UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/572,664	12/16/2014	Nicholas Spring	18873.105127	1903

20786 7590 07/08/2020

KING & SPALDING
1180 PEACHTREE STREET , NE
ATLANTA, GA 30309-3521

EXAMINER
BARHAM, BETHANY P

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
07/08/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ATLIPDOCKETING@kslaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NICHOLAS SPRING and GARRY T. GWOZDZ

Appeal 2020-000846
Application 14/572,664
Technology Center 1600

Before DONALD E. ADAMS, ELIZABETH A. LAVIER, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals[2] from Examiner's decision to reject claims 1–10, 21–23, and 25–27 (Appeal Br. 5; *see also* Office Act.[3] 2). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

---

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as "Arbor Pharmaceuticals" (Appellant's March 28, 2019 Appeal Brief (Appeal Br.) 3).

[2] This Appeal is related to Appeal 2019-005431 (Application 15/408,924) (*see* Appeal Br. 4).

[3] Examiner's July 2, 2018 Non-Final Office Action.

STATEMENT OF THE CASE

Appellant's disclosure "relates to topical formulations containing avermectin for use in the prophylactic and therapeutic treatment of a head lice infestation in humans" (Spec.[4] ¶ 2). Claims 1–3, 5, 21–23, and 25 are reproduced below:

> 1. A topical pediculicidal formulation comprising about 0.1% to about 2.0% by weight ivermectin, a solubilizer, olive oil, a non-ionic surfactant, and about 30% to 40% by weight water.

(Suppl. Appeal Br.[5] 2.)

> 2. The topical pediculicidal formulation of claim 1, comprising about 0.5% by weight ivermectin.

(*Id.*)

> 3. The topical pediculicidal formulation of claim 1, further comprising shea butter.

(*Id.*)

> 5. The topical pediculicidal formulation of claim 1, further comprising one or more paraben preservatives.

(*Id.*)

> 21. The topical pediculicidal formulation of claim 5, wherein the paraben preservative is selected from the group consisting of methylparaben, propylparaben, ethylparaben, butylparaben, isobutylparaben, isopropylparaben, benzylparaben, sodium salts thereof, and any combination thereof.

(*Id.* at 3.)

> 22. The topical pediculicidal formulation of claim 21, wherein the formulation has a rate of killing permethrin resistant SF-HL

[4] Appellant's December 16, 2014 Specification.
[5] Appellant's May 24, 2019 Supplemental Appeal Brief.

> head lice that is 3.2 to 3.8 times faster than ivermectin in solution at the same weight%, wherein the solution is water.

(*Id.*)

> 23. The topical pediculicidal formulation of claim 1, wherein the formulation is indirectly ovicidal.

(*Id.*)

> 25. The topical pediculicidal formulation of claim 2, wherein the shea butter is present from about 1% to about 5% by weight.

Grounds of rejection before this Panel for review:

Claim 25 stands rejected under 35 U.S.C. § 112(b).

Claims 1, 2, 4–10, 21–23, 26, and 27 stand rejected under 35 U.S.C. § 103 as unpatentable over the combination of Manetta[6] and Hittel.[7]

Claims 1–10, 21–23, and 25–27 stand rejected under 35 U.S.C. § 103 as unpatentable over the combination of Manetta, Hittel, Patt,[8] and Diembeck.[9]

Claims 1–10, 21–23, and 25–27 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4–8, and 23–25 of Spring '153.[10]

Claims 1–10, 21–23, and 25–27 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14–18, 21–25, and 39–41 of Spring '595.[11]

---

[6] Manetta et al., WO 2004/093886 A1, published Nov. 4, 2004.
[7] Hittel, US 6,136,806, issued Oct. 24, 2000.
[8] Patt, US 6,927,206 B2, issued Aug. 9, 2005.
[9] Diembeck et al., WO 98/36730, published Aug. 27, 1998.
[10] Spring et al., US 8,791,153 B2, issued July 29, 2014.
[11] Spring et al., US 8,927,595 B2, issued Jan. 6, 2015.

DEFINITENESS:

ISSUE

Does the preponderance of evidence support Examiner's conclusion that the phrase "the shea butter," as set forth in Appellant's claim 25, lacks antecedent basis?

