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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ISA ODIDI and AMINA ODIDI

Appeal 2019-000699
Application 11/432,226
Technology Center 1600

Before FRANCISCO C. PRATS, RAE LYNN P. GUEST, and DEBORAH KATZ, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* KATZ.

Opinion Dissenting-in-part filed by *Administrative Patent Judge* GUEST.

DECISION ON APPEAL

Appellant[1] seeks our review,[2] under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 155–180. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE.

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[1] We use the word "Appellant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party-in-interest as Intellipharmaceutics Corp. (Appeal Br. 3.)

[2] We consider the Final Office Action issued September 27, 2017 ("Final Act."), the Appeal Brief filed April 19, 2018 ("Appeal Br."), the Examiner's

Appellant's Specification is directed to analgesic compositions that prevent drug abuse, dose dumping in the presence of alcohol, and timed or extended release in gelatin capsules. (Specification filed August 11, 2010 ("Spec.") ¶ 1.)

Appellant's claim 155 recites:

> A pharmaceutical composition comprising:
> (i) an active pharmaceutical agent selected from the group consisting of an opioid and an opiate; and
> (ii) 40-50% by weight of an oil selected form the group consisting of almond oil, canola oil, castor oil, corn oil, cottonseed oil, mineral oil, olive oil, olive-pomace oil, peanut oil, safflower oil, sesame oil, soybean oil, sunflower oil, and mixtures thereof; and
> (iii) at least 15% by weight of a controlled-release agent selected from the group consisting of hydroxypropyl methylcellulose (hypromellose), hydroxypropyl cellulose, and polyethylene oxide,
> wherein the composition is a non-aqueous paste.

(Appeal Br. 24.)

Appellant's independent claim 168 is similar to claim 155 except that it recites "(ii) 3-50% by weight of an oil" selected from the group recited in claim 155 and includes "(iv) a carbomer, wherein the carbomer is at least 5% by weight of the pharmaceutical composition but less than or equal to 8% by weight of the pharmaceutical composition . . . ." (Appeal Br. 26.)

Appellant's independent claim 180 is also similar to claim 155, but recites only hydroxypropyl methylcellulose (hypromellose) as a controlled-

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Answer issued on September 5, 2018 ("Ans."), the Reply Brief filed November 5, 2018 ("Reply Br.").

release agent and also requires "(iv) 0.5-20% by weight of a clay mineral . . . ." (Appeal Br. 28.)

The Examiner makes the following rejections:

claims 155 and 164–167 under 35 U.S.C. § 102(b) or, in the alternative, § 103(a) over Aungst[3] (*see* Final Act. 4–5);

claims 155–159, 162–173, and 175–180 under 35 U.S.C. § 103(a) over Aungst and Sackler[4] (*see id.* at 5–9);

claims 155, 160, 161, and 164–167 under 35 U.S.C. § 103(a) over Aungst and Carrara[5] (*see id.* at 9–10); and

claims 155–179 under 35 U.S.C. § 103(a) over Aungst, Sackler, and Carrara (*see id.* at 10).

As the Examiner finds, Aungst teaches opioid-containing pharmaceutical compositions that include an opioid, 30–80% vehicle, and 20–30% polymeric substance in Table A. (*See* Final Act. 4, citing Aungst abstract, Table A, and 5:30–34.) As the Examiner also finds, Aungst teaches that the polymeric substance can be hydroxypropylcellulose in a gel form. (*see* Final Act. 4, citing Aungst 5:30–24.)

The Examiner finds that Aungst teaches that the vehicle can be selected from a group that includes mineral oil, sesame oil, and olive oil. (*See* Final Act. 4, citing Aungst, Table 1.) Appellant disputes this finding. (*See* Appeal Br. 15–17.)

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[3] Aungst and DiLuccio, U.S. Patent 4,626,539, issued December 2, 1986.
[4] Sackler, U.S. Patent Application Publication 2003/0068370 A1, published April 10, 2003.
[5] Carrara et al., US Patent Application Publication 2006/0153905 A1, published July 13, 2006.

> First, Appellant points to the portion of Aungst that states:
>
> > By the term "suitable pharmaceutical carrier" is meant any non-toxic pharmaceutically suitable vehicle which comprises any polar protic solvent with a molecular weight of less than 600. Suitable carriers include propylene glycol or polyethylene glycol. Propylene glycol is a preferred carrier or vehicle, and any other carriers which may be used are then considered as excipients.

(Aungst 4:53–60; *see* Appeal Br. 15.) According to Appellant, this portion of Aungst teaches that suitable carriers or vehicles can only be polar protic solvents within a specific molecular weight range. Appellant argues that this portion of Aungst is contrary to the Examiner's finding that Aungst teaches vehicles, such as mineral, sesame, or olive oil, can be selected from Table 1 because none of these are polar protic solvents. (*See* Appeal Br. 15–16.)

