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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JONNIE R. WILLIAMS

Appeal 2018-006659
Application 15/426,617
Technology Center 1600

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and JOHN G. NEW, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1, 4, 5, 7– 9, 19–24, 26, and 28. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[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 CV Sciences, Inc. Appeal Br. 2.

STATEMENT OF THE CASE

The following rejections are before us for review:

(1) Claims 1, 4, 5, 7– 9, 19–22, 24, 26, and 28, under 35 U.S.C. § 103(a) as being unpatentable over Andersen,[2] Hatsukami-A,[3] Morgan,[4] and Zuardi[5] (Final Act. 5–8 (entered Dec. 20, 2017)); and

(2) Claim 23, under 35 U.S.C. § 103(a) as being unpatentable over Andersen, Hatsukami-A, Morgan, Zuardi, and Hatsukami-B,[6] (Final Act. 8–9.

Claim 1 is representative and reads as follows:

> 1. A method of treating smokeless tobacco addiction comprising administering to an individual in need thereof a pharmaceutical composition comprising nicotine, a therapeutically effective amount of cannabidiol, and a pharmaceutically acceptable vehicle therefor.

Appeal Br. i (Claims App.).

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[2] US 8,603,440 B2 (issued Dec. 10, 2013).
[3] Dorothy K. Hatsukami & Herbert H. Severson, *Oral spit tobacco: addiction, prevention and treatment*, 1 NICOTINE & TOBACCO RESEARCH 21–44 (1999).
[4] Celia J.A. Morgan et al., *Cannabidiol reduces cigarette consumption in tobacco smokers: Preliminary findings*, 38 ADDICTIVE BEHAVIORS 2433–2436 (2013).
[5] Antonio Waldo Zuardi, *Cannabidiol: from an inactive cannabinoid to a drug with wide spectrum of action*, 30 REV. BRAS. PSIQUIATR. 271–280 (2008).
[6] Dorothy K. Hatsukami et al., *Effects of Behavioral and Pharmacological Treatment on Smokeless Tobacco Users*, 64 J. CONSULTING AND CLINICAL PSYCHOL. 153–161 (1996).

OBVIOUSNESS—
ANDERSEN, HATSUKAMI-A, MORGAN, AND ZUARDI

The Examiner's Prima Facie Case

In rejecting claims 1, 4, 5, 7– 9, 19–22, 24, 26, and 28, the Examiner cited Andersen as evidence that chewing gum compositions containing anti-smoking compounds, such as nicotine, and having a number of other features recited in Appellant's claims, including a pharmaceutical vehicle, were known in the art. Final Act. 5.

The Examiner found that Andersen differed from the rejected claims in that Andersen "does not teach cannabidiol as the anti-smoking agent, and does not teach the amounts of nicotine or cannabidiol in the chewing gum of the claimed method. Also, while Andersen teaches a method comprising nicotine and an anti-smoking aid, Andersen does not teach a method of treating smokeless tobacco addiction." *Id.*

The Examiner cited Hatsukami-A, Morgan, and Zuardi as evidence that, despite the differences between Andersen and Appellant's claims, a skilled artisan would nonetheless have considered the processes of Appellant's claims obvious. *See id.* at 5–8.

In particular, the Examiner cited Hatsukami-A as teaching that nicotine gum was a logical choice for treating smokeless tobacco addiction because smokeless tobacco users "may experience physical dependence to nicotine, and since nicotine replacements have been shown to reduce the withdrawal symptoms from cigarettes. The nicotine gum has the advantage of providing a similar pharmacokinetic curve to that of spit tobacco (pg[.] 37, 'Pharmacological treatments')." *Id.* at 6.

The Examiner also noted that, although Hatsukami-A "teaches that 2 mg dose of nicotine in chewing gum was not statistically effective for

treating spit tobacco users (pg[.] 38, col[.] 1, lines 5–22)," Hatsukami-A nonetheless "postulates that this dosage may be too low and states: 'It is entirely possible that a higher dose gum (e.g., 4 mg nicotine gum) may have resulted in a better success rate among ST [spit tobacco] users' (pg[.] 38, second col[.], bottom 5 lines)." *Id.*

The Examiner cited Morgan and Zuardi as evidence that it would have been obvious to include cannabidiol in Hatsukami-A's nicotine gum treatment of smokeless tobacco addiction. *Id.* at 7. Specifically, the Examiner cited Morgan as teaching that cannabidiol was a potentially excellent treatment for nicotine withdrawal because of its anxiolytic properties. *Id.* (citing Morgan 2434). And, the Examiner cited Zuardi as disclosing specific cannabidiol dosages that reduce anxiety symptoms. *Id.* (citing Zuardi 273).