ANALYSIS

Examiner finds that Appellant's claim 25 depends from Appellant's claims 1 and 2 and neither Appellant's claim 1 nor 2 refer to shea butter (Office Act. 3). In addition, Examiner finds that Appellant does not contest this rejection (*see* Ans.[12] 3 (Examiner finds that "Appellant presents no arguments with respect to the rejection of claim 25 under [35 U.S.C. §] 112(b)")).

"If a ground of rejection stated by the examiner is not addressed in the appellant's brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it." Manual of Patent Examining Procedure (MPEP) § 1205.02 (9th Ed., Rev. 08.2017 (Jan. 2018)).

Accordingly, this rejection is summarily affirmed.

CONCLUSION

The preponderance of evidence supports Examiner's conclusion that the phrase "the shea butter," as set forth in Appellant's claim 25, lacks antecedent basis. The rejection of claim 25 under 35 U.S.C. § 112(b) is affirmed.

[12] Examiner's September 9, 2019 Answer.

OBVIOUSNESS:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Manetta discloses a pharmaceutical composition that may be in the form of a cream or gel (Manetta 4:7–14; *see id.* at 4:13 (Manetta discloses shampoo formulations); Office Act. 4; *cf.* Suppl. Appeal Br. 2 (Appellant's claim 10 depends from and further limits the formulation of Appellant's claim 1 to "a cream, gel or pomade")).

FF 2. Manetta discloses a composition comprising: a) an oily phase comprising fatty substances; b) at least one surfactant-emulsifier; c) ivermectin; d) one or more solvent(s) and/or propenetrating agent(s) for the active agent; e) one or more gelling agent(s); and f) water (*see* Manetta 6:15–23; *see also* Office Act. 4–5).

FF 3. Manetta discloses that the "oily phase" of its composition "may comprise, for example, vegetable, mineral, animal or synthetic oils, silicone oils, Guerbert alcohols or other substances, and mixtures thereof" (Manetta 6:24–7:2; *see also id.* at 7:7–9 (Manetta discloses that the vegetable oil may be "sweet almond oil, palm oil, soybean oil, sesame oil and sunflower oil"); Office Act. 4).

FF 4. Manetta discloses that "[t]he oily phase . . . may be present at a content of between 3 and 50% by weight relative to the total weight of the composition" (Manetta 8:19–22).

FF 5. Manetta discloses that its composition "advantageously comprises up to 15% by weight of suitable surfactant-emulsifier" (Manetta 9:14–16).

FF 6. Manetta discloses that its "composition . . . comprises from 0.001 to 10%[, preferably 0.1 to 5%,] of ivermectin by weight relative to the total weight of the composition" (Manetta 9:20–22; *see* Office Act. 4).

FF 7. Manetta discloses that its "composition . . . contains from 0.1 to 20% . . . of a solvent and/or propenetrating agent for the ivermectin active agent" (Manetta 10:9–11).

FF 8. Manetta discloses that its "composition . . . may also comprise aqueous phase gelling compounds ranging from 0.01 to 5% by weight relative to the total weight of the composition" (Manetta 10:13–16).

FF 9. Manetta discloses that its "composition . . . contains water ranging from 30 to 95%" (Manetta 11:25–26; *see* Office Act. 4).

FF 10. Manetta exemplifies a composition comprising:

Ingredients	% by weight relative to the total weight of the composition
Ivermectin	1.00
Glycerol	4.0
Acrylate C10-30 alkyl acrylate crosspolymer	0.2
Methyl para-hydroxybenzoate	0.2
Disodium EDTA	0.05
Citric acid monohydrate	0.05
Isopropyl palmitate	4.0
Cetyl alcohol	3.5
Stearyl alcohol	2.5
Oleyl alcohol	2.0
Ceteareth-20	3.0
Sorbitan monostearate	2.0
Dimethicone 200 20 cs	0.5
Propyl para-hydroxybenzoate	0.1
Propylene glycol	2.0
Phenoxyethanol	1.0
10% sodium hydroxide	qs pH
Water	qs 100

(Manetta 21–22; *see* Office Act. 4 (Examiner finds that "[o]leyl alcohol, cetyl alcohol, stearyl alcohol, methylparaben (methyl para-

hydroxybenzoate), and propylparaben (propyl para-hydroxybenzoate) are . . . [examples of] nonionic surfactants and paraben preservatives" and solvents "include propylene glycol, ethanol, isopropanol, butanol, N-methyl-2-pyrrolidone, or DMSO, polysorbate 80, phenoxyethanol, and mixtures thereof").)

