

1 meet the written description, enablement, and utility requirements of 35 U.S.C. §§ 101 and 112(a).
2 Because the Court concludes that all claims of the patents-in-suit are invalid, the Court does not
3 reach the issues raised in CreAgri’s Motion for Summary Judgment of Infringement or Pinnaclife’s
4 Motion for Summary Judgment of Noninfringement.

5 **I. BACKGROUND**

6 **A. Factual Background**

7 CreAgri and Pinnaclife both sell products, including dietary supplements, containing olive-
8 derived phenolic compounds intended to promote health. Pl. Opp. at 2.² Olives naturally contain
9 the phenolic compounds oleuropein, hydroxytyrosol, and tyrosol. ’808 Patent 2:9–30. Olive oil is a
10 principal fat component of the Mediterranean diet, which has been linked to a lower incidence of
11 certain ailments, such as coronary heart disease and some cancers. *Id.* 2:9–14. Massive amounts of
12 “waste water” or “vegetation water” are produced as a byproduct of olive oil production.

13 Discarding this water creates a significant economic burden for olive oil mills. *See* Francesco
14 Visioli, et al., 47 *Antioxidant and Other Biological Activities of Olive Mill Waste Waters*, J. Agric.
15 Food Chem., 3397–3401 (1999), *available at* Marshall Decl. Ex. D, ECF No. 103-2. Because of
16 the known health benefits of olives and olive extracts, efforts have been made to leverage olive
17 mill vegetation water for therapeutic uses, rather than simply discarding it as waste. CreAgri has
18 secured, and now asserts, two patents over certain compositions of phenols derived from this waste
19 water and uses thereof. ’808 Patent; ’599 Patent.

20 The ’808 Patent, entitled “Method of Obtaining a Hydroxytyrosol-Rich Composition from
21 Vegetation Water,” claims, despite its title, *compositions* of olive-derived dietary supplements
22 containing hydroxytyrosol and oleuropein or hydroxytyrosol and tyrosol at certain weight ratios.
23 *See* ’808 Patent at 3:43–51. The ’808 Patent contains two independent claims and four dependent
24 claims, all of which CreAgri asserts in this case. Independent claim 1 recites a range of
25 hydroxytyrosol-to-oleuropein weight ratios and reads as follows:

26 A dietary supplement comprising an aqueous extract of olives containing a weight ratio of
27 hydroxytyrosol to oleuropein of between about 5:1 and about 200:1.

28 ² Phenolic compounds are compounds with one or more phenyl (-C₆H₅OH) groups. Def. MSJ at 2.
A compound with more than one phenyl group is a polyphenol.

1 Claims 2 through 4 depend from claim 1. Claim 2 recites a narrower range of hydroxytyrosol-to-
2 oleuropein weight ratios. Claim 3 recites a dried supplement in powder form, and claim 4 recites
3 an extract “in the form of a tablet, capsule, pill, or confection food additive.” Independent claim 5
4 is similar to claim 1 except that it recites a range of hydroxytyrosol-to-tyrosol weight ratios:

5 A dietary supplement comprising an aqueous extract of olives containing a weight ratio of
6 hydroxytyrosol to tyrosol of between about 3:1 and about 50:1.

7 Dependent claim 6 recites a narrower range of hydroxytyrosol-to-tyrosol weight ratios. CreAgri
8 filed the '808 Patent on August 31, 2001, and the Patent issued on July 9, 2002. *Id.*

9 The '599 Patent, entitled “Method for Treatment of Inflammation,” relates to using olive
10 plant extracts to “treat[] AIDS-associated neurological disorders, inflammation and inflammation-
11 associated disorders.” '599 Patent 1:10–14 (“Field of the Invention”). The claims recite methods
12 for treating specified inflammatory conditions with various mixtures of hydroxytyrosol or
13 hydroxytyrosol and oleuropein. *See* '599 Patent. The '599 Patent contains two independent claims
14 and fourteen dependent claims. The first independent claim, claim 1, reads as follows:

15 A method of treating a subject having an inflammatory condition characterized by a
16 detectable clinical symptom or change in a level of a biochemical marker with respect to
17 the normal range of the marker, the method comprising:

18 administering to the subject a dose corresponding to between about 0.1 mg/kg body
19 weight and 2000 mg/kg body weight daily of a first treatment agent comprised of an
20 olive plant extract having a weight ratio of hydroxytyrosol to oleuropein of between
21 about 1:1 and about 200:1; and

22 continuing said administration until there is observed a return of the marker level to the
23 normal range or a desired change in the clinical symptom,

24 where the marker or the clinical symptom is selected from the group consisting of

25 (i) elevated levels of C-reactive protein in the case of coronary inflammation;

26 (ii) respiratory distress in the case of bronchial inflammation; and

27 (iii) elevated CSF levels of isoprostanes or clinical symptoms determined from
28 neuropsychological testing in the case of neuro inflammation.

29 All fourteen of the dependent claims depend from claim 1. The other independent claim, claim 16,
30 uses a slightly different therapy—substantially purified hydroxytyrosol and oleuropein—to treat a
31 broader set of conditions:

32 A method of treating an inflammatory condition in a subject in need of such treatment,
33 comprising administering to said subject a dosage amount corresponding to between about
34 0.1 mg/kg body weight and 2000 mg/kg body weight daily of substantially purified
35 hydroxytyrosol or a substantially purified mixture of hydroxytyrosol and oleuropein,
36 wherein said inflammatory condition is in response to a condition selected from the group

1 consisting of: delayed type hypersensitivity reaction, psoriasis, an autoimmune disease,
2 organ transplant, pain, fever, and tissue graft rejection.

3 CreAgri filed the '599 Patent on February 13, 2003, and, following a long prosecution history, the
4 Patent issued on July 10, 2012. '599 Patent.

5 **B. Procedural Background**

6 CreAgri filed its Complaint on December 23, 2011, alleging that Pinnaclife's olive-derived
7 supplements infringe the '808 Patent. ECF No. 1. Following a first amendment and a successful
8 Motion to Dismiss some of CreAgri's claims, *see* ECF Nos. 27, 46, CreAgri filed its operative
9 complaint on January 1, 2013, alleging infringements of both the '808 and '599 Patents. *See* ECF
10 No. 50. In its answer, Pinnaclife included counterclaims seeking declaratory judgments of
11 invalidity and noninfringement of the '808 and '599 Patents, as well as a declaratory judgment that
12 the '808 Patent was unenforceable due to inequitable conduct. *See* ECF No. 55. The Court issued
13 an order construing the disputed claims of the Patents on April 16, 2013. ECF No. 67 ("Claim
14 Construction Order"). Pinnaclife now moves for summary judgment on invalidity and
15 noninfringement and CreAgri moves for summary judgment of infringement.

16 **II. LEGAL STANDARD**

17 **A. Summary Judgment**

18 Summary judgment is appropriate if, viewing the evidence and drawing all reasonable
19 inferences in the light most favorable to the nonmoving party, there are no genuine disputed issues
20 of material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a);
21 *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). At the summary judgment stage, the Court
22 "does not assess credibility or weigh the evidence, but simply determines whether there is a
23 genuine factual issue for trial." *House v. Bell*, 547 U.S. 518, 559–60 (2006). A fact is "material" if
24 it "might affect the outcome of the suit under the governing law," and a dispute as to a material fact
25 is "genuine" if there is sufficient evidence for a reasonable trier of fact to decide in favor of the
26 nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Mere conclusory,
27 speculative testimony in affidavits and moving papers is insufficient to raise genuine issues of fact
28 and defeat summary judgment. *See Thornhill Publ'g Co. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir.
1979).

1 The moving party bears the initial burden of identifying those portions of the pleadings,
2 discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex*
3 *Corp.*, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial, it
4 must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving
5 party, but on an issue for which the opposing party will have the burden of proof at trial, the party
6 moving for summary judgment need only point out “that there is an absence of evidence to support
7 the nonmoving party’s case.” *Id.* at 325; accord *Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978,
8 984 (9th Cir. 2007). Once the moving party meets its initial burden, the nonmoving party must set
9 forth, by affidavit or as otherwise provided in Rule 56, “specific facts showing that there is a
10 genuine issue for trial.” *Liberty Lobby*, 477 U.S. at 250 (internal quotation marks omitted). If the
11 nonmoving party’s “evidence is merely colorable, or is not significantly probative, summary
12 judgment may be granted.” *Id.* at 249–50 (internal citations omitted).

13 **B. Invalidity**

14 Patents are presumed to be valid. 35 U.S.C. § 282(a). A party challenging the validity of a
15 patent bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v.*
16 *i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011). The parties dispute the effect of various PTO
17 proceedings on the applicable standard of proof. However, as explained in more detail below,
18 nothing about the initial PTO examination of the patents-in-suit or certain reexamination
19 proceedings regarding the ’808 Patent changes the presumption of validity in this case. *Microsoft*
20 *Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2250 (2011) (“Nothing in § 282’s text suggests that
21 Congress meant to depart from that understanding to enact a standard of proof that would rise and
22 fall with the facts of each case.”).

23 **III. THE ’808 PATENT**

24 Pinnaclife contends that all claims of the ’808 Patent are invalid as anticipated under 35
25 U.S.C. § 102 or obvious under 35 U.S.C. § 103. In particular, Pinnaclife directs the Court to U.S.
26 Patent No. 6,358,542 (“Cuomo”) and an article entitled “Polyphenolic Content in Five Tuscany
27 Cultivars of *Olea europaea* L.” (“Romani”) as invalidating prior art. The Court finds that all
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1 claims of the '808 Patent are invalid as anticipated by Cuomo, Romani, or both, and therefore the
2 Court GRANTS Pinnaclife's Motion for Summary Judgment of Invalidity as to the '808 Patent.

3 A patent claim is invalid for anticipation if, among other reasons, "the invention was . . .
4 described in a printed publication in this or a foreign country . . . , more than one year prior to the
5 date of the application for patent in the United States," 35 U.S.C. § 102(b) (2006), or "the invention
6 was described in . . . a patent granted on an application for patent by another filed in the United
7 States before the invention by the applicant for patent," *id.* § 102(e) (2006).³ A claim is anticipated
8 under § 102, and thus invalid, "if each and every limitation is found either expressly or inherently
9 in a single prior art reference." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368,
10 1374 (Fed. Cir. 2001) (internal quotation marks and citation omitted); *accord Eli Lilly & Co. v.*
11 *Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1375 (Fed. Cir. 2006). Put simply, "[t]hat which
12 infringes, if later, would anticipate, if earlier." *Peters v. Active Mfg.*, 129 U.S. 530, 537 (1889)
13 (internal quotation mark omitted).