Based on the references' combined teachings, the Examiner reasoned that a skilled artisan would have considered it obvious to

> modify the chewing gum method of Andersen by adding nicotine in the claimed amounts, and cannabidiol as the smoking cessation aid in the claimed amounts, and using the method to treat smokeless tobacco addiction since Hatsukami-A teaches that a nicotine chewing gum comprising the claimed amount of nicotine would be a reasonable method of treating smokeless tobacco addiction since the method has successfully treated tobacco smoking addiction, Morgan teaches that cannabidiol is useful in treating cigarette smoking addiction likely due to its anti-anxiety effects, and Zuardi teaches oral dosing of the claimed amounts of cannabidiol are useful for treating anxiety disorders . . . .

Id.

The Examiner reasoned further:

> [G]enerally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. *See* MPEP 2144.06.

Id. at 7–8

Analysis

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .
>
> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

We select claim 1 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(iv). Having carefully considered the arguments and evidence advanced by Appellant and the Examiner, Appellant does not persuade us that the preponderance of the evidence fails to support the Examiner's conclusion of obviousness as to claim 1.

Appellant's claim 1 recites a method of treating smokeless tobacco addiction by administering, to a patient in need of such treatment, a pharmaceutical composition comprising nicotine, a therapeutically effective amount of cannabidiol, and a pharmaceutically acceptable vehicle. Appeal Br. i (Claims App.).

The fact that Andersen includes no specific disclosure of using its nicotine-containing gum to treat smokeless tobacco addiction (*see* Appeal Br. 6–8) does not persuade us that the Examiner erred in concluding that the

process recited in claim 1 would have been obvious. It is well settled that "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. . . . [The reference] must be read, not in isolation, but for what it fairly teaches in combination with the prior art as a whole." *See In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

In the present case, in addition to Andersen, the Examiner's rejection relies on Hatsukami-A, Morgan, and Zuardi. *See* Final Act. 5–8. Just because Andersen alone might not suggest the process recited in Appellant's claim 1 does not demonstrate that the claimed process would have been unobvious.

As to treating smokeless tobacco addiction with nicotine, although the passage in Hatsukami-A cited by the Examiner acknowledges that studies involving gum containing 2 mg of nicotine were not effective in providing total abstinence, the reference nonetheless expressly suggests increasing the dosage, and also suggests that nicotine gum would be beneficial in reducing nicotine withdrawal symptoms:

> In summary, the results do not support nicotine replacement as effective treatment agents for total abstinence. ***It is entirely possible that a higher dose gum (e.g., 4 mg nicotine gum) may have resulted in a better success rate among ST [smokeless tobacco] users.*** On the other hand, perhaps nicotine gum is too similar to the ST use behavior. Although nicotine patch and nicotine gum do not result in enhanced abstinence outcomes compared to placebo, ***nicotine replacements have been observed to significantly reduce nicotine withdrawal symptoms . . . and may prevent a slip from becoming a relapse . . . . Thus, nicotine replacements may still provide some benefits to the individual who is trying to quit ST use.***

Hatsukami-A 38–39 (emphasis added; citations omitted)

Given Hatsukami-A's express suggestion to administer 4 mg nicotine gum, as well as the gum's potential benefits in relation to nicotine withdrawal symptoms, Appellant does not persuade us that a skilled artisan lacked motivation or a reasonable expectation of success in administering 4 mg nicotine gum to a subject in need of treatment for smokeless tobacco addition. *See* Appeal Br. 9–10; Reply 2–3.

