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Paper 28
Entered: December 27, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DERMIRA, INC.,
Petitioner,

v.

PUREPHARM, INC.,
Patent Owner.

Case IPR2015-01593
Patent 8,679,524 B2

Before LORA M. GREEN, DEBORAH KATZ, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

INTRODUCTION

Dermira, Inc. ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–10 of U.S. Patent No. 8,679,524 B2 ("the '524 patent," Ex. 1001). On January 7, 2016, the Board instituted a review of the patentability of the challenged claims. Paper 6 ("Dec."). Thereafter, Purepharm, Inc. ("Patent Owner") filed a Response (Paper 15 ("PO Resp.")), and Petitioner filed a Reply (Paper 25).

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–3 and 5–10 of the '524 patent are unpatentable. Petitioner, however, has failed to meet its burden of proof regarding the unpatentability of claim 4.

Related Proceedings

Petitioner also filed IPR2015-01594, seeking an *inter partes* review of U.S. Patent No. 8,252,316 B2, a patent in the same family as the '524 patent. Pet. 1. We instituted trial in that case, and issue a final decision therein concurrently with this Final Written Decision. *See Dermira, Inc. v. Purepharm, Inc.*, Case IPR2015-01594 (PTAB Dec. 27, 2016) (Paper 28).

The '524 Patent

The '524 patent relates to a method of topically applying glycopyrrolate to reduce excessive sweating in localized areas for those who suffer from the condition. Ex. 1001, 1:13–16.

Before the invention of the '524 patent, using topical glycopyrrolate to reduce excessive sweating had been known for two decades. *Id.* at 1:25–3:3. According to the '524 patent, however, "[u]sing the previously

available delivery methods, the topical application of glycopyrrolate can be messy and inconvenient." *Id.* at 3:60–62. The '524 patent discloses "a pad containing an amount of glycopyrrolate in solution, for topical application of a therapeutically effective amount of glycopyrrolate, which is useful in reducing sweating in humans." *Id.* at 3:7–10.

Illustrative Claim

Claim 1 is the only independent claim. It reads:

> 1. A method of reducing sweating by applying a dosed amount of glycopyrrolate solution to effect the topical application of a therapeutically effective amount of glycopyrrolate to a part of the human body, with the exception of mucous membranes, so as to reduce sweating on said part of the human body, the dosed amount of glycopyrrolate solution contained in an absorbent pad applied to said part of the human body and made of a material capable of containing the dosed amount for application, wherein said amount of glycopyrrolate in solution is an amount ranging from 1.0 wt. % to 6 wt. %.

Reviewed Grounds of Unpatentability

The Board instituted trial to review the following grounds of unpatentability:

Claims	Basis	Reference(s)
1, 2, 9, and 10	§ 102	Hays[1]
1, 2, 4, 5, and 8–10	§ 103	Bobrove[2] and Bodor[3]
3 and 6–8	§ 103	Bobrove, Bodor, and Thaman[4]

Patent Owner notes that we did not address claim 7 in the Decision to Institute and thus "it is presumed that this claim is deemed to be patentable over the prior art relied upon by the Petitioner." PO Resp. 1. This statement is incorrect. As Patent Owner acknowledges, we instituted to review, among other grounds, whether "claims 3 and 6–8" would have been obvious over asserted prior art. *Id.* Claim 7 is subsumed under "claims 6–8."

ANALYSIS

As an initial matter, we emphasize that in an *inter partes* review, the burden of persuasion is on the petitioner to prove unpatentability, and that burden never shifts to the patent owner. *See* 35 U.S.C. § 316(e); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir.

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[1] Leonard L. Hays, *The Frey Syndrome: A Review and Double Blind Evaluation of the Topical Use of a New Anticholinergic Agent*, 88 THE LARYNGOSCOPE 1796–1824 (1978) (Ex. 1009, "Hays").
[2] Bobrove et al., U.S. Patent No. 5,962,505, issued Oct. 5, 1999 (Ex. 1008, "Bobrove").
[3] Nicholas Bodor, U.S. Patent No. 4,824,676, issued Apr. 25, 1989 (Ex. 1030, "Bodor").
[4] Thaman et al., U.S. Patent No. 4,891,227, issued Jan. 2, 1990 (Ex. 1010, "Thaman").

2015). Thus, we do not hold the challenged claims unpatentable simply because, as Petitioner alleges, Patent Owner has not taken certain actions. *See* Reply 8–9 (stating, for example, that Patent Owner did not take the deposition of the witness for Petitioner, and did not offer any expert testimony in support of its own argument). Instead, we analyze the entire record developed during trial in analyzing the patentability of the challenged claims.