14 Anticipation under § 102 is a two-step inquiry. *See Medichem, S.A. v. Rolabo, S.L.*, 353
15 F.3d 928, 933 (Fed. Cir. 2003). The first step is claim construction. *Id.*; *see Amazon.com, Inc. v.*
16 *Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("claim must be construed
17 before determining its validity just as it is first construed before deciding infringement." (quoting
18 *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 996 n.7 (Fed. Cir. 1995) (Mayer, J.,
19 concurring), *aff'd*, 517 U.S. 370 (1996)). The second step is a comparison of the properly construed
20 claim to the prior art. *Medichem*, 353 F.3d at 933.

21 The Court previously construed the claims in its claim construction order. *See* ECF No. 67
22 at 40. As relevant here, the Court construed the following terms of the '808 Patent:

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26
27 ³ On September 16, 2011, the America Invents Act was enacted into law. *See* Pub. L. 112-29, 125
28 Stat. 285 ("AIA"). The AIA fundamentally changes the rules of invalidity under 35 U.S.C. § 102.
See id. at § 3(b)(1). The application for the '808 Patent, however, was filed before the effective
date of the AIA, and therefore the prior version of § 102 applies. *See id.* at § 3(n).

Claim Language	Construction
“comprising” or “comprised of”	“including but not limited to”
the preamble “a dietary supplement” in Claims 1 and 5 of the ’808 Patent	the preamble “a dietary supplement” in Claims 1 and 5 of the ’808 Patent is not a claim limitation.
weight ratios claimed in the ’808 Patent	the claimed weight ratios in Claims 1 and 5 of the ’808 Patent apply to the “aqueous extract of olives,” not to the “dietary supplement.”
“aqueous extract of olives”	“an aqueous solution containing a water-soluble preparation from an olive plant,” with no restriction on the process by which the “aqueous solution” is obtained.

A. Significance of the PTO Final Office Action

The ’808 Patent is currently under reexamination before the PTO in *Ex Parte* Reexamination of U.S. Patent No. 6,416,808. As part of that reexamination, and after the summary judgment briefing in this case concluded, the PTO rejected all the claims of the ’808 Patent in a Final Office Action. *See* ECF No. 140. The PTO examiner found claims 1-5 anticipated by Cuomo and claim 6 obvious in light of Cuomo. *Id.* The examiner further concluded that claims 1 and 4-6 were anticipated by Romani; that claim 2 was obvious in light of Romani; and that claims 3 and 4 were obvious in light of Romani in view of Cuomo. *Id.* Cuomo and Romani are the same prior art references that Pinnacliffe has asserted against the ’808 Patent in this case. In their briefs, the parties debate the significance of an earlier non-final action in the same reexamination as it pertains to the present motion. This debate applies to the recently issued Final Office Action as well. For the following reasons, the Court determines that neither the Final Office Action nor the non-final action is due deference, and thus the Court conducts an independent review of the parties’ invalidity arguments.

As stated above, a patent is presumed valid in litigation. 35 U.S.C. § 282. In a reexamination, however, there is no such presumption. *In re Swanson*, 540 F.3d 1368, 1377 (Fed. Cir. 2008). The difference in standard of proof significantly reduces the relevance of the PTO’s conclusions. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1428 (Fed. Cir. 1988) (“The two forums

1 take different approaches in determining invalidity and on the same evidence could quite correctly
2 come to different conclusions.”). At least one other court has found that “the examiners’
3 conclusions on reexamination are not relevant to the merits” of a summary judgment motion.
4 *Sigram Schindler Beteiligungsgesellschaft mbH v. Cisco Sys., Inc.*, 726 F. Supp. 2d 396, 415 (D.
5 Del. 2010). Another court has struck evidence of reexamination proceedings from consideration at
6 summary judgment, and the Federal Circuit has ruled that such evidence should be kept from a
7 jury. *Tesco Corp. v. Weatherford Int’l Inc.*, 750 F. Supp. 2d 780, 793–94 (S.D. Tex. 2010)
8 (granting a motion to strike evidence of reexamination proceedings with respect to invalidity);
9 *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1343 (Fed. Cir. 2009).

10 Moreover, although the PTO office action is final, CreAgri still may file a response to the
11 examiner that may result in the PTO’s withdrawal of its invalidity conclusion. *See* 37 C.F.R.
12 § 1.116. CreAgri also may appeal the PTO’s decision to the Patent Trial and Appeal Board
13 (“PTAB”), *see* 35 U.S.C. § 134(b), and, from there, may appeal any adverse PTAB decision to the
14 Federal Circuit, *see* 35 U.S.C. § 141. The PTO will issue a certification canceling any claims of the
15 ’808 Patent determined to be unpatentable only after the time for appeal has expired or any appeal
16 proceeding has terminated. *See* 35 U.S.C. § 307(a). Thus, the PTO’s conclusions are “final” in
17 name only; the PTO’s adverse decisions are still subject to substantial review. Therefore, the Court
18 reviews Pinnaclife’s invalidity contentions without regard to the PTO’s office actions.

19 **B. Anticipation by Cuomo**

20 Pinnaclife contends that Cuomo anticipates claims 1-5 of the ’808 Patent. *See* Def. MSJ at
21 9–12. Claims 1, 2, and 5 of the ’808 Patent all claim a dietary supplement by way of two
22 limitations: (1) an “aqueous extract of olives,” with (2) a weight ratio range of either
23 hydroxytyrosol to oleuropein (claims 1 and 2) or hydroxytyrosol to tyrosol (claim 5). Claims 3
24 and 4, which depend from claim 1, each recite an additional limitation concerning the supplement
25 form. Claim 3 requires a supplement that is “dried to provide a powder extract,” and claim 4 recites
26 a supplement that contains an extract “in the form of a tablet, capsule, pill, or confection food
27 product.” *Id.*
28

1 CreAgri does not contest that Cuomo discloses the weight ratio ranges in claims 1-5 of the
 2 '808 Patent,⁴ nor does it contest that Cuomo discloses the additional limitations on supplement
 3 forms in claims 3 and 4.⁵ As shown in the chart below, the parties' only dispute over whether
 4 Cuomo anticipates claims 1-5 of the '808 Patent centers on whether Cuomo discloses an "aqueous
 5 extract of olives."

Claim	Limitation	Parties' Positions
All	"an aqueous extract of olives"	<i>Disputed</i>
1, 3, 4	"containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1."	Disclosed by Cuomo
2	"a weight ratio of hydroxytyrosol to oleuropein of between about 10:1 and about 100:1."	
3	"supplement is dried to provide a powder extract."	
4	"extract is in the form of a tablet, capsule, pill, or confection food additive."	
5	"containing a weight ratio of hydroxytyrosol to tyrosol of between about 3:1 and about 50:1."	

16
 17 The Court is persuaded that no reasonable jury could conclude that Cuomo fails to clearly
 18 and convincingly disclose an "aqueous extract of olives." Accordingly, Pinnaclife is entitled to
 19 summary judgment that claims 1-5 of the '808 Patent are invalid as anticipated by Cuomo. Cuomo,
 20 which was filed prior to the filing date of the '808 Patent, discloses several "methods of extracting
 21 anti-oxidant compositions from olives and the by-products of olive oil production." Cuomo, at 1:8–
 22 10. Using several examples, Cuomo provides information about various compositions extracted by
 23 way of the disclosed methods. Example 4 of Cuomo describes a method for obtaining a solid
 24 antioxidant composition from an olive pulp. The procedure calls for washing the pulp with water (a
 25 polar aqueous solvent) to obtain a mixture containing the antioxidants, washing with methanol (a

26
 27 ⁴ Table 2 of Cuomo sets forth the percentage—by weight—of hydroxytyrosol, tyrosol, and
 oleuropein found in what the Court ultimately determines is an "aqueous extract of olives."
 Cuomo, at 14:38–52.

28 ⁵ Cuomo teaches using the extracted compositions in a nutritional supplement "in any convenient
 form, such as a powder, a tablet or a capsule." Cuomo, at 8:63–9:8.

1 polar organic solvent), freezing the resulting organic solution, and evaporating the methanol,
2 leaving a solid antioxidant composition. *Id.*, 10:63–11:6. At this point, the solid antioxidant
3 composition is not “an aqueous extract of olives” as that term was construed by the court because it
4 is dry.⁶ But Example 11 then describes taking the antioxidant composition from Example 4,
5 dissolving it in 80% aqueous methanol, treating it with hydrochloric acid, and analyzing the acid-
6 treated extract for antioxidant activity and phenolic content using a variety of techniques. *Id.*,
7 14:13–20.

8 The Court concludes that Example 11’s description of an 80% *aqueous* methanol solution
9 comprising the dissolved olive pulp from Example 4 plainly describes an “aqueous solution
10 containing a water-soluble preparation from an olive plant,” and therefore no reasonable jury could
11 conclude that the reference fails to disclose the “aqueous extract of olives” limitations of claims 1
12 through 5 of the ’808 Patent.

13 In contending otherwise, CreAgri argues that a liquid extract that includes methanol, such
14 as that disclosed in Example 11, cannot be an aqueous extract, even if that extract also includes
15 water. *See* Pl. Opp. at 6 (“[T]he ’808 Patent claims are [sic] directed towards ‘aqueous extracts’ are
16 not meant to encompass ‘aqueous-alcoholic extracts’ of the type that are discussed in Cuomo.”).
17 The Court disagrees.

18 At the outset, CreAgri’s argument is a new and untimely claim construction argument.
19 CreAgri now essentially asserts that the scope of “aqueous extract” is limited to pure water extracts
20 and therefore excludes aqueous-alcoholic extracts such as the 80% aqueous methanol extract of
21 Cuomo’s Example 11. But the Court held that an “aqueous extract of olives” is “an aqueous
22 solution containing a water-soluble preparation from an olive plant,” not, as CreAgri contends, that
23 an “aqueous extract” is pure water. Neither party asked for a construction of “aqueous extract” that
24 would exclude “aqueous-alcoholic” extracts. In fact, CreAgri proposed a broad construction of
25 “aqueous extract of olives” and in doing so relied on a broad dictionary definition of “aqueous”
26 that itself suggests “aqueous-alcoholic” extracts are merely a subset of “aqueous” extracts. *See*

27 _____
28 ⁶ During claim construction, CreAgri unsuccessfully sought a construction of “aqueous extract of
olives” that would have included a powdered extract, so long as it was derived from water. *See*
ECF No. 67 at 24.