In particular, that the prospective nature of the relevant disclosures in Hatsukami-A do not absolutely predict success does not persuade us that, viewing the relevant teachings of Hatsukami-A in context, a skilled artisan lacked a reasonable expectation of success in administering nicotine, particularly at the suggested dosage of 4 mg. *See In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) ("[O]bviousness does not require absolute predictability of success. . . . [F]or obviousness under § 103 . . . all that is required" is a reasonable expectation of success.). Indeed, rather than throwing "'metaphorical darts at a board filled with combinatorial prior art possibilities,'" Appeal Br. 8 (quoting *Kubin*, 561 F.3d at 1360), Hatsukami-A identifies the specific therapeutic agent, a specific dosage, and expected benefits. *See* Hatsukami-A 38–39.

Appellant also does not persuade us that the cited references would have failed to suggest combining cannabidiol with nicotine when treating smokeless tobacco addiction, as recited in Appellant's claim 1. *See* Appeal Br. 10–11.

Specifically, in a study of 24 smokers involving a cannabidiol-containing inhaler, Morgan discloses that, as compared to placebo, subjects treated with cannabidiol "significantly reduced the number of cigarettes

smoked by ~40% during treatment. Results also indicated some maintenance of this effect at follow-up. ***These preliminary data, combined with the strong preclinical rationale for use of this compound, suggest CBD to be a potential treatment for nicotine addiction that warrants further exploration***." Morgan 2433 (Abstract; emphasis added).

Morgan explains that "CBD [cannabidiol] is . . . a potentially excellent treatment of addiction due to its anxiolytic properties, as anxiety is a key symptom often observed in withdrawal from nicotine and other drugs." *Id.* at 2434.

Given Morgan's disclosure that cannabidiol was potentially an excellent treatment for nicotine addiction due to its anxiolytic properties, we agree with the Examiner that a skilled artisan, treating smokeless tobacco-related nicotine addiction with nicotine gum as suggested by Hatsukami-A, had a good reason for, and a reasonable expectation of success in, including cannabidiol in the nicotine gum used in Hatsukami-A. Appellant, therefore, does not persuade us that the Examiner erred in determining that the cited references would have suggested a process having all of the steps and features of Appellant's claim 1. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[W]hen a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious.") (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976)); *see also In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980) ("It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.").

Because the Examiner's conclusion of obviousness is based only on the teachings in the prior art, we are not persuaded that the Examiner improperly relies on hindsight. *See* Reply Br. 5.

Appellant does not persuade us, moreover, that a skilled artisan would have viewed nicotine gum and cannabidiol as mutually exclusive treatments for smokeless tobacco-related nicotine addiction. *See* Appeal Br. 11 ("Morgan plainly contemplates administering CBD to individuals who are not using nicotine replacement therapy (NRT). There would be no need to treat nicotine *withdrawal* symptoms in individuals who receive nicotine as part [of] a smoking cessation treatment.").

As the Supreme Court explained in *KSR*, when determining whether the prior art supplies a reason for practicing the claimed subject matter, the analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418; *see also id.* at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

In the present case, we agree with the Examiner that, when administering nicotine gum to treat smokeless tobacco-related nicotine addiction as taught in Hatsukami-A, a skilled artisan would have reasonably inferred that it would be useful to also administer cannabidiol to ameliorate the symptoms of anxiety that accompany the addiction, as taught in Morgan. Given the references' teachings that both nicotine gum and cannabidiol would be useful for treating smokeless tobacco-related nicotine addiction, and given the absence of any specific evidence teaching away from co-administration of nicotine replacement therapy and an anxiolytic agent,

we are not persuaded that a skilled artisan lacked a good reason for, or a reasonable expectation of success in, administering a cannabidiol-containing nicotine gum to treat smokeless tobacco-related nicotine addiction.

In sum, and for the reasons discussed, Appellant does not persuade us that the cited references fail to provide a prima facie case of obviousness as to Appellant's claim 1. We are not persuaded, moreover, that Appellant has advanced objective evidence of nonobviousness sufficient to outweigh the evidence of prima facie obviousness presented by the Examiner.

Appellant's contentions regarding evidence of nonobviousness do not appear in the Argument section of the Appeal Brief, but are instead presented in the Summary of Claimed Subject Matter. *See* Appeal Br. 3. Appellant's contentions regarding objective evidence of nonobviousness, in their entirety, read as follows:

> The present inventor made the surprising and unexpected discovery that co-administering a combination of nicotine and cannabidiol (CBD) is particularly efficacious for the treatment of smokeless tobacco addiction, thereby presenting a solution to a long-felt but unresolved need. Specification, ¶ [07]; Examples 3 and 4. In some aspects, a gum base containing nicotine and the other components is compounded, and CBD is infused into an outer portion of the chewing gum. See, e.g., dependent claim 5. Alternatively, CBD and nicotine may be substantially uniformly contained in the gum base. Specification, ¶ [42].

