been administered to humans or animals." *Id.* at 1321. It described the first two papers as showing that treating humans with galantamine and atropine raised levels of cortisol and adrenocorticotropic hormone. *Id.* The '318 patent did not explain the significance of increasing these hormonal levels, but one skilled in the art at the time could have inferred that, because the production of these hormones takes place in the brain, "galantamine was able to cross the blood-brain barrier and have effects within the brain." *Id.* The specification then briefly summarized four scientific papers reporting on animal experimentation, which showed that galantamine (1) affected brain wave activity in rabbits, (2) increased short-term memory in dogs, and (3) reversed a form of drug-induced amnesia in rats (although the specification did not suggest that this drug-induced amnesia was similar to Alzheimer's). *Id.* Importantly, however, as the Federal Circuit noted, "[t]he specification did not provide analysis or insight connecting the results of any of these six studies to galantamine's potential to treat Alzheimer's disease in humans." *Id.*

The specification then noted that a certain experimental methodology, discussed in the prior art, would "'provide[ ] a good animal model for Alzheimer's disease in humans.'" *Id.* at 1321 n.3 (quoting the '318 patent). In that experiment, a lesion would be placed in a certain part of an animal's brain, causing deficiencies in acetylcholine "'similar in magnitude to that seen in early to moderate stage Alzheimer's disease.'" *Id.* (quoting the '318 patent). "The specification cited the prior art for the conclusion that '[d]rugs that can normalize these abnormalities would have a reasonable expectation of efficacy in Alzheimer's disease.'" *Id.* at 1322 (quoting the '318 patent). However, "the specification did not refer to any then-existing animal test results involving the administration of galantamine in connection with this animal model of Alzheimer's disease." *Id.*

In response to the examiner's original rejection of the application, the applicant, Dr. Bonnie Davis, stated, *inter alia*, that (1) "experiments are underway using animal models which are expected to show that treatment with galanthamine does result in an improvement in the condition of those suffering from Alzheimer's disease," and (2) it was "expected that data from this experimental work will be available in two to three months and will be submitted to the Examiner promptly thereafter." *Id.* at 1322 (citation omitted). After the patent was issued, the results from one such experiment were published; they suggested that galantamine could be a promising treatment for Alzheimer's. *Id.*

Because there was no relevant experimental data at the time of application, however, the Federal Circuit held that the '318 patent did not establish utility and was therefore invalid. *Id.* at 1325; *see also id.* at 1327 ("Thus, at the end of the day, the specification, even read in the light of the knowledge of those skilled in the art, does no more than state a hypothesis and propose testing to determine the accuracy of that hypothesis. That is not sufficient."). The Federal

Circuit explained that the '318 patent could not claim the benefit of the later animal testing results, because enablement is "determined as of the effective filing date of the patent's application." *Id.* at 1323, 1325. Nor could the '318 patent be patented as a mere idea or research proposal, for "[a] process or product which either has no known use or is useful only in the sense that it may be an object of scientific research is not patentable. . . . [I]nventions do not meet the utility requirement if they are objects upon which scientific research could be performed with no assurance that anything useful will be discovered in the end. Allowing ideas, research proposals, or objects only of research to be patented has the potential to give priority to the wrong party and to confer power to block off whole areas of scientific development, without compensating benefit to the public." *Id.* at 1324 (citations omitted). The patent was invalid, the Federal Circuit stated, because "[t]ypically, patent applications claiming new methods of treatment are supported by test results," including "results from animal tests or in vitro experiments"; but in the case at hand, "neither in vitro test results nor animal test results involving the use of galantamine to treat Alzheimer's-like conditions were provided." *Id.* at 1324–25.

In so holding, *In re '318* acknowledged that utility could be established by reference to prior art. But the applicant there did not "contend that the prior art animal testing summarized in the '318 patent application's specification established utility." *Id.* at 1325.