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Decision to Institute, we determined that under the broadest reasonable interpretation, "dosed amount," as recited in claim 1, is not limited by the volume of the glycopyrrolate solution. Dec. 6. Similarly, we concluded that an "absorbent pad" is not limited by the volume of the glycopyrrolate solution it absorbs. *Id.* Patent Owner challenges our interpretations as rendering "the term[s] 'dose' and 'solution' [to] have absolutely no meaning in the claim whatsoever." PO Resp. 4. Patent Owner appears to refer to its arguments presented in the Preliminary Response

(Paper 5 ("Prelim. Resp.")). *See, e.g.*, PO Resp. 8. Our Rule does not allow incorporating by reference arguments from one document into another. 37 C.F.R. § 42.6(a)(3). For purposes of this Decision, we nevertheless consider Patent Owner's position that the term "'[d]osed amount' refers to a specific predetermined unitized amount to be applied for the purpose of reducing sweating." *See* Prelim. Resp. 19.[5] According to Patent Owner, "an amount of glycopyrrolate in concrete units" is determined by "the concentration . . . multiplied by the volume of the solution." *Id.* at 23–24. We, again, reject Patent Owner's argument.

In interpreting claim terms, the claims themselves provide substantial guidance. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Here, the challenged claims recite the dosed amount of glycopyrrolate in solution as "an amount ranging from 1.0 wt. % to 6 wt. %" (claim 1); "an amount ranging from 2.0 wt. % to 6.0 wt. %" (claim 9); and "an amount ranging from 2.0 wt. % to 4.0 wt. %" (claim 10). Because the claims describe the dosed amount by the strength/concentration, they support our conclusion that term "dosed amount" is not limited by the volume of the glycopyrrolate solution.

When conducting claim construction, we also rely heavily on the written description for guidance as to the meaning of the claims. *In re*

[5] Even in the Preliminary Response, Patent Owner did not present a clear interpretation of the term "absorbent pad." Instead, Patent Owner merely repeated the claim language that the absorbent pad is "one made of a material capable of containing the dosed amount for application." *See* Prelim. Resp. 17, 21.

Translogic Tech., 504 F.3d at 1257. The Specification of the '524 patent does not employ the term "dosed amount." In fact, the term "dose" only appears once in the written description, and in that context, it does not inform us of the meaning of "dosed amount." *See* Ex. 1001, 4:57–58 (stating "the patient may not wish to increase the oral dose"). According to Patent Owner, however, the '524 patent "speaks of a concentration of the glycopyrrolate in the solution (0.25% to 6%, particularly 1, 2, or 3%) *and* a mass amount in terms of mg, greater than 2.5 milligrams to not more than 60 milligrams." PO Resp. 9 (citing Ex. 1001, 3:7–15) (emphasis added). We disagree.

Contrary to Patent Owner's assertion, in describing the amount of glycopyrrolate in solution, the Specification excerpt Patent Owner relies on uses the disjunctive "or," and not the additive "and," to connect the concentration and the mass amount. *See* Ex. 1001, 3:12–15 (stating "the amount of glycopyrrolate in solution is greater than 0.25% and not more than 6%, particularly 1%, 2% or 3% glycopyrrolate, *or* greater than 2.5 milligrams and not more than 60 milligrams of glycopyrrolate" (emphasis added)). The transposable usage of the strength/concentration and the weight to describe the amount of glycopyrrolate in solution in the Specification confirms our determination that the term "dosed amount," as used in the '524 patent, is not limited by the volume of the glycopyrrolate solution.

In addition, the '524 patent discloses:

> A concentration of glycopyrrolate greater than 0.1% is desirable since 0.1% has been shown to be ineffective. A 1%

> glycopyrrolate solution was initially chosen for testing purposes. However, the range of glycopyrrolate can vary to meet the needs of the patient. The upper limit could be at least as high as 6%, although mild side effects begin to present themselves after 4%.

Id. at 5:44–50 (internal citations omitted). According to the '524 patent, although "[m]ost patients enjoy effective control of sweating using the regular strength of 2% glycopyrrolate," "topical glycopyrrolate should be made in the range of a 0.25% to 6% solution to deal with individual variability." *Id.* at 7:61–67. In other words, when discussing the effectiveness of glycopyrrolate in reducing sweating, the '524 patent only refers to the strength/concentration, and not the volume, of the solution, or the weight of glycopyrrolate applied. *See also id.* at 8:1–46 (describing treating patients with pads containing 1%, 1.5%, 2%, and 3% glycopyrrolate solutions, without mentioning the volume applied).

Patent Owner points out the '524 patent describes several pads, each of which holds a specific volume of the glycopyrrolate solution with a predetermined weight of glycopyrrolate. PO Resp. 9–10 (citing Ex. 1001, 6:25–49 (the pad holds one milliliter of solution with 10 mg of glycopyrrolate); 3:16–18, 36–48 (the pad holds one milliliter of a 2% glycopyrrolate solution). According to Patent Owner, these embodiments demonstrate that a "dosed amount" is "a predetermined unitized amount of glycopyrrolate . . . to be administered to a patient to reduce sweating without the risk of providing the patient with too much of the drug." PO Resp. 10. We are not persuaded.

Although "it is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim . . . this is not to be

confused with adding an extraneous limitation appearing in the specification, which is improper." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Thus, we decline to import the volume of the glycopyrrolate solution or weight of glycopyrrolate from specific embodiments and narrow our interpretation of the term "dosed amount."