1 ECF No. 47 at 10 (relying on “the McGraw-Hill Dictionary of Scientific and Technical Terms”
2 which “defines the word aqueous as something that is ‘relating to’ water.”). For its part, Pinnaclife
3 initially proposed a construction of “aqueous extract of olives” that would have resolved this issue
4 in CreAgri’s favor, contending in the parties’ Joint Claim Construction Chart that “[a]s used in the
5 ’808 patent, an ‘aqueous extract’ is *not* an ‘aqueous-alcoholic extract.’” ECF No. 43 at 3 (emphasis
6 added). Yet Pinnaclife, possibly realizing the impact on anticipation, withdrew this proposal, *see*
7 ECF No. 49 at 14 n.3, with no objection from CreAgri. CreAgri’s attempt to relitigate the
8 construction of “aqueous extract” at the summary judgment stage must be rejected.

9 Moreover, CreAgri’s new claim construction argument fails on the merits. The
10 specification of the ’808 Patent makes clear that the invention includes—rather than excludes—the
11 use of aqueous-alcoholic extracts. The following passage is key:

12 The hydroxytyrosol obtained by the method *of the invention* can be
13 administered orally or parenterally. Oral dosage forms can be in a solid or
14 liquid form. Such dosage forms can be formulated from purified
15 hydroxytyrosol or *they can be formulated from aqueous or aqueous-*
16 *alcoholic extracts*. Regarding the latter, aqueous or aqueous-alcoholic
17 (e.g., water-methanol or water-ethanol) extracts can be spray-dried to
18 provide a dry powder that can be formulated into oral dosage forms with
19 other pharmaceutically acceptable carriers. *The aqueous or aqueous-*
20 *alcoholic extracts* can be formulated to contain various weight ratios of
21 hydroxytyrosol to oleuropein of between 5:1 and 200:1, preferably
22 between about 10:1 and about 100:1. *The extracts* may also be formulated
23 to contain various weight ratios of hydroxytyrosol and tyrosol of between
24 about 3:1 and about 50:1, preferably between about 5:1 and about 30:1.

20 ’808 Patent at 7:41–56 (emphases added). In so describing the oral dosage forms “of the
21 invention,” this passage explains that forms can be “formulated from aqueous or aqueous-alcoholic
22 extracts.” ’808 Patent at 7:44–45. The passage then discloses that the aqueous or aqueous-alcoholic
23 extracts can contain the exact weight ratios claimed in the patent.

24 This passage provides strong evidence of the scope of the claims. More than merely a
25 preferred embodiment, this passage describes “the invention” as a whole. *See, e.g., Trading Techs.*
26 *Int’l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1353–54 (Fed. Cir. 2010) (concluding that specification’s
27 “reference to ‘the present invention’ strongly suggests” that the claim carries the same meaning).
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1 Thus, the “strong presumption against a claim construction that excludes a disclosed embodiment,”
2 *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011), applies
3 here with even more force. Because the patentee described the invention as being formulated from
4 aqueous-alcoholic extracts, this Court refuses to exclude aqueous-alcoholic extracts from the scope
5 of the “aqueous extract” claim language.

6 CreAgri contends that this passage favors its interpretation. According to CreAgri, because
7 the passage lists “aqueous or aqueous-alcoholic extracts,” in the disjunctive, an aqueous extract
8 must be different than an aqueous-alcoholic extract. The Court concludes that the specification’s
9 passing use of the disjunctive to connect overlapping adjectives is ambiguous at best. That
10 ambiguity is insufficient to exclude aqueous-alcoholic extracts from the scope of the invention
11 when the specification expressly states that aqueous-alcoholic extracts are included. Indeed, to
12 adopt CreAgri’s reading would be to improperly import a purported limitation—that an “aqueous
13 extract” excludes an “aqueous-alcoholic extract”—from the specification into the claims. *See*
14 *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc). Accordingly, to avoid any
15 doubt, the Court holds that its construction of “aqueous extract of olives” encompasses “aqueous-
16 alcoholic extracts.”

17 CreAgri makes a half-hearted argument that Cuomo still fails to disclose the claimed
18 “aqueous extract of olives,” even under a construction of an “aqueous extract of olives” that
19 includes “aqueous-alcoholic extracts.” CreAgri relies on a declaration from its expert, Dr. Bruce
20 German, to contend that an extract that includes methanol, such as that disclosed in Example 11,
21 cannot be an aqueous extract. *See* ECF No. 118-4 at 32–33 ¶ 65 (“German Decl.”). But Dr. German
22 fails even to acknowledge that Example 11 expressly analyzes an *aqueous* methanol solution for
23 phenolic content. Instead, Dr. German focuses on Cuomo’s Example 4, in which the phenols are
24 first contained in a pure methanol solution. Dr. German neglects to mention that in Example 11
25 those phenols are dissolved in an aqueous methanol solution, a solution that Cuomo elsewhere
26 expressly describes as a “polar *aqueous* solvent.” 6:50–52; *see id.* (“Most preferably, the polar
27 aqueous solvent is a mixture of water and methanol . . .”). Neither CreAgri nor its expert can
28 create an issue of fact by ignoring the most pertinent disclosure in the asserted prior art. On this

1 record, no reasonable jury could conclude that Example 11 fails to disclose an “aqueous extract of
2 olives” as the Court has construed the term.

3 Because CreAgri has failed to show that a genuine issue of fact exists as to whether Cuomo
4 discloses the claimed “aqueous extract of olives,” and because Cuomo by clear and convincing
5 evidence discloses all other limitations in claims 1-5 of the ’808 Patent, the Court concludes that
6 Pinnaclife is entitled to summary judgment of anticipation as to those claims.⁷

7 **C. Anticipation by Romani**

8 Pinnaclife separately contends that Romani anticipates claims 1, 2, 5, and 6 of the ’808
9 Patent. Def. MSJ at 13–15. Similar to claims 1, 2, and 5—discussed above with respect to
10 Cuomo—dependent claim 6 (together with its independent claim) covers a dietary supplement
11 comprising (1) an aqueous extract of olives with (2) a weight ratio of hydroxytyrosol and tyrosol of
12 between about 3:1 and about 30:1. As with Cuomo, the parties’ dispute over Romani centers on
13 whether Romani discloses the claimed “aqueous extract of olives.”

14 The Romani reference, published over a year before the filing date of the ’808 Patent,
15 discloses the polyphenolic content of five different cultivars of olive fruits from a coastal area in
16 Tuscany. According to the article, four of the five cultivars (Rossellino, Ciliegino, Cuoricino, and
17 Grossolana) had never before been analyzed. *See* Romani at 964, col. 2. Crucially, Romani reports
18 that the naturally occurring weight ratio of hydroxytyrosol to tyrosol in the Rossellino cultivar is
19 approximately 10:1, which falls within the range of weight ratios recited in claims 5 and 6 of the
20 ’808 Patent. *See id.* at Table 2. CreAgri does not dispute that Romani discloses the weight ratio
21 recited in claims 5 and 6 of the ’808 Patent. CreAgri also concedes that Romani discloses a
22 naturally occurring weight ratio of hydroxytyrosol to oleuropein in the Rossellino cultivar of 69:1,
23 which falls within the ranges set forth in claims 1 and 2 of the ’808 Patent. Pl. Opp. at 10. Again,
24 the Court provides a chart for simplicity.

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27 ⁷ Pinnaclife also contends that Cuomo anticipates or renders obvious claim 6 of the ’808 Patent.
28 Because the Court concludes that Pinnaclife is entitled to summary judgment that Romani
anticipates claim 6, it does not reach Pinnaclife’s contentions as to claim 6 and Cuomo.

Claim	Limitation	Parties' Positions
All	"an aqueous extract of olives"	<i>Disputed</i>
1	"containing a weight ratio of hydroxytyrosol to oleuropein of between about 5:1 and about 200:1."	Disclosed by Romani (Table 2)
2	"a weight ratio of hydroxytyrosol to oleuropein of between about 10:1 and about 100:1."	
5	"containing a weight ratio of hydroxytyrosol to tyrosol of between about 3:1 and about 50:1."	
6	"containing a weight ratio of hydroxytyrosol to tyrosol of between about 5:1 and about 30:1."	

The Court now turns to whether Romani discloses "an aqueous extract of olives." PinnacLife contends that, in reporting its procedure to analyze the polyphenolic compounds in the five different olive species, Romani describes an intermediate step in which the weight ratios of polyphenolic compounds claimed in the '808 Patent exist in an "aqueous solution." The Court concludes that no reasonable jury could find otherwise. In particular, Romani recounts a procedure in which the authors took olive pulps frozen in liquid nitrogen, ground them, and then used ethanol to extract the wanted polyphenols. Romani at 964, col. 2. The authors next concentrated the ethanolic extract and rinsed it with acid water to a final volume of 250 mL, forming what Romani itself calls an "aqueous solution." *Id.* Then, the aqueous solution was "defatted"—*i.e.*, the lipophilic compounds were removed—into a concentrated "aqueous phase" of 250 mL. *Id.* at 964 col. 2–965 col. 1. Both the "aqueous solution" and the defatted "aqueous phase" plainly constitute an "aqueous extract of olives" under the Court's claim construction.

CreAgri does not dispute that the expressly disclosed "aqueous solution" and "aqueous phase" compositions in Romani constitute an "aqueous extract of olives." Instead, CreAgri contends that the end result of the Romani process is not an "aqueous extract" because the authors ultimately analyzed the polyphenolic content of the olives using a "liquid-solid extraction" process that used two additional solvents—ethyl acetate and acid methanol—to create dry fractions from the aqueous solution. *See* Pl. Opp. at 9.

1 Taking CreAgri’s description of these later steps as true, the steps nevertheless fail to create
2 a material issue of fact as to whether the solution disclosed in Romani is an “aqueous extract of
3 olives.” Once again, CreAgri’s argument disregards this Court’s claim construction ruling. The
4 Court has already concluded that the construction of “aqueous extract of olives” is not tied to any
5 particular process, a construction that CreAgri wanted. *See* ECF No. 67 at 31–32. Accordingly,
6 Romani’s disclosure of an “aqueous solution” and “aqueous phase” is an express disclosure of the
7 “aqueous extract” limitation regardless of whether later steps in the extraction process reduce those
8 preparations to a solid. Romani does not suggest, and CreAgri does not contend, that the
9 polyphenolic profiles change depending on the phase of the described olive extracts. To the
10 contrary, Romani discloses using the dry fractions to determine the polyphenolic content of the
11 original olive. The premise of this procedure is that the intermediate steps in the measurement
12 process (during which the authors obtain the aqueous extract of olives) do not alter the
13 hydroxytyrosol, tyrosol, and oleuropein levels naturally found in the Rossellino cultivar, levels that
14 indisputably fall within the ratios stated in claims 1–2 and 56 of the ’808 Patent.

