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Paper: 8
Entered: June 23, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PETIQ, INC.,
Petitioner,

v.

BAYER INTELLECTUAL PROPERTY GMBH,
Patent Owner.

IPR2022-00304
Patent 7,910,122 B2

Before TINA E. HULSE, ROBERT A. POLLOCK, and JAMIE T. WISZ, *Administrative Patent Judges*.

WISZ, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

PetIQ, Inc. ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–3 of U.S. Patent No. 7,910,122 B2 (Ex. 1001, "the '122 patent"). Bayer Intellectual Property GmbH ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.").

Under 35 U.S.C. § 314(a), the Board "may not authorize an *inter partes* review to be instituted unless . . . 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." For the reasons explained below, upon consideration of the Petition, Preliminary Response, and the evidence of record, we determine that the information presented in the Petition does not show that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we do not institute an *inter partes* review.

A. Real Parties-in-Interest

Petitioner identifies PetIQ, Inc. as the real party-in-interest. Pet. 2. Patent Owner identifies Elanco US Inc. as the real party-in-interest. Paper 5, 1.

B. Related Matters

The parties do not identify any related matters. *See* Pet. 3; Paper 5, 1.

C. The '122 Patent

The '122 patent, titled "Active Compound-Containing Solid Moulded Bodies for External Use Against Parasites on Animals," discloses solid molded bodies such as neck collars, pendants for neck collars (medallions), ear tags, collars for attachment to limbs or body parts, adhesive strips, and

films or stripping films, which contain active compounds for controlling parasites on animals. Ex. 1001, codes (54), (57); 1:5–7, 2:31–35.

According to the '122 patent, "[a]ctive-containing moulded bodies for controlling parasites in animals have been known for a long time" but the disadvantage of prior molded bodies was the required use of phthalic esters, which could lead to environmental contamination. Ex. 1001, 1:9–28. The '122 patent expresses a desire to replace these phthalates with "environmentally compatible ingredients which are less toxic." *Id.* at 1:29–30. The patent states that this aim was achieved by "using particular fatty acid esters of polyhydric alcohols (e.g. di- and triglycerides or propylene glycol esters)." *Id.* at 1:37–39. A preferred ester is propylene glycol and caprylic and/or capric acid (propylene glycol octanoate decanoate), which can be obtained under the trade name Miglyol 840. *Id.* at 2:13–15, 2:19–23.

According to the '122 patent, "[t]hermoplastic and flexible thermoplastic" substances such as polyolefins or polyvinyl resins are suitable as carrier substances for the molded bodies. Ex. 1001, 2:36–42. Such polymers include polyvinyl chloride ("PVC"), polypropylene, polyethylene, and EDPM [Ethylene Propylene Diene Monomer]. *Id.* at 2:53–3:3. The patent also describes the use of active ingredients aimed at controlling ectoparasites, including various species of fleas, ticks, mites, flies, and lice. *Id.* at 4:3–9. Preferred active ingredients include flumethrin and imidacloprid. *Id.* at 6:66–67; 7:1–10.

The '122 patent includes four working examples. Ex. 1001, 9:5–10:57. Example 4 describes a composition satisfying the requirements of claim 1 of the patent and includes the following components: (i) 10 g imidacloprid, (ii) 5 g flumethrin, (iii) 21 g di-n-butyl adipate, (iv) 9 g

propylene glycol octanoate decanoate, (v) 2 g epoxidized soybean oil, (vi) 1 g stearic acid, (vii) 51 g PVC, and (viii) 1 g pigment mixture. *Id.* at 10:29–42; Pet. 9; Prelim. Resp. 6. The ingredients were mixed until they formed a homogenous mixture, which was then shaped into solid molded neck collars and medallions by injection moulding. *Id.* at 10:42–52.

All four example compositions of the '122 patent were tested for activity against fleas (Ctenocephalides felis) and ticks (Ixodes ricinus and Ixodes holocyclus). Ex. 1001, 10:58–11:3. Activities of greater than 90% over a period of 5–6 months were observed for all formulations identified in the Examples. *Id.* at 11:41–45, 12:28–32, 13:14–18.

D. Challenged Claims

Petitioner challenges claims 1–3 of the '122 patent. Claim 1, which is the only independent claim of the '122 patent, is illustrative of the challenged claims, and is reproduced below:

> 1. A solid moulded body for external use against parasites on animals, the solid moulded body comprising a mixture of:
>
> a. Polyvinyl chloride;
>
> b. Propylene glycol dicaprylocaprate at concentration of from about 5% to about 17.5% by weight of the solid moulded body;
>
> c. Imidacloprid at concentration of from about 1% to about 20% by weight of the solid moulded body; and,
>
> d. Flumethrin at concentration of from about 1% to about 20% by weight of the solid moulded body.