*In re '318* also noted, without endorsing, the possibility that utility could be established by arguments or reasoning.[9] *Id.* at 1326. But it found that the insights that the applicant

[9] "Janssen argues that in some circumstances utility may be established without testing the proposed treatment in the claimed environment or a sufficiently similar or predictive environment; that is, Janssen argues that utility may be established by analytic reasoning. Although no case has been called to our attention where utility was established simply by analytic reasoning, the PTO's Manual of Patent Examining Procedure ('MPEP') has recognized that 'arguments or reasoning' may be used to establish an invention's therapeutic utility." *In re '318*, 583 F.3d at 1326.

proffered to establish utility were not described in the patent specification; rather, they were post-hoc arguments made in litigation, and therefore insufficient to establish utility at the time of the application. *Id.*

In *Rasmusson*, the Federal Circuit upheld the Board of Patent Appeals and Interferences' determination that a patent for the use of finasteride to treat prostate cancer was invalid for lack of utility. 413 F.3d at 1322. The applicant had argued that "a person of ordinary skill in the art at the time of his applications would have believed that administering a therapeutically effective amount of finasteride could be used for treating human prostate cancer," and that as a result, "he did not need to provide any data to demonstrate the efficacy of finasteride." *Id.* at 1323. The Federal Circuit disagreed. It upheld the Board's finding that a person of ordinary skill in the art would not have believed that finasteride was effective in treating prostate cancer. *Id.* at 1324 ("Based on scientific articles and expert testimony from both parties, the Board found that a person of ordinary skill in the art as of [the filing date] would not have concluded that a selective 5αR inhibitor [such as finasteride] would have any anti-tumor effects, because the anti-tumor effects shown by published experiments involving multi-active 5αR inhibitors could be attributable to contaminating activities having no relation to 5αR inhibition."). Therefore, the court held, the applicant needed to present evidence as to the utility of the claimed invention. *Id.* at 1323 ("[W]here there is no indication that one skilled in the art would accept without question statements as to the effects of the claimed drug products and no evidence has been presented to demonstrate that the claimed products do have those effects, an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement.") (citation omitted).

The applicant in *Rasmusson* argued that "the enablement requirement of section 112 does not mandate a showing of utility or, if it does, it mandates only a showing that it is 'not

implausible' that the invention will work for its intended purpose." *Id.* at 1325. The Federal Circuit rejected this argument, too:

> [W]e have required a greater measure of proof, and for good reason. If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.

*Id.*

Considered together, *In re '318* and *Rasmusson* instruct that a medical patent whose utility is not immediately apparent to a person of ordinary skill in the art demands a measure of proof. Such proof typically requires experimental results but may, in the rare case, be accomplished by analytical reasoning. The '948 patent, critically, fails these requirements. It is not supported by experimental results—whether human, animal, or in vitro. The closest thing to "results" is the Polen letter, attached to the '710 application, describing three patients who apparently benefited from the administration of the composition. But, as noted, the outcomes described in that letter hardly constitute experimental results; consequently, plaintiffs have not even attempted to rely on the Polen letter. *See supra* n.8. That leaves plaintiffs only two possible methods of support: belief in the patent's efficacy by a person of ordinary skill in the art, or analytical reasoning. However, as discussed *infra*, plaintiffs only halfheartedly argue that the patent can be sustained on either ground.

Instead, plaintiffs attempt to distinguish *In re '318* and *Rasmusson* from their case.

First, they argue that the enablement requirement demands only that a person of ordinary skill in the art be able to make or use the invention based on the disclosures in the patent without undue experimentation. Pl. Br. 11, 15–18. Although that is clearly one of the requirements of

enablement, *In re '318* and *Rasmusson* underscore that it is not the only such requirement. Plaintiffs do not cite any contrary caselaw.