In its Preliminary Response, Patent Owner relied on the dictionary definition of "dose." Prelim. Resp. 19–20 (citing Ex. 2007) (stating dose means "the quantity to be administered at one time, such as a specified amount of medication"). In its Response, Patent Owner alleges that in the Decision to Institute, we erred in not commenting on the dictionary definition it offered. PO Resp. 8. In support of its position, Patent Owner relies on *PPC Broadband, Inc. v. Corning Optical Communications RF, LLC*, 815 F.3d 747 (Fed. Cir. 2016). PO Resp. 8. Even if we adopt Patent Owner's reading of that case in its entirety, however, *PPC* appears to stand for exactly the opposite of Patent Owner's argument. Indeed, according to Patent Owner, in *PPC*, the Federal Circuit concluded that the Board unreasonably relied on a dictionary definition in claim construction, and "failed to account for how the claims themselves and the specification inform the ordinary skilled artisan as to precisely which ordinary definition the patentee was using." *Id.* at 7–8. It is unclear how, in this case, our analyses based on the claim language and the specification, and not the dictionary definition, runs afoul of the established law on claim construction.

Moreover, although extrinsic evidence, such as dictionaries, may be useful, "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence," including

the claims and the specification. *In re Hiok Nam Tay*, 579 F. App'x 999, 1000 (Fed. Cir. 2014) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc)). Thus, we may consider such evidence only if "the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Phillips*, 415 F.3d at 1322–23. Here, assuming, without deciding, that the dictionary definition supports Patent Owner's argument, it cannot override our conclusion based on the intrinsic evidence.

As a result, we determine that, under the broadest-reasonable-interpretation standard, "dosed amount," as recited in claim 1, is not limited by the volume of the glycopyrrolate solution. And because an absorbent pad is "one made of a material capable of containing the dosed amount for application," we similarly determine that an "absorbent pad" is not limited by the volume of the glycopyrrolate solution it absorbs. These determinations as to the scope of "dosed amount" and "absorbent pad" are sufficient for purposes of this Decision, and we need not further address the two terms.

Anticipation by Hays

Petitioner asserts that Hays discloses each and every limitation of claims 1, 2, 9, and 10. Pet. 24–32. In support of its patentability challenge, Petitioner relies on the Declaration of Dr. Richard H. Guy (Ex. 1003). After reviewing the entire record, we determine that Petitioner has established by a preponderance of the evidence that claims 1, 2, 9, and 10 are anticipated by Hays.

Claim 1

Hays discloses that "[g]lycopyrrolate is effective in both a distilled water base and a vanishing cream base in 0.5 to 1% concentration. It completely controls gustatory sweating for several days or more." Pet. 30 (citing Ex. 1009, 1821). Hays instructs that glycopyrrolate solutions should be carefully applied while avoiding the mouth, nose, and eyes. *Id.* at 31 (citing Ex. 1009, 1798, 1809). For example, it discloses applying a cotton applicator dipped in the glycopyrrolate solution to the skin while holding the hair up out the way to treat patients with gustatory sweating in the hairline. *Id.* (citing Ex. 1009, 1819). Dr. Guy testifies that an ordinary artisan would have understood the cotton applicator in Hays "as being any of a cotton ball, a cotton pad, a cotton swab, or having a cotton component as a part of a larger applicator." Ex. 1003 ¶ 90. According to Hays, glycopyrrolate in concentrations of 0.5%, 1.0%, and up to 4% provided effective control of gustatory sweating with no significant side effects. Pet. 31 (citing Ex. 1009, 1819). Thus, we agree with Petitioner that Hays discloses each and every limitation of claim 1.

Patent Owner counters that the cotton applicator of Hays is not the same as the absorbent pad recited in claim 1 because (1) Hays provides no specifications for the applicator; (2) Hays does not control the amount of glycopyrrolate in the applicator; and (3) Hays does not control the number of applications a patient can apply. PO Resp. 12. We are not persuaded by Patent Owner's arguments.

Claim 1 recites an absorbent pad that is "made of a material capable of containing the dosed amount of glycopyrrolate solution for application."

It does not specify the types of materials the pad is made of. We note that, claim 8, which depends from claim 1, further recites "the absorbent pad is a non-cotton absorbent pad." As a result, we conclude that the absorbent pad recited in claim 1 can be made of either cotton or non-cotton material. *See Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir. 1999) (explaining that generally, a limitation in a dependent claim should not be read into the independent claim from which it depends). In Hays, the applicator is made of cotton and saturated with glycopyrrolate solution. It is of little consequence that Hays does not provide other descriptions, including a specific manufacturer, of the cotton applicator. *See* PO Resp. 12 (arguing "[n]o manufacturer is stated and the applicator is not described" in Hays).

In addition, as explained above, the claimed dosed amount is not limited by the volume of glycopyrrolate solution. Instead, claim 1 recites that the "amount of glycopyrrolate in solution is an amount ranging from 1.0 wt. % to 6 wt. %," and that the amount is therapeutically effective so as to reduce sweating of the body part treated. In Hays, the cotton applicator, saturated with 1.0% and up to 4% glycopyrrolate solution, provided complete control of gustatory facial sweating. Ex. 1009, 1807, 1819. Thus, the cotton applicator in Hays satisfies the "made of a material capable of containing the dosed amount of glycopyrrolate solution for application," as required in claim 1.

