Trials@uspto.gov
571.272.7822

Paper No. 11
Entered: November 7, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERIAL, INC.,
Petitioner,

v.

FIDOPHARM, INC.,
Patent Owner.

Case IPR2016-01182
Patent 8,829,038 B2

Before MICHAEL P. TIERNEY, LORA M. GREEN, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Merial, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–21 of U.S. Patent No. 8,829,038 B2 (Ex. 1002, "the '038 patent"). Paper 1 ("Pet."). Fidopharm, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 6.

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition and the Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we institute an *inter partes* review of claims 1–21 of the '038 patent.

A. Related Proceedings

According to Petitioner, the '038 patent is not the subject of any other proceedings. Pet. x.

B. The '038 Patent and Relevant Background

The '038 patent, relates to parasiticidal formulations containing Fipronil, or related 1-N-arylpyrazole pesticides, used to treat mammalian ectoparasites, including fleas and ticks. Ex. 1002, Abstract, 1:14–30. The Specification states that while "[p]arasiticidal formulations comprising Fipronil are marketed for use in the home treatment of domestic pets, e.g., cats and dogs" (*id.* at 1:36–38), these formulations have relatively low flash points, which "presents a safety risk during use in the home, and during

manufacture, distribution and storage" (*id.* at 1:40–49). "Accordingly, the object of the present invention is to provide a parasiticidal formulation comprising Fipronil having improved safety while maintaining parasiticidal efficacy." *Id.* at 1:54–56. "In particular, formulations of the present invention have been shown to have flashpoints between 47° C. and 52°C. and are therefore safer than the known formulations in the prior art." *Id.* at 2:4–7.

The Specification discloses parasiticidal formulations comprising "up to 8% by weight" of at least one C_1-C_6 alcohol cosolvent (*id.* at 1:60–65; *see* 2:39–43), exemplified by "methanol, ethanol, propanol, isopropanol or butanol, and combinations thereof" (*id.* at 2:44–46). The Specification also provides three exemplary formulations, each of which includes "5.0 wt% ethanol" as the C_1-C_6 alcohol cosolvent. *Id.* at 4:1–31; 5:18–67.

C. Challenged Claims

Claims 2–21 depend, directly or indirectly, from claim 1, which recites (paragraphing added):

> 1. A parasiticidal formulation comprising:
>
> from about 8 to about 12% by weight Fipronil, or a veterinary acceptable derivative thereof;
>
> less than about 5% by weight of the formulation of ethanol; and
>
> at least one organic solvent which is not ethanol.

D. The Asserted Prior art and Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 12):

Ground	Reference(s)	Basis	Claim(s)
1	Freehauf[1]	§ 102	1, 3–5, and 7–17
2	Freehauf in view of Jeannin[2] or Young[3]	§ 103	6
3	Etchegaray	§ 102	1–3 and 7–19
4a	Etchegaray	§ 103	1–3 and 7–21
4b	FRONTLINE TOP SPOT References[4, 5]	§ 103	1–3 and 7–21
5	Etchegaray in view of Maddison,[6] Jeannin, or Young	§ 103	4–6
6	Pan[7]	§ 102	1–3, 9, and 18–19

[1] Freehauf et al., WO 2009/027506 A2, published March 5, 2009. Ex. 1008.

[2] Jeannin, US 6,096,329, issued Aug. 1, 2000. Ex. 1029.

[3] Young et al., *Efficacy of fipronil/(S)-methoprene combination spot-on for dogs against shed eggs, emerging and existing adult cat fleas (Ctenocephalides felis, Bouché*, 125 VETERINARY PARASITOLOGY 397–407. Ex. 1033.

[4] Material Safety Data Sheet for Fipronil 9.7% w/w Frontline Top Spot, printing date Oct. 23, 2001. Ex. 1020.

[5] Page 19 from: WHOLE DOG JOURNAL (2002). Ex. 1028.

[6] Jill E. Maddison, et al., SMALL ANIMAL CLINICAL PHARMACOLOGY, 1077–1035 (2002). Ex. 1034.

[7] Pan and Zhang, CN 101129357A, published Feb. 27, 2008. Ex. 1030 (certified English translation); *see* Ex. 1009 (original).

Petitioner also relies on the declarations of technical experts, Dr. Witchey-Lakshmanan (Ex. 1015), Saijun Gong (Ex. 1017), and Dr. Clark (Ex. 1013). Petitioner further relies on the declarations of Messrs. Sheppard and Jackson (Ex. 1011 and 1032, respectively) to establish the prior art date of certain cited references. Patent Owner relies on evidence of unexpected results as set forth in the Petrick Declaration[8] submitted during the prosecution leading to the issuance of the '038 patent. Prelim. Resp. 45.

II. ANALYSIS

A. Real Parties in Interest

Patent Owner asserts that the Board should deny the Petition because Petitioner, Merial, Inc., failed to identify related entities, Merial Ltd. and Merial LLC, or its parent corporation, Sanofi, as real parties-in-interest as required under 35 U.S.C. § 312(a)(2). Prelim. Resp. 16–24; *see id*. at 17 (arguing that "[t]he failure to list all real parties in interest prevents the Board from considering the Petition"). For the reasons set forth below, we are not persuaded that the Petition should be denied on this basis.

i. Legal Principles

"Courts invoke the terms 'real party-in-interest' and 'privy' to describe relationships and considerations sufficient to justify applying conventional principles of estoppel and preclusion." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012) ("Trial Practice Guide"). "Whether a party who is not a named participant in a given

[8] Declaration under 37 C.F.R. § 1.132 of David Petrick, dated March 12, 2013. Ex. 1006.

proceeding nonetheless constitutes a 'real party-in-interest'. . . to that proceeding is a highly fact-dependent question." *Id.* (citing *Taylor v. Sturgell*, 553 U.S. 880 (2008). Although multiple factors may be considered, "[a] common focus of this inquiry is whether the non-party exercised or could have exercised control over the proceeding." *Id.* There is, however, "no bright-line test for determining the necessary quantity or degree of participation to qualify as a 'real party-in-interest'. . . based on the control concept." Trial Practice Guide at 48,759 (citing *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 759 (1st Cir. 1994)).

Although Petitioner bears the burden of correctly identifying the real parties-in-interest, "[w]e generally accept the petitioner's identification of real parties-in-interest at the time of filing the petition." *See Zerto, Inc. v. EMC Corp.*, Case IPR2014-01254, slip op. at 6 (PTAB Mar. 3, 2015) (Paper 35) (citing Office Patent Trial Practice Guide, 77 Fed. Reg. at 48,695). To overcome this presumption, a patent owner must provide sufficient rebuttal evidence to reasonably bring in to question the accuracy of petitioner's disclosure. *Id.* at 6–7. If the patent owner provides such evidence, the burden, nevertheless, remains on the petitioner to establish that it has complied with § 312(a)(2). *Id.* at 7.

ii. Sanofi

Patent Owner first asserts that Sanofi should be named a real party-in-interest because Petitioner, Merial, Inc., is its wholly owned subsidiary. Prelim. Resp. 22 (citing Ex. 2001, 1; 2002, 19, 67). The board has not found the existence of a parent-subsidiary relationship alone sufficient to justify a parent corporation's status as a real party-in-interest. Patent Owner, however, further argues that two passages in a Sanofi annual report provide

evidence that "Sanofi has control over [Merial, Inc.'s] actions as they relate to this IPR and is also financing this IPR." Prelim. Resp. 22.

The first of these passages states that: "The Sanofi parent company raises the bulk of the Group's external financing and uses the funds raised to meet, directly or indirectly, the financing needs of its subsidiaries. The parent company operates a cash pooling arrangement under which any surplus cash held by subsidiaries is managed centrally." *Id*. (quoting "Ex. 2005 at 72 (Sanofi 20-f report)")[9] (emphasis removed). Contrary to Patent Owner's allegations, we see no evidence that the above-quoted references to "external financing" or central management of "surplus cash" refer to the financing or control of this, or any other, IPR proceeding. *See id.* at 23.

Patent Owner also points us to a passage in the report stating that, although individual subsidiaries (including Merial, Inc.) bear "responsibility of research and development in their respective fields," "within the integrated R&D organization, the definition of strategic priorities and the coordination of R&D efforts are done globally." *Id.* at 24 (quoting Ex. 2002, 72) (emphasis removed). On its face, this passage appears to relate to strategic priorities *with respect to research and development*, and having no obvious bearing on the financing or control of IPR proceedings.

Taken as a whole, Patent Owner has not provided credible or sufficient evidence showing that Sanofi exercised or could have exercised control over this proceeding. Accordingly, Patent Owner has not reasonably brought into question Petitioner's disclosure of real parties-in-interest with respect to Sanofi.

---

[9] Patent Owner has not submitted an Exhibit 2005. The quotation does appear, however, at page 73 of Exhibit 2002.

iii. Merial Ltd. and Merial LLC

Patent Owner asserts that Merial Ltd., Merial LLC, and possibly Merial S.A.S, should be named real parties-in-interest because "[a]ll of the Merial entities together are held out publically as simply 'Merial," such that "it is impossible for anyone to know where one Merial entity ends and another Merial entity begins." Prelim. Resp. 18, 21 n.2; *but see* Ex. 2002, 72 (Sanofi report distinguishing between Merial, Inc. and Merial S.A.S.) Patent Owner notes, for example, that Dr. Judy Jarecki-Black, a back-up counsel for Petitioner in this matter, has at times represented Merial Ltd. as well as Merial Inc., and lists the same contact information with respect to both companies. *Id.* at 19–20. Patent Owner further asserts that "[u]nder Delaware statute, Merial LLC is 'deemed to be the same entity' as Merial Limited."[10] *Id.* at 20–21.

Taken as a whole, we do not find persuasive Patent Owners present argument that Merial Ltd. and Merial LLC should be named real parties-in-interest. Counsel for Patent Owner may, nevertheless, request an initial conference call to discuss reasons why Petitioner should be required to submit an amended mandatory notice adding Merial Ltd., Merial LLC, and/or Merial S.A.S as real parties-in-interest.

B. Improper Incorporation by Reference

Patent Owner requests that we exclude all or part of Petitioner's declaration evidence (Exs. 1015, 1013, 1017, 1011, and 1032) as improperly incorporated by reference in contravention of 37 C.F.R. § 42.6(a)(3).

---

[10] We consider this argument a clear attempt to elevate form over substance, particularly in light of Petitioner's public declaration that "Merial Limited and Merial LLC are the same entity." *See* Ex. 2003, 1.

Prelim. Resp. 8–16. We determine that on this record, Petitioner has not improperly incorporated material by reference—most particularly with respect to evidence supporting the grounds instituted. Accordingly, we decline to exercise our discretion to exclude Petitioner's declaration evidence.

C. Person of Ordinary Skill in the Art.

For the purpose of this Decision, we accept Petitioner's undisputed contention that a person of ordinary skill in the art as of the effective filing date of the '038 patent "would be a formulation scientist having at least a college degree in chemistry, chemical engineering, pharmacy, pharmaceutical sciences or an equivalent field and several years of experience formulating parasiticidal compositions." Pet. 7 (citing Ex. 1015 ¶ 33.). According to Petitioner, such a person "would also have several years of experience evaluating the efficacy and aesthetic and other characteristics of parasiticidal compositions through whole organism and animal studies, or would have access to a skilled team of colleagues, such as veterinarians and parasitologists, with such experience. *Id.*; *see* Prelim. Resp. 7 (implicitly accepting Petitioner's definition of POSA). The level of ordinary skill in the art is further demonstrated by the prior art asserted in the Petition. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

D. Claim Construction

In an *inter partes* review, the Board gives claim terms in an unexpired patent their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). "Under a broadest

reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history." *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016); *see also In re Bigio*, 381 F.3d 1320, 1325 (Fed Cir. 2004) ("Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification . . . when [it] expressly disclaim[s] the broader definition.").

Only terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc*., 200 F.3d 795, 803 (Fed. Cir. 1999). The disputed terms in this proceeding relate to the upper and lower bounds of the claim phrase "less than about 5% by weight of the formulation of ethanol," as recited in independent claim. We also address the terms "from about 8 to about 12% by weight Fipronil," and "formulated for spot-on delivery." No other claim terms require construction at this time.

i. Upper Limit of "less than about 5% . . . ethanol"

Petitioner argues that "from the claim's use of the term 'about' [] that the upper limit of the claimed range must be greater than exactly 5%, and would encompass at least up to 5.9% w/w ethanol. . . . and could even be greater than 5.9%" Pet. 9–11 (citing Ex. 1015 ¶¶37–39). In support of this position, Petitioner points to "the patentee's technological aim of ensuring that the formulations 'have a flashpoint of greater than 36°C. (97°F.)'[, which] can be achieved by keeping the C1–C6 alcohol cosolvent (*e.g.* ethanol) at 8% w/w or lower.'" *Id*. at 11 (citing Ex. 1015 ¶ 38–39; Ex. 1002, Abstract, 2:3–4, 39–43). Patent Owner argues that Petitioner's construction

is unreasonable, but declines to provide an alternative construction. Prel. Resp. 28–32.

We agree with Patent Owner that Petitioner's construction is unreasonable. Although the '038 patent does disclose up to 8% by weight ethanol, it also expressly presents "about 5% by weight of the formulation" as an alternative to 8% w/w.[11] Ex. 1002, 2:39–43. Moreover, as Patent Owner points out, "the more narrow range of 'less than about 5%' ethanol was actually claimed." Prelim. Resp. 30.

The text of the '038 patent provides no express definition of the term "about," and only uses the word once in the context of ethanol content—in terms identical to that of claim 1. *See* Ex. 1002, 2:43. We, therefore, look to the level of precision employed by the inventors in illustrating their invention. The Specification discloses three representative examples, each reciting "5.0 wt% ethanol." *Id*. 4:1–36; 5:24–67 (same). The inventor's use of the significant digit indicates that "less than about 5% . . . ethanol" does not extend to 5.1%.

ii. Lower Limit of "less than about 5% . . . ethanol"

Petitioner, supported by the testimony of Dr. Witchey, contends that "'*less than* about 5% by weight of the formulation of ethanol' would encompass a formulation having 0% ethanol." Pet. 8 (citations omitted); Ex. 1015 ¶ 36. Patent Owner argues that the claim term "cannot be construed as completely excluding ethanol" because "the '038 Patent

[11] We accept Dr. Witchey's uncontroverted testimony that "'by weight of the formulation'" is equivalent to 'weight/weight' percentage ('w/w %' or 'wt %'; gram per 100 grams of the formulation)." *See* Ex. 1015 ¶ 35.

specification explicitly teaches that at least some amount of ethanol is required to be present in the formulation." Prelim. Resp. 27–28.

We do not find Patent Owner's arguments persuasive. The Specification discloses parasiticidal formulations comprising "up to 8% by weight" of at least one C_1-C_6 alcohol cosolvent. *Id.* at 1:60–65; *see* 2:39–43. The Specification, however, places no lower limit on the amount of C_1-C_6 alcohol in a formulation. Nor does it require that any such alcohol is ethanol. *See id.* at 2:44–46. ("Examples of the C_1 to C_6 alcohol co-solvent are methanol, ethanol, propanol, isopropanol or butanol, and combinations thereof."). Thus, to the extent Specification may be read to require at least some (undefined) amount of a C_1-C_6 alcohol, the "comprising" language of claim 1 permits the use of, e.g., "methanol, . . . propanol, isopropanol or butanol, and combinations thereof" either instead of, or in addition to the "less than about 5% . . . ethanol" expressly recited in the claim. *See id*.

In view of the above, we construe "less than about 5% by weight of the formulation of ethanol," as used in claim 1, to encompass a formulation having 0% ethanol.

iii. "from about 8 to about 12% by weight Fipronil"

Claim 1 recites "from about 8 to about 12% by weight Fipronil," but does not expressly recite whether "by weight" refers to a weight to weight (w/w) or weight to volume (w/v) measurement. The Specification, however, uniformly refers to weight to weight measurements, including with respect to Fipronil. *See e.g.*, Ex. 1002, 2:23–28 (Fipronil percentages "by weight of the formulation"); 4:3 ("9.7 wt % Fipronil"); 4:12, 24 ("9.8 wt % Fipronil"). In view of the Specification, we interpret "from about 8 to about 12% by weight Fipronil," as meaning "from about 8 to about 12% w/w Fipronil."

See also Ex. 1015 ¶ 35 (testifying to the equivalence of: "by weight of the formulation" and "weight/weight" percentages, designated "w/w %," "wt %," or "gram per 100 grams of the formulation").

iv. "formulated for spot-on delivery"

We accept, for clarity, Petitioners presently undisputed definition of "formulated for spot-on delivery," as used in dependent claim 17, to mean, "a formulation that can be deposited onto the skin of an animal by local point application." Pet. 11; *see* Ex. 1002, 4:36–43, 60–62; Ex. 1015 ¶ 40; Prelim. Resp. 25.

E. Principles of Law

To anticipate a patent claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). "Anticipation requires the presence in a single prior art disclosure of all elements of a claimed invention arranged as in the claim." *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1383 (Fed. Cir. 2011) (citations omitted). To show anticipation, however, "[it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention." *Net MoneyIN v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (citing *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972)).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). A party that petitions the Board for a determination of obviousness must show that "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007)).

F. Grounds 1 and 2

Petitioner's Ground 1 challenges claims 1, 3–5, 7–17 as anticipated by Freehauf. Pet. 14–18. In Ground 2, in which Petitioner challenges claim 6 as obvious over Freehauf as combined with Jeannin or Young, Petitioner relies on Jeannin or Young as providing motivation "to modify the formulations disclosed in Freehauf to include S-methoprene in the claimed amounts to improve the formulations' efficacy, thereby rendering claim 6 obvious." *Id*. at 19. According to Patent Owner, the Petition fails to demonstrate that Freehauf discloses the "from about 8 to about 12% by weight Fipronil, or a veterinary acceptable derivative thereof," required by independent claim 1. Prelim. Resp. 33. Patent Owner's contention is well founded.

Freehauf is directed to "improved fipronil formulations useful in controlling ectoparasites on a domestic animal." Ex. 1008 ¶ 6. In setting forth its obviousness position, Petitioner relies on Freehauf's teaching that such formulations "typically comprise fipronil at a concentration of about 10% (w/v)." Pet. 14 (quoting Freehauf ¶ 6). Petitioner further relies on

Freehauf's disclosure of "[a] spot-on solution . . . for treatment or prevention of tick and/or flea infestation" comprising "fipronil: 10%." *Id*. at 14–15 (citing Ex. 1008 ¶ 50).

As Patent Owner points out, Petitioner presents no credible argument or analysis showing that the "10%" or 10% (w/v)" Fipronil disclosed in Freehauf satisfies the "from about 8 to about 12% by weight Fipronil" limitation of claim 1. *See* Prelim. Resp. 33–34. Stated differently, Petitioner fails to show that the percent, or weight per volume percent, of Fipronil disclosed in Freehauf expressly or inherently falls within the claimed range.

Petitioner relies on the same evidence with respect to the related obviousness challenge of Ground 2. *See* Pet 18 (stating that, "[a]s discussed above, Freehauf anticipates claims 1, 4 and 5. Claim 6 merely adds that the amount of S-methoprene is from about 5% to about 25 % by weight of the formulation."). Neither Petitioner, nor Petitioner's expert, Dr. Witchey, provide a credible explanation as to why either Freehauf or the secondary references teach or suggest "from about 8 to about 12% by weight Fipronil, or a veterinary acceptable derivative thereof," as required by claim 1. *See* Pet. 18–19 (citing Ex. 1015 ¶¶ 75, 142–153).

We do note that, in discussing the contribution of Young, Dr. Witchey states that, "[e]ven though a different unit is used in these references, namely, 'weight per volume' instead of 'weight per weight,' as previously explained, these two units are virtually equivalent to each other because the density of these formulation are close to 1 g/cm3." Ex. 1015, ¶ 149 (referencing ¶ 54 n.6). Dr. Witchey's testimony, however, refers to the amount of *S-methoprene* in a formulation. *See id*. at ¶¶ 148–149. Similarly, paragraph 54, note 6, of her report provides conversion information relating

to co-solvents, such as ethanol. *See* ¶ 54 n.6. Again, we do not read these statements as applying to Fipronil

For the reasons set forth above, we conclude that Petitioner has not established a reasonable likelihood that claims 1, 3–5, 7–17 are anticipated by Freehauf, or that claim 6 is rendered obvious by Freehauf in light of Jeannin or Young.

G. Ground 3

Petitioner contends that claims 1–3 and 7–19 are anticipated by Etchegaray.[12] Pet. 19–25. For the purposes of this discussion, we focus on independent claim 1.

Etchegaray teaches "spot on" topical parasiticidal formulations comprising:

> (a) an insecticidal active substance, preferably fipronil (Ex. 1007, 1:64–2:3; 4:15–18);
>
> (b) a crystallization inhibitor, e.g., the non-ionic surfactant, polysorbate 80 (*id*. at 2:65–3:7; 5:25–26);
>
> (c) "an organic solvent having a dielectric constant of between 10 and 35," for example, ethanol, isopropanol, methanol, diethylene glycol monomethyl ether, or diproply glycol monomethyl ether (DGME) (*id*. at 3:13–15; 4:52–65);
>
> (d) "an organic co-solvent having a boiling point below 100° C. . . . and having a dielectric constant of between 10 and 40," such as ethanol, isopropanol, or methanol (*id*. at 3:13–16; 6:9–10); and

[12] Petitioner contends that "[a]lthough Etchegaray was considered during the prosecution of the '038 patent, the Examiner apparently was not made aware that Etchegaray discloses the limitation 'less than about 5% by weight of the formulation of ethanol.'" Pet. 20.

> optionally, antioxidants, such as butylated hydroxyanisole (BHA) and/or butylated hydroxytoluene (BHT) (*id*. at 4:33–35; 6:11–16).

See Ex. 1015 ¶ 47–49. Etchgaray presents a table disclosing exemplary compositions 1–12 made using 10 grams of Fipronil in a total volume of 100 ml. Ex. 1007, 6:77–7:35. With reference to the same table, Etchgaray provides additional compositions (Examples 13–24) made by increasing the Fipronil to 12.5 grams in the same total volume. *Id*. at 7:58–8:24.

Petitioner contends that Etchegaray Example 14 anticipates claim 1 of the '038 patent insofar as it inherently contains 12.08% w/w Fipronil and 5.77% w/w ethanol. *See* Pet. 21 (relying on Ex. 1017 ¶¶16–26, Apx. D; Ex. 1015 ¶¶ 100–103). Because the 5.77% w/w ethanol in Etchegaray Example 14 exceeds the upper limit of the claim limitation, "less than about 5% by weight of the formulation of ethanol," as construed above, we decline to institute under § 102.

In the alternative, Petitioner argues that Etchegaray Example 14 satisfies the ethanol limitation because "[t]he co-solvent ethanol can also be replaced with isopropanol or methanol, resulting in zero ethanol in the formulation. (Exh. 1007, col. 6, ll. 9–10.)." Pet. 22. An anticipating "reference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures." *Arkley*, 455 F.2d at 587. On the facts before us, we are not convinced that this standard is met. Nor, considering the evidence as a whole, are we convinced that one of ordinary skill in the art would at once envisage Petitioner's proposed solvent substitution for Example 14, thus, arriving at the claimed combination. *See Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed.

Cir. 2015) ("a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." (*quoting In re Petering*, 301 F.2d 676, 681–682 (CCPA 1962)).

For the reasons set forth above, we conclude that Petitioner has not established a reasonable likelihood that claims 1–3 and 7–19 are anticipated by Etchegaray.

H. Grounds 4a, 4b, and 5

Petitioner contends that the challenged claims are invalid for obviousness in view of Etchegaray or the FRONTLINE TOP SPOT References (claims 1–3 and 7–21), and further in view of Maddison, Jeannin, or Young, with respect to claims 4–6. Pet. 26–53. An overview of Etchegaray is presented above. As set forth in paragraphs 66–68 of Dr. Witchey's declaration, the FRONTLINE TOP SPOT References disclose ectoparasiticidal formulations comprising 9.7% w/w Fipronil, 7.7% w/w ethanol, polyvinylpyrrolidone, BHA, BHT, and DGME. *See* Pet. 25–26.

Focusing on claim 1, Petitioner presents evidence that Etchegaray teaches parasiticidal formulations in which "the cosolvent (e.g. ethanol) can range between 0–32.7% (w/v), which overlaps with the claimed range of 'less than about 5% by weight'". Pet 29 (citing Ex. 1015 ¶¶ 48–54, Table I). Petitioner's evidence includes Dr. Witchey's testimony that she "calculated the preferred ranges in Etchegaray for component (d), the co-solvent that is optionally ethanol, to be between 3.8–32.7% w/v, preferably between 4.4–30.0% w/v." Ex. 1015 ¶51; *see id*. at Table I, ¶¶52–56.

To illustrate the overlap between the teachings of Etchgaray and the ethanol limitation of claim 1, Petitioner further contends that "an example formulation prepared according to the teaching in Etchegaray was determined to have 4.31% w/w ethanol," as well as Fipronil and a non-ethanol organic solvent (DGME) within the claimed ranges. *See* Pet. 29 (*citing* Ex. 1017 ¶ 15, Appx. B; Ex. 1015 ¶ 58); *see also* Ex. 1015 ¶¶ 57–58, Appx. C (relying on Ex. 1017 ¶¶ 6–15, Appx. A–B).

According to Dr. Witchey, a person of ordinary skill in the art at the time the invention was made would have understood that "spot-on parasiticidal formulations for domestic animals did not require ethanol or any other C1-C6 alcohol to be effective." Ex. 1015 ¶ 89. "When ethanol was included as a co-solvent, its amount could be as low as, *e.g.*, 3.8% w/w or even a low as 0%." *Id*. (*citing id*. at ¶¶ 51-56). Moreover, because "[i]t would have been understood that ethanol is a flammable drying agent associated with risks of ignition and of skin irritation (*id*. (*citing id.* at ¶¶ 119–126),

> [a] person of ordinary skill in the art as of March 18, 2009, would have been motivated to reduce the ethanol content in the Frontline® TOP SPOT formulation and the Etchegaray formulations to, for example, reduce any flammable risk of the formulations or any dryness and irritation of the pet's skin at the spot of application. Such a reduction would have been mere routine experimentation for a formulation scientist, with a reasonable expectation of success, consisting merely of a predictable variation with obvious potential benefits.

Id. ¶ 119; *see also* Pet. 32–34 (discussing motivation to combine with a reasonable expectation of success).

Dr. Witchey further testifies that "the art was clear that the presence of ethanol is nonessential for the efficacy of the formulation, and its slight

reduction, even its complete removal, would not be expected to have a material effect on the efficacy of the formulation." Ex. 1015 ¶ 128. Thus, for example, "replacing the amount of ethanol in the disclosed formulations, in whole or in part, with isopropanol, would be no more than a simple and predictable use of elements known in the art according to their established functions." *Id*. ¶ 129; *see* Pet. 30.

Patent Owner responds, inter alia, that Petitioner's analysis relies on impermissible hindsight and fails to take into account the evidence of unexpected results submitted during prosecution in the Petrick Declaration. Prelim. Resp. 39–45. Petitioner has, however, set forth a reasoned argument for obviousness which, on this record, Patent Owner has adequately not rebutted. With respect to Patent Owner's evidence of secondary considerations, Dr. Clark testifies on behalf of Petitioner that, "the Petrick Declaration does not establish any such unexpected efficacy of the formulations claimed in the '038 patent." *See* Ex. 1013 ¶ 16; *see also* Pet. 34–48 (arguing, *inter alia*, that "the studies in the Petrick Declaration did not compare the claimed formulation with the closest prior art . . . [and] are not commensurate in scope with the protection sought by the claims").

Dr. Clark testifies that, contrary to the assertion of the Petrick Declaration, one of ordinary skill in the art "would have understood that drying agents such as ethanol were added to fipronil spot-on parasiticidal formulations for aesthetic reasons, whose action was confined to shortly after administration of the product, and would not have expected a reduction in the level of the drying agent from about 10% to about 5% to have much, if any, effect on the efficacy of a formulation against fleas, flea eggs, or ticks." Ex. 1013 ¶ 26. Dr. Clark also testifies to numerous errors and deficiencies

in the design, analysis, and interpretation of the studies underlying the Petrick Declaration. *See id*. ¶¶ 28–60. As but one example, Dr. Clark notes that the commercial products used as comparators contained different ingredients from the test formulations such that "it is impossible to conclude that any such difference in efficacy was due to the minor differences in the amounts of ethanol as opposed to the difference in the other ingredients." *Id*. ¶ 28; *see* ¶¶ 50–55; *see also* Pet. 35, n.3 ("As explained by Dr. Witchey, it would have been expected that reducing the ethanol concentration of the prior art formulations would result in higher flashpoints. (Exh. 1015, ¶ 122.)." Accordingly, on the present record, we find that Petitioner has demonstrated a reasonable likelihood that one of ordinary skill in the art would have considered it obvious to modify the teachings of Etchegaray or the FRONTLINE TOP SPOT References to arrive at the invention of claim 1.

With respect to Ground 5, obviousness further in view of Maddison, Jeannin, or Young, Patent Owner further contends that "the Petition fails to explain why it would have been obvious to add S-methoprene to the formulation disclosed by Example 14 of Etchegaray." Prelim. Resp. 46. Patent Owner, however, has not addressed the specifics of Petitioner's reasons to combine the reference teachings. *See* Pet. 51–53 (pointing to teachings in Maddison, Jeannin, and Young as evidence that "a POSA would have known to combine an IGR such as methoprene with fipronil to improve efficacy of parasiticide formulations").

Upon review of Petitioner's analysis and supporting evidence, we determine that there is a reasonable likelihood that Petitioner would prevail in demonstrating the unpatentability of the challenged claims as obvious in

view of Etchegaray or the FRONTLINE TOP SPOT References (claims 1–3 and 7–21) and further in view of Maddison, Jeannin, or Young (claims 4–6).

I. Ground 6

Petitioner also contends that claims 1–3, 9, and 18–19 are anticipated by Pan. Pan is directed to "a pharmaceutical composition containing fipronil as well as its application in preparing a medicament for killing auricular mites in animals." Ex. 1030, Abstract. The composition

> preferably comprises . . . fipronil 0.5 to 30%, pyrrolidone 1 to 10%, ethanol or benzyl alcohol 1 to 30%, dimethyl sulfoxide (DMSO) 0.5 to 20%, ascorbic acid 0.2 to 1.0%, lidocaine 0.1 to 3%, and making up to 100% with ethyl oleate, wherein the percentages of ethanol or benzyl alcohol, and ethyl oleate are percentages by volume, and all remaining percentages are percentages by weight.

Id. at 1–12. For the preparation of Embodiment 4, Pan recites:

> Measure 10 g of fipronil and 10 g of eprinomectin, then add 5 ml of ethanol, 5 ml of dimethyl sulfoxide (DMSO), 35 ml of N, N-dimethyl formamide, 15 ml of azone and 5 ml of Tween, as well as 0.1 g of vitamin K, 0.2 g of tetracaine, mix them well, and then use glycerol triacetate to make up the volume to 100 ml, so as to prepare a spray preparation or drop preparation containing 10% fipronil and 15% ivermectin.

Id. at 14.

Relying on the declarations of Mr. Gong and Dr. Witchey, Petitioner asserts that "Pan's Embodiment 4 was replicated and determined to inherently contain 9.50% w/w fipronil, 3.74% w/w ethanol, and the non-ethanol organic solvent N, N-dimethyl formamide." Pet. 54 (citing Ex. 1017 ¶¶ 38–46, Appx. H; Ex. 1015 ¶¶ 71–74). Petitioner further presents claim charts showing a correspondence between the teachings of Pan and each element of claims 1–3, 9, and 18–19. Pet. 54–56.

Patent Owner urges that we deny institution on Ground 6 because Petitioner allegedly fails to "set[] forth any analysis as to how it arrived at the 9.50% w/w fipronil and 3.74% w/w ethanol concentrations it states are inherent, and instead leaves that analysis to the supporting declarations." Prelim. Resp. 47. As noted in section II(B), above, we decline to exercise our discretion to exclude Petitioner's declaration evidence. Accordingly, on the present record, Petitioner has demonstrated a reasonable likelihood of showing that claims 1–3, 9, and 18–19 are anticipated by Pan.

III. CONCLUSION

For the foregoing reasons, we find that the information presented in the Petition establishes a reasonable likelihood that the Petitioner would prevail in showing that claims 1–3 and 7–21 are invalid as obvious over Etchegaray or the FRONTLINE TOP SPOT References; that claims 4–6 are invalid as obvious in view of Etchegaray in view of Maddison, Jeannin, or Young; and that claims 1–3, 9, and 18–19 are anticipated by Pan.

This is not a final decision as to the construction of any claim term or the patentability of claims 1–3, 5, and 6. Our final decision will be based on the full record developed during trial.

IV. ORDER

For the reasons given, it is

ORDERED that *inter partes* review is instituted with regard to the following asserted grounds:

4a: Claims 1–3 and 7–21 of the '038 patent under 35 U.S.C. § 103(b) as obvious over Etchegaray;

4b: Claims 1–3 and 7–21 of the '038 patent under 35 U.S.C. § 103(b) as obvious over the FRONTLINE TOP SPOT References;

5: Claims 4–6 of the '038 patent under 35 U.S.C. § 103(b) as obvious over Etchegaray in view of Maddison, Jeannin, or Young; and

6: Claims 1–3, 9, and 18–19 of the '038 patent under 35 U.S.C. § 102(b) as anticipated by Pan.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '038 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is limited to the grounds listed in the Order. No other grounds are authorized.

PETITIONER:

John Patrick Elsevier
Wanli Tang
Matthew W. Johnson
JONES DAY
jpelsevier@jonesday.com
wtang@jonesday.com
mwjohnson@jonesday.com

Judy Jarecki-Black
John Ezcurra
MERIAL INC.
judy.jarecki@merial.com
john.ezcurra@merial.com

Mark Russell
VEDDER PRICE
mrussell@vedderprice.com

PATENT OWNER:

James Murphy
Patrick Woolley
POLSINELLI PC
jpmurphy@polsinelli.com
PWoolley@Polsinelli.com