Second, plaintiffs argue that, because "'[a]n inventor need not know the why of the scientific and technological principles underlying an invention,'" it was sufficient for the '948 patent to disclose simply that the invention *works*, without explaining *why* it works. Pl. Br. 4 (quoting *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428 (1911) and citing *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1341 (Fed. Cir. 1991) (Newman, J., dissenting). Plaintiffs are incorrect. An applicant's bald assertion that his or her invention "works," unsupported by data or reasoning, is insufficient. Otherwise, the rule of *In re '318* and *Rasmusson* could be defeated by rote conclusory language in every patent.[10]

Third, plaintiffs insist that the '948 patent does provide "data," because "numerous therapeutic effects are disclosed as having been 'found' by the inventors." Pl. Br. 12. But the statement that a result has been "found" is a conclusion, not data. *See* Merriam-Webster's Dictionary, www.merriam-webster.com (defining "conclusion" as "a final decision or judgment: an opinion or decision that is formed after a period of thought or research"; defining "data" as "factual information . . . used as a basis for reasoning, discussion, or calculation"). Plaintiffs' argument would allow patent applicants to evade the requirements of *In re '318* and *Rasmusson* simply by asserting that they have "found" certain results.

Fourth, plaintiffs attempt to distinguish *In re '318* and *Rasmusson* on the grounds that the chemical compositions at issue in those cases were not novel, unlike the '948 patent, which

[10] To be sure, the law does not require that scientifically valid results be ignored merely because the causes of those results remain shrouded in mystery. *Cf. CreAgri*, 2013 WL 6673676 at *21 ("[A]lthough a patentee need not generally know how or why the invention works, such explanations do become necessary where, as here, the inventor did not know at the time of filing whether the invention was in fact operable.") (citation omitted). But that is not the circumstance here.

creates a novel composition out of known compounds. Pl. Br. 18–19. But the core principle of those cases—that an application to patent a chemical composition for use in human treatment must include supporting data unless a person with ordinary skill in the art would accept the allegations as obviously correct—applies equally to new or synergistic combinations of known chemical compounds as it does to known combinations. *See also Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1365 (Fed. Cir. 2011) ("The test for written description is the same whether the claim is to a novel compound or a novel combination of known elements."). Plaintiffs do not point to language in *In re '318* or *Rasmusson* that supports such a distinction, nor do they explain why such a distinction is logically persuasive. And plaintiffs' proposal would enable an applicant to evade the ordinary requirements of enablement by simply combining an active ingredient, without any supporting data as to utility, with an anodyne flavor-enhancer.

Fifth, plaintiffs contend that, "although the claims in [*In re '318* and *Rasmusson*] were specifically drawn to *methods* for treating specific claimed conditions, none of the patent specifications in those cases described any such method," whereas the '948 patent specifications "explicitly describe the compositions and clearly state the inventors had demonstrated that they had the disclosed therapeutic effects." Pl. Br. 19–20. The import of this argument is unclear. To the extent plaintiffs suggest that the patents in *In re '318* and *Rasmusson* failed because they did not sufficiently describe *how* the claimed compounds should be administered, or, perhaps, the precise dosage or composition of the treatment, they misread those cases. In fact, those decisions turned on the applicants' failure to explain *why* the claimed compounds would be useful for the claimed purpose. Alternatively, to the extent plaintiffs suggest that the '948 patent is directed to a composition, not a use, their argument is belied by the plain text of the patent: it

claims "[a] nutritional composition for the treatment of connective tissue in mammals." '948 patent at col. 4 ll. 54–55; *see also In re Gardner*, 427 F.2d 786, 788 (CCPA 1970) ("[B]y claiming pharmaceutical compositions 'having antidepressant activity' and methods 'of producing antidepressant activity' which consist in administering the compounds, [applicants] are claiming in terms of use" and must "disclose how to use, as section 112 ordains.").