FF 11. Manetta discloses that ivermectin is known as an "antiparasitic medicinal product for veterinary use" and is effective against, *inter alia*, some lice (Manetta 1:21–27).

FF 12. Manetta "relates to the use of ivermectin for producing a topical pharmaceutical composition intended for the treatment of rosacea" (Manetta 1:3–5; Office Act. 4).

FF 13. Examiner finds that Manetta does "not teach olive oil in its composition" (Office Act. 5).

FF 14. Hittel "relates to a treating agent for rosacea" that is formulated into a pharmaceutical composition (Hittel 1:4–5; *id.* at 2:61–66; *see* Office Act. 5).

FF 15. Hittel discloses that its composition can be formulated as a gel or cream for external topical use, wherein such an external preparation comprises an oily base or a mixture of two or more oily bases, which include, for example, "peanut oil, sesame oil, soybean oil, safflower oil, avocado oil, sunflower oil, corn oil, rape seed oil, cotton seed oil, castor oil, camellia oil, palm oil, olive oil, poppy seed oil, [and] coconut oil" (Hittel 3:9–12; *see id.* at 3:64–4:4; *see also* Office Act. 5).

FF 16. Examiner finds that the combination of Manetta and Hittel do not suggest a composition comprising shea butter (*see* Office Act. 8).

FF 17. Patt "relates to the treatment of a dermatological condition and, more specifically, to the treatment of rosacea, by topical application of a composition comprising a peptide copper complex" (Patt 1:8–11; *see* Office Act. 8).

FF 18. Patt discloses a topical composition comprising: (a) a carrier, (b) at least one peptide copper complex, and (c) a skin lightening agent, a sunscreen agent, a skin conditioning agent, a skin protectant, *an emollient*, a humectant, or a mixture thereof (Patt 2:4–11; *see* Office Act. 8).

FF 19. Patt discloses:

> An emollient[, such as mineral oil or shea butter glycerides,] . . . is a cosmetic ingredient that can help skin maintain a soft, smooth, and pliable appearance. Emollients are able to provide these benefits, largely owing to their ability to remain on the skin surface, or in the stratum corneum, to act as a lubricant and reduce flaking.

(Patt 11:31–61; *see* Office Act. 8.)

FF 20. Examiner finds that Diembeck discloses compositions for use in the treatment of rosacea that comprise, *inter alia*, 2 wt. % shea butter (*see* Office Act. 8).

ANALYSIS

Claim Interpretation:

Appellant's only independent claim, claim 1, is drawn to a formulation, i.e. composition (*see* Suppl. Appeal Br. 2). The claimed composition comprises: (a) about 0.1% to about 2.0% by weight ivermectin, (b) a solubilizer, (c) olive oil, (d) a non-ionic surfactant, and (e) about 30% to 40% by weight water (*id.*). The foregoing limitations, set forth in the body of Appellant's claim 1, define a structurally complete invention.

The preamble of Appellant's claim 1 recites the intended use of the claimed composition, by characterizing the claimed composition as a "topical pediculicidal formulation" (*id.*). In this regard, we note that the absence of the phrase "topical pediculicidal" from the preamble of Appellant's claim 1 does "not affect the structural definition . . . of the [formulation, i.e. composition, as is set forth in the body of the claim] itself." *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810 (Fed. Cir. 2002). Stated differently, the formulation, as claimed, does not change simply by naming it a topical pediculicidal formulation, or otherwise stating its purpose or intended use.

A "preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Catalina*, 289 F.3d at 808 (citations omitted); *see also Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003) ("[A] preamble simply stating the intended use or purpose of the invention will usually not limit the scope of the claim, unless the preamble provides antecedents for ensuing claim terms and limits the claim accordingly."); *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("[W]here a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation."); *In re Schreiber*, 128 F.3d 1473, 1475 (Fed. Cir. 1997) (finding preamble language reciting a dispensing top "for passing only several kernels of a popped popcorn at a time" not limiting because it did not impose any structural limitations on the claimed dispenser); *In re Taylor*, 484 F. App'x 540, 541 (Fed. Cir. 2012) (finding

preamble language reciting a mix "for making low-calorie, palatable food or food components" non-limiting because it did not impose any structural limitations on the claimed mix).