Appellant argues further that although Table 1 lists mineral, sesame, and olive oils, they are provided merely as a comparison for flux levels of the opioid through the skin, not as actual compositions with a gelling agent. (*See* Appeal Br. 16, citing Aungst 6:17–25.) According to Appellant, Aungst teaches the superiority of propylene glycol and other protic polar solvents over oils and aqueous vehicles and, thus, would fail to motivate one of ordinary skill to substitute an oil-based vehicle and even teaches away from such vehicles or carriers. (*See* Appeal Br. 16–17.)

We agree that Aungst fails to teach a composition with the ingredients recited in claim 155 and, thus, fails to anticipate claim 155. We are not persuaded that Aungst teaches away from using the oils recited in claim 155, because it proposes them as potential vehicles without expressly discouraging their use. Nevertheless, we agree with Appellant that those of

ordinary skill in the art would not have had a reason or been motivated to use oil-based vehicles instead of the protic polar solvents because Aungst demonstrates that the oil-based vehicles have inferior flux levels. We also agree that because Aungst fails to provide a reason to use the recited oil-based vehicle, it fails to render the claimed composition obvious. *In re Susi*, 440 F.2d 442 (CCPA 1971), cited by the Examiner (*see* Ans. 5), holds that even inferior products can render a composition obvious, but Aungst fails to teach a complete composition with the ingredients recited in claim 155 and fails to provide a reason why those of ordinary skill in the art would have selected them.

Accordingly, we reverse the rejection of claims 155 and claims 164–167, which depend on claim 155, under both § 102(b) and § 103(a) over Aungst.

The Examiner also rejects claims 155–159, 162–173, and 175–180 under 35 U.S.C. § 103(a) over Aungst and Sackler. (*See* Final Act. 5–9.) The Examiner cites Sackler for its teaching of bentonite as a gelling agent in abuse-resistant drug compositions, along with hydroxypropylmethylcellulose as a release modifying agent. (*See* Final Act. 6, citing Sackler ¶¶ 49, 94.) Because these teachings do not cure the deficiency of Aungst regarding inclusion of oil, we are not persuaded that the combination of Aungst and Sackler render these claims, or the claims that depend on them, obvious.

The Examiner rejects claims 155, 160, 161, and 164–167 under 35 U.S.C. § 103(a) over Aungst and Carrara. (*See* Final Act. 9–10). The Examiner also rejects claims 155–179 under 35 U.S.C. § 103(a) over

Aungst, Sackler, and Carrara. (*See id.* at 10.) The Examiner cites Carrara for its teaching of pharmaceutical compositions for transdermal patches that include opioids, gelling agents, such as hydroxypropylcellulose and hydroxypropyl methylcellulose, and emollients, such as mineral oil. (*See* Carrara abstract, ¶¶ 73, 79, 87; *see* Final Act. 9.) Carrara teaches mineral oil at about 1.0 to about 30.0 % w/w. (*See* Carrara ¶ 87.)

Because Appellant's claims 155 and 168 require mineral oil at 40—50% by weight and the Examiner does not provide a reason why one of ordinary skill would have modified the teaching of Carrara to use more mineral oil, we are not persuaded that Carrara renders the claimed compositions obvious or cures the deficiencies of Aungst.

Independent claim 168 requires oil at 3–50% by weight, which overlaps with the teaching of mineral oil in Carrara. But, claim 168 also requires a carbomer at "at least 5% by weight of the pharmaceutical composition but less than or equal to 8% by weight of the pharmaceutical composition." (*See* Appeal Br. 26.) Sackler teaches the use of carbomers in a pharmaceutical composition and Carrara teaches carbomer at about 0.2% to about 30%. (*See* Carrara ¶ 79; *see* Final Act. 7.) Although the Examiner finds that it would have been obvious to a person of ordinary skill in the art at the time that the invention was made to add 1–10% by weight of carbomer as a gelling agent to the composition of Aungst in light of teaching in Aungst of gelling agents, the Examiner fails to address the limitation of claim 168 wherein the carbomer is "less than or equal to 8% by weight of the pharmaceutical composition." (*See* Final Act. 7, citing Aungst 5:30–33.)

Accordingly, we are not persuaded that the combination of Aungst and Carrara renders claim 168 obvious.

We reverse the rejection of claims 155, 168, and 180, and the claims that depend on them, over the combination of Aungst and Carrara or over the combination of Aungst, Sackler, and Carrara under 35 U.S.C. § 103(a).

Conclusion

Upon consideration of the record and for the reasons given, we reverse the Examiner's rejections.

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
155, 164–167	102	Aungst		155, 164–167
155, 164–167	103	Aungst		155, 164–167
155–159, 162–173, 175–180	103	Aungst, Sackler		155–159, 162–173, 175–180
155, 160, 161, 164–167	103	Aungst, Carrara		155, 160, 161, 164–167
155–179	103	Aungst, Sackler, Carrara		155–179
Overall Outcome				**155–180**

REVERSED

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Technology Center 1600

Before FRANCISCO C. PRATS, RAE LYNN P. GUEST, and DEBORAH KATZ, *Administrative Patent Judges*.