Sixth, plaintiffs attempt to distinguish *In re '318* and *Rasmusson* on the grounds that, in those cases, "the claims were based on pure speculation," and that "neither the specification nor the prior art provided any indication that the compound recited in the claims would actually be effective for the treatment of the condition recited." Pl. Br. 20. But plaintiffs do not explain why the benefits claimed by the '948 patent are any less speculative, apart from the fact that the prior art had revealed that combinations of subsets of its ingredients were effective in treating connective tissue. *See Merck*, 874 F.2d at 808 ("[W]hen an inventor tries to distinguish his claims from the prior art by introducing evidence of unexpected 'synergistic' properties, the evidence should at least demonstrate 'an effect greater than the sum of the several effects taken separately.'") (quoting *Sakraida*, 425 U.S. at 282).

Plaintiffs' brief may also be read to assert that, at summary judgment, the Court cannot conclude that a person of ordinary skill in the art would not have recognized that the claimed composition would be therapeutically effective.[11] *See* Pl. Br. 21–22 ("Defendants have simply presented no evidence that a person of ordinary skill in the art at the original filing date would not have immediately recognized, upon reading the original specification, that the claimed composition would be therapeutically effective for the treatment of connective tissue.

[11] Plaintiffs never expressly argue, *in haec verba*, that a person of ordinary skill *would* have recognized the effectiveness of the claimed composition. *See* Pl. Br. 21–22; Tr. 40. That may be because they wished to avoid conceding that the '948 patent is invalid as obvious. *See* Tr. 12–13, 30, 33.

Consequently, there remain material fact issues regarding the sufficiency of the disclosures of the Specifications, clearly precluding summary judgment."); Tr. 40 ("But let's just assume that we have to get to that question, whether one of ordinary skill in the art would accept it as obviously true. Okay? Again, it's a fact issue. All the cases that they cited say it's a fact issue.").

But this argument too relies on speculation. Plaintiffs have not concretely explained why a person of ordinary skill in the art would have recognized the utility of the claimed composition. Plaintiffs do not, for example, explain what relevant knowledge about treatment of connective tissue a person of ordinary skill would have brought to bear; nor do they explain concretely what additional insight such a person would have gained upon reading the specification. Plaintiffs do not explain why a person of ordinary skill would have regarded the composition as described as useful. Instead, plaintiffs essentially state that such a person should defer to the application's conclusory claim that this is so. Plaintiffs have failed to establish a genuine issue of material fact.[12] *See* Fed. R. Civ. P. 56(c)(1) (to survive summary judgment motion, opposing party must

[12] The expert report of Daniel T. Johnston does not address defendants' utility argument. *See* Johnston Decl. ¶ 12 ("I have been informed that the test for enablement is whether a person skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation."). Because defendants also made their utility argument under the heading of written description, the Johnston Declaration's statements about written description could be read, generously, to touch on utility. To the extent any of Johnston's statements can be so read, those statements are conclusory and no more than repetitions of counsel's argument; they therefore fail to defeat summary judgment. *See id.* ¶ 4 ("It is my opinion that, based on a reading of the original application's specification, without a doubt, one of ordinary skill in the art would understand that the inventors had in their possession, as of the filing date of the application, a 'a [sic] nutritional composition for the treatment of connective tissue in mammals comprising: a therapeutically effective amount . . . .' As discussed below, the original specification is replete with teachings regarding such compositions, for both oral and injectable administrations, and regarding the many therapeutic effects of such compositions."); *id.* ¶ 17 ("[T]he inventors disclosed that they has [sic] 'found' that the disclosed competition had those effects. In my opinion, a person of ordinary skill would view that as a disclosure of actual results. In my opinion, this further conveyed to a person of ordinary skill at the time that the inventors were in possession of [sic] composition that was therapeutically effective."); *id.* ¶ 21 ("In summary, the original '710 specification discloses numerous therapeutic effects that had

establish a genuine issue of fact by "citing to particular parts of materials in the record."); *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) ("A party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment.") (citation omitted); *CreAgri*, 2013 WL 6673676, at *19 ("[E]ven if it could consider the results at issue, the Court would not conclude that the results create an issue of fact as to whether persons of ordinary skill in the art would accept without question the utility of the claimed treatment as of the filing date of the invention."); *see also In re '318*, 583 F.3d at 1326 ("Nor was there evidence that someone skilled in the art would infer galantamine's utility from the specification, even if such inferences could substitute for an explicit description of utility.").