15 CreAgri also contends that Pinnaclife’s arguments with respect to Romani must meet an
16 “enhanced” burden of proof because “[t]he Romani reference was already cited to the PTO
17 during the initial prosecution of the ’808 patent.” Pl. Opp. at 8 (citing *Creative Compounds, LLC v.*
18 *Starmark Labs.*, 651 F.3d 1303, 1313 (Fed. Cir. 2011)). To the extent CreAgri is arguing that
19 Pinnaclife’s proof must be more than clear and convincing, the Federal Circuit has recently
20 rejected that argument. *See OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc.*, 701 F.3d 698, 705
21 (Fed. Cir. 2012) (“While prior consideration of a reference during prosecution may carry some
22 weight, the burden to prove invalidity does not change; at all times, it remains a showing ‘by clear
23 and convincing evidence.’”) (quoting *Microsoft Corp.*, 131 S. Ct. at 2242). Moreover, “[w]hether
24 the examiner actually considered this issue can only be determined by reviewing the prosecution
25 history.” *In re NTP, Inc.*, 654 F.3d 1268, 1278 (Fed. Cir. 2011). Yet there is no evidence from the
26 prosecution history that the examiner—or anyone at the PTO—ever considered Romani during
27 prosecution of the ’808 Patent. In fact, the title page of the ’808 Patent cites 22 references,
28 including 3 that were cited by the examiner, and Romani was not among any of them. The ’808

1 Patent specification also includes a “References” section. ’808 Patent at 1:16–64. This
2 “References” section does include Romani, as one of 24 unique references that do not appear on
3 the ’808 Patent’s title page.⁸ The only description of Romani in the entire ’808 Patent, however, is
4 in the specification’s citation of Romani—along with 2 other articles—to describe possible
5 “[a]dditional purification methods.” *Id.* at 7:23–27. Romani is never cited in the ’808 Patent’s
6 specification as containing any information on polyphenolic weight ratios. Therefore, the ’808
7 Patent provided no indication to the examiner that Romani discloses polyphenolic weight ratios:
8 Romani was cited in a list of 25 other “References” in the body of the specification, the ’808 Patent
9 only mentioned Romani later in the specification as being relevant for another purpose, and even
10 there Romani was second in a string cite of three references. As a result, it is unlikely the PTO
11 examiner ever considered Romani as a potentially invalidating reference. With the prosecution
12 history being devoid of any mention of Romani—at least until the patent examiner in the current
13 *Ex Parte* Reexamination found some of the ’808 Patent’s claims invalid as anticipated by
14 Romani⁹—the Court simply cannot draw an inference of validity in CreAgri’s favor sufficient to
15 overcome the plain anticipating disclosure of Romani.

16 In sum, Pinnaclife has established the absence of an issue of material fact as to the
17 anticipation of claims 1–2 and 5–6 of the ’808 Patent by the Romani reference.

18 As to the claim elements added in dependent claims 3 and 4, the parties agree that Romani
19 does not disclose these limitations. Pinnaclife makes a compelling argument that claims 3 and 4 are
20 obvious in light of Romani in view of Cuomo, but given that the Court found above that claims 3
21 and 4 are anticipated by Cuomo, the Court declines to reach Pinnaclife’s obviousness contention.

22 **D. Whether the ’808 Patent claims unpatentable natural phenomena under section**
23 **101**

24 Pinnaclife has also moved for summary judgment of invalidity on the grounds that the ’808
25 Patent claims natural phenomena and therefore is invalid under 35 U.S.C. § 101. As all claims of
26

27 ⁸ The ’808 Patent’s “References” section includes 25 total references: 24 unique references
including Romani, and one other reference that also appears on the title page.

28 ⁹ Note that, as discussed in Section II.A, the Court does not rely on the PTO decision here. The
Court draws its independent conclusions based on a review of the evidence in this case.

1 the '808 Patent are invalid under section 102 in light of either Cuomo or Romani, the Court
2 declines to address the parties' arguments as to section 101.

3 **IV. THE '599 PATENT**

4 The '599 Patent claims methods of treating a broad range of inflammatory conditions using
5 various forms of hydroxytyrosol. Pinnaclife challenges the validity of all claims of the '599 Patent
6 on written description, enablement, and utility grounds, contending that "the specification of the
7 '599 Patent does not support or enable the use of any hydroxytyrosol-rich composition to treat
8 inflammation conditions claimed because the specification provides no data whatsoever to support
9 the anti-inflammatory effects of the claimed olive-derived preparations." Def. MSJ at 19. The
10 Court is satisfied that Pinnaclife has met its burden to show the absence of a genuine dispute as to
11 any material issues for all three doctrines and therefore GRANTS Pinnaclife's Motion for
12 Summary Judgment of Invalidity as to the '599 Patent.

13 **A. The "Written Description" Requirement of Section 112**

14 **1. Applicable Law**

15 Under 35 U.S.C. § 112(a), a patent specification must contain "a written description of the
16 invention."¹⁰ Under this written description requirement, the specification "must clearly allow
17 persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad*
18 *Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (internal quotation
19 marks and alterations omitted). This test requires "an objective inquiry into the four corners of the
20 specification from the perspective of a person of ordinary skill in the art" to determine whether the
21 specification shows that "the inventor actually invented the invention claimed." *Id.* Although
22 "[c]ompliance with the written description requirement is a question of fact," it is, like most factual
23 questions, "amenable to summary judgment in cases where no reasonable fact finder could return a
24 verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307
25 (Fed. Cir. 2008).

26
27 ¹⁰ The passage of the AIA did not materially affect the written description, utility, or enablement
28 requirements. The AIA redesignated the provisions of section 112, such that what was previously
designated the first paragraph of section 112 is now designated section 112(a). *See* AIA § 4(c). For
convenience, the Court refers to the redesignated provision of section 112.

1 dosage levels is also broad. Both independent claims recite a dosage level for each respective
2 ailment ranging from about 0.1 mg/kg body weight to 2000 mg/kg body weight, meaning that, for
3 an average male of approximately 80 kg, the claimed treatment is effective for all conditions at a
4 daily dosage level anywhere from 8 mg to 160,000 mg. Various dependent claims narrow that daily
5 dosage to between about 0.3 mg/kg and 1 mg/kg (claim 10) and about 0.6 mg/kg (claim 11).

6 **a. The specification fails to show that Dr. Crea possessed the full scope of**
7 **the invention**

8 A person of ordinary skill in the art would be unable to conclude from the specification that
9 the inventor of the '599 Patent possessed the claimed invention.¹² Although the specification does
10 describe the compositions used by the claimed methods in some detail—including how to obtain
11 them from olive vegetation water—the specification repeatedly disclaims the novelty of obtaining
12 the compositions themselves. *See, e.g., id.* at 5:54–55 (“The olive-derived phenolic compounds
13 employed herein can be prepared by a number of methods known in the art.”). Instead, the
14 specification conclusively reveals that the inventor sought to claim a method of treating
15 inflammation based on no more than a hope that olive-derived compositions would one day be
16 used effectively to treat inflammation caused by a wide variety of factors. As the inventor himself
17 conceded during his deposition, this patent was filed with the anticipation that the compositions
18 could be used as claimed, but without data showing as much. *See* Marshall Decl. Ex. C at 174:7–23
19 (“Crea Dep.”), ECF No. 161-3 (“A: I learned early in my career that you can file patents, they are
20

21 ¹² The parties disagree as to the level of ordinary skill in the art. CreAgri’s expert, Dr. German,
22 expresses his preference for a relatively low level of skill, finding one having ordinary skill in the
23 art to be “someone with a bachelor’s degree or higher in Food Science or related Biological fields
24 related to diet and health and/or several years of experience in the life sciences research industry.”
25 German Decl. ¶ 28. In contrast, Pinnaclife’s expert, Dr. Visioli, asserts that one with ordinary skill
26 in the art has “a Ph.D. in the biological sciences, including biology, chemistry, biochemistry,
27 biotechnology, nutritional biology, food science, or a similar field, and at least 2 years of
28 experience studying phenolic compounds of olives and the health effects of the Mediterranean
diet.” Visioli Rep. ¶ 15. Without taking a position on the issue, the Court assumes for the purposes
of Pinnaclife’s Motion for Summary Judgment of Invalidity that CreAgri’s proposed lower level of
ordinary skill in the art applies. Because the specification provides no data—or even a study
design—as to most of the claimed treatments, the Court’s analysis on written description does not
turn on the parties’ debate over the level of ordinary skill in the art. Therefore, the Court finds all
claims of the '599 Patent invalid despite using CreAgri’s proposed lower level of ordinary skill in
the art.

1 prophetic. . . . Q: You anticipate that this would work? A: Right. Q: But you don't actually have the
2 data yet showing that it would work? A: Yeah. . . .”).

