

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERIAL, INC.,
Petitioner,

v.

SERGEANT'S PET CARE PRODUCTS, INC.,
Patent Owner.

Case IPR2016-00798
Patent 8,614,244 B2

Before TONI R. SCHEINER, SHERIDAN K. SNEDDEN, and
SUSAN L. C. MITCHELL, *Administrative Patent Judges*.

MITCHELL, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Petitioner Merial, Inc. (“Petitioner”) filed a revised Petition (Paper 5, “Pet.”) requesting an *inter partes* review of claims 1–22 (the “challenged claims”) of U.S. Patent No. 8,614,244 B2 (Exhibit 1001, “the ’244 patent”). See 35 U.S.C. §§ 311–319. Patent Owner Sergeant’s Pet Care Products, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 10 (“Prelim. Resp.”).

We have jurisdiction under 35 U.S.C. § 314. To institute an *inter partes* review, we must determine that the information presented in the Petition shows “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(a). For the reasons set forth below, we conclude that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims of the ’244 patent. Therefore, we deny institution of an *inter partes* review for claims 1–22 of the ’244 patent.

B. Related Proceedings

Both parties indicate that the ’244 patent is not involved in any co-pending litigation or administrative matter. Pet. 12–13; Paper 9, 3.

C. The ’244 Patent (Ex. 1001)

The ’244 patent involves a spot-on pesticide composition for mammals, such as dogs and cats, that has low concentrations of active components, fipronil, a pyrethroid, such as cyphenothrin, and optionally an insect growth regulator, which are parasitically effective against a variety of insects and pests, such as fleas and ticks, and is formulated for convenient local application on a dog or cat’s skin. Ex. 1001, Abstract, 1:13–25; 2:29–

37. The composition also includes an organic solvent and may optionally include an antioxidant. *Id.* at 2:42–44. Lower concentrations of the active ingredients minimize the risk of adverse effects. *Id.* at 2:19–24, 37–38.

D. Illustrative Claims

Claims 1, 10, 16, 19, and 20 are independent claims of the '244 patent. Claims 2–9 depend directly or indirectly from claim 1, claims 11–15 depend directly or indirectly from claim 10, claims 17–18 depend directly or indirectly from claim 16, and claims 21–22 depend directly from claim 20. Claim 1 is illustrative of the challenged claims and recites:

1. A method of killing insect and pest pupae and adults on an animal, which method comprises administering a localized cutaneous application between the shoulders of the animal, a spot-on composition comprising 8% to 11% (w/w) fipronil, 3% to 16% (w/w) cyphenothrin, and 60% to 80% (w/w) organic solvent.

Ex. 1001, 28:40–45.

The remaining independent claims have a narrower range for cyphenothrin and some additional components in the spot-on compositions. *See id.* at 29:4, 6 (narrowing range to 4% to 6% (w/w) for cyphenothrin and adding antioxidant for claim 10), 29:22–23, 25 (narrowing range to 4% to 6% (w/w) for cyphenothrin and adding S-methoprene and an antioxidant for claim 16), 30:10–11, 13 (narrowing range to 4% to 6% (w/w) for cyphenothrin and adding pyriproxyfen and an antioxidant for claim 19), 30:19–20 (narrowing range to 4% to 6% (w/w) for cyphenothrin and specifying diethylene glycol monoethyl ether for the organic solvent for claim 20).

E. The Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims are unpatentable based on the following grounds. Pet. 8.

References	Basis	Claims Challenged
Sirinyan ¹ and Garden ²	§ 103	1–7 and 10–22
Sirinyan, Garden, and the EPA Review ³	§ 103	8 and 9

Petitioner relies also on the Declaration of Jeffrey N. Clark, D.V.M., Ph.D. Pet. 1–60; *see* Ex. 1002.