As noted, the Federal Circuit has raised, without endorsing, the possibility "that in some circumstances utility may be established without testing the proposed treatment," but instead through "arguments or reasoning." *In re '318*, 583 F.3d at 1326; *see also CreAgri*, 2013 WL 6673676, at *20 (citing *In re '318* for proposition that "circumstances where analytic reasoning alone will demonstrate utility are likely to be rare," and noting that, as in *In re '318*, the applicant "points to no precedent in which such evidence was sufficient to satisfy utility and enablement"). Here, plaintiffs do not argue that the '948 patent should be the first to be upheld solely on the basis of analytical reasoning. And for good reason: The only reasoning in the '948 patent is the statement that collagen acts as a transporter for sodium hyaluronate and/or chondroitin sulfate. '948 patent at col. 4 ll. 43–48. That reasoning does not pertain to all four ingredients—rather,

---

been confirmed by the inventors, several example compositions, several preferred dosage ranges, and that the composition is for use in mammals. These detailed disclosures clearly conveyed to a person of ordinary skill at the time that the Petitos' [sic] had in their possession a 'nutritional composition for the treatment of connective tissue in mammals comprising: a therapeutically effective amount' of the recited ingredients."); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1310 (Fed. Cir. 2008) (a "conclusory expert declaration" is "not sufficient to raise a genuine issue of material fact"); *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997) ("an expert's report is not a talisman against summary judgment").

only to three—and it does nothing to distinguish the '948 patent from the prior art, which included the use of collagen with a variant of sodium hyaluronate and with chondroitin sulfate. *See* '948 patent at col. 1 ll. 20–28 (citing U.S. Pat. No. 4,837,024, which described a topical composition for wound healing that combined collagen with a variant of sodium hyaluronate); *id.* at col. 2 ll. 20–25 (citing a dietary supplement created by Richardson Labs, Inc. to reconstitute bone cartilage which combined collagen with chondroitin sulfate). Put differently, the analytical reasoning here, such as it is, does no more than hypothesize why the prior art is effective. There is no reasoning to explain why the claimed invention should or would have a further synergistic effect. *See Merck*, 874 F.2d at 808 ("[W]hen an inventor tries to distinguish his claims from the prior art by introducing evidence of unexpected 'synergistic' properties, the evidence should at least demonstrate 'an effect greater than the sum of the several effects taken separately.'") (quoting *Sakraida*, 425 U.S. at 282).

In the end, plaintiffs' arguments amount to little more than an attempt to distract this Court from binding precedent and from the silence of the '948 patent as to the utility of the claimed invention. Plaintiffs have raised no genuine issue of material fact as to this point, and no reasonable jury could conclude that the '948 patent meets the utility requirement. Summary judgment is, therefore, granted to defendants on this ground.

**B. Written Description**

Defendants separately argue that the '948 patent's failure to substantiate its effectiveness causes it to fail the written description requirement.

The written description requirement arises out of § 112, which states that a patent "specification shall contain a written description of the invention." *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) ("Since its inception, this court has

consistently held that § 112, first paragraph, contains a written description requirement separate from enablement."). It requires that a patent specification "describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Id.* The sufficiency of the written description is a question of fact that can be resolved on summary judgment. *PowerOasis*, 522 F.3d at 1307.