The rejection over the combination of Manetta and Hittel:

Initially, we acknowledge Appellant's contention that "Examiner has not addressed . . . the level of ordinary skill in the art" (Appeal Br. 10 and 22; Reply Br. 3 (Appellant contends that Examiner "failed to resolve the level of ordinary skill in the art"); *see also* Appeal Br. 12–14). Appellant's contention, however, is not persuasive because the prior art relied upon by Examiner is representative of the level of ordinary skill in this art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) ("[T]he absence of specific findings on the level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown."' (Quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

As discussed above, Appellant's only independent claim, claim 1, is drawn to a composition comprising: (a) about 0.1% to about 2.0% by weight ivermectin, (b) a solubilizer, (c) olive oil, (d) a non-ionic surfactant, and (e) about 30% to 40% by weight water (*see* Suppl. Appeal Br. 2). Similarly, Manetta discloses a topical composition comprising: (a) from 0.001% to 10% by weight ivermectin, (b) a solubilizer, (c) an oily phase comprising an oil such as sesame oil, soybean oil, sunflower oil, or palm oil, (d) a non-ionic surfactant, and (e) from 30% to 95% water (*see* FF 1–10). In addition, although Manetta discloses that ivermectin compositions are

known to be effective against some lice, Manetta discloses that its composition is "intended for the treatment of rosacea" (*see* FF 11–12).

Examiner recognizes that Manetta does not disclose a composition comprising olive oil, but finds that Hittel discloses a topical composition for the treatment of rosacea that, like Manetta, comprises an oily phase comprising an oil such as sesame oil, soybean oil, sunflower oil, palm oil or olive oil (*see* FF 14–15; *cf.* FF 2–3).

Thus, Examiner concludes, based on the combination of Manetta and Hittel, that, at the time Appellant's invention was made, it would have been prima facie obvious to use olive oil, as disclosed by Hittel, for the oily phase oil in Manetta's composition, because Manetta and Hittel both disclose a topical composition, such as a cream or gel, for the treatment of rosacea, which comprises, *inter alia*, an oily phase composed of the same or similar oils (*see* Office Act. 5 (citing *In re Fout*, 675 F.2d 297, 301 (CCPA 1982) ("Express suggestion to substitute one equivalent for another need not be present to render such substitution obvious."); *see also* FF 1–15).

We find no error in Examiner's prima facie case of obviousness.

Claim 1:

Appellant's contention that "not every formulation of ivermectin is pediculicidal" at least to some degree, lacks an evidentiary basis on this record and is, therefore, not persuasive (*see* Appeal Br. 22). *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

For the foregoing reasons, we find that the intended use of Appellant's composition, as set forth in the preamble of Appellant's claim, is *not*

"necessary to give life, meaning and vitality to the claim[]." *See Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951) (The language in a preamble will be given effect if it is "necessary to give life, meaning and vitality to the claims."). Therefore, we are not persuaded by Appellant's contention that the "term 'pediculicidal,'" as recited in the preamble of its claim 1, further limits the claimed composition (*see* Appeal Br. 22; Reply Br. 4–7; *cf.* Ans. 4–5).

We are not persuaded by Appellant's contention that Manetta and Hittel are non-analogous art and, therefore, Examiner erred by relying upon these references to support the obviousness rejection on this record (*see* Appeal Br. 22–25; *see also* Reply Br. 8–11). Two criteria have evolved for determining whether prior art is analogous: (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Clay*, 966 F.2d 656, 658–59 (Fed. Cir. 1992). On this record, Manetta and Hittel relate to the formulation of topical compositions for the treatment of rosacea (*see* FF 1–20). As discussed above, ivermectin is effective as the active agent in compositions for the treatment of rosacea (*see*, *e.g.*, FF 2). Thus, those of ordinary skill in this art would have found these references pertinent to the particular problem with which Appellant is involved, i.e. formulating "a topical . . . [composition] compris[ing] a pharmaceutically effective amount of an avermectin compound, solubilizers, suspending agents, preservatives, non-ionic surfactants, humectants, and water" (*see* Spec. ¶ 28; *see also* Appeal Br. 23–24 (Appellant contends that the particular problem to which it was

concerned is *the development and introduction of a topical formulation* that is safe, effective, convenient to use, and not previously marketed for Appellant's intended use); Ans. 5–7).