Patent Owner also contends that the cotton applicator of Hays is not the same as the absorbent pad recited in claim 1 because the glycopyrrolate solution in Hays is not uniform. PO Resp. 14–15. According to Patent

Owner, glycopyrrolate forms aggregates when in solution. *Id.* at 14. As a result, Patent Owner argues, because the aggregates sink to the bottom of a container, in Hays, the cotton applicator dipped into the solution may contain very little glycopyrrolate. *Id.* at 14–15. We are not persuaded.

Patent Owner appears to rely on data in Hays 1982[6] to support its argument about glycopyrrolate aggregation. *Id.* at 29–31. Hays 1982 states "[r]oll-on solutions in which the concentration to glycopyrrolate exceeded 2% caused crystals." Ex. 1014, 421. According to Patent Owner, data in Hays 1982 showed reduced effectiveness of glycopyrrolate solutions at higher concentrations. PO Resp. 29–30. Patent Owner contends that those observations "*can be explained* by the observations" made in the declarations submitted during the prosecution (Exs. 1021–1023). PO Resp. 31 (emphasis added).

We observe that data in Hays 1982 contradict certain testimonies the declarants proffered during prosecution. For example, the declarant in Exhibit 1023 testified that glycopyrrolate-containing solutions can form crystals at concentrations starting from 0.5%. Ex. 1023 ¶ 8. Yet, as Patent Owner recognizes, a solution containing 2% glycopyrrolate is more effective in reducing sweating than one containing 1% glycopyrrolate, which in turn, is more effective in reducing sweating than one containing 0.5% glycopyrrolate. PO Resp. 29–30 (citing Ex. 1014, Fig. 3). As a result, we

[6] Hays et al., *The Frey Syndrome: A Simple, Effective Treatment*, 90 OTOLARYNGOL. HEAD NECK SURG. 419–25 (1982) (Ex. 1014, "Hays 1982").

are not persuaded that the crystals allegedly observed at concentrations starting from 0.5% are due to the concentration of glycopyrrolate in solution.

Moreover, Attwood,[7] another reference Patent Owner relies on, also contradicts testimonies the declarants proffered during prosecution. Patent Owner relies on Attwood for the proposition that "all anticholinergics generally, and glycopyrrolate specifically, form aggregates when in solution." *Id.* at 14. Attwood states, as Patent Owner repeatedly emphasizes, "[a]ll of the compounds studied showed some degree of aggregation, with scattering intensities in excess of those calculated for monomers." Ex. 1034, 1985; *see*, *e.g.*, PO Resp. 27, 37, 38, 40 (quoting Ex. 1034, 1985). One of the compounds studied in Attwood is glycopyrronium bromide (IIIa), i.e., glycopyrrolate. Ex. 1034, 1984. According to Attwood, the critical micellar concentration for glycopyrrolate is 0.189 mol/kg, i.e., 7.5% of glycopyrrolate. Ex. 1034, 1986; *see also* Prelim. Resp. 12–13 (converting glycopyrrolate concentration from mol/kg into %).

Attwood states that the scattering curves of glycopyrrolate (IIIa) and some other compounds "showed abrupt changes of slope over narrow, well-defined concentration regions. At concentrations below the critical concentration, the scattering of such compounds did not deviate significantly from that calculated for unassociated monomers." Ex. 1034, 1985. Because the glycopyrrolate solutions tested in the Exhibits 1021–1023 are up to 6%,

[7] D. Attwood, *Micellar and Nonmicellar Association of Antiacetylcholine Drugs in Aqueous Solution*, 80 JOURNAL OF PHYSICAL CHEMISTRY 1984–87 (1976) (Ex. 1034, "Attwood").

below 7.5%, the critical micellar concentration for glycopyrrolate, we are not persuaded that the crystals allegedly observed were due to the concentration of glycopyrrolate in solution. Similarly, because Hays examined "up to 4% glycopyrrolate" solution (Ex. 1009, 1819), below 7.5%, the critical micellar concentration for glycopyrrolate, we are not persuaded that the glycopyrrolate solution in Hays is not uniform. As a result, we conclude that the cotton applicator in Hays satisfies the "made of a material capable of containing the dosed amount of glycopyrrolate solution for application," as required in claim 1.

In sum, for the reasons discussed above and for the reasons stated in the Petition, Petitioner has established by a preponderance of the evidence that Hays discloses each and every limitation of claim 1.

Claims 2, 9, and 10

Claims 2, 9, and 10 depend from claim 1. Hays discloses applying the cotton applicator saturated with the glycopyrrolate solution to a mapped area affected by gustatory facial sweating. Ex. 1009, 1807. Thus, Hays satisfies "wherein the part of the human body comprises one or both of the face and the groin," as recited in claim 2. Hays discloses using "up to 4% glycopyrrolate" solution to effectively treat gustatory facial sweating. Ex. 1009, 1819. Thus, Hays satisfies the amount of glycopyrrolate in solution in an amount "ranging from 2.0 wt. % to 6.0 wt. %," and "ranging from 2.0 wt. % to 4.0 wt. %," as recited in claims 9 and 10, respectively.

In sum, Petitioner has established by a preponderance of the evidence that Hays anticipates claims 2, 9, and 10.