"[T]he purpose of the written description requirement is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *Ariad*, 598 F.3d at 1352 (citation omitted). A "specification fails to meet the written description requirement" when it describes "only a generic invention that it purports to claim." *Id*. at 1350. The written description requirement therefore prevents an applicant from patenting a broader set of items than he or she actually invented or discovered. *See id.* at 1349–50 ("[A]n adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries. . . . [A] sufficient description of a genus instead requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus.").

The written description requirement overlaps, to some degree, with the enablement requirement. Indeed, the Federal Circuit has stated that "[p]erhaps there is little difference in some fields between describing an invention and enabling one to make and use it," and that "written description and enablement often rise and fall together." *Id.* at 1352. At the same time, the written description requirement retains independent force, because "requiring a written description of the invention plays a vital role in curtailing claims that do not require undue

experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described." *Id.*

Defendants here do not assail the patent's written description for failure, for example, to adequately describe the invention's ingredients or their concentrations.[13] Instead, defendants argue that the patent fails the written description requirement for much the same reason as it fails the utility requirement: it states insufficient evidence of its efficacy.[14] Defendants essentially contend that, because the written description requirement demands a description of an *invention*, a written description that does not disclose an actual invention, but only a "wish or plan for obtaining the claimed invention," *see Boston Scientific*, 647 F.3d at 1362 (citation omitted), fails the written description requirement. *See* Def. Br. 11; Def. Reply Br. 3. On this reasoning, of course, an invention that failed for lack of utility would almost always fail, too, for lack of written description, because the absence of utility would equate to the absence of an invention.

The case law does support that where an invention fails the utility requirement, it often will fail the written description requirement. *See Boston Scientific*, 647 F.3d at 1362 ("A mere wish or plan for obtaining the claimed invention is not adequate written description.") (citation omitted); *Ariad*, 598 F.3d at 1351 (written description requires that a patent specification "must

---

[13] Tr. 7–8 ("THE COURT: Suppose the patent had gotten a little more specific and had pinned down a precise ratio or a precise amount. Would that be enough? MR. LIEBERMAN: No. And let me explain why. . . I don't think the problem with the patent is the broad ranges. . . . I don't think the problem is that each of the four ingredients is not defined in a way that one could find it, for example, in a chemical supply store.").

[14] *See, e.g.*, Tr. 8–9 ("The problem is that the claim is that this combination is therapeutically effective to treat connective tissue, and there is no proof, no evidence, no data, no basis upon which a person could conclude that it really is effective to do that. . . . But if I don't have experiments, if I don't have data . . . then it doesn't satisfy the utility requirement and it also doesn't satisfy the written description requirement."); Tr. 22 ("Utility is: Is there sufficient proof that this thing is useful. . . . And written description is . . . does the specification, the four corners of the specification, prove that the inventors had actually invented something."); *see also* Def. Reply Br. 1–9 (making essentially identical arguments in written description and utility portions of brief).

describe an invention understandable to that skilled artisan and show that the inventor *actually invented* the invention claimed") (emphasis added); *cf. Rasmusson*, 413 F.3d at 1325 (statute requires that "the inventor enable an *invention* rather than merely proposing an unproved hypothesis") (emphasis added). And here, plaintiffs' failure to satisfy the utility requirement is so stark—there is literally no data cited in the Petitos' application for the '948 patent to substantiate their claim that the combination of four independently effective existing ingredients adds synergistic efficacy—that the Court has no difficulty concluding that the written description requirement, too, has not been satisfied. The patent is, therefore, invalid under the written description requirement.

**CONCLUSION**

For the foregoing reasons, the '948 patent fails the utility requirement of §§ 101 and 112. Defendants' motion for summary judgment as to invalidity is granted. The Court therefore need not need address defendant's second ground for seeking summary judgment, to wit, that the '948 patent is not entitled to an earlier filing date. Dkt. 33.

The Clerk is respectfully directed to terminate all pending motions, and to close this case.

SO ORDERED.

Paul A. Engelmayer

Paul A. Engelmayer
United States District Judge

Dated: July 31, 2014
New York, New York