GUEST, *Administrative Patent Judge*, dissenting-in-part.

I agree with the majority's finding that Aungst does not anticipate the claimed invention because Table 1 of Aungst only expressly describes compositions that include an opioid (naloxone) and mineral, sesame, or olive oil, but not in combination with a controlled release agent. *See* Aungst, Table 1. Further, I agree with the majority that Aungst does not teach away from the claimed invention because it does not expressly discourage the use of any particular vehicle. However, I disagree with the majority's determination that it would not have been obvious to one of ordinary skill in the art to have used one of mineral oil, sesame oil, or olive oil as an alternative vehicle in the composition broadly taught by Aungst in Table A. I agree with the Examiner (Ans. 5) that Aungst suggests using one of

mineral oil, sesame oil, or olive oil as an alternative vehicle because Table 1 describes exactly what the skilled artisan would have expected in doing so for transdermal opioid delivery.

Indeed, Aungst teaches in Table A a broad composition having four components: (1) an opioid, (2) a vehicle, (3) a penetration enhancer, and (4) excipients. Aungst, col. 5, Table A. Aungst further teaches that the components of Table A can also be mixed with hydroxypropylcellulose (for example) to provide the composition in the form of a gel. *Id.* at col. 5, ll. 30–34. Under the subheading "Vehicle," Aungst teaches that Table 1 describes "[d]rug penetration through skin . . . evaluated using naloxone *in a variety of vehicles*" and lists the vehicles with "the highest naloxone fluxes" and that "[n]on-aqueous vehicles provided higher fluxes of naloxone than aqueous vehicles." Aungst, col. 6, ll. 18–25 (emphasis added). One of ordinary skill in the art would have understood from Table 1 how all of the listed known transdermal "vehicles" would have functioned in terms of solubility (Naloxone Concentration (mg/ml), flux (μg/cm^2 hr.), and lag-time (hours) in evaluating the usefulness of each of the listed vehicles for transdermal opioid delivery. Accordingly, Aungst suggests any of the vehicles listed in Table 1 for their known intended purpose as vehicles in a transdermal opioid drug composition and the skilled artisan would have selected from the list depending on the desired results. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). Moreover, as pointed out by the Examiner (Final Rej. 12), Aungst teaches that the "vehicle chosen will also effect the

consistency of the pharmaceutical composition" suggesting the skilled artisan could choose vehicles, for example from Table 1, for desired consistency.

Appellant contends that the authors of Aungst expressly limited the list of "suitable pharmaceutical carriers" to include only "polar protic solvents having a molecular weight of less than 600" and, in doing so, implicitly relegated all the other vehicles identified in Table 1 as "unsuitable." Reply Br. 3–4. I disagree that the defined "suitable pharmaceutical carrier" is so limited in Aungst. The first sentence reads, "[b]y the term 'suitable pharmaceutical carrier' is meant any non-toxic pharmaceutically suitable vehicle *which comprises* any polar protic solvent with a molecular weight of less than 600." Aungst, col. 4, ll. 53–56 (emphasis added). I read this paragraph more broadly than the majority, as merely identifying preferences within a very broad class of "non-toxic pharmaceutically suitable vehicle[s]." I believe the skilled artisan would look to Table 1 and immediately recognize other non-toxic pharmaceutically suitable vehicles in addition to polar protic solvents with a molecular weight of less than 600, and in doing so be motivated to use them based on their known transdermal vehicle properties. Indeed, I note that Table 1 shows similar transdermal flux of olive oil (3.5 $\mu g/cm^2$ hr.) and Polyethylene Glycol 400 (3.4 ± 0.6 $\mu g/cm^2$ hr.), even though olive oil achieves a similar flux with a lower concentration of solubilized naloxone. Aungst, Table 1. Yet, Appellant argues that Aungst teaches away "based on the low flux issues" (Appeal Br. 17) even though Aungst references polyethylene glycol, with a similar flux rate, as a "[s]uitable carrier." *See* Aungst, col. 4, ll. 56–

57. Even if Table 1 suggests that olive oil, for example, is an inferior vehicle, whether because of the flux rate or solubility limitations, I find no error with the Examiner's reasoning (Ans. 5) and note that "[a] known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). As the Examiner also noted (Ans. 4), a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Labs.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("[A]ll disclosures of the prior art, including unpreferred embodiments, must be considered.") (*quoting In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976)).

Finally, Appellant has not argued that the vehicles recited in the claims are critical or present unexpected results in their use as vehicles over the preferred vehicles. *See generally* Appeal Br., Reply Br. Accordingly, I am not persuaded that the Examiner erred in rejecting claim 155, and the claims that depend therefrom as obvious over the teachings of Aungst alone or further in view of additional prior art.