Id.

It is well settled that, to be persuasive of nonobviousness, evidence of unexpected results must show that the results were actually unexpected, that the results are commensurate in scope with the claimed subject matter, and that unexpectedness is based on a comparison to the closest prior art. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007); *In re*

Huai-Hung Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011); *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991). In arguing unexpected results, other than the conclusory statement quoted above, Appellant presents no specific discussion of the cited portions of the Specification, or how those portions of the Specification meet the criteria, noted above, regarding unexpected results.

In any event, Appellant's Example 3 discloses an experiment involving an individual who had used smokeless tobacco for over 20 years, and who had unsuccessfully attempted to quit though nicotine replacement therapy and hypnosis. *See* Spec. ¶ 56. Example 3 discloses that, immediately upon beginning daily periodic use of commercially available Nicorette® gum containing 4 mg nicotine and infused with 50 mg cannabidiol, the individual was able to cease smokeless tobacco use, and had not used smokeless tobacco after 8 weeks of treatment. *See id.* ¶ 57.

Appellant's Example 4 discloses an experiment involving 10 habitual and chronic users of smokeless tobacco products. *Id.* ¶ 58. The individuals were given the same gum used in Example 3, and were instructed to use as much of the gum as needed to satisfy cravings for a period of 24 hours. *Id.* After the 24 hour test period, "all of the subjects (10/10) reported that they used the chewing gum in lieu of the smokeless tobacco products they normally would have consumed; and all of the subjects (10/10) reported that the chewing gum was effective to significantly block cravings for smokeless tobacco." *Id.*

Appellant does not explain specifically how or why the experiments described in Examples 3 and 4 constitute a comparison to the closest prior art, nor does Appellant explain how or why the results of the experiments

are commensurate in scope with the treatment method recited in claim 1. Appellant, moreover, does not explain specifically why the results described in Examples 3 and 4 would have been unexpected, particularly given the suggestions in Hatsukami-A and Morgan that nicotine gum and cannabidiol would be useful for treating nicotine withdrawal symptoms. In addition, although we acknowledge the assertion in the Specification that the combination of nicotine and cannabidiol has synergistic activity (*see* Spec. ¶ 7), Appellant does not identify in the record the specific evidence or comparison upon which the assertion of synergy is based.

As to Appellant's assertion of solving a long-felt but unresolved need, our reviewing court's predecessor has explained that an allegation of a long felt but unsolved problem in the art "is not evidence of unobviousness unless it is shown . . . that the widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." *In re Allen*, 324 F.2d 993, 997 (CCPA 1963) (citing *Toledo Pressed Steel Co. v. Standard Parts, Inc.*, 307 U.S. 350, 356 (1939)). In the present case, Appellant does not identify any specific evidence in relation to the efforts of others, or how long the asserted need has been felt.

In sum, for the reasons discussed, we are not persuaded that Appellant has explained adequately why the cited portions of the Specification constitute evidence of unexpectedness sufficient to outweigh the evidence of prima facie obviousness in the prior art advanced by the Examiner. Nor are we persuaded that Appellant has advanced an adequate evidentiary basis for finding that the process recited in Appellant's claim 1 solves a long felt but unmet need.

Accordingly, we find that the preponderance of the evidence supports the Examiner's conclusion of obviousness as to claim 1. We, therefore, affirm the Examiner's rejection of claim 1 over Andersen, Hatsukami-A, Morgan, and Zuardi. Because they were not argued separately, claims 4, 5, 7– 9, 19–21, 24, 26, and 28 fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Appellant contends that claim 22 is separately patentable because the nicotine dosage of "about 3 mg" recited in claim 22 is outside the dosage of 4 mg of nicotine suggested by Hatsukami-A. Appeal Br. 11–12. In particular, Appellant contends, because claim 21 recites an upper endpoint of about 4 mg of nicotine, it is not reasonable to interpret claim 22's recitation "about 3 mg of nicotine" to encompass a gum having 4 mg of nicotine. *See id.* We are not persuaded.