Ex. 1001, 14:2–11. Challenged claims 2–3 depend from claim 1.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–3 of the '122 patent are unpatentable in view of the following grounds. Pet. 5.

Ground	Claims Challenged	Statutory Basis	References
1	1–3	§ 103(a)[1]	Dorn,[2] Reul[3]
2	1–3	§ 103(a)	Dorn, Choi[4]

Petitioner relies on the Declaration of Alan A. Marchiondo, Ph.D. (Ex. 1003) in support of its contentions. Patent Owner relies on the Declarations of Irwin C. Jacobs, Ph.D. (Ex. 2001) and Ian F. Burgess (Ex. 2002) in support of its Preliminary Response.

II. ANALYSIS

A. Principles of Law

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

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

[1] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. § 103. Based on the filing date of the '122 patent, we apply the pre-AIA version of § 103.
[2] Dorn et al., US 6,232, 328 B1, issued May 15, 2001 (Ex. 1004, "Dorn").
[3] Reul et al., US 4,331,651, issued May 25, 1982 (Ex. 1006, "Reul").
[4] Choi et al., AU 200135068 A1, published June 21, 2001 (Ex. 1005, "Choi").

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). "An obviousness determination requires finding both '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.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio–Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)). A conclusion of obviousness "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

B. Person of Ordinary Skill in the Art

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986).

Petitioner, relying on the testimony of Dr. Marchiondo (Ex. 1003), contends that a person of ordinary skill in the art ("POSITA") as of the relevant date would have "had an M.S., Ph.D., or equivalent degree in chemistry, biology, microbiology, biochemistry, chemical engineering, or related fields, and at least two years' work experience or post-doctoral

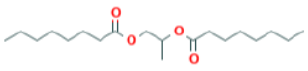
training in parasitology or the research and development of products for controlling ectoparasites in animals." Pet. 25 (citing Ex. 1003 ¶¶ 30–31).

Patent Owner does not dispute Petitioner's definition of a person of ordinary skill in the art for purposes of the institution decision. Prelim. Resp. 7. Because Petitioner's proposed definition is unopposed at this stage and is not inconsistent with the cited prior art, we adopt it for the purposes of this Decision.

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner provides a proposed construction for the term "propylene glycol dicaprylocaprate." Pet. 14–15. Specifically, Petitioner proposes that the term should be construed to mean "a fractionated coconut oil that presents as an odorless, colorless liquid, with the following chemical structure:



."

Id. at 14. Petitioner also contends that "propylene glycol dicaprylocaprate" is "a lipophilic ester composed of propylene glycol and caprylic and/or capric acid that can be obtained commercially under the trade name Miglyol® 840" and that "[o]ther names for this substance are propylene glycol dicaprylate, dicaprate; propylene glycol octanoate decanoate; and

caprylic/capric acid-1,2-propanediol diester." *Id.* at 15 (citing Ex. 1003 ¶ 116).

Patent Owner contends that Petitioner's proposed construction of "propylene glycol dicaprylocaprate" is not necessary to decide the petition but, for purposes of institution, both parties agree that "Miglyol® 840, propylene glycol dicaprylate/dicaprate, propylene glycol octanoate decanoate, and caprylic/capric acid-1,2-propanediol diester all fall within the scope of the claim term 'propylene glycol dicaprylocaprate' as recited in Claim 1." Prelim. Resp. 8–9 (citing Pet. 15; Ex. 2001 ¶ 9) (emphasis omitted).

Upon review of the parties' arguments and the evidence of record, we determine that "propylene glycol dicaprylocaprate" does not require express construction for purposes of this Decision. We agree with Patent Owner that, for purposes of this Decision, it is sufficient that the parties agree that Miglyol 840 and the other terms recited by Patent Owner fall within the scope of the claim term "propylene glycol dicaprylocaprate." *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.")).

D. Asserted Obviousness of Claims 1–3 over Dorn in View of Reul

Petitioner contends that claims 1–3 would have been obvious over the combined disclosures of Dorn and Reul. Pet. 25–36. Patent Owners dispute Petitioner's contentions. Prelim. Resp. 9–34.

1. Dorn (Ex. 1004)

Dorn, titled "Non-Systemic Control of Parasites," is directed to the "[u]se of agonists and antagonists of the nicotinergic acetylcholine receptors of insects for the non-systemic control of parasitic insects, such as fleas, lice, and flies, on humans and on animals." Ex. 1004, codes (54), (57). Dorn discloses that the active compounds can be administered in the form of suitable preparations including solutions or concentrates, emulsions and suspensions, formulations, and solid preparations including shaped articles containing the active compound. *Id.* at 6:61–62, 7:4–15.

The "shaped articles" of Dorn can be in the form of collars, attachments to collars (such as medallions), ear tags, and bands affixed to limbs. Ex. 1004, 9:33–39. "Suitable polymers for the preparation of the shaped articles are thermoplastic and flexible" and "[p]articular mention" is made of PVC. *Id.* at 9:40–58. The "shaped articles can furthermore comprise the additives customary for plastics" including "pigments, stabilizers, flow agents, glidants, and mould release agents." *Id.* at 22:28–31.

Dorn also discloses the use of plasticizers for the polyvinyl-resin-based shaped articles "such as the esters of azelaic acid, maleic acid, ricinoleic acid, myristic acid, palmitic acid, oleic acid, sebacic acid, stearic acid and trimellithic acid, as well as complex linear polyesters, polymeric plasticizers and epoxidized soybean oils." Ex. 1004, 9:58–10:3. The amount of plasticizer can range "approximately 10% to 50% by weight, preferably approximately [from] 20 to 45% by weight, of the entire composition." *Id.* at 10:3–6.

According to Dorn, "[i]n the preparations and shaped articles, the active compounds can be present in the form of a mixture with synergists or

other active compounds." Ex. 1004, 17:5–7. Dorn lists a number of active compounds, including flumethrin and imidacloprid. *Id*. at 22:24–27, 22:32–35.

2. Reul (Ex. 1006)

Reul, titled "Depot Body on the Basis of Silicone Rubber and Process for the Preparation Thereof," is directed to depot bodies made of silicone rubber "for applying active substances to the skin, for example the nasal mucous membrane, of cattle." Ex. 1006, codes (54), (57), 1:8–10. The depot bodies of Reul include the active ingredients, silicone rubber, and "optionally solid additives, from 2 to 50 weight %, relative to silicone rubber, of a release-promoting substance or mixture of such substances." *Id.* at 1:44–50. According to Reul, the release promoting substances are "only slightly soluble in water but soluble in silicone rubber," and were found to "ensure a satisfactory release of active ingredient from the depot body." *Id.* at 2:33–36. These release-promoting substances of Reul "either do not affect the mechanical properties of the silicone rubber at all or only to an insignificant extent" and "reduce[d] the viscosity of the silicone mass," thus allowing "an increased concentration of active ingredient." *Id.* at 2:38–47. Reul discloses that caprylic/capric acid-1,2-propanediol diester (®Miglyol 840) is a preferred release-promoting additive. *Id.* at 3:7–30.

The depot bodies of Reul are preferably applied to the mucosae using a nose clamp and are suitable for applying steroid hormones, antibiotics, chemotherapeutic agents, prostaglandins, or vitamins. Ex. 1006, 3:54–56, 3:60–64.

3. Petitioner's Position

Petitioner contends that the limitations of claims 1–3 are disclosed in Dorn and Reul and that a person of ordinary skill in the art would have been motivated to combine the teachings of these references with a reasonable expectation of success. Pet. 29–36. Specifically, Petitioner contends that Dorn discloses solid molded bodies that include all the limitations of claim 1 except for limitation (b) which recites, "[p]ropylene glycol dicaprylocaprate at [a] concentration of from about 5% to about 17.5% by weight of the solid moulded body." *Id.* at 33–36 (claim chart). Petitioner relies on Reul's teaching of Miglyol 840 to provide this disclosure. *See id.* at 33–35 (citing Ex. 1006, 3:7–25, 3:31–37). According to Petitioner, "a person of ordinary skill in the art would have had strong motivation at the time of the invention to use Miglyol® 840 in the composition of Dorn based on a POSITA's knowledge and the teachings of Reul." *Id.* at 29.

In arguing a motivation to combine the teachings of Dorn and Reul, Petitioner contends that, on or before the priority date of the '122 patent, controlled-release molded bodies for long-acting dermal parasiticide administration were well known and Dorn and Reul both teach that incorporating active compounds into these polymer-based molded bodies was an effective method of administering ectoparasiticides or other active ingredients. Pet. 29–30 (citing Ex. 1003 ¶ 153; Ex. 1004, 7:4–14, 9:33–38; Ex. 1007, 1:6–10; Ex. 1008, 2:7–29). Petitioner further contends that:

> At the time of the alleged invention, one of ordinary skill in the art knew that spreading agents (sometimes known in the art as spreading oils, carriers, or release promoting agents, and particularly liquid solvents) were advantageously used in ectoparasiticide-containing molded bodies to enhance the uniform release of the active compound and significantly increase the period of activity.

Id. at 30 (citing Ex. 1003 ¶ 155, Ex. 1004, 8:1–3, 10:7–10; Ex. 1006, 1:45–51; Ex. 1007, 2:15–20; Ex. 1008, 1:65–2:17). Further, according to Petitioner, those skilled in the art "understood that compounds incompatible with the base polymer material of the molded body would serve as primary targets for spreading agent selection given the need to enhance migration of the active ingredient out of the polymer body." *Id.* (citing Ex. 1003 ¶ 156; Ex. 1006, 2:14–67; Ex. 1007, 2:15–20; Ex. 1008, 1:65–2:17; Ex. 1019, 2–6).

Petitioner contends that Reul discloses antiparasitic formulations using a "release-promoting substance" in combination with a polymer molded body, and discloses that "[s]uitable release-promoting additives include" alcohols and esters such as "caprylic/capric acid-1,2-propanediol diester (®Miglyol 840)." Pet. 34 (citing Ex. 1006, 1:44–50, 3:5–25). Petitioner also asserts that Reul teaches the benefits of adding Miglyol 840 as a spreading agent to a polymer molded body for controlled-release parasiticide products and Miglyol 840 was known to enhance migration of active ingredients across biological membranes. Pet. 31 (citing Ex. 1003 ¶¶ 157–158; Ex. 1006, 1:44–50, 2:63–3:37; Ex. 1009, 44; Ex. 1015, 2:55–66).

According to Petitioner, it would have been obvious to a POSITA to combine the "Miglyol® 840 disclosed in Reul as a 'release-promoting' agent with the PVC-based resin described in Dorn to promote the controlled-release of active compounds" because Miglyol 840 is "a tasteless, odorless, inexpensive, and readily-available spreading compound with a known tendency to enhance dermal absorption." *Id.* at 31 (citing Ex. 1003 ¶ 159; Ex. 1006, 2:33–47, 2:57–62, 3:7–30; Ex. 1009, 45–46; Ex. 1014, 4:6–13, 4:35–38). Petitioner further contends that "Dorn reinforces the benefit of

adding spreading oils to ectoparasitic drug delivery devices, noting specifically dipropylene glycol pelargonate (a C9/C9 diester)." *Id.* (citing Ex. 1003 ¶ 160; Ex. 1004, 8:1–3).

According to Petitioner, "[g]iven the similarities between Miglyol® 840 and dipropylene glycol pelargonate, and dipropylene glycol pelargonate's use in the art as a spreading agent, one of ordinary skill in the art would have had a reasonable expectation of success in substituting the spreading agent in Dorn with Miglyol® 840." Pet. 31–32 (citing Ex. 1003 ¶ 161). Petitioner also asserts that a POSITA would have expected the addition of Miglyol 840 to PVC to induce a more uniform and effective controlled-release of active ingredients from the PVC body because of known prior art combinations involving Miglyol 840 with both silicone rubber (as taught in Reul) and other polymeric materials. *Id.* at 32 (citing Ex. 1003 ¶ 163). Lastly, Petitioner contends that, "the addition of Miglyol® 840 to PVC in a molded body for dermal delivery on animals also served to accommodate the industry's growing trend away from the use of environmentally harmful phthalates." *Id.* (citing Ex. 1003 ¶ 163).

With regard to claim 1's limitation that the propylene glycol dicaprylocaprate be present at a weight percent limitation of "about 5% to about 17.5% by weight of the solid moulded body," Petitioner cites to disclosure from Dorn and Reul as allegedly teaching this limitation. Pet. 33–34. Specifically, Petitioner cites to Dorn's discussion of the use of plasticizers for the polyvinyl-resin-based shaped articles, and that the amount of plasticizer in these compositions can range from approximately 10 to 50% by weight, preferably approximately 20 to 45% by weight. *Id.* at 34 (citing Ex. 1004, 9:58–60, 10:3–6). Petitioner also cites to Reul's

disclosure of "antiparasitic formulations using a 'release-promoting substance' in combination with a polymer molded body, with a concentration preferably 5 to 40, weight %, relative to polymer body." *Id.* at 34 (citing Ex. 1006, 1:44–50, 3:5–6).

4. Patent Owner's Position

Patent Owner contends that Petitioner's proposed substitution of Miglyol 840 from Reul for the dipropylene glycol pelargonate in the compositions of Dorn would not achieve a PVC "solid moulded body," as claimed. Prelim. Resp. 20–23. Specifically, Patent Owner asserts that the discussion of dipropylene glycol pelargonate in Dorn is a component of Dorn's "[p]our-on and spot-on formulations," which are liquid solution preparations, and not PVC solid preparations. *Id.* at 21 (citing Ex. 1004, 7:51–55; 8:1–3). Thus, according to Patent Owner, "when one performs Petitioner's substitution of Miglyol® 840 for dipropylene glycol pelargonate (as urged at Pet. 31–32), one achieves a *liquid solution preparation* containing Miglyol® 840, not a PVC molded body containing Miglyol® 840." *Id.* at 22. Patent Owner contends that Petitioner fails to address the additional modification of Dorn of first adding dipropylene glycol pelargonate to Dorn's PVC molded body. *Id.* at 22.

Patent Owner also asserts that, even if Miglyol 840 were added to Dorn's PVC molded body, Petitioner fails to adequately meet the "about 5% to about 17.5%" weight limitation for propylene glycol dicaprylocaprate recited in the claims. Prelim. Resp. 23–31. According to Patent Owner, although Petitioner relies on Dorn's disclosure of 10% to 50% by weight of plasticizer to meet this limitation, Dorn's plasticizers were not relied on by Petitioner for its proposed modification of Dorn. *Id.* at 25. In contrast,

Petitioner relied on the substitution of Miglyol 840 for Dorn's spreading oils (dipropylene glycol pelargonate) and Dorn does not disclose any amount of spreading oils, or dipropylene pelargonate, to use in any of its formulations. *Id.* at 25–26 (citing Pet. 26–27; Ex. 1004, 10:3–6; Ex. 2001 ¶ 20). Patent Owner further contends that Petitioner has not shown that Miglyol 840 was a known plasticizer for PVC as of the effective filing date nor has Petitioner shown that Miglyol 840 performs the same (or substitutable) function as a plasticizer in Reul and Dorn. *Id.* at 28 (citing Ex. 2001 ¶ 14 (citing Exs. 2001–2013)).

With regard to the disclosure from Reul relied on by Petitioner, Patent Owner contends that Reul expresses the weight percentage of the release-promoting substance "relative to silicone rubber," rather than relative to the entire depot body. Prelim. Resp. 30 (citing Ex. 1006, 1:44–50). By contrast, according to Patent Owner, claim 1 of the '122 patent recites the weight percent of propylene glycol dicaprylocaprate relative to the "weight of the solid moulded body," which includes polyvinyl chloride, imidacloprid, and flumethrin. *Id.* Patent Owner contends that Petitioner has not attempted to convert Reul's weight percent of the release-promoting substance into a value relative to the weight of the solid molded body. *Id.* at 31.

5. Analysis

For the reasons explained below, upon consideration of the Petition, Preliminary Response, and the evidence of record, we are not persuaded that Petitioner has provided sufficient argument and supporting evidence to demonstrate a reasonable likelihood that challenged claims 1–3 would have been obvious over the combined teachings of Dorn and Reul.

First, Petitioner has not presented sufficient evidence to show that one of ordinary skill in the art would have been motivated to substitute Miglyol 840 from Reul into the solid preparations of Dorn. Petitioner argues that the similarities between Miglyol 840 and dipropylene glycol pelargonate, and dipropylene glycol pelargonate's use in the art as a spreading agent, would have led one of ordinary skill in the art to have a reasonable expectation of success in substituting the spreading agent in Dorn with Miglyol 840. Pet. 31–32. However, as discussed by Patent Owner, Dorn's discussion of dipropylene glycol pelargonate (and spreading oils generally) is in the context of adjuvants that may be used in liquid solutions for use as "pour-on and spot-on formulations." *See* Prelim. Resp. 10–17, 20–23; Ex. 1004, 7:4–7, 8:1–2. These pour-on formulations are different than Dorn's solid preparations, which include shaped articles made of PVC. *See* Ex. 1004, 7:15–8:10 (discussing solutions for pour-on formulations), 9:9–22:31 (discussing solid preparations). While Dorn also discusses the use of adjuvants that can be used with its solid preparations, this discussion mentions preservatives, antioxidants, colorants, lubricants, and glidants, but does not include the use of spreading agents.[5] Ex. 1004, 9:18–22. Thus, Petitioner has not sufficiently explained how or why one of ordinary skill in the art would have swapped out the dipropylene glycol pelargonate from

[5] Dorn also states that its shaped articles can comprise the "additives customary for plastics" such as "pigments, stabilizers, flow agents, glidants and mould release agents." Ex. 1004, 22:28–31. This list also does not include spreading oils or dipropylene glycol pelargonate and Petitioner does not cite to this disclosure in its claim chart.

Dorn's pour-on formulations with the Miglyol 840 disclosed in Reul in order to obtain a PVC solid molded body including Miglyol 840.[6]

Second, even if one of ordinary skill in the art did use the Miglyol 840 from Reul in the solid PVC compositions of Dorn, Petitioner has not presented sufficient evidence to show that these references teach the presence of Miglyol 840 at the recited weight limitation of "about 5% to about 17.5% by weight of the solid moulded body." As discussed above, Petitioner relies on Dorn's disclosure of spreading agents (such as dipropylene glycol pelargonate) in arguing that one of ordinary skill in the art would have had a reasonable expectation of success in substituting the Miglyol 840 in the compositions of Dorn. *See* Pet. 31–32. However, Dorn does not disclose any weight percentage for dipropylene glycol pelargonate or any of the disclosed spreading agents. Petitioner instead relies on Dorn's disclosure of plasticizers in amounts of 10 to 50%, preferably approximately from 25% to 45% by weight, to supply this disclosure. Pet. 41–42. In order for this argument to be persuasive, Petitioner must show that one of ordinary skill in the art would have been motivated to, and would have had a reasonable expectation of success in, substituting the plasticizers of Dorn with Miglyol 840 as disclosed in Reul. For the reasons explained below, we find that Petitioner has failed to do so.

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[6] Petitioner's claim chart also cites to Dorn's disclosure of hydrophobic phase oils, noting that mono and diglycerides of the C8/C10-fatty acids are suitable hydrophobic phase oils. Pet. 34 (citing Ex. 1004, 8:19–26). However, this disclosure is in the context of oils that can be used in the emulsions and suspensions of Dorn, and not in the discussion of Dorn's solid preparations. *See* Ex. 1004, 8:11–9:8 (discussing emulsions), 9:9–22:31 (discussing solid preparations). Thus, we similarly find that this disclosure would not have provided one of ordinary skill in the art with the motivation to use Miglyol 840 in the solid preparations of Dorn.

As acknowledged by Petitioner, Miglyol 840 is disclosed in Reul for its use as a release-promoting substance or spreading agent. *See, e.g.*, Pet. 31, 34 (citing Ex. 1003 ¶ 157; Ex. 1006, 1:44–50, 2:63–3:37). Petitioner does not show that Miglyol 840 is being used as a plasticizer in Reul such that one of ordinary skill in the art would have been motivated to use it in the compositions of Dorn in the amounts specified by Dorn for plasticizers. We credit the testimony of Patent Owner's declarant, Dr. Jacobs, that a "uniformly accepted definition of plasticizer" is "a substance or material incorporated in a material … to increase its flexibility, workability, or distensibility." Ex. 2001 ¶ 12 (citing Ex. 2012, 173). In contrast, Reul states that its release-promoting substances (including Miglyol® 840) "either do not affect the mechanical properties of the silicon rubber at all or only to an insignificant extent." Ex. 1006, 2:38–40. We further credit the testimony of Dr. Jacobs that Reul's "release-promoting substances … do not function as a plasticizer in silicone rubber, at least under the 'universally accepted definition' of a 'plasticizer' discussed above." Ex. 2001 ¶ 39 (further testifying that "Reul does not mention any 'plasticizer' in general, and does not teach or suggest that caprylic/capric acid-1,2-propanediol diester or Miglyol® 840 functions as a plasticizer in silicone rubber.").

Petitioner and their declarant, Dr. Marchiondo, also appear to distinguish spreading agents and plasticizers. For example, Dr, Marchiando states that "[s]ubstances known as plasticizers are routinely compounded in PVC or other polymers in order to make the end-product more durable, flexible, stable, and resistant to wear and tear" and then goes on to discuss how phthalates are common and well known plasticizers for PVC. Ex. 1003

¶¶ 46–47 (citing Ex. 1001, 1:15–30). Dr. Marchiondo then states that, "[o]ther common additives to polymers designed for molded bodies designed for drug delivery products include, *inter alia*, stabilizers, lubricants, fillers, colorants, and emollients, sometimes known in the art as 'spreading agents.'" *Id.* ¶ 48 (citing Ex. 1004, 8:1–3, 10:6–9; Ex. 1005, 11:4–17; Ex. 1006, 1:45–51; Ex. 1007, 2:15–20; Ex. 1008, 1:50–2:29). Petitioner similarly appears to distinguish plasticizers and spreading agents in stating that, "[t]he art taught that periods of activity in collars containing spreading agents were increased as compared to traditional PVC collars prepared using plasticizers such as phthalates and adipates." Pet. 17 (citing Ex. 1003 ¶ 53; Ex. 1008, 2:24–53, 8:30–52).

Petitioner also includes one sentence in their motivation to combine argument that "the addition of Miglyol® 840 to PVC in a molded body for dermal delivery on animals also served to accommodate the industry's growing trend away from the use of environmentally harmful phthalates." Pet. 32. However, for the reasons discussed above, Petitioner does not provide sufficient evidence that one of ordinary skill in the art would have been motivated to substitute Miglyol 840, which is used as a release-promoting substance in Reul, for the plasticizers of Dorn (and in the amounts specified by Dorn).

We are also not persuaded by Petitioner's reliance on Reul's disclosure of the amount of release-promoting substance to teach the weight limitation of "propylene glycol dicaprylocaprate at [a] concentration of from about 5% to about 17.5% by weight of the solid moulded body." Specifically, Petitioner's claim chart cites to Reul's disclosure of the use of a "'release-promoting substance' in combination with a polymer molded body,

with a concentration preferably 5 to 40, weight %, *relative to polymer body*." Pet. 34 (citing Ex. 1006, 1:44–50, 3:5–6) (emphasis added). However, the cited portion of Reul actually discloses the weight percentage of the release-promoting substance "relative to silicone rubber":

> In accordance with the invention, this object is achieved by providing a depot body on the basis of silicone rubber, which contains, in addition to the active ingredient(s) silicone rubber and optionally solid additives, from 2 to 50 weight %, *relative to silicone rubber*, of a release-promoting substance or mixture of such substances.

Ex. 1006, 1:44–50 (emphasis added); *see also* 3:1–6. Reul discloses the presence of "active ingredient(s)" and "optionally solid additives" in addition to the silicone rubber and the release-promoting substance. *Id.* at 1:44–50. Thus, we agree with Patent Owner that the weight percent in Reul is expressed relative only to the silicone rubber rather than the entire depot body. *See* Prelim. Resp. 30. In contrast, claim 1 of the '122 patent recites the weight percent of the propylene glycol dicaprylocaprate relative to the "weight of the solid moulded body," which also includes polyvinyl chloride, imidacloprid, and flumethrin. Petitioner does not acknowledge this difference in weight percentages nor do they attempt to convert Reul's weight percent of the release-promoting substance into a value relative to the weight of the solid molded body. Thus, we are not persuaded that the disclosure of Reul teaches the weight percent limitations of the claims. *See* 35 U.S.C. § 312(a)(3); *see also Intelligent Bio-Sys.*, 821 F.3d at 1369 ("It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'").

In view of the foregoing, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that the subject matter of challenged claims 1–3 would have been obvious over the combined disclosures of Dorn and Reul.

E. Asserted Obviousness of Claims 1–3 over Dorn in View of Choi

Petitioner contends that claims 1–3 would have been obvious over the combined disclosures of Dorn and Choi. Pet. 36–44. Patent Owner disputes Petitioner's contentions. Prelim. Resp. 34–40.

1. Choi (Ex. 1005)

Choi, titled "Pour-on formulations containing polymeric material, glycols and glycerides," is directed to "avermectin topical pour-on formulations" against ectoparasites and endoparasites, such as "heartworms and nematodes." Ex. 1005, 4:32–5:3.[7] Choi discloses topical formulations containing (i) glycols, glycerides, or their derivatives, (ii) a parasiticidal active ingredient, and (iii) an optional polymeric material. *Id.* at Abstract. More specifically, the formulation of Choi may be in the form of a topical pour-on formulation having an avermectin compound (0.005–10% w/v), an antioxidant (0.005–1% w/v), and a carrier consisting of glyceride, glycol, or derivatives thereof (40–100% q.s, v/v). *Id.* at 6:3–9. According to Choi, its formulations "provide superior efficacy against endoparasites and ectoparasites when compared to conventional formulations and to maintain the concentration of the active compound in the milk of dairy animals below a safe concentration for human consumption." *Id.* at Abstract.

[7] The cited page numbers in Exhibit 1005 refer to the page numbers added by Petitioner located at the bottom right side of the page.

The formulations of Choi "are prepared using solvents such as water, alcohols such as ethanol, methanol, isopropanol and the like, propylene glycol esters, glycerides, or their derivatives as the carrier." Ex. 1005, 5:6–9. Choi describes a variety of glyceride and glycol carriers, including Miglyol 840. *Id.* at 11:4–14. The carriers provide "good penetration and spreadability of the active compound" when applied to the animals, "even at cold temperatures." *Id.* at 11:15–17.

2. Petitioner's Position

Petitioner contends that the limitations of claims 1–3 are disclosed in Dorn and Choi and that a person of ordinary skill in the art would have been motivated to combine the teachings of these references with a reasonable expectation of success. Pet. 36–43. As with ground 1, Petitioner contends that Dorn discloses solid molded bodies that include all the limitations of claim 1 except for limitation (b), which recites "[p]ropylene glycol dicaprylocaprate at [a] concentration of from about 5% to about 17.5% by weight of the solid moulded body." *See* Pet. 41–44 (claim chart). For this limitation, Petitioner cites to Choi's disclosure of the use of Miglyol 840 (a C8/C10 diester) in antiparasitic formulations as a preferred carrier because it provides "good penetration and spreadability of the active compound even in cold temperatures." *Id.* at 42 (citing Ex. 1005, 5:25–28, 10:27–30, 11:4–17, 15:5–22:30, 27:30–28:3, 31:6–7).

In arguing that one of ordinary skill in the art would have been motivated to combine the disclosures of Dorn and Choi, Petitioner makes the same arguments as used in ground 1 with respect to combining Dorn and Reul. *Compare* Pet. 29–32, *with* Pet. 37–41.

3. Patent Owner's Position

Patent Owner contends that ground 2 fails for the same reasons as for ground 1. Prelim. Resp. 36–40. Patent Owner further asserts that ground 2 also fails because all of the formulations in Choi are liquid pour-on formulations wherein Miglyol 840 is the "carrier" in which all other ingredients are dissolved and suspended. *Id.* at 36 (citing Ex. 2001 ¶¶ 41–42). Patent Owner contends that Choi's carrier is the predominant component occupying most of the volume in the formulation. *Id.* (citing Ex. 2001 ¶¶ 44–46). Thus, according to Patent Owner, "if one were to consider substituting Miglyol® 840 in Choi for any component in Dorn's PVC solid preparations, the most direct functional analog to Choi's Miglyol® 840 'carrier' would be Dorn's PVC 'carrier,' not some minor amount 'adjuvant' or 'additive' in Dorn." *Id.* at 36–37 (citing Ex. 1004, 9:10–14).

Patent Owner also argues that Choi's statement that Miglyol 840 imparts "good penetration" of the active compound would actually be undesirable for the delivery of imidacloprid and flumethrin because these agents work non-systematically on the exterior of the animal's body (haircoat and skin) and are generally not absorbed transdermally. Prelim. Resp. 37–38 (citing Ex. 2002 ¶ 35).

4. Analysis

For many of the same reasons as discussed above for ground 1, we are not persuaded that Petitioner has provided sufficient argument and supporting evidence to demonstrate a reasonable likelihood that challenged claims 1–3 would have been obvious over the combined teachings of Dorn and Choi.

First, Petitioner has not presented sufficient information to show that one of skill in the art would have been motivated to substitute Miglyol 840 from Choi in the solid preparations of Dorn. As discussed above, Dorn describes the use of dipropylene glycol pelargonate in connection with its liquid, pour-on formulations and not in connection with its solid preparations. Petitioner has not sufficiently explained how or why one of ordinary skill in the art would substitute the Miglyol 840, used in the liquid formulations of Choi, into the solid articles of Dorn. This lack of explanation is especially evident considering Petitioner's reliance on the substitution of Miglyol 840 for dipropylene glycol pelargonate, which is used in Dorn's liquid pour-on formulations. Further, we credit the testimony of Dr. Jacobs that Choi is directed to liquid pour-on formulations wherein Miglyol 840 is the "carrier" in which all other ingredients are dissolved or suspended. *See* Prelim. Resp. 36 (citing Ex. 2001 ¶¶ 41–42). We find that Petitioner has also not sufficiently explained why one of ordinary skill in the art would substitute the Miglyol 840, used as a carrier in the pour-on formulations of Choi, as an adjuvant or additive in the solid articles of Dorn.

In addition, we also credit the testimony of Dr. Jacobs that transdermal absorption is not a desired way to deliver imidacloprid and flumethrin to an animal. Prelim. Resp. 38 (citing Ex. 2002 ¶ 35 (citing Exs. 2016–2017)). Thus, we agree that Choi's goal of using Miglyol 840 to promote "good penetration" of imidacloprid and flumethrin through the skin is something a person of ordinary skill would have wanted to avoid in the treatment of ectoparasites using imidacloprid and flumethrin. *Id.*

We also find that Petitioner has not sufficiently shown that Dorn and Choi disclose the use of "propylene glycol dicaprylocaprate at a

concentration of from about 5% to about 17.5% by weight of the solid moulded body." Petitioner's citation to the weight percent of plasticizers in Dorn is not persuasive for the same reasons discussed for ground 1. Similarly, Petitioner has not shown that Miglyol 840 acts as plasticizer in the pour-on formulations of Choi such that it would be substituted for the plasticizers in the solid preparations of Dorn in the amounts specified by Dorn.

Petitioner does not cite to any weight percentages from Choi in its claim chart but does cite to portions of Choi in other parts of its Petition. Specifically, Petitioner states that "[t]he formulation disclosed in Choi contains the active ingredient (avermectin) and at least 50% of the glycol or glyceride or polymeric material," and "[m]ore specifically, Choi recites that the formulation may be in the form of a topical pour-on formulation having an avermectin compound (0.005–10% w/v), an antioxidant (0.005–1% w/v), and a carrier consisting of glyceride, glycol, or derivatives thereof (40–100% q.s, v/v)." Pet. 36 (citing Ex. 1005 Abstract, 6:3–9). Presumably Petitioner does not rely on this disclosure for teaching the "about 5% to about 17.5%" weight limitation of claim 1 nor has Petitioner persuasively shown that one of skill in the art would use the claimed weight percentage of Miglyol 840 in the PVC-based solid compositions of Dorn based on this disclosure.

In view of the foregoing, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that the subject matter of challenged claims 1–3 would have been obvious over the combined disclosures of Dorn and Choi.

III. CONCLUSION

For the reasons set forth above, Petitioner has not demonstrated a reasonable likelihood of prevailing with respect to challenged claims 1–3 of the '122 patent. Thus, we do not institute an *inter partes* review with respect to the challenged claims.

IV. ORDER

It is

ORDERED that the Petition is *denied* and no *inter partes* review is instituted.

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