II. ANALYSIS

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016). Under the broadest reasonable interpretation approach, claim terms are given their ordinary and customary meaning as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Neither party believes that any claim term or phrase needs to be expressly interpreted. *See* Pet. 10; Prelim. Resp. 5–39 (offering no express

¹ PCT App. WO 2008/080542 A2, published Jul. 10, 2008 (Ex. 1004, “Sirinyan”). The Sirinyan reference is a German-language reference. Petitioner provided a certified English-language translation (Ex. 1005).

² US Patent 4,902,510, issued Feb. 20, 1990 (Ex. 1006, “Garden”).

³ Mark Suarez, *EPA Product Performance/Efficacy Review for Sergeant’s Cyphenothrin Squeeze-On for Dogs, Sergeant’s Cyphenothrin + IGR Squeeze-On for Dogs, and Sergeant’s Cyphenothrin + Methoprene Squeeze-On for Dogs*, Nov. 7, 2006 (Ex. 1007, “the EPA Review”).

constructions). We agree that we do not need to interpret expressly any claim term or phrase to resolve whether a trial should be instituted. *See, e.g., Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

B. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter 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 said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

In that regard, an obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR*, 550 U.S. at 418; *see Translogic*, 504 F.3d at 1259. We are mindful that the level of

ordinary skill in the art also is reflected by the prior art of record.⁴ *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

We analyze the asserted grounds of unpatentability in accordance with the above-stated principles.

C. Obviousness over Sirinyan and Garden

Petitioner contends that claims 1–7 and 10–22 are unpatentable under 35 U.S.C. § 103 as obvious over Sirinyan and Garden. Pet. 8, 13–40. Petitioner asserts that Sirinyan teaches a spot-on formulation that can contain an α -cyanopyrethroid, such as cyphenothrin, and an N-arylpyrazole, such as fipronil, for controlling ticks and fleas on dogs and cats. Pet. 2, 14. Petitioner also states that one of ordinary skill in the art would have experimented in a routine manner to find the claimed workable ranges for fipronil *Id.* at 15–17. Petitioner relies on Garden to teach that cyphenothrin

⁴ Petitioner states that the level of skill in the art at the time of the invention is a person who “would have been highly educated to a level such as a doctorate in veterinary medicine (D.V.M.) or a Ph.D. in parasitology with at least several years of experience in topical veterinary formulations.” Pet. 1, n.1 (citing Ex. 1002 ¶ 30). The Petitioner also posits that a person of ordinary skill in the art “would have either personally possessed, or had access to, knowledge and skills from clinical research veterinarians and pharmaceutical formulation scientists.” *Id.* Patent Owner does not offer an explicit definition for one of ordinary skill in the art. *See* Prelim. Resp. 5–39. We apply Petitioner’s stated level of ordinary skill in the art, which is supported by Dr. Clark because of the sophistication of the technology and the educational level of those who work in this area. *See In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995)

had already been formulated in topical compositions for use against pests on animals in the claimed ranges. *Id.* at 18–19.

Patent Owner counters that “Petitioner has failed to establish that, at the time of this invention, it was known or expected that a low concentration of cyphenothrin (3% to 16%) in combination with fipronil would achieve a spot-on composition having a long-lasting and increased efficacy against ectoparasites, such as fleas and ticks.” Prelim. Resp. 6.

We agree with Patent Owner that the cited combination of references does not teach cyphenothrin in the claimed ranges for use with fipronil in a spot-on treatment against ectoparasites, for the reasons discussed below.

1. *Sirinyan (Ex. 1005)*

Sirinyan teaches compositions for controlling parasites on animals using N-arylpyrazole, such a fipronil, and a pyrethroid in a formulation comprising aliphatic cyclic carbonates and aliphatic cyclic or acyclic polyethers. Ex. 1006 ¶ 1–2. Sirinyan discusses the interaction between N-arylpyrazoles, such as fipronil, and pyrethroids, stating that most pyrethroids “have to be considered to be antagonists rather than synergists of the N-arylpyrazoles.” *Id.* ¶ 9. In discussing the pyrethroids used in the compositions, Sirinyan states

For the compositions, the combination partners of the N-arylpyrazoles are preferably arthropodicidal pyrethroids, in particular of the cyanopyrethroid (for example flumethrin), type-1 pyrethroid (for example permethrin) or non-ester pyrethroid (etofenprox) type.