3 . The prophetic approach to patenting is not proper absent some indication that the named
4 inventor has “actually perform[ed] the difficult work of ‘invention’—that is, [he has] conceive[d]
5 of and complete[d] the final invention.” *Ariad*, 598 F.3d at 1351. A description that amounts “to no
6 more than a ‘wish’ or ‘plan’ for obtaining [the claimed invention]” fails the written description
7 requirement. *Id.* at 1350 (citing *Fiers v. Revel*, 984 F.2d 1164, 1170–71 (Fed. Cir. 1993)). Indeed,
8 very little of the ’599 Patent’s specification is directed to treating inflammation using olive-derived
9 phenols at all. Only about two-and-a-half columns of the nineteen-column specification discusses
10 inflammation. *See* ’599 Patent, 12:30–14:62 (subsection E, entitled “Treatment of Inflammation or
11 Inflammation-Associated Conditions”). Although the claims are directed to methods of treating
12 inflammations of various causes, the primary aspect discussed in the specification is “a method of
13 treating an AIDS-associated *neurological* disorder,” *id.* at 5:31–32 (emphasis added), and
14 “[a]dditional *neurological* diseases and disturbances contemplated for treatment by the method of
15 the invention,” *id.* at 10:23–24 (emphasis added). *See also id.* at 2:33–36 (“[I]t is an object of the
16 invention to provide, in one aspect, a method of treating an AIDS-associated neurological disorder
17 in a subject in need of such treatment.”); 8:1–63 (discussing HIV-1 Associated Dementia); *id.* at
18 8:64–9:12 (HIV-Associated Myelopathy); 9:13–9:46 (peripheral neuropathy, “a very common and
19 disabling problem encountered in HIV infection.”); 9:47–10:6 (Cytomegalovirus, “a frequent
20 secondary viral infection in AIDS patients”); 10:7–21 (Progressive Multifocal
21 Leukoencephalopathy, “a lethal secondary viral infection mostly occurring in AIDS patients with
22 advanced immunodeficiency”); *see also id.* at 11:44–12:29 (methods of biological testing AIDS-
23 associated neurological disorders).¹³

24 _____
25 ¹³ The ’599 Patent suggests that olive-derived phenols can also treat “Alzheimer’s disease;
26 Parkinson’s disease; motor neuron diseases such as amyotrophic lateral sclerosis (ALS),
27 Huntington’s disease and syringomyelia; ataxias, dementias; chorea; dystonia; dyslnesia;
28 encephalomyelopathy; parenchymatous cerebellar degeneration; Kennedy disease; Down
syndrome; progressive supranuclear palsy; DRPLA, stroke or ischemic injuries; thoracic outlet
syndrome, trauma; electrical brain injuries; decompression brain injuries; multiple sclerosis;
epilepsy; concussive or penetrating injuries of the brain or spinal cord; brain injuries due to
exposure of military hazards such as blast over-pressure, ionizing radiation, and genetic
neurological conditions.” 10:23–38.

1 Even the subsection in the specification discussing inflammation does not explain why the
2 inventor believed that olive-derived compositions were likely to treat any (much less all) the
3 claimed conditions. Instead, that subsection largely discusses inflammation and its various causes
4 generically and abstractly. *See id.* at 12:42–46 (“Typically, inflammation is a very localized
5 response that serves to expulse, attenuate by dilution, and isolate the damaging agent and injured
6 tissue. The body’s response becomes an agent of disease when it results in inappropriate injury to
7 host tissues . . .”). The specification acknowledges in this section that the “composition of this
8 invention depends on a variety of factors” and thus “the route and frequency of administration, and
9 the particular compound employed . . . may vary widely.” *Id.* at 14:26–32. Yet at no point does the
10 specification explain why the inventor believed that the hydroxytyrosol and oleuropein
11 compositions recited in the claims would counteract any of the listed causes of inflammation. The
12 closest the specification comes to describing the method of treatment recited in the claims is a near
13 verbatim (and conclusory) reproduction of the claim language itself. *See id.* at 13:10–43 (“The
14 method [of the present invention] includes administering to the subject a pharmaceutically effective
15 amount of substantially purified hydroxytyrosol or a substantially purified mixture of
16 hydroxytyrosol and oleuropein.”); 14:33–37 (“The pharmaceutical compositions may contain
17 active ingredient in the range of about 0.1 to 2000 mg/kg body weight, preferably in the range of
18 about 0.3 to 50 mg/kg and most preferably about 0.6 mg/kg.”). But “generic claim language
19 appearing *in ipsius verbis* in the original specification does not satisfy the written description
20 requirement if it fails to support the scope of the genus claimed.” *Ariad*, 598 F.3d at 1350. Here,
21 neither the claims nor the specification discloses that the inventor possessed a treatment for
22 inflammation caused by any of the claimed conditions, much less all of them.

23 **b. The specification’s examples fail to support the claimed invention**

24 In contending that the specification adequately supports the claimed invention, CreAgri
25 points to five studies described in the specification. Pl. Opp. at 19 (citing ’599 Patent, 16:21–
26 19:24). Pinnaclife responds that these studies are bare research proposals that cannot demonstrate
27 that Dr. Crea possessed the invention. CreAgri primarily relies on these studies as prophetic; the
28 specification reports only limited “[i]nitial results” for one of the five proposals. ’599 Patent,

1 18:36–38. “Prophetic examples are routinely used in the chemical arts, and they certainly can be
2 sufficient to satisfy the written description requirement.” *Ariad*, 598 F.3d at 1357. A disclosure is
3 insufficient, however, when it “is not so much an ‘example’ as it is a mere mention of a desired
4 outcome.” *Id.* The Court finds that the studies outlined in the specification are mere mentions of a
5 desired outcome rather than permissible prophetic examples, and thus, the specification’s examples
6 fail to support the claimed invention.

7 The first study—by far the most robustly outlined study in the patent—is described in three
8 separate “Examples.” *See* ’599 Patent, 16:40–18:38. These examples outline study procedures, data
9 analysis procedures, and subject selection procedures, respectively, for a “pilot safety and
10 tolerability” study of “the active ingredient”¹⁴ in HIV-positive men and women “with signs and
11 symptoms of HIV-associated cognitive-motor syndrome or frank [AIDS dementia complex].” *Id.* at
12 16:45–18:38. The specification discloses that “initial results” from this study “showed a
13 statistically significant favorable change in 8-isoprostane levels in the urine.” *Id.* at 18:36–38.
14 Beyond this statement, the ’599 Patent provides no results, either realized or predicted.

15 This study provides insufficient support for the full scope of the claimed method of treating
16 inflammation. The study is directed to the AIDS-related neurological treatment discussed in the
17 specification, not the treatment of the various causes of inflammation recited in the claims. *See,*
18 *e.g., id.* at 16:45–47 (proposing participants who suffer from “HIV-associated cognitive
19 dysfunction”); *id.* at 11:59–63 (describing Example 1 as using an “exemplary *neuropsychological*
20 test” (emphasis added)). Moreover, the limited finding regarding a change in 8-isoprostane levels
21 in the urine has little relevance to the full scope of the claimed therapy. Independent claim 1 uses
22 isoprostane found in cerebrospinal fluid (“CSF”) as a marker for the purposes of administering the
23 therapy, whereas the study measures isoprostane in the urine, without explaining how the two are
24 related. Assuming for purposes of this motion that a person of ordinary skill in the art would
25 understand the two isoprostane levels to be sufficiently related, the study’s small dataset as to

26
27 ¹⁴ The example specifies the active ingredient to be “20 mg total phenols” but does not refer
28 explicitly to hydroxytyrosol or oleuropein, the two substances named in the independent claims.
’599 Patent at 16:46. The Court assumes for purposes of PinnacLife’s summary judgment motion
that a person of ordinary skill in the art would understand the examples to refer to the compositions
recited in the claims.

1 isoprostane levels does not support the effectiveness of the patented therapy as to the full scope of
2 the claims (including the other two ailments recited in claim 1 and the other six claimed in claim
3 16). Acknowledging the small sample size (“up to 32 subjects”), the specification itself states that
4 this study is to be used only as “a pilot safety and tolerability study” and that “statistical
5 significance is not expected for the primary efficacy endpoint in this small study.” *Id.* at 18:8–13.
6 The ’599 Patent’s own predicted result, therefore, is that the study will not serve to demonstrate the
7 efficacy of the therapy, and the Court will not read the study’s abbreviated findings as more
8 persuasive than the patentee believed possible.

9 Example 4 of the ’599 Patent briefly sets out the remaining four studies, outlining the basic
10 procedures for three human models and one mouse model for testing the effectiveness of an “active
11 agent”¹⁵ with regard to arthritis. *Id.* at 18:44–19:17. Again, these proposed studies cannot describe
12 the full scope of the claims, as arthritis is only relevant to two of the claimed seven ailments in
13 claim 16 and none of the three in claim 1. Moreover, these study designs fail to disclose any results
14 whatsoever, whether realized or predicted. *See id.* The ’599 Patent outlines the experiments in one
15 or two short paragraphs of description each; this “example” reads like an internal draft study
16 proposal, not a written description of the invention for the public. *See id.* at 18:44–48 (“Test a
17 group of individuals with Rheumatoid Arthritis and a group with Osteoarthritis with the stress
18 reactivity protocol, before and after 4 weeks of active agent (20 mg total phenols) supplementation
19 and compare to controls over the same time period with no supplementation.”); *id.* at 18:51–54
20 (“Test individuals with Rheumatoid Arthritis, before and after 10 weeks of active agent
21 supplementation and compare to a group doing water aerobic exercise and a control group that
22 does no intervention.”); *id.* at 18:58–59 (“Test individuals with Rheumatoid Arthritis, with and
23 without active agent supplementation for four weeks”); *id.* at 18:63–65 (“Evaluate increasing
24 concentrations of active agent in a collagen-induced arthritis mouse model at 1.3 mg, 13 mg and
25 130 mg/mouse; with and without Cox-2 inhibitors.”). These study proposals in fact demonstrate
26

27
28 ¹⁵ As discussed in note 8, *supra*, the specification defines “active agent” as “20 mg total phenols.”
’599 Patent at 18:46; *see also id.* at 18:52, 18:58, 18:63 (referencing “active agent” in model
description).

1 that the inventor had not yet done the difficult work of inventing the claimed therapy. They do
2 nothing to demonstrate that the inventor possessed the invention.

3 **c. The '599 Patent does not inherently disclose a sufficient description of**
4 **the claimed invention to a person of ordinary skill in the art**

5 CreAgri also contends that the '599 Patent inherently satisfies the written description
6 requirement because “the general principle that olive phenols, such as hydroxytyrosol, had anti-
7 inflammatory properties was known by others in the art.” Pl. Opp. at 19. In support of this
8 statement, CreAgri directs the Court to its expert’s declaration and five prior art references cited in
9 the '599 Patent. Considering each in turn, the Court finds that none of this evidence raises a triable
10 issue of fact.

11 Although a patentee may satisfy the written description requirement by an inherent
12 disclosure, “the missing descriptive matter must necessarily be present in the application’s
13 specification such that one skilled in the art would recognize such a disclosure.” *PowerOasis*, 522
14 F.3d at 1306 (quoting *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1159 (Fed. Cir. 1998)) (alteration
15 omitted). In other words, the written description requirement “is ‘not a question of whether one
16 skilled in the art *might* be able to construct the patentee’s [invention] from the teachings of the
17 disclosure Rather, it is a question whether the application necessarily discloses that particular
18 [invention].” *Id.* (quoting *Martin v. Mayer*, 823 F.2d 500, 505 (Fed. Cir. 1987) (emphasis in
19 original); *see id.* at 1306–07 (“[T]hat the [claim element] may be obvious from the disclosure is not
20 enough[.]”) (citing *TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co.*,
21 264 F.3d 1111, 1118–20 (Fed. Cir. 2001))).