Manetta and Hittel both disclose topical cream or gel formulations of ivermectin that comprise, *inter alia*, an oily phase (*see* FF 2, 3, 14, and 15). Manetta and Hittel both disclose that appropriate oils for this oily phase may be sesame oil, soybean oil, sunflower oil, or palm oil (*id.*). Hittel further discloses that olive oil may also be an appropriate oil for the oily phase of topical cream or gel formulations of ivermectin (*see* FF 14–15). Thus, notwithstanding Appellant's contention to the contrary, Examiner's reliance on equivalency to support a conclusion would have been prima facie obvious to use Hittel's olive oil as the oily phase in Manetta's composition is supported by the evidence relied upon by Examiner (*see* FF 2, 3, 14, and 15; *see also* Ans. 7–8; *cf.* Appeal Br. 25; Reply Br. 11–12).

We are not persuaded by Appellant's contention that a person of ordinary skill in this art would not have selected olive oil from Hittel's disclosure of appropriate oils for the oily phase of topical cream or gel formulations of ivermectin for use in Manetta's composition for the same purpose (Appeal Br. 25 and 26–28; *cf.* Ans. 8–9; Reply Br. 12–17). *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 335 (1945) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle. It is not invention.").

The amount of water in Manetta's composition encompasses and, therefore, makes obvious the water concentration recited in Appellant's claim (*see* Suppl. Appeal Br. 2). *See Iron Grip Barbell Co. v. USA Sports,*

Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004) ("[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness."). Therefore, we are not persuaded by Appellant's contention that "Manetta fails to render obvious the amount of water recited in claim 1" (Appeal Br. 29; Reply Br. 17; *cf.* Ans. 10–11).

Claims 22–23:

As discussed above, Manetta discloses a topical composition comprising: (a) from 0.001% to 10% by weight ivermectin, (b) a solubilizer, (c) an oily phase comprising an oil such as sesame oil, soybean oil, sunflower oil, or palm oil, (d) a non-ionic surfactant, and (e) from 30% to 95% water (*see* FF 1–10). The amount of ivermectin and water in Manetta's composition encompasses the concentrations as recited in Appellant's claims (*see* Suppl. Appeal Br. 3). *See Iron Grip Barbell Co.*, 392 F.3d at 1322 ("[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness."). In addition, Manetta discloses that its composition may be formulated as a shampoo (*see* FF 1). Thus, the evidence on this record supports a conclusion that if Manetta's composition were used as a topical pediculicidal formulation, the killing rate and ovicidal activity recited in Appellant's claims 22–23 would have been inherent in Manetta's composition (*see* FF 1–12; *cf.* Appeal Br. 26; Reply Br. 13–14).

Furthermore, we find no evidence on this record to support a conclusion that the selection of olive oil from Hittel's disclosure of appropriate oils for the oily phase of topical cream or gel formulations of ivermectin for use in Manetta's composition for the same purpose would

affect the activity of Manetta's active agent, ivermectin, for any purpose (*see* FF 1–15).

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on "inherency" under 35 U.S.C. § 102, on "prima facie obviousness" under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977) (footnote omitted).

For the foregoing reasons, we are not persuaded by Appellant's unsupported contention that Examiner failed "to meet the high standard required to rely on inherency, at least because the components ingredients in the prior art are not provided in the same combination, in the same amounts or the applied to the same site of action as presently claimed." (Appeal Br. 26; *see also* Reply Br. 7–8).

