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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRIS V. SIMMONS and DANNY CARRERO

Appeal 2019-005185
Application 13/900,323
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review, under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 17, 20–23, 25, 27–33, and 36–40. (Appeal Brief filed Jan. 15, 2019 ("App. Br.") 6.) We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM, but designate our affirmance as a new ground of rejection.

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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 Parties in Interest as Professional Compounding Centers of America and Best Pet Rx IP, Inc. (*See* App. Br. 2.)

INTRODUCTION

Appellant's Specification provides a method of treating otitis by administering an otic pharmaceutical composition. (Specification dated May 22, 2013 ("Spec.") ¶ 7.) The composition may include a poloxamer vehicle and a variety of active pharmaceutical ingredients (API). (*Id.*) The composition forms a liquid at room temperature and converts to a gel at body temperature due to the poloxamer. (*Id.* ¶ 9.) The Specification discloses the composition may include poloxamer 407, which converts from liquid to gel at temperatures at about 64° F. (*Id.* ¶ 40.) The composition may also include a combination of poloxamer 407 and poloxamer L-64. (*Id.* ¶ 41.) Poloxamer L-64 increases the composition's gelation temperature to about 85° F. *Id.*

Appellant's claim 17 recites:

> A method of treating otitis comprising administering an otic pharmaceutical composition into the ear canal of an animal, wherein the composition is a liquid when administered and comprises
>
> a) an active pharmaceutical ingredient (API); and
>
> b) at least two poloxamers in a solvent, wherein the at least two poloxamers are selected from a group comprising poloxamer L-64 and poloxamer 407; and
>
> wherein the otic pharmaceutical composition is converted from a liquid to a gel at body temperature inside the ear canal of the animal at about 85 degrees Fahrenheit.

(App. Br. 15.) Independent claims 39 and 40 include a concentration of 20–30% poloxamer 407. (*Id.* at 19–20.)

The Examiner rejects the claims as follows:

Claims Rejected	35 U.S.C. §	Basis	Non-Final Office Action
17, 20–23, 25, 27–33, 36–40	103	Lichter,[2] Meadows[3]	6–11
17, 20–23, 27–28, 33, 39, 40	103	Lichter '018,[4] Meadows	11–15

ANALYSIS

Claims 17, 39, and 40 as obvious over Lichter and Meadows

The Examiner finds Lichter teaches a method of treating otitis media, by administering an otic pharmaceutical composition into the inner or middle ear. (Non-Final Office Action dated April 13, 2018 ("Non-Final Act.") 6.) The Examiner finds the composition contains an active agent and 10–40% of a thermoreversible polymer, specifically poloxamer 407. (*Id.*) The Examiner finds Lichter teaches the composition undergoes a phase transition between room temperature and body temperature, and the gelation temperature may range from about 20–30° C. (*Id.* at 7.)

The Examiner finds "Lichter does not teach poloxamer 184 (i.e., L-64)." (*Id.* at 8.) The Examiner finds that Meadows teaches synergistic poloxamer mixtures for administering active agents. (*Id.* at 8–9.) The synergistic mixtures result from differences between poloxamers, particularly in the polyethylene oxide portion. (*Id.* at 9.) Specifically, Meadows teaches a synergistic combination of poloxamer 407 and

[2] Lichter et al., US 2013/0116210 A1, published May 9, 2013.
[3] Meadows et al., US 8,460,644 B2, issued June 11, 2013.
[4] Lichter et al., US 8,399,018 B2, issued Mar. 19, 2013.

poloxamer 188. (*Id.*) The Examiner finds Meadows teaches that poloxamer 184 would have been expected to result in a similar synergistic mixture when combined with poloxamer 407, due to the differences between poloxamer 407 and poloxamers 188 and 184. (*See id.*) The Examiner finds "that merely substituting a combination of two poloxamer vehicles for another would have a reasonable expectation of success in achieving delivery of the claimed API in an efficient manner." (*Id.* at 10.)

Appellant argues Lichter does not teach a poloxamer combination including "L-64 (poloxamer 184)." (App. Br. 7.) Appellant argues, therefore, that Lichter's otic composition containing only poloxamer 407 would begin to gel at about 64° F. (*Id.*) Appellant argues that Meadows also does not teach a specific mixture of P407 and L-64; however, "Meadows at least mentions L-64 once (as poloxamer 184, see col. 6, line 12)." (*Id.* at 7–8.)

Appellant argues further that Meadows does not teach that poloxamer combinations are synergistic with respect to adjusting gelation temperature. (Reply Brief filed June 25, 2019 ("Reply Br.") 4.) Rather, Meadows teaches poloxamer combinations form synergistic mixtures for solubilizing drugs. (*Id.*) Appellant argues Meadows further discloses a preference for poloxamer mixtures that do not cause gelling. (*Id.* at 5, citing Meadows 9:1–7.) Accordingly, Appellant argues that the prior art as a whole does not support the Examiner's rationale for combining the references. (*Id.*)

We are not persuaded. Contrary to Appellant's arguments, Lichter expressly teaches combining poloxamer 407 with poloxamer 188 to manipulate the gelation temperature of an otic composition. (Lichter ¶ 613.)

Lichter teaches an equation for estimating the "gelation temperature of F127(P407)/F68(P188) mixture" as:

$$T_{gel} = -1.8(\%\ F127) + 1.3(\%\ F68) + 53$$

(*Id.* ¶ 616.) The equation teaches that adding poloxamer 188 increases the gelation temperature. (*See id.*)

Lichter teaches a composition containing 20% poloxamer 407 and 10% poloxamer 188. (*Id.* ¶ 614, Table 5.) Lichter's equation estimates a gelation temperature of 30° C (86° F) for the composition containing 20% poloxamer 407 and 10% poloxamer 188. (*See id.* ¶¶ 614, 616.) Therefore, Lichter teaches an otic formulation containing poloxamer 188 and poloxamer 407 that converts from a liquid to a gel at body temperature at about 85° F.

Meadows teaches that there is little difference between poloxamer 188 and poloxamer 184. (*See* Meadows 6:9–15.) Therefore, a person of ordinary skill in the art would have expected poloxamer 184 to share similar properties with poloxamer 188 for increasing the gelation temperature in combination with poloxamer 407. Because combining poloxamer 184 with poloxamer 407 would have been expected to increase the gelling temperature of Lichter's otic compositions similar to the combination with poloxamer 188, we sustain the Examiner's rejection. "[W]hen a patent claims a structure already known in the prior art that is altered by the mere substitution of one element for another known in the field, the combination must do more than yield a predictable result." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007), citing *United States v. Adams*, 383 U.S. 39, 50-51 (1966). Because our reasoning differs from the Examiner's, we designate

our affirmance as a New Ground of Rejection to provide Appellant a fair opportunity to address these teachings and new position.

Appellant does not provide separate arguments for the rejection of the dependent claims. (*See* App. Br. 6–12.) Accordingly, we affirm the Examiner's rejection of claims 17, 20–23, 25, 27–33, 36–40 as being obvious under 35 U.S.C. § 103.

Claims 17, 39, and 40 as obvious over Lichter '018 and Meadows

The Examiner finds Lichter '018, similarly to Lichter, teaches treating otitis with otic pharmaceutical compositions that convert from liquid to gel at body temperature. (*See* Non-Final Act. 11–15.) The Examiner finds one of ordinary skill would have combined the poloxamer 407 composition taught by Lichter '018 with poloxamer 184 in view of Meadows. (*Id.*) Appellant presents the same arguments against Lichter '018 and Meadows as presented against Lichter and Meadows. (*See* App. Br. 12–13.)

Lichter '018 teaches the same equation for estimating the increase in gelation temperature by combining poloxamer 188 with poloxamer 407, as discussed with respect to Lichter above. (Lichter '018, 100:54–101:26.) Accordingly, for the reasons set forth above, we affirm the Examiner's rejection of claims 17, 20–23, 27–28, 33, 39, and 40 as obvious over Lichter '018 and Meadows. Because our reasoning differs from the Examiner's, we designate our affirmance as a New Ground of Rejection to provide Appellant a fair opportunity to address these teachings and new position.

CONCLUSION

Upon consideration of the record and the reasons given, the rejection of claims 17, 20–23, 25, 27–33, 36–40 under 35 U.S.C. § 103 is sustained.

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed	New Grounds
17, 20–23, 25, 27–33, 36–40	103	Lichter, Meadows	17, 20–23, 25, 27–33, 36–40		17, 20–23, 25, 27–33, 36–40
17, 20–23, 27–28, 33, 39, 40	103	Lichter '018, Meadows	17, 20–23, 27–28, 33, 39, 40		17, 20–23, 27–28, 33, 39, 40
Overall Outcome			17, 20–23, 25, 27–33, 36–40		17, 20–23, 25, 27–33, 36–40

We have entered a new ground of rejection for independent claim 31 pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides that "[a] new ground of rejection . . . shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner . . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

37 C.F.R. § 41.50(b)