Here, α -cyanopyrethroids (for example alpha-cypermethrin, cyfluthrin, beta-cyfluthrin, cyhalothrin, cypermethrin, deltamethrin, fenvalerate, flucythrinate, flumethrin, tau-fluvalinate) are preferably employed in a

concentration range of from 0.01 to 5% by weight, and a synergist is added, if appropriate Particular preference is given to using cypermethrin, cyfluthrin, deltamethrin and flumethrin in a concentration range of from 0.025 to 0.25% by weight. Very particular preference is given to using flumethrin in a concentration range of from 0.05 to 1.25% by weight.

Type-1 pyrethroids (for example allethrin, bioallethrin, permethrin, phenothrin, remethrin, tetramethrin, transfluthrin) are preferably employed in a concentration range of from 20 to 70% by weight. *Particular preference is given here to permethrin, cyphenothrin in a concentration range of from 30 to 60% by weight.* Very particular preference is given to using permethrin in concentrations of from 40 to 50% by weight.

Id. ¶¶ 15–17 (citation omitted) (emphasis added).

Sirinyan also states that “customary organic or inorganic antioxidants may be used for stabilizing the formulations” that are “[u]sually, from 0.01 to 1% by weight, preferably from 0.05% to 0.5%, particularly preferably from 0.075 to 0.2% by weight” *Id.* ¶ 44. Other active components that Sirinyan asserts may be included are growth inhibitors, and juvenile hormone analogues, varying within wide range limits from 0.1 to 7.5% by weight, preferably from 0.25 to 5.0% by weight, particularly preferably from 0.25 to 2.5% by weight. *Id.* ¶ 48. In discussing use of a synergist, Sirinyan states that “[i]n the formulations according to the invention, synergists are preferably used for α -cyanopyrethroids, namely in a synergist:pyrethroid ratio of 20-50:1. The preferred synergist is MGK264.” *Id.* ¶ 49 (citation omitted).

2. *Garden (Ex. 1006)*

Garden discusses a spot-on formulation containing a pyrethroid insecticide at a concentration of 7.5 to 75 kg/m³. Ex. 1006, Abs. Petitioner

asserts that 7.5 kg/m³ corresponds to 0.75% w/v.⁵ Pet. 19 (citing Ex. 1006 1:35–36). Garden states that preferred pyrethroid insecticides include cyphenothrin. *Id.* at 1:45–2:39. Garden’s formulation does not use fipronil.

3. *Analysis*

Petitioner asserts that the “alleged ‘invention’ involved nothing more than taking a prior art spot-on composition of fipronil and cyphenothrin, and through routine experimentation developing a low concentration composition having predictable properties.” Pet. 2 (citation omitted). Petitioner points out that the inventor of the ’244 patent admitted during prosecution that fipronil was known to work well with cyphenothrin, *id.* (citing Ex. 1003 ¶ 10), and that cyphenothrin was known to be fast acting, *id.*; Ex. 1003, 228–229 ¶ 6.

Petitioner offers the Sirinyan reference as teaching an α -cyanopyrethroid and fipronil spot-on formulation for controlling fleas and ticks on animals where the α -cyanopyrethroids “are preferably employed in a concentration range of from 0.01 to 5% by weight, and a synergist is added, if appropriate.” Pet. 14–15. As Petitioner points out, however, Sirinyan further provides that type-1 pyrethroids are used in a concentration range from 20 to 70% by weight, and cyphenothrin in particular is explicitly called out to be used in a concentration range of from 30 to 60% by weight. *Id.* at 15. Petitioner posits that the only difference between the challenged claims and the prior art is the specific amount of cyphenothrin. *Id.* at 21.

Petitioner asserts, despite the preferred concentration range provided for cyphenothrin in Sirinyan, that Sirinyan also discloses a much lower

⁵ Dr. Clark states that there is typically a very close correlation between percent w/v and percent w/w. Ex. 1002 ¶ 69.

concentration range for α -cyanopyrethroids within the claimed range, and Garden also shows that low concentrations of α -cyanopyrethroids work as a topical parasiticide. Pet. 21. Petitioner concludes that one of ordinary skill in the art would have reasonably expected that cyphenothrin, in the claimed combination, would work at such low concentrations without loss of efficacy because of the additive effect of cyphenothrin and fipronil. *Id.* at 22. In addition, Petitioner contends that α -cyanopyrethroids are classified as Type I and/or Type II based on the symptomology they produce in insects and mammals, and cyphenothrin “is referred to as a type I/II pyrethroid” because it “produces Type II symptoms as well as Type I symptoms.” *Id.* at 10, 17 (citing Ex. 1002 ¶ 51). As such, Petitioner contends that one of ordinary skill in the art “would reasonably expect that cyphenothrin would work effectively at the lower levels . . . [of] the other Type II α -cyanopyrethroids disclosed in [Sirinyan].” *Id.* at 17.

Finally, Petitioner contends that a person of ordinary skill would have been motivated to find a lower effective concentration of cyphenothrin because cyphenothrin had the known drawback of causing paresthesia, a detrimental skin condition. Pet. 4, 12, 23, and 25 (citing Ex. 1003 ¶ 9).

Patent Owner asserts that the

teachings in the art at the time clearly established that (1) a higher concentration of cyphenothrin (at least 20%) was needed in combination with fipronil in order to achieve an effective composition and (2) low concentrations of certain pyrethroids, other than cyphenothrin, alone or in combination with other actives or synergists, achieved some efficacy against pests. Nothing in the art taught that cyphenothrin specifically, worked effectively at low concentrations.

Prelim. Resp. 6.

Specifically, Patent Owner asserts that Sirinyan explicitly teaches a high concentration of cyphenothrin, and also teaches that a lesser amount of certain α -cyanopyrethroids can be effective if combined with a synergist. Prelim. Resp. 8, 21. Patent Owner concludes that the petition “fails to provide any explanation why a POSA would ignore the express teaching in Sirinyan that certain pyrethroids, including cyphenothrin, required high concentration for efficacy in combination [with] fipronil” *Id.* at 21.

In addressing the teachings of the combination of references asserted, Patent Owner states that

Despite Sirinyan’s clear teachings, the Petitioner argues that the teachings of Garden would motivate a POSA to simply lower the concentration of cyphenothrin to the range claimed by the ’244 Patent. Petitioner’s reliance on Garden is misplaced, conclusory, and insufficient as Garden only provides general statements about α -cyanopyrethroids. Garden simply categorizes cyphenothrin as an α -cyanopyrethroid species based on the structure of the compound and other compounds possessing a cyano group.

Id. at 8. Patent Owner states that this is especially true because Sirinyan implicitly evidences that α -cyanopyrethroid species are unpredictable. *Id.* at 25 (stating that “not all pyrethroids were found to work effectively with fipronil at the same concentrations”). Patent Owner also asserts that Sirinyan makes clear that pyrethroids and pyrazoles are antagonistic compounds making their combination unpredictable. *Id.* at 27.

In reviewing the teachings of the combination of Sirinyan and Garden, we find that Petitioner has failed to show a reasonable likelihood of success that any of the challenged claims are unpatentable. The key limitation missing from any teaching or suggestion of the combination is “3% to 16%

(w/w) cyphenothrin” (or any narrower range therein) combined with fipronil.

Sirinyan provides a formulation using fipronil and cyphenothrin, but expressly states that cyphenothrin should be used in a concentration range of from 30 to 60% by weight, which is well outside of any of the claimed ranges for cyphenothrin in the challenged claims. As Patent Owner points out, a lower range within the claimed range is called out for *other* α -cyanopyrethroids with the possible use of a synergist (that is not required in the challenged claims), but not for cyphenothrin. Prelim. Resp. 7–8, 21, 29–32. We agree with Patent Owner that Petitioner has failed to show why one of ordinary skill in the art would ignore the express teaching of Sirinyan and lower the concentration of cyphenothrin to a claimed range in a formulation with fipronil.