Secondary Considerations:

Appellant contends that it "provided evidence (including evidence of unexpected results) that [its] claims . . . are non-obvious over Manetta in view of Hittel," because "one of ordinary skill would not have been motivated to substitute the olive oil disclosed in Hittel for the fatty substances disclosed in Manetta[] as required by all pending claims" (Appeal Br. 26; *see* Spec. ¶¶ 102–134). In this regard, in addition to Appellant's contentions discussed above, Appellant contends that:

> [O]ne of skill in the of skill in the art would understand that numerous substances disclosed . . . [by Hittel as appropriate oils for the oily phase in a topical cream or gel formulation of ivermectin] are unsuitable for use in treating patients with rosacea-*including but not limited to olive oil*. Notably, olive oil has a high oleic acid (OA) to linoleic (LA) acid ratio, where high OA concentrations can damage the skin barrier and cause irritation. Tanojo H. et al. Journal of Controlled Release, Vol. 58, Issue 1, 8 March 1999, Pages 97- 104. This is in contrast to various other oily components disclosed in Hittel. Sunflower oil (which is preferred for use on the skin) contains about 23% oleic acid and about 66% linoleic acid. Moreover, there could be no reasonable expectation of success if the product causes damage to the skin barrier and irritation, particularly given the need to treat children. . . . Appellant[] . . . submitted the Tanajo reference as objective evidence of [non-obviousness].

(Appeal Br. 28; *see id.* (citing Spec. ¶ 27) (Appellant contends that its Specification "describes one goal of the present invention as providing a product that is 'safe, will appeal to the patient for ease of use'.") Appellant, however, does not identify, and we do not find, a disclosure in Tanojo of olive oil, sunflower oil, or any other oil. Appellant also did not identify, and we do not find, a disclosure of rosacea in Tanojo. Thus, we are not persuaded by Appellant's unsupported contentions relating to evidence of non-obviousness or unexpected results (*see* Appeal Br. 28; Reply Br. 17–18; *cf.* Ans. 9–11). *See Pearson*, 494 F.2d at 1405 ("Attorney's argument in a brief cannot take the place of evidence.").

Appellant also fails to direct our attention to a comparison of their claimed formulation against the closest prior art, i.e. Manetta. *See In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.").

Therefore, we are not persuaded by Appellant's contention that it "demonstrated unexpected results, in the form of data showing the superior pediculicidal properties of the claimed formulation," which "shows that lice treated with the [claimed] composition would exhibit a faster mortality rate response than lice treated with unformulated 0.5% ivermectin" (Appeal Br. 29; Reply Br. 18). Appellant failed to establish an evidentiary basis on this record to support its inference that its evidence of unexpected results is "relevant to the issue of unexpected results over the closest prior art" (*see* Appeal Br. 29; Reply Br. 18). Therefore, we are not persuaded by Appellant's contentions regarding unexpected results.

The rejection over the combination of Manetta, Hittel, Patt, and Diembeck:

Based on the combination of Manetta, Hittel, Patt, and Diembeck, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious to incorporate shea butter into the compositions suggested by the combination of Manetta and Hittel, because Patt and Diembeck disclose shea butter, like Manetta's fatty substances, is useful as an emollient in topical compositions for rosacea treatment (Office Act. 8; *see* FF 1–20). We find no error in Examiner's prima facie case of obviousness.

Claim 1:

For the reasons set forth above, we find no error in Examiner's conclusion that the combination of Manetta and Hittel makes obvious Appellant's claim 1. *See In re Kronig*, 539 F.2d 1300, 1302 (CCPA 1976)

(In affirming an obviousness rejection, the Board may rely upon less than all the references cited by the Examiner.).

Claim 3:

As discussed above, Appellant's claimed invention is drawn to a composition not a method of treating lice. In this regard, Patt and Diembeck, like Manetta and Hittel, relate to the formulation of topical compositions for the treatment of rosacea (*see* FF 1–20). As discussed above, ivermectin is effective as the active agent in compositions for the treatment of rosacea (*see*, *e.g.*, FF 2). Thus, those of ordinary skill in this art would have found these references pertinent to the particular problem of with which Appellant is involved, i.e. formulating "a topical . . . [composition] compris[ing] a pharmaceutically effective amount of an avermectin compound, solubilizers, suspending agents, preservatives, non-ionic surfactants, humectants, and water" (*see* Spec. ¶ 28; *see also* Appeal Br. 23–24 (Appellant contends that the particular problem to which it was concerned is *the development and introduction of a topical formulation* that is safe, effective, convenient to use, and not previously marketed for Appellant's intended use); Ans. 12).