22 CreAgri cites Dr. German’s declaration, which states that “it is inherent in the description
23 of the patent and the appropriate markers to be measured that these be applied to a susceptible
24 population using markers that were well understood by persons of skill in the art.” German Decl.
25 ¶ 95. Dr. German does not cite to the specification for this proposition, but presumably he refers to
26 the paragraph in the specification that lists the relevant biomarkers. *See* '599 Patent at 13:30–42
27 (“The marker or the clinical symptom may include any number of markers or clinical symptoms
28 which are generally known in the art to be associated with inflammation. Preferably, the symptoms

1 and markers are associated with specific types of inflammation. These include (i) the symptoms
2 and markers in joint pain and swelling in the case of joint inflammation; (ii) elevated levels of C-
3 reactive protein in the case of coronary inflammation; (iii) respiratory distress in the case of
4 bronchial inflammation; and (iv) elevated CSF levels of isoprostanes or functional or
5 psychofunctional indicators in the case of neuro-inflammation. The marker may be a cytokine,
6 such as TNF- α , interleukin-1, interleukin-6, and/or interleukin-8. Other markers include
7 corticotrophin, cortisol and/or prolactin.”). Because the ’599 Patent’s specification at most
8 discloses how to measure whether the claimed treatment works, not whether the claimed treatment
9 in fact works, the Court finds that the ’599 Patent’s disclosure of the relevant biomarkers is
10 insufficient to create an inherent disclosure of the full scope of the claimed invention.

11 Crucially, CreAgri’s expert does not opine that the ’599 Patent inherently discloses the
12 claimed method of treatment. To the contrary, Dr. German acknowledges in the same paragraph on
13 which CreAgri relies that inflammation is a “complex and diverse process[.]” German Decl. ¶ 95.
14 Dr. German goes on to explain that “[t]he patent discloses reasonable and appropriate biomarkers.”
15 *Id.* These biomarkers, according to the specification, are used to detect whether an individual may
16 have an inflammatory condition. ’599 Patent at 13:17–20. And claim 1, for example, uses these
17 same biomarkers to determine whether the claimed treatment has achieved its therapeutic effect.
18 But CreAgri never points to anywhere in the specification showing that the claimed treatment does
19 have its therapeutic effect. Thus, at most, Dr. German’s declaration states that the ’599 Patent
20 inherently discloses how to measure *whether* the treatment works as claimed, not that the treatment
21 *does* work as claimed. That statement fails to create an issue of material fact as to whether the
22 specification actually or inherently discloses that the inventor possessed the claimed invention.

23 In addition, CreAgri attempts to create an issue of fact by pointing to the ’599 Patent
24 specification’s incorporation of five prior art references that discuss hydroxytyrosol’s anti-
25 inflammatory effect. None of those references, however, demonstrate the medical efficacy of
26 hydroxytyrosol, hydroxytyrosol together with oleuropein, or olive plant extract having a given ratio
27 of hydroxytyrosol to oleuropein, for treating inflammation arising out of the numerous causes
28 recited in the claims of the ’599 Patent. The Court addresses each of the references in turn.

1 • The Fehri reference, *see* Lee Decl. Vol. 2, Ex. 14, ECF No. 118-5, reported tests of
2 the anti-inflammatory effects of olive leaf extract in mice but without reference to
3 hydroxytyrosol or oleuropein. Moreover, the article concludes that the observed anti-
4 inflammatory effect “could be investigated” in therapeutics, not that olive leaf extract has a
5 therapeutic use.

6 • The Ragione reference, *see* Lee Decl. Vol. 3, Ex. 15, ECF No. 118-6, reported tests
7 of hydroxytyrosol for apoptogenic activity and, although it found success with respect to a
8 leukemia-based cell line, the article concluded that two colon cell lines, in contrast, “were
9 completely resistant to the apoptogenic capability of DPE” and therefore “the programmed
10 cell death due to the olive oil phenol is specific for cell phenotype,” *id.* at 735–36. In other
11 words, the article was unable to draw a conclusion about the general anti-inflammatory
12 effect of hydroxytyrosol, much less hydroxytyrosol’s anti-inflammatory effect on the
13 various ailments recited in the claims of the ’599 Patent.

14 • The Visioli reference, authored by Pinnaclife’s expert, *see* Marshall Decl. Ex. D,
15 reported tests of olive mill wastewater extract but made only the following conclusion:

16 OMWW [olive mill wastewater] extracts *could* . . . decrease the
17 production of pro-inflammatory factors. Additional studies are needed to
18 verify if such anti-inflammatory effects could also take place *in vivo* and
19 the exact enzymatic target of the bioactive compounds. . . . OMWW are
20 rich in antioxidant compounds that could be . . . employed . . . , following
21 appropriate trials to evaluate their safety and efficacy, as prophylactic
22 agents in the prevention of certain radical-induced human diseases.

23 *Id.* at 3401 (emphasis added). Thus, like the ’599 Patent itself, the Visioli reference is, at
24 best, prophetic only.

25 • The Kohyama and Petroni references, *see* Marshall Decl. Vol. 3, Exs. L–M, ECF
26 No. 103-4, provided *in vitro* results suggesting that enzymes involved in inflammatory
27 processes could be inhibited by hydroxytyrosol, but both also stressed the need for *in vivo*
28 testing. *Id.* Ex. L at 350; *Id.* Ex. M at 158–59.

These references all reflect a field actively exploring the possibility of the anti-
inflammatory use of hydroxytyrosol and oleuropein, as well as substances known to contain

1 hydroxytyrosol and oleuropein, but not at the point of inherently appreciating the use of these
2 substances to treat coronary, bronchial, and neuro inflammation (claim 1) or inflammation caused
3 by delayed type hypersensitivity reaction, psoriasis, and autoimmune disease, organ transplant,
4 pain, fever, and tissue graft rejection (claim 16).

5 ***

6 In sum, the cited prior art does not suggest that persons having ordinary skill in the art
7 would understand the specification’s disclosure to describe that the inventor invented what was
8 claimed. The study outlines disclosed in the specification itself all reveal that the inventor’s
9 statements of invention are, at best, premature. The written description requirement prohibits
10 inventors from “preempt[ing] the future before it has arrived,” *Billups-Rothenberg, Inc. v.*
11 *Associated Regional & University Pathologists, Inc.*, 642 F.3d 1031, 1036 (Fed. Cir. 2011)
12 (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)), yet here the inventor left “[t]he
13 actual inventive work” of generating the claimed treatment “for subsequent inventors to complete,”
14 *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011). Accordingly,
15 the claims of the ’599 Patent are invalid for failure to meet the written description requirement of
16 section 112.

17 **B. The “Enable . . . To Use” Requirement of Section 112(a)**

18 **1. Applicable Law**

19 As the *en banc* Federal Circuit has noted, “written description and enablement often rise
20 and fall together.” *Ariad*, 598 F.3d at 1352. “In order to satisfy the enablement requirement of
21 section 112, an applicant must describe the manner of making and using the invention ‘in such full,
22 clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the
23 same’” *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322 (Fed. Cir. 2005)
24 (quoting 35 U.S.C. § 112). “The how to use prong of section 112 incorporates as a matter of law
25 the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical
26 utility for the invention.” *In re Ziegler*, 992 F.2d 1197, 1200 (Fed. Cir. 1993). Thus, “[i]f a patent
27 claim fails to meet the utility requirement because it is not useful or operative, then it also fails to
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1 meet the how-to-use aspect of the [section 112] enablement requirement.” *In re ’318 Patent*
2 *Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) (emphasis omitted).

3 Because “[e]nablement, or utility, is determined as of the application filing date,” *In re*
4 *Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995), an invention will not be considered useful for the
5 purposes of section 101 where, at the time of filing, “there is a complete absence of data supporting
6 the statements which set forth the desired results of the claimed invention”—even if the invention
7 is later proven useful or operable. *Rasmusson*, 413 F.3d at 1323 (quotations omitted); *see also*
8 *Brenner v. Manson*, 383 U.S. 519, 535 (1966) (“Congress intended that no patent be granted on a
9 chemical compound whose sole ‘utility’ consists of its potential role as an object of use-testing.”).

10 Furthermore, “[i]f mere plausibility were the test for [enabling disclosures of utility] under
11 section 112, applicants could obtain patent rights to ‘inventions’ consisting of little more than
12 respectable guesses as to the likelihood of their success.” *Rasmusson*, 413 F.3d at 1325. But the
13 Patent Act does not provide for the patenting of mere research proposals or hypotheses. *In re ’318*
14 *Patent Infringement Litig.*, 583 F.3d at 1324. “[A] patent is not a hunting license. It is not a reward
15 for the search, but compensation for its successful conclusion.” *Brenner*, 383 U.S. at 536.

16 “In the context of determining whether sufficient utility as a drug, medicant, and the like in
17 human therapy has been alleged, it is proper . . . to ask for substantiating evidence unless one with
18 ordinary skill in the art would accept the allegations as obviously correct.” *Rasmusson*, 413 F.3d at
19 1323 (internal quotation marks omitted). In this regard, “[t]he full scope of the claimed invention
20 must be enabled,” meaning that a “patentee who chooses broad claim language must make sure the
21 broad claims are fully enabled.” *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).
22 Regardless of the breadth of the claims, “[t]ypically, patent applications claiming new methods of
23 treatment are supported by test results.” *In re ’318 Patent Infringement Litig.*, 583 F.3d at 1324.
24 However, “testing need not be conducted by the inventor,” and “human trials are not required.” *Id.*

25 Whether a disclosure is enabling under 35 U.S.C. § 112(a) is a question of law based on
26 underlying factual inquiries. *See Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369 (Fed.
27 Cir. 1999). Whether an invention is operative, and hence has utility within the meaning of § 101,
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1 appears to be one of those factual inquiries. *See In re Dash*, 118 F. App'x. 488, 490 (Fed. Cir.
2 2004) (citing *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000)).

3 **2. Analysis of the '599 Patent**

4 A patent is deemed useful where “one skilled in the art would accept without question
5 statements as to the effect of the claimed drug products.” *Rasmusson*, 413 F.3d at 1323
6 (alternations and internal quotation marks omitted). Alternatively, there must be some quantum of
7 data or reasoning that supports the inventor’s contention that a therapy operates as claimed. *See In*
8 *re '318 Patent Infringement Litig.*, 583 F.3d at 1326. The Court will consider each of these
9 alternatives with respect to the '599 Patent.

10 **a. One skilled in the art would not, at the time of filing, accept**
11 **without question the '599 Patent's bare assertion of the claimed**
12 **treatments' effectiveness**

13 Pinnaclife argues that one having ordinary skill in the art would not accept an assertion that
14 hydroxytyrosol and oleuropein have therapeutic anti-inflammatory qualities. The Court agrees. On
15 this point, Pinnaclife’s expert, Dr. Francesco Visioli,¹⁶ provides clear and uncontroverted evidence:
16 “[b]y 2002, no researcher working in the field of olive-derived polyphenols had published reliable
17 data establishing that either hydroxytyrosol or oleuropein showed *in vivo* anti-inflammatory
18 activity.”¹⁷ Marshall Decl. Ex. N. (“Visioli Rep.”) ¶ 33, ECF No. 103-5. “[I]n the 1999-2002 time
19 period, anti-inflammatory activity could not be inferred from research showing that olive-derived
20 polyphenols exhibit antioxidant activity.” *Id.* ¶ 34. That is, Dr. Visioli contends that the
21 compounds in question were not known at the time of filing to provide the alleged therapeutic
22 effects and their known antioxidant properties were not grounds for inferring such therapeutic
23 effects.

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25
26 ¹⁶ CreAgri has separately moved to disqualify Dr. Visioli based on a purported conflict of interest.
27 *See* ECF No. 80. The Court will issue a separate order concluding that CreAgri has failed to show
28 that Dr. Visioli should be disqualified from assisting Pinnaclife in this case.

¹⁷ “*In vivo*” activity refers to activity “within living organisms,” whereas “*in vitro*” activity refers to
activity in “artificial environments outside living organisms (such as in a test tube or culture
media).” *In re '318 Patent Infringement Litig.*, 583 F.3d at 1324 n.7.

1 CreAgri’s expert, Dr. German, protests that he is “unable to determine the evidentiary
2 basis” of the second of these two opinions. German Decl. ¶ 55. But Dr. German does not reject or
3 otherwise controvert either of Dr. Visioli’s opinions that the therapeutic effect of olive-derived
4 polyphenols had not been established in the art. *See id.* Instead, he cites two articles written by Dr.
5 Visioli that Dr. German contends “assert that antioxidant activity was *related* to anti-inflammatory
6 activity in 2001 and 2002.” German Decl. ¶ 55 (emphasis added). CreAgri has not provided a copy
7 of these articles to the Court, and Dr. German’s description of them fails to create an issue of fact
8 as to whether a person of ordinary skill in the art would accept the claimed therapeutic effect of
9 olive-derived phenolic compounds, in humans or other animals.

10 To avoid any doubt, the Court independently obtained and examined the two articles
11 authored by Dr. Visioli and cited by Dr. German, and has discovered that neither establishes a
12 recognition in the art of the therapeutic effects of olive-derived polyphenols.

13 The first article, “Antiatherogenic Components of Olive Oil,” summarizes in three pages
14 other studies. Francesco Visioli and Claudio Galli, *Antiatherogenic Components of Olive Oil*,
15 *Current Atherosclerosis Rep.*, Jan. 2001, at 64–67. The article expresses hope that phenolic
16 compounds in olives could have therapeutic effects, but it provides no evidence whatsoever of
17 those effects.

18 The second article, entitled “Antioxidant and Other Biological Activities of Phenols from
19 Olives and Olive Oil,” supplies new and successful experimental results, but its ultimate
20 conclusion runs against CreAgri’s position that a person of ordinary skill in the art would accept
21 the claimed therapeutic effect of the claimed treatment methods. Francesco Visioli, et al.,
22 *Antioxidant and Other Biological Activities of Phenols from Olives and Olive Oil*, *Med. Res. Rev.*,
23 Jan. 2002, at 65–75. The article summarizes that “[t]o date, these data represent the first, albeit
24 limited, experimental evidence of a healthful effect of olive oil components on human health. In
25 the future, availability of pure—or even labeled—compounds in adequate quantities and
26 development of appropriate methodologies will further clarify the metabolic fate of phenolic
27 micronutrients, including those of olive oil.” *Id.* at 71.

1 These statements, albeit hopeful that later research will prove a link between phenols in
2 olives and better health, demonstrate that the link was not accepted in the art at the time of the '599
3 Patent's filing. Instead, this article represents some of the first steps of investigating which
4 elements of the Mediterranean diet produce beneficial health effects. The article concludes that
5 "[i]t is in fact difficult to single out an individual component of [the Mediterranean] diet and
6 correlate it with the observed lower incidence of CHD [coronary heart disease] and certain
7 cancers." *Id.* at 72. Therefore, not only are Dr. German's assertions insufficient to create a fact
8 issue, but the articles he cites do not support the notion that a person of ordinary skill in the art
9 would accept without question that the claimed olive-derived phenolic compounds would have the
10 claimed therapeutic effects.

11 Next, CreAgri argues that one with ordinary skill in the art would nevertheless have
12 "knowledge of the *possible* anti-inflammatory effects of olive polyphenols" and would therefore
13 "recognize the significant benefit of the claimed inventions." Pl. Opp. at 22 (emphasis added). The
14 undisputed record does show that, prior to the time of filing, some amount of investigation had
15 been performed into the possible anti-inflammatory effects of olive mill wastewater and of olive-
16 derived phenols. In particular, CreAgri points to five scientific articles cited in the patent
17 specification as demonstrative of what was known in the art, *Id.* at 17, and Pinnaclife concedes that
18 three of these references are reflective of research in the field, Def. MSJ at 21. These are the same
19 references considered above in the written description section, and CreAgri reiterates the same
20 arguments with respect to written description and enablement. The Court rejects CreAgri's
21 arguments here as well, finding that, based on the references cited in the specification, a person of
22 ordinary skill in the art would not accept without question the effectiveness of the claimed
23 therapies in treating the ailments listed in the claims.

24 In addition, CreAgri submits post-filing articles, authored by the inventor, regarding what
25 CreAgri claims are completed studies based on the proposals disclosed in Example 4 from the
26 specification. *See* Lee Decl. Vol. 3, Ex. 19 ("Manuscript received 11 February 2005. . . .
27 [A]ccepted 21 March 2005"); Ex. 20 ("Received 17 January 2007 . . . accepted 5 June 2007.").
28 CreAgri argues that the Court should consider these results in its enablement analysis as

1 “pertain[ing] to the accuracy of a statement already in the specification.” Pl. Opp. at 22 (quoting
2 *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 925 (Fed. Cir. 2011)). However, the
3 Court cannot consider CreAgri’s post-filing test results as evidence of the utility of the claimed
4 methods of treating inflammation. “Enablement is determined as of the effective filing date of the
5 patent's application.” *In re ’318 Patent Infringement Litig.*, 583 F.3d at 1323. Where results “were
6 not available at the time of the application,” they cannot be used to establish utility or enablement.
7 *Id.*, 583 F.3d at 1325; *see also* Marshall Decl. Ex. C 175 (“Crea Dep.”), ECF No. 103-2 (“[T]he
8 patent was filed while we were doing the study, and the results weren’t available.”).

9 The Federal Circuit has created a narrow exception to the rule that post-filing data cannot
10 support utility. In *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), the Federal Circuit allowed such
11 evidence “to substantiate any doubts as to the asserted utility” where those test results “pertain[] to
12 the accuracy of a statement already in the specification.” *Id.*, 51 F.3d at 1567 n.19. Read too
13 broadly, however, the *Brana* exception would swallow the rule that “[e]nablement, or utility, is
14 determined as of the application filing date.” *Id.* Where actual results, garnered post-filing, mirror
15 or otherwise substantiate predicted results, it is plain that those results will pertain to the accuracy
16 of a statement in the specification within the meaning of *Brana*. Here, however, the ’599 Patent
17 makes no assertions whatsoever regarding the outcomes of the proposed studies, *see supra* Part
18 III.A.2.b (discussing “Example 4” of the ’599 Patent), so the study designs provided in the
19 specification are not sufficiently prophetic such that later-achieved results can support the utility of
20 the claimed invention. *See Brana*, 51 F.3d at 1567 n. 19 (post-filing results “do[] not render an
21 insufficient disclosure enabling, but instead go[] to prove that the disclosure was in fact enabling
22 when filed (i.e., demonstrated utility)”).

23 Moreover, even if it could consider the results at issue, the Court would not conclude that
24 the results create an issue of fact as to whether persons of ordinary skill in the art would accept
25 without question the utility of the claimed treatment as of the filing date of the invention. The first
26 study—a measurement in mice of a marker linked to inflammation called “tumor necrosis factor- α ”
27 (“TNF- α ”)—explicitly disclaims the anti-inflammatory effects of hydroxytyrosol, both as to the
28 mouse model in question and with regard to other, undisclosed anti-inflammatory cell models. Lee

1 Decl. Ex. 19 at 1478 (“HT [Hydroxytyrosol] . . . was ineffective at attenuating TNF- α production
2 in this cell system. We evaluated the effectiveness of pure HT in other anti-inflammatory cell
3 models and found that it was also ineffective in those models (unpublished results).”). The study
4 concludes that “although the major phenolic compound of hydrolyzed olive water is
5 [hydroxytyrosol], the anti-inflammatory activity [found in the study] may be attributable to another
6 component of the water that is as yet unidentified.” *Id.* Thus, CreAgri’s own evidence demonstrates
7 that the effectiveness of hydroxytyrosol as an anti-inflammatory was still uncertain to those of
8 ordinary skill in the art even after the date of filing.

9 The second study measured the effect of “olive extract supplement” on male and female
10 volunteers suffering from osteoarthritis or Rheumatoid arthritis. Lee Decl. Ex. 20 at 475.
11 Significantly, the arthritis study did not reference relative concentrations of hydroxytyrosol to
12 oleuropein, or, indeed, even mention either substance. *See Id.* Further, given that the study only
13 measures the effects of the “olive extract supplement” on Rheumatoid arthritis and osteoarthritis,
14 even a study finding that the supplement was successful in 100% of cases could not enable the full
15 scope of the ’599 Patent’s claims, as the claims recite treating coronary, bronchial, and neuro
16 inflammation (claim 1), and inflammation from psoriasis, organ transplant, fever, and tissue graft
17 rejection (claim 16). As CreAgri highlights, this study was generally a success, finding a
18 statistically significant reduction in several of the subjects’ inflammation symptoms over the
19 placebo group. *Id.* at 473–76. It is possible that, as to claims to an olive extract supplement
20 treatment for Rheumatoid arthritis and osteoarthritis, this study could form the basis of an enabling
21 disclosure. However, these are not the claims at issue. As discussed above, even if this data was
22 available at the time the patent was filed, the arthritis study cannot enable any of the ’599 Patent’s
23 claims, as it does not mention hydroxytyrosol or oleuropein. And, even if the data was available
24 pre-filing, and even assuming that the “olive extract supplement” in the study was a supplement
25 with the claimed ratios of hydroxytyrosol to oleuropein, the arthritis study still cannot enable the
26 full scope of the ’599 Patent’s claims because it only deals with the treatment of arthritis, without
27 mentioning any of the other claimed ailments.
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1 In sum, Pinnaclife has satisfied its burden of establishing that no reasonable jury could
2 conclude that a person of ordinary skill in the art would accept without question the general
3 assertion that olive-derived phenols would effectively treat the various forms of inflammation as
4 recited in the claims. The '599 Patent's claims are not enabled on this basis.

5 **b. The specification and the prior art references do not otherwise**
6 **establish utility**

7 Although the operability of a patented therapy need not be demonstrated by testing in order
8 to satisfy the utility and enablement requirements, if the claimed effect would not otherwise be
9 accepted by one of ordinary skill in the art, there must nevertheless be some quantum of data or
10 reasoning that supports the inventor's contention that a therapy operates as claimed. *See In re '318*
11 *Patent Infringement Litig.*, 583 F.3d at 1326. The PTO's Manual of Patent Examining Procedure
12 ("MPEP")¹⁸ provides that "[a]s a general matter, evidence of pharmacological or other biological
13 activity of a compound will be relevant to an asserted therapeutic use if there is a *reasonable*
14 *correlation* between the activity in question and the asserted utility." MPEP § 2107.03 (emphasis
15 added). Such a correlation may be demonstrated by "statistically relevant data documenting the
16 activity of a compound or composition, arguments or reasoning, documentary evidence (*e.g.*,
17 articles in scientific journals), or any combination thereof." *Id.*; *see also Cross v. Iizuka*, 753 F.2d
18 1040, 1050 (Fed. Cir. 1985) (finding a "reasonable correlation" between *in vitro* results and
19 purported *in vivo* utility of a pharmaceutical).

20 As the Federal Circuit noted in *In re '318 Patent Infringement Litig.*, circumstances where
21 analytic reasoning alone will demonstrate utility are likely to be rare, *see* 583 F.3d at 1326, and
22 CreAgri points to no precedent in which such evidence was sufficient to satisfy utility and
23 enablement.¹⁹ In *In re '318 Patent Infringement Litig.*, the Federal Circuit upheld a ruling of

24 ¹⁸ "The MPEP . . . [is] not binding on this court, but may be given judicial notice to the extent [it
25 does] not conflict with the statute." *In re Fisher*, 421 F.3d 1365, 1372 (Fed. Cir. 2005) (internal
quotation marks omitted).

26 ¹⁹ CreAgri looks to *Brana* and *Actavis* to support the utility of the '599 Patent. *See* Pl. Opp. at
27 21–22. Neither case involved facts comparable to those at bar. In *Brana*, the Federal Circuit found
28 that there was sufficient evidence of utility for chemical compounds intended for use as antitumor
substances where the patentee disclosed *in vitro* results of the claimed compound's effectiveness
and where the claimed compound was structurally similar to a compound proven to be effective *in*
vivo. *See* 51 F.3d at 1563, 1567. In *Actavis*, the FDA had authorized using the compound at issue
for the claimed treatment in human clinical trials, which, the court highlighted, already required the

1 invalidity concerning a patent for a method of treating Alzheimer’s disease where the specification
2 grounded the compound’s efficacy on its other known effects as described in the scientific
3 literature and made no reference to either *in vitro* or *in vivo* testing. *See In re ’318 Patent*
4 *Infringement Litig.*, 583 F.3d 1321–22. While the Court did not rule out the possibility of
5 disclosing utility through “analytic reasoning” based on known properties, it found that any
6 analytic insights made by the inventor were “nowhere described in the specification,” and therefore
7 did not need to reach the question of whether such insights were sufficient. *Id.* at 1326.
8 Accordingly, although a patentee need not generally know “how or why the invention works,” *In*
9 *re Cortright*, 165 F.3d 1353, 1359 (Fed. Cir. 1999) (internal quotation marks omitted), such
10 explanations do become necessary where, as here, the inventor did not know at the time of filing
11 whether the invention was in fact operable and instead rests the invention’s asserted operability on,
12 as the inventor himself conceded, “prophe[cy].” *See Crea Dep.* at 174:7–23.

13 Here, as in *In re ’318 Patent Infringement Litig.*, the specification provides nothing that
14 could be considered argument or analytic reasoning. The ’599 Patent specification, at ten pages
15 long, is at the very least more lengthy than that of the patent invalidated by *In re ’318 Patent*
16 *Infringement Litig.* *See In re ’318 Patent Infringement Litig.*, 583 F.3d at 1321 (“The specification .
17 . . . was only just over one page in length”). It is not, however, any more revealing as to the claimed
18 therapy. Although the specification presents various means of *testing* whether the claimed
19 invention would work as to a small subset of the recited causes of inflammation, *see* ’599 Patent at
20 cols. 10–13, 16–19, it does not explicitly provide any analytic reasoning as to why the invention
21 would work as claimed.

22 The ’599 Patent does not claim a therapy, it claims a research hypothesis. “[R]esearch
23 hypotheses do not qualify for patent protection.” *Ariad*, 598 F.3d at 1353. Because a reasonable
24

25 applicant to “provide a convincing rationale to those especially skilled in the art (*e.g.*, the [FDA])
26 that the investigation may be successful.” 435 F. App’x at 924 (internal quotation marks omitted).
27 Moreover, the compound at issue in *Actavis* was known to have the same relevant biological
28 activity exhibited by another drug used to treat the same condition named in the patent, even
though the other drug’s safety was questioned. *Id.* at 920, 926. Here, CreAgri has not disclosed *in vivo* “evidence of success in structurally similar compounds,” *Brana*, 51 F.3d at 1567, or any suggestion that the FDA has approved human trials of the claimed or similar substances.

1 jury could not conclude that a person of ordinary skill in the art reading the patent at the time of
2 filing would recognize the utility of the full scope of the claimed therapies, the claims are not
3 enabled and are therefore invalid pursuant to sections 101 and 112. The Court therefore grants
4 PinnacLife's Motion for Summary Judgment on invalidity as to the '599 Patent.

5 **C. Whether the '599 Patent is invalid as indefinite under 35 U.S.C. § 112(b)**

6 PinnacLife has also moved for summary judgment of invalidity on the grounds that the '599
7 Patent is invalid as indefinite under 35 U.S.C. § 112(b). As all claims of the '599 Patent are invalid
8 for failure to meet the written description and enablement requirements of subsection 112(a), the
9 Court declines to address the parties' arguments as to indefiniteness.

10 **V. CONCLUSION**

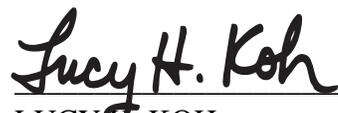
11 For the foregoing reasons, the Court GRANTS PinnacLife's Motion for Summary Judgment
12 of Invalidity in its entirety. Because CreAgri asserts no patents beyond those the Court now rules
13 invalid, the Court DENIES as moot CreAgri's Motion for Summary Judgment of Infringement.
14 Moreover, as CreAgri's only causes of action seek to enforce patents the Court now rules invalid in
15 their entirety, the case is hereby DISMISSED. Accordingly, the Court dismisses PinnacLife's first
16 Counterclaim for a Declaratory Judgment of Noninfringement of the '808 and '599 Patents and
17 second Counterclaim for a Declaratory Judgment of Unenforceability of the '808 Patent without
18 prejudice.²⁰ All other outstanding motions besides the administrative motions to seal and the
19 motion to disqualify Dr. Visioli are DENIED as moot.²¹

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21 ²⁰ The Federal Circuit has held that a summary judgment grant of noninfringement does not moot a
22 counterclaim for invalidity. *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1370 (Fed.
23 Cir. 2004). The Federal Circuit has held similarly with respect to a counterclaim for
24 unenforceability. *Zenith Elects. Corp. v. PDI Commc'n Sys., Inc.*, 522 F.3d 1348, 1366–67 (Fed.
25 Cir. 2008). Rather than moot the claim, the Federal Circuit has instructed district courts to either
26 hear the claim or dismiss it without prejudice. *Liquid Dynamics*, 355 F.3d at 1371 (“A district court
27 judge faced with an invalidity counterclaim challenging a patent that it concludes was not infringed
28 may either hear the claim or dismiss it without prejudice, subject to review only for abuse of
discretion.”); *see also Korszun v. Pub. Techs. Multimedia, Inc.*, 96 F. App'x 699, 700 (Fed. Cir.
2004) (“(1) the district court can proceed to trial on the invalidity counterclaims and adjudicate
them to finality, thus ‘end[ing] the litigation on the merits and leav[ing] nothing for the court to do
but execute the judgment[,];’ . . . (2) the district court can dismiss the counterclaims; (3) the district
court can, where proper, enter judgment under Federal Rule of Civil Procedure 54(b); and (4) the
procedures of 28 U.S.C. § 1292(b), (c)(1) can be invoked.” (quoting *Nystrom v. TREX Co.*, 339
F.3d 1347, 1350–51 (Fed. Cir. 2003)) (citation omitted)). Here, the Court is faced with the reverse
situation of a grant of summary judgment on invalidity with outstanding counterclaims for

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IT IS SO ORDERED.

Dated: December 18, 2013



LUCY H. KOH
United States District Judge

noninfringement and unenforceability. To ensure that the Federal Circuit will have proper jurisdiction for an appeal of this decision, and out of an abundance of caution, the Court dismisses the counterclaims without prejudice rather than as moot. *See Nystrom*, 339 F.3d at 1350–51 (Fed. Cir. 2003).

²¹ The parties have filed various administrative motions to seal. The Court will address those motions in a separate order.