Claims 21 and 22 depend from claim 19, which recites a treatment method similar to that recited in claim 1, discussed above. *See* Appeal Br. ii (Claims App.). Claims 21 and 22 limit the amounts of nicotine and cannabidiol administered in the claimed treatment method, and are reproduced below:

> 21. The method of claim 19, wherein the therapeutically effective dose comprises from about 1 ***to about 4 mg of nicotine*** and from about 3 to about 200 mg of cannabidiol.
>
> 22. The method of claim 19, wherein the therapeutically effective dose comprises from about 1 ***to about 3 mg of nicotine*** and from about 4 to about 180 mg of cannabidiol.

Id. (emphasis added).

"The use of the word 'about,' avoids a strict numerical boundary to the specified parameter." *Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007)

(quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)*; see also In re Harris*, 409 F.3d 1339, 1343 (Fed. Cir. 2005) ("[U]se of the term 'about' shows that the applicants did not intend to limit the claimed ranges to their exact end-points.").

"[T]he word 'about' does not have a universal meaning in patent claims[;]" rather, "the meaning depends on the technological facts of the particular case." *Pall Corp.*, 66 F.3d at 1217; *see also Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995) ("The meaning of the word 'about' is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the . . . disclosure to those skilled in the art."). Thus, in evaluating the scope of the term "about," it is appropriate to determine how the Specification and other claims use the term, as well as considering the effects of varying the parameter described by the term. *Pall Corp.*, 66 F.3d at 1217.

In the present case, the Specification discloses that "***[t]he amount of nicotine present in a dosage form may vary over a wide range***, but by way of example often ranges from about 0.1 to about 10 mg, more usually from about 0.5 to about 8 mg, and typically ranges from about 1 to about 6 mg, about 2 to about 5 mg, or about 3 to about 4 mg." Spec. ¶ 18 (emphasis added).

Given the Specification's disclosure that useful amounts of nicotine may vary over a wide range, as opposed to a particular amount of nicotine (such as 3 mg) being critical to the invention, we agree with the Examiner that a skilled artisan would have interpreted the term "about 3 mg nicotine" in claim 22 to encompass nicotine amounts significantly higher than 3 mg nicotine, including the 4 mg dosage taught in Hatsukami-A.

The fact that Appellant's claim 21 also encompasses the 4 mg dosage taught in Hatsukami-A does not persuade us that the Examiner erred in interpreting claim 22 as encompassing a 4 mg dosage. *See Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1370 (Fed. Cir. 2007) ("[O]verlapping patent claims are not unusual, and the overlap does not require us to construe the 'composite composition' claims to cover subject matter that differs from the subject matter covered by the other two sets of claims.").

In sum, for the reasons discussed, Appellant does not persuade us that the Examiner erred in maintaining the obviousness rejection of claim 22 over Andersen, Hatsukami-A, Morgan, and Zuardi. We, therefore, affirm the Examiner's rejection of claim 22 over those references.

OBVIOUSNESS— ANDERSEN, HATSUKAMI-A, MORGAN, ZUARDI, AND HATSUKAMI-B

The Examiner's Prima Facie Case

In rejecting claim 23, which depends from claim 19 discussed above, the Examiner relied on the teachings noted above in Andersen, Hatsukami-A, Morgan, and Zuardi, and cited Hatsukami-B as evidence that it would have been obvious to administer the smokeless tobacco addiction treatment more than once daily. Final Act. 8–9.

Analysis

In traversing the Examiner's rejection of claim 23, Appellant relies on the arguments discussed above in relation to the combination of Andersen, Hatsukami A, Morgan, and Zuardi. Because, for the reasons discussed

above, we do not find those arguments persuasive, we also affirm the Examiner's rejection of claim 23.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
1, 4, 5, 7– 9, 19–22, 24, 26, and 28	§ 103(a) over Andersen, Hatsukami-A, Morgan, and Zuardi	1, 4, 5, 7– 9, 19–22, 24, 26, and 28	
23	§ 103(a) over Andersen, Hatsukami-A, Morgan, Zuardi, and Hatsukami-B	23	
Overall Outcome		1, 4, 5, 7– 9, 19–24, 26, and 28	

TIME PERIOD

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