Obviousness over Bobrove, Bodor, and Thaman

Petitioner asserts that claims 1, 2, 4, 5, and 8–10 would have been obvious over the combination of Bobrove and Bodor, and that claims 3 and 6–8 would have been obvious over the combination of Bobrove, Bodor, and Thaman. Pet. 32–54. After reviewing the entire record, we determine that Petitioner has established obviousness of claims 1–3 and 5–10 by a preponderance of the evidence. Petitioner, however, has failed to meet its burden of proof regarding the unpatentability of claim 4.

Level of Ordinary Skill

The parties disagree over the level of ordinary skill.[8] *See* Pet. 17–18; PO Resp. 3; Reply 9. For purposes of this Decision, we do not need to resolve this dispute because the prior art itself reflects an appropriate skill level. *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

Patent Owner also argues that Dr. Guy, Petitioner's declarant, does not qualify as one of ordinary skill in the art because he is not a clinician, physician, or pharmacist. PO Resp. 3–4. We disagree with Patent Owner on this issue. All asserted references relate to topical administration of pharmaceutical compositions. *See, e.g.*, Ex. 1008, 4:1; Ex. 1010, 2:35–38; Ex. 1030, 3:60–61. In addition, the challenged '524 patent relates to the topical delivery of glycopyrrolate to reduce excessive sweating and minimize side effects. Ex. 1001, Abstract, 1:13–21. Dr. Guy has over 30 years of experience in fields including topical drug delivery, transdermal

[8] We note that Patent Owner's position is only attorney argument, unsupported by evidence.

drug delivery, prediction and assessment of skin penetration, and topical drug bioavailability. Ex. 1003 ¶¶ 3, 6, 7, Appendix A. We determine that Dr. Guy has exceeded the level of ordinary skill in this case, and thus, accord proper weight to his testimony.

Patent Owner also asks the Board to give no weight to the Guy Declaration because of alleged factual errors. PO Resp. 22. We will address the facts asserted by Dr. Guy and the support to which he cites as appropriate in this Decision.

Claims 1, 2, 9, and 10

Bobrove and Bodor each teaches a method of reducing sweating by applying a glycopyrrolate solution to a part of the human body. For example, Bobrove teaches topically administering glycopyrrolate compounds to treat hot flashes and the perspiration associated therewith. Ex. 1008, 5:29–32. Bodor teaches transdermal delivery of an anticholinergic agent, including glycopyrrolate, in an amount sufficient to have a local anti-secretory effect on skin. Ex. 1030, 1:10–17, 9:18–28, 16:34.

In Bobrove, glycopyrrolate is applied to the skin surface to be treated, preferably the face, including the cheeks, neck, and forehead, taking care to avoid eyes, nose, and mouth, as recited in claims 1 and 2. Ex. 1008, 5:33–39, *see also id.* at 4:1–10 (stating glycopyrrolate is administered topically to areas including the face and groin). Bobrove teaches applying glycopyrrolate using a roll-on applicator. *Id.* at 6:12–13, 26–27, 37–39.

Although Bobrove does not explicitly teach "an absorbent pad," it teaches topical glycopyrrolate compositions in the forms of suspensions, emulsions, solutions, alcoholic solutions, and ointments. *Id.* at 4:53–55.

According to Petitioner, absorbent pads would have been a well-known and predictable method for the topical application of drugs in these forms to the skin. Pet. 34–35 (citing Ex. 1003 ¶¶ 16–19). We agree. Whether an ordinary artisan is one with a degree in chemistry, biopharmaceutical science, pharmacy, or pharmaceutical science and years of experience and technical training, as Petitioner contends (*see* Pet. 17–18), or a clinician, physician, or pharmacist with knowledge and experience in the treatment of hyperhidrosis in humans, as Patent Owner argues (*see* PO Resp. 3), such a person would have known to use an absorbent pad for applying a topical composition. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007) ("A person of ordinary skill is also a person of ordinary creativity, not an automaton.").

Moreover, Bodor specifically teaches "an absorbent pad." According to Bodor, the anticholinergic agent, including glycopyrrolate, can be placed onto an applicator such as a cotton swab or cloth, and the applicator is then rubbed on the skin. Ex. 1030, 15:5–9, 15:39–42 (stating the anticholinergic agent can be "absorbed on an applicator such as a piece of cotton cloth or other suitable soft pliable material").

Patent Owner counters that neither Bobrove nor Bodor teaches the concept of applying a dosed amount of a glycopyrrolate in an absorbent pad for treating sweating. PO Resp. 17. We are not persuaded. As explained above, we determine that "dosed amount," as recited in the challenged claims, is not limited by the volume of the glycopyrrolate solution. Here, Bobrove teaches topical solutions with about 0.05% to 5.0%, and preferably from about 0.5% to 2.5%, of glycopyrrolate. Ex. 1008, 4:39–46. In other

words, Bobrove teaches glycopyrrolate in an amount overlapping with those ranges of amounts recited in claims 1, 9, and 10. Thus, a preponderance of the evidence supports Petitioner's argument that the combination of Bobrove and Bodor teaches each and every limitation of claims 1, 2, 9, and 10. *See* Pet. 34–36, 39–47.

Next, we determine whether Petitioner has demonstrated that one of ordinary skill in the art would have had a reason to combine the teachings of Bobrove and Bodor. Petitioner asserts that an ordinary artisan would have had a reason to combine Bobrove with Bodor. Pet. 33–35; Reply 19–20.[9] Patent Owner disagrees. PO Resp. 18–19. According to Patent Owner, Bodor addresses "insensible perspiration of human skin," an issue different from hyperhidrosis, the subject of Bobrove. *Id.* Thus, Patent Owner argues, "Bodor has nothing to do with . . . a method that applies a therapeutically effective amount of glycopyrrolate to reduce sweating." *Id.* We find Petitioner's argument more persuasive.

Patent Owner is correct that Bodor, in one aspect, relates to an improved transdermal delivery system. Ex. 1030, 3:63–65. A separate, independent object of Bodor, however, is "to deliver, to an area of skin, an anticholinergic agent in an amount sufficient to have a local antisecretory effect on the area of skin." Ex. 1030, 3:66–4:1. Similarly, Bobrove aims to treat perspiration associated with hot flashes with transdermal application of

[9] In the Reply, Petitioner cites to Exhibit 1011, a U.S. patent also issued to Bobrove. Reply 19–20. Exhibit 1011 is unrelated to Exhibit 1008 ("Bobrove"), on which we instituted this trial. Nevertheless, the teachings of Exhibit 1011 that Petitioner relies on are also disclosed in Bobrove.

glycopyrrolate. Ex. 1008, 2:52–55. Thus, both Bobrove and Bodor teach methods of reducing sweating with glycopyrrolate.

Bobrove specifically teaches applying a "roll on" glycopyrrolate solution. *Id.* at 6:26–27, 6:36–37. It, however, also generally teaches that glycopyrrolate is administered topically. *Id.* at 4:1. Thus, one of ordinary skill in the art would have had a reason to look for other means to apply glycopyrrolate. As Dr. Guy testifies, "[t]here are a limited number of ways to topically deliver a drug to a patient's skin." Ex. 1003 ¶ 16. In addition, Bobrove suggests to avoid the eyes, nose, and mouth during the topical administration. Ex. 1008, 5:39. Given these considerations, Bodor provides an effective alternative: a cotton cloth to absorb the drug and rub it on the skin. Ex. 1030, 15:39–54; *see also* Ex. 1003 ¶¶ 17, 99–103, 116 (explaining that, at the time of the invention, an ordinary artisan would have known that use of medicated pads "allowed for topical application of a solution, for example to a subject's face, while excluding application to sensitive areas such as the eyes or mucous membranes"). Thus, we conclude Petitioner has shown, by a preponderance of the evidence, that an ordinary artisan would have had a reason to combine the teachings of Bobrove and Bodor.

In sum, Petitioner has shown, by a preponderance of the evidence, that an ordinary artisan would have had a reason to combine the teachings of Bobrove and Bodor, and that the combination teaches each and every limitation of claims 1, 2, 9, and 10.

Claims 4, 5, and 8

Claim 4 depends from claim 1 and further recites that "the applying step [of claim 1] is performed in combination with the administration of

another oral and/or topical therapy for reduction of sweating." Petitioner contends that Bodor suggests this additional limitation. Pet. 36–37.

Bodor teaches that the application of an anticholinergic, such as glycopyrrolate, "to prevent perspiration and thus indirectly enhance transdermal delivery of a pharmaceutically active, preferably non-anticholinergic, drug." Ex. 1030, 3:41–46. Petitioner emphasizes that although Bodor prefers, it does not require, the second drug to be non-anticholinergic. Pet. 37; Reply 21–22. According to Petitioner, this preference does not amount to teaching away from a non-preferred embodiment. Pet. 37; Reply 21. Because the second drug in Bodor broadly includes "transdermally deliverable physiologically or pharmacologically active substances," Petitioner argues, Bodor encompasses "anticholinergic drugs, even if non-preferred, as an additional topical therapy for reduction of sweating." Pet. 37 (citing Ex. 1030, 2:4–8).

Petitioner may well be correct that preferring a non-anticholinergic does not necessarily exclude administering "another oral and/or topical therapy for reduction of sweating," as required by challenged claim 4. Petitioner, however, does not point to any credible evidence or otherwise explain why an ordinary artisan would have chosen another therapy to reduce sweating to be administered in combination with glycopyrrolate. Without some articulated reasoning with rational underpinning as to why an ordinary artisan would have added a second therapeutic for reducing sweating to the transdermal patch of Bodor, which uses the anticholinergic to eliminate the formation of an aqueous layer between the delivery system and the skin to enhance the penetration of the transdermal drug being

delivered, Petitioner has not met its burden of demonstrating that claim 4 would have been obvious over the combination of Bobrove and Bodor. *See KSR*, 550 U.S. at 418.

Petitioner has, however, demonstrated that the combination of Bobrove and Bodor teaches the additional limitations of claims 5 and 8. Claim 5 depends from claim 1 and further requires that the glycopyrrolate solution of claim 1 "is a 5 wt. % to 66 wt. % ethanol solution." Bobrove teaches alcohols as suitable excipients. Ex. 1008, 4:54–55, 5:6. It also exemplifies a glycopyrrolate lotion having 25% ethanol. *Id.* at 6:3–10 (including 75 ml ethanol in a total volume of 300 ml). Petitioner acknowledges that the 25% ethanol in Bobrove may not be weight percentage, as recited in claim 5. Pet. 37 n.4. But, "[b]ecause of the broad ranges claimed," Petitioner argues, the ethanol percentage taught in Bobrove falls within the claimed range. *Id.* We find Petitioner's argument persuasive. We also are persuaded that an ordinary artisan "would have understood that using absorbent pads containing hydroalcoholic solutions of dermatological agents for topical application to skin was not only well known, but also well accepted in the marketplace." *See id.* at 38 (citing Ex. 1003 ¶¶ 18, 19; Ex. 1024, 566, 645–46, 700). Thus, we adopt Petitioner's reasoning as our own, and conclude that Petitioner has shown, by a preponderance of the evidence, that Bobrove teaches the additional limitation of claim 5.

Claim 8 depends from claim 1 and further recites that the absorbent pad is a non-cotton absorbent pad. Bodor teaches absorbing the anticholinergic agent, such as glycopyrrolate, "on an applicator such as a

piece of cotton cloth or other suitable soft pliable material." Ex. 1030, 15:39–42. We agree with Petitioner, and adopt its reasoning as our own, that the "other suitable soft pliable material" taught in Bodor satisfies the "non-cotton absorbent pad" required in claim 8.

In sum, Petitioner has shown, by a preponderance of the evidence, that an ordinary artisan would have had a reason to combine the teachings of Bobrove and Bodor, and that the combination teaches each and every limitation of claims 5 and 8, but not of claim 4.

Claims 3 and 6–8

Petitioner argues that claims 3 and 6–8 are rendered obvious by the combination of Bobrove, Bodor, and Thaman. Pet. 48–54. Thaman teaches multiple-layer laminated medicated cleansing pads, which contain a salicylic acid active composition for treating acne. Ex. 1010, 1:5–8.

Claim 3 depends from claim 1 and further recites that the absorbent pad comprises rayon and polypropylene. In Thaman, the nonwoven fabrics for the pads comprise any of the common textile-length fibers, including rayon and polypropylene, as recited in claim 3. Ex. 1010, 2:60–3:15.

Claim 6 depends from claim 3 and further requires that the absorbent pad has a ratio of rayon to polypropylene of 75:25 by weight. Thaman exemplifies a two-layer non-cotton pad with rayon making up 75 wt % of the first layer and polypropylene making up 33 wt % of the second layer. Ex. 1010, 8:30–39. Acknowledging that this is not the 75:25 rayon to polypropylene ratio recited in claim 6, Petitioner nevertheless argues that an ordinary artisan would have reached the claimed ratio through routine

optimization. Pet. 50–51. We agree with Petitioner, and adopt its analysis as our own.

"[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). Here, the combination of the asserted prior art teaches each and every limitation of claims 1 and 3, from which claim 6 depends. In addition, Thaman teaches a pad with rayon and polypropylene composition. Thus, the "general conditions" of claim 6 are disclosed. Patent Owner does not point to, and we do not find, any credible evidence indicating the criticality of the 75:25 rayon to polypropylene ratio recited in claim 6. We are persuaded that the ratio of rayon and polypropylene is a result-effective variable and its optimization is within the capabilities of one skilled in the art. This is especially so as the challenged '524 patent determines the absorbency of rayon/polypropylene pads by "using the brand of Kleentest™ #9807 2.125 diameter pads, comprised of 75% rayon and 25% polypropylene by weight." Ex. 1001, 6:27–30.

Claim 7 depends from claim 1 and further recites that "the dosed amount is around 1 ml of the glycopyrrolate solution." Petitioner refers to Thaman for teaching that the thickness of the cloth directly provides the required absorbent capacity of the cloth. Pet. 51 (citing Ex. 1010, 4:29–42). Indeed, according to Thaman, the absorbent properties of the cloth "are provided merely by building up the thickness of the cloth" and "any thickness necessary to obtain the required absorbent capacity can be used." Ex. 1010, 4:29–42. Thus, we agree with Petitioner that an ordinary artisan

"would have known to alter the thickness, size, or a combination of known variables of the pad to absorb the desired volume of glycopyrrolate." *See* Pet. 52.

Patent Owner counters that "Thaman gives absolutely no hint of controlling the volume of the solution when using the cloth to treat acne." PO Resp. 47. As a result, according to Patent Owner, Petitioner arrives at the 1 ml of the glycopyrrolate solution recited in claim 7 through hindsight. *Id.* We find Patent Owner's argument unpersuasive.

First, Patent Owner does not point to, and we do not find, any credible evidence indicating the criticality of the 1 ml volume recited in claim 7. In fact, according to the challenged '524 patent, the commercially available Kleentest™ #9807 2.125 diameter pads "hold about 1 mL of liquid, are easy to apply to skin, and do not drip." Ex. 1001, 6:28–29, 45–46.

Second, Patent Owner's argument attacking references individually is not persuasive because the patentability challenge is based on combinations of references. *In re Keller*, 642 F.2d 413, 426 (CCPA 1981). Instead, we must read each prior art reference, not in isolation, but for what it fairly teaches in combination with the other references as a whole. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Here, Thaman teaches that the volume of the solution absorbed in an absorbent pad is determined by the size and thickness of the pad. Ex. 1010, 4:29–42. Both Bobrove and Bodor teach reducing sweating by topically applying glycopyrrolate in "an effective amount" (Ex. 1008, 2:65–67) or in "an amount sufficient to have a local antisecretory effect" but "insufficient to cause a systemic effect" (Ex. 1030, 3:66–4:2). Because an ordinary artisan "is also a person of

ordinary creativity, not an automaton," we are persuaded that such a person would have known to adjust the volume of the glycopyrrolate solution absorbed in the absorbent pad so the pad holds sufficient amount of glycopyrrolate to effectively reduce sweating without significant side effects. *See KSR*, 550 U.S. at 421.

Claim 8 depends from claim 1 and further recites that the absorbent pad is a non-cotton absorbent pad. As explained above, Bodor teaches "suitable soft pliable material" other than cotton to make an applicator. Ex. 1030, 15:39–42. Thaman also teaches pads made of wool and synthetic or man-made cellulosic fibers, such as rayon. Ex. 1010, 3:2–5. In sum, we determine that the combination of Bobrove, Bodor, and Thaman teaches each and every limitation of claims 3 and 6–8.

Petitioner asserts that an ordinary artisan would have had a reason to combine the teachings of Thaman with those of Bobrove and Bodor. Pet. 48–49. Citing the Guy Declaration, Petitioner contends an ordinary artisan would have known that salicylic acid has antiperspirant properties. *Id.* at 48 (citing Ex 1003 ¶¶ 20, 120, 121). Thus, Petitioner argues that all three references teach "treatments of dermatological disorders in humans using pads mediated with an antiperspirant," and it would have been obvious to "substitute one known antiperspirant on an absorbent pad for another known antiperspirant." *Id.*

Patent Owner challenges Dr. Guy's testimony on this issue. PO Resp. 19. According to Patent Owner, the references Dr. Guy relies on do not support the conclusion that salicylic acid has antiperspirant properties. *Id.* at 22–25. Patent Owner further argues that the structure of salicylic acid is

different from that of the anticholinergics illustrated in Bodor. *Id.* at 25–26. As a result, Patent Owner asserts that salicylic acid is not an antiperspirant and an ordinary artisan would not have combined Thaman's teaching of the pads with the teachings of glycopyrrolate in Bobrove and Bodor. *Id.* at 19. We, again, find Patent Owner's arguments unpersuasive.

Patent Owner does not dispute that Benohanian,[10] one of the two references Dr. Guy relies on in addressing this issue, explicitly states that salicylic acid has "antiperspirant properties of its own." PO Resp. 23 (quoting Ex. 1035, 702). Patent Owner, however, asserts that Martindale,[11] the reference Benohanian refers to, which is also the second reference Dr. Guy relies on, "only claims that salicylic acid is bacteriostatic and fungicide, and makes no mention of antiperspirant properties." *Id.* But, Martindale plainly states that salicylic acid is applied externally for the treatment of hyperhidrosis, the exact same condition addressed in Bobrove. Ex. 1036, 212. Patent Owner concedes this but goes on to argue that "[s]alicylic acid may be used in patients with hyperhidrosis, not as an antiperspirant, but as an antibacterial and antifungal." PO Resp. 23. Patent Owner, however, does not offer any credible evidence to support this assertion. We are not persuaded by mere attorney argument.

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[10] Benohanian et al., *Localized Hyperhidrosis Treated with Aluminum Chloride in a Salicylic Acid Gel Base*, 37 INT'L J. DERMATOLOGY 701–08 (1996) (Ex. 1035, "Benohanian").
[11] Martindale, W., THE EXTRA PHARMACOPOEIA, Pharmaceutical Press 212–13 (17th ed. 1979) (Ex. 1036, "Martindale").

Patent Owner also contends that because salicylic acid has a structure different from that of the anticholinergics illustrated in Bodor, it is not an antiperspirant. *Id.* at 25–26. Patent Owner does not assert anticholinergics as the only antiperspirants. Thus, we are not persuaded that salicylic acid is not an antiperspirant merely because it does not have the structure of the anticholinergics.

In sum, Petitioner has presented credible evidence and persuasive argument to show that salicylic acid has antiperspirant properties and that one of ordinary skill in the art would have had a reason to substitute glycopyrrolate onto the pad of Thaman to reduce sweating. We further agree with Petitioner's argument, which Patent Owner does not dispute, that "using an absorbent pad for topical application of ***any*** dermatological agent is an obvious choice." Pet. 48–49 (citing Ex. 1003 ¶¶ 16–19). As a result, we conclude Petitioner has shown, by a preponderance of the evidence, that an ordinary artisan would have had a reason to combine the teachings of Bobrove, Bodor, and Thaman, and that the combination teaches each and every limitation of claims 3 and 6–8.

CONCLUSION

We conclude that Petitioner has shown by a preponderance of the evidence that claims 1–3 and 5–10 of the '524 patent are unpatentable. Petitioner, however, has failed to meet its burden of proof regarding the unpatentability of claim 4.

ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claim 4 of the ’524 patent has not been shown to be unpatentable;

FURTHER ORDERED that claims 1–3 and 5–10 of the ’524 patent are held unpatentable;

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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