Garden does not provide any such impetus. As Patent Owner states, Garden describes the activity of cypermethrin and alphacypermethrin (two particular species of the α -cyanopyrethroid genus) without fipronil and without additionally providing any specific teaching with respect to cyphenothrin except to include it in a listing as an α -cyanopyrethroid. Prelim. Resp. 8 (citing Ex. 1006, Examples 1-15); Ex. 1006, 2:15–33 (stating preferred compounds include cyphenothrin). The listing of cyphenothrin as one of a list of preferred pyrethroids, without more, would not suggest to one of skill in the art that a lower amount of cyphenothrin should be used in a formulation with fipronil.

As Patent Owner shows, Sirinyan describes how not all pyrethroids are found to work with fipronil at the same concentrations. Prelim. Resp. 25 (citing Ex. 1005 ¶¶ 5, 16–18). Also, Sirinyan specifically describes a lower

concentration range for certain α -cyanopyrethroids, specifically including alphacypermethrin and cypermethrin, the two α -cyanopyrethroids described in Garden. Therefore, Garden does not appear to add any new teaching concerning the amount of α -cyanopyrethroids to be used with fipronil. Sirinyan, however, also sets forth a higher concentration range specifically for cyphenothrin. Ex. 1005 ¶¶ 15–17. Petitioner argues that this preferred range does not teach away from any other disclosed ranges. Pet. 16.

A reference may be said to “teach away” when a person of ordinary skill “upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.” *Allergan, Inc. v. Sandoz Inc.*, No. 2014-1275, slip op. at 16 (Fed. Cir. Aug. 4, 2015) (quoting *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)). There can be no teaching away when there is no underlying teaching that exists from which to teach away.

We agree that Sirinyan does not constitute a “teaching away” from a lower concentration range for cyphenothrin because no lower concentration range for cyphenothrin was discussed at all—but neither does it suggest the claimed range of cyphenothrin in combination with the other elements of the claimed formulation, such as fipronil. Nor does Garden add anything that would have led one of ordinary skill in the art to lower the concentration range disclosed in Sirinyan. We agree with Patent Owner that the petition “fails to provide any explanation why a POSA would ignore the express teaching in Sirinyan that certain pyrethroids, including cyphenothrin, required high concentration for efficacy in combination [with] fipronil while other pyrethroids required low concentration for efficacy in combination with fipronil.” Prelim. Resp. 21.

We find that Petitioner has failed to show that it has a reasonable likelihood of prevailing on any of claims 1–7 or 10–22.

D. Obviousness over Sirinyan, Garden, and the EPA Review

Petitioner contends that claims 8 and 9, which each depend from claim 1, are unpatentable under 35 U.S.C. § 103 as obvious over Sirinyan, Garden, and the EPA review. Pet. 8, 40–59. Petitioner relies on the EPA Review to teach the additional limitations of claims 8 and 9. For the reasons set forth above, we find that Petitioner has failed to show that it has a reasonable likelihood of prevailing on either of claims 8 or 9.

E. Real Parties-In-Interest

Patent Owner asserts that Merial Limited, Merial LLC, and Sanofi had a measure of control over this proceeding requiring them to be named as real parties-in-interest. Pet. 9–17. Because we have found that Petitioner has failed to show a reasonable likelihood that it would prevail on any challenged claim, we need not address whether these parties constitute real parties-in-interest. *Lumentum Holdings, Inc. v. Capella Photonics, Inc.*, IPR2015-00731, slip op. at 5 (PTAB March 2, 2016) (holding satisfying the requirements of 35 U.S.C. § 312(a) is not jurisdictional). Any real party-in-interest issue is moot.

III. CONCLUSION

After reviewing the information presented in the Petition and the Preliminary Response, as well as the evidence of record, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing that any of claims 1–22 of the '244 patent are unpatentable.

IV. ORDER

Accordingly, it is

ORDERED that the Petition is *denied* as to all challenged claims of the '244 patent.

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