For the foregoing reasons, we are not persuaded by Appellant's contention that "neither Patt nor Diembeck represent analogous art," because "[s]imilar to Hittel, neither reference teaches or suggests a topical composition comprising *ivermectin* and similar to Manetta and Hittel, neither teaches a topical composition *for use in treating lice*" (Appeal Br. 30; Reply Br. 18–19).

We are not persuaded by Appellant's contention that one of ordinary skill in this art would not have been motivated to select shea butter from Patt's list of emollients (*see* Appeal Br. 30–31; Reply Br. 19–20; *cf.* Ans. 12–13). *See Sinclair*, 325 U.S. at 335 ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle. It is not invention.").

We are also not persuaded by Appellant's contention that because Diembeck discloses the use of shea butter in one of twenty example, it fails to "provide any guidance to select shea oil from the oily substances disclosed therein or any advantage to be gained by substituting the same for the fatty substances of Manetta" (Appeal Br. 30–31; *see* Reply Br. 20). *See Merck & Co. Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("Disclos[ure of] a multitude of effective combinations does not render any particular formulation less obvious."). In addition, we note that Diembeck was not applied in isolation, but, rather, was applied in combination with Manetta, Hittel, and Patt. Patt discloses the utility of shea butter as an emollient in topical compositions (*see* FF 18–19; *see also* Ans. 13). Diembeck adds to the combination of Manetta, Hittel, and Patt by suggesting the amount of shea butter to add to a topical composition, i.e. 2% by weight (*see* FF 20).

Thus, we find no error in Examiner's combination of Manetta, Hittel, Patt, and Diembeck to suggest the composition of Appellant's claim 3 (*see* FF 1–20). For the foregoing reasons, we are not persuaded by Appellant's contention that "Patt or Diembeck, alone or in combination, [fails to] remedy the deficiencies of Manetta and Hittel," as the combination applies to

Appellant's claim 3 (Appeal Br. 30). For the same reasons, we are not persuaded by Appellant's contention that Examiner's rejection is based on the "improper use of hindsight" (Appeal Br. 31).

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claims 1, 22, and 23 under 35 U.S.C. § 103 as unpatentable over the combination of Manetta and Hittel is affirmed. Claims 2, 4–10, 21, 26, and 27 are not separately argued and fall with claim 1.

The rejection of claims 1 and 3 under 35 U.S.C. § 103 as unpatentable over the combination of Manetta, Hittel, Patt, and Diembeck is affirmed. Claims 2, 4–10, 21–23, 26, and 27 are not separately argued and fall with claim 1. Claim 25 is not separately argued and falls with claim 3.

OBVIOUSNESS-TYPE DOUBLE PATENTING:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness-type double patenting?

ANALYSIS

Appellant's claim 1, reproduced above, is representative.

On this record, Appellant does not contest the rejections of claim 1 under the judicially created doctrine of obviousness-type double patenting (*see* Ans. 13–14 ("Appellant presents no arguments with respect to the rejection of claims 1-10, 21-23, and 25-27 on the ground of nonstatutory

double patenting as being unpatentable over claims 1, 4-8 and 23-25 of [Spring '153] and claims 1, 14-18, 21-25, and 39-41 of [Spring '595]")). Appellant also did not file a terminal disclaimer to moot these rejections.

"If a ground of rejection stated by the examiner is not addressed in the appellant's brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it." MPEP § 1205.02 (9th Ed., Rev. 08.2017 (Jan. 2018)).

Accordingly, the obviousness-type double patenting rejections are summarily affirmed.

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness-type double patenting.

The rejection of claims 1–10, 21–23, and 25–27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4–8, and 23–25 of Spring '153 is affirmed.

The rejection of claims 1–10, 21–23, and 25–27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14–18, 21–25, and 39–41 of Spring '595 is affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
25	112(b)	Indefiniteness	25	
1, 2, 4–10, 21–23, 26, 27	103	Manetta, Hittel	1, 2, 4–10, 21–23, 26, 27	
1–10, 21–23, 25–27	103	Manetta, Hittel, Patt, Diembeck	1–10, 21–23, 25–27	
1–10, 21–23, 25–27		Nonstatutory Double Patenting, Spring '153	1–10, 21–23, 25–27	
1–10, 21–23, 25–27		Nonstatutory Double Patenting, Spring '595	1–10, 21–23, 25–27	
Overall Outcome			1–10, 21–23, 25–27	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED