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

The time period for reply, if any, is set in the attached communication.
This is an appeal\(^1\) under 35 U.S.C. § 134 involving claims to a method for treatment of a dry mucus membrane disorder. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

\(^1\) Appellants identify the Real Party in Interest as Dynamis Pharmaceuticals, Inc. (see App. Br. 2).
Statement of the Case

Background

“Dry eye (keratoconjunctivitis sicca or keratitis sicca) is a chronic dryness of the corneal and conjunctival surfaces and results from a decrease in the production of tear components or from an altered ratio of the individual oil, water and mucus components to each other” (Spec. 1). “There is an interest in treating dry eye with agents that can increase mucin production” (Spec. 2).

The Claims

Claims 1 and 3–28 are on appeal. Independent claims 1 and 21 are representative and read as follows:

1. A method for treatment of a dry mucus membrane disorder selected from the group consisting of dry eyes, dry mouth and constipation, the method comprising administering to a patient in need of said treatment an effective amount of a compound of the formula:

   \[
   \begin{align*}
   &\begin{array}{c}
   R_9 \quad R_7 \quad R_5 \quad R_3 \quad R_1 \quad R \\
   R_{11} \quad C \quad C \quad C \quad C \quad C \quad \text{NH}
   \end{array} \\
   &\begin{array}{c}
   R_{10} \quad R_8 \quad R_6 \quad R_4 \quad R_2 \\
   \end{array}
   \end{align*}
   \]

   \( (i) \)

   wherein R represents a substituted or unsubstituted alkyl (C₁–C₄), said alkyl substituents being selected from the group of hydroxy, carboxy, and phosphono substituents;

   R₁ and R₂ are the same or different and represent a radical selected from the group consisting of hydrogen and hydroxymethyl radicals;

   R₃ and R₄ are the same or different and represent a hydrogen or hydroxy radical;

   R₅ and R₆ are different and represent either a hydrogen or hydroxy radical;
R₇ and R₈ are different and represent either a hydrogen or hydroxy radical;
R₉, R₁₀ and R₁₁ are the same or different and represent a radical selected from the group consisting of hydrogen, alkyl (C₁–C₂), hydroxyalkyl and hydroxy radicals;
n represents either 0 or 1,
the pharmaceutically acceptable inorganic base, organic base, inorganic acid, and methane sulfonic acid salts and isomeric forms of said compound.

21. A method for treating a dry mucus membrane disorder selected from the group consisting of dry eyes, dry mouth and constipation in a patient in need thereof by administering to said patient a therapeutically effective amount of a therapeutic composition that increases mucin production in said patient, said composition comprising meglumine or a pharmaceutically acceptable salt thereof and a pharmaceutically acceptable carrier medium, said meglumine being the only therapeutically active component of said composition that is effective to increase mucin production in said patient.

The Issue

The Examiner rejected claims 1 and 3–28 under 35 U.S.C. § 103(a) as obvious over Johnson² (Ans. 4–5).

The Examiner finds that Johnson teaches “the use of meglumine as an osmolyte for hydrating the surfaces in the body, such as eye which can be used concurrently or sequentially with a sodium channel blocker” (Ans. 4). The Examiner finds that the “treatment of dry eye is taught in claims 5 and 7–13” (Ans. 4). The Examiner finds it obvious “to use meglumine and the salts of meglumine for the treatment of dry eye, considering that Johnson

lists such components as osmolytes, which can be used concurrently, before and after the use of sodium channel blockers to increase mucosal hydration and mucosal clearance” (Ans. 4–5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that Johnson render the claims obvious?

Findings of Fact

1. Johnson teaches “treatments comprising the use of osmolytes together with sodium channel blockers that are more potent, more specific, and/or absorbed less rapidly from mucosal surfaces” (Johnson ¶ 16).

2. Johnson teaches that “[a]ctive osmolytes useful in the present invention that are ionic osmolytes include any salt of a pharmaceutically acceptable anion and a pharmaceutically acceptable cation” (Johnson ¶ 88).

3. Johnson teaches that “[p]harmaceutically acceptable cations that can be used to carry out the present invention include . . . meglumine (N-methyl D-glucamine) . . . Particularly preferred cations include . . . meglumine” (Johnson ¶ 90).

4. Claim 1 of Johnson teaches a “method of treating a disease ameliorated by increased mucociliary clearance and mucosal hydration comprising administering to a subject in need of increased mucociliary clearance and mucosal hydration an effective amount of an osmolyte and a sodium channel blocker” (Johnson 20, claim 1) and claim 5 of Johnson further teaches the “method of claim 1, wherein the disease is one or more conditions selected from the group consisting of . . . dry eye” (Johnson 23, claim 5).
Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”


Analysis

Claim 1

Appellants contend that “Johnson only contemplates the use of meglumine salts. Nowhere does Johnson expressly or impliedly suggest the use meglumine, _per se_, i.e., in the form of its free base” (Br. 5).

We are not persuaded. Claim 1 is not limited to the “free base” form of meglumine, expressly encompassing the “methane sulfonic acid salts” as well as “organic base” and inorganic acid” forms. Appellants provide no evidence suggesting that the meglumine of Johnson does not fall within the scope of claim 1. See In re Self, 671 F.2d 1344, 1348 (CCPA 1982) (“[A]ppellant’s arguments fail from the outset because . . . they are not based on limitations appearing in the claims.”)

Appellants contend that “Johnson emphatically and unequivocally teaches the use of an osmotically active agent and a sodium channel blocker in combination” (Br. 6). Appellants contend that the use of an osmotically active salt alone would render Johnson unsatisfactory for its intended purpose, where such purpose requires two compounds acting in combination. Therefore, Johnson provides no motivation or rationale to an ordinary artisan to administer only one half of a proposed combination, i.e., an osmotically active salt and a sodium channel blocker.

(Br. 5).
We do not find these arguments persuasive for claim 1. Claim 1 recites a method “comprising” the administration of meglumine. The transitional term “comprising” is “inclusive or open-ended and does not exclude additional, unrecited elements or method steps.” Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1327 (Fed. Cir. 1999). Thus, claim 1 encompasses the use of the osmotically active agent meglumine along with a sodium channel blocker as taught by Johnson (FF 1, 3), where Johnson further directly suggests their use for dry eye (FF 4). Thus, in order to render claim 1 obvious, Johnson may comprise both meglumine and a sodium channel blocker, which would not render Johnson unsatisfactory for its intended purpose.

Appellants contend that

Johnson proposes the use of osmolytes, particularly hypertonic saline, in combination with sodium channel blockers as hydrating treatments in other ailments resulting from dysfunctional mucosal membranes. However, this proposition could not be viewed as a plausible teaching to a person having ordinary skill in the art, at least with regard to dry eye and dry mouth, since hypertonic saline is well known to have a drying effect in both conditions.

(Br. 7).

We are not persuaded. A teaching away requires a reference to actually criticize, discredit, or otherwise discourage the claimed solution. See In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed”).
Not only does Johnson fail to criticize the use of osmolytes for
treatment of dry eye, Johnson specifically claims the use of osmolytes, in
combination with sodium channel blockers, for treatment of dry eye (FF 4).
Appellants do not identify any specific teaching in Johnson that discourages
or criticizes the use of osmolytes in dry eye.

We have considered the statement in the Barker Declaration\(^3\) that
A person having ordinary skill in the art, in view of Johnson,
would be dissuaded from using osmotically active salts (e.g.,
hypertonic saline and meglumine chloride) in the treatment
of a dry mucous membrane disorder, such as dry eye, as the
use of such compositions would appear to exacerbate, rather
than ameliorate the condition in the absence of a sodium
channel blocker.

(Barker Dec. ¶ 7). Dr. Barker’s statement suggests that it is the use of
meglumine alone that would be avoided, not the combination of sodium
channel blockers and meglumine taught by Johnson for dry eye. Because, as
already noted, claim 1 does not exclude the use of sodium channel blockers,
the evidence in the Barker Declaration does not overcome the obviousness
rejection of claim 1.

Claim 17

Appellants contend that “Johnson does not teach or suggest the use of
meglumine as a free base” (Br. 10).

We do not find this argument persuasive because claim 17 uses the
open transitional language “comprising” and does not limit the compound of
formula I to the free base form of meglumine. “[L]imitations are not to be

\(^3\) Declaration of Dr. Felix M. Barker II, dated Jan. 29, 2012.
read into the claims from the specification.” In re Van Geuns, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

**Claim 18**

Appellants contend that “[c]laim 18 recites ‘said therapeutic agent consisting essentially of’ an alkylamino-polyhydroxyalkane and thus necessarily excludes the concomitant application of a sodium channel blocker as defined in Johnson” (Br. 12). Appellants contend that “the use of such a sodium channel blocker in the present invention would ‘materially affect the basic and novel characteristic(s) of the claimed invention’ where the present invention is directed to the increase in goblet cell concentration, which thereby increases mucin production” (Br. 12).

We find this argument persuasive, and the Examiner provides no specific rebuttal (see Ans. 6 “Appellant’s arguments regarding claims . . . 18 . . . have been noted”). In particular, Appellants contend that “[s]odium channel blockers are known to reduce goblet cell counts” (Br. 12) and the Specification teaches that the “inner layer of mucus is produced by goblet cells” (Spec. 1). Thus, because claim 18 requires administration of an agent that “increases mucin production” and the sodium channel blockers would have been expected to decrease, rather than increase, mucin production, we agree with Appellants that the use of sodium channel blockers would materially affect the basic and novel characteristics of the method of claim 18, and are excluded by the “consisting essentially of” language.

**Claims 21 and 27**

Appellants contend that claim 21 recites “meglumine being the only therapeutically active component of said composition that is effective to
increase mucin production in said patient’’” (Br. 15; emphasis omitted). Appellants contend that “[c]laims 21 and 27 are nonobvious over Johnson for at least the reason that Johnson fails to teach or suggest the feature of increasing mucin production in a patient” (Br. 15).

We are not persuaded. Johnson expressly suggests the use of osmolytes such as meglumine for treatment of dry eye (FF 1, 3, 4). As Appellants’ earlier arguments acknowledge, the only therapeutically active component of Johnson that would function to increase mucin production is meglumine, because sodium channel blockers would not be expected to increase mucin production (see Br. 13). Both claims 21 and 27 use the open claim language “comprising” and simply requires that the meglumine is the “only therapeutically active component . . . effective to increase mucin production”, not that meglumine is the only therapeutically active component of the composition. Thus, claims 21 and 27 are open to the use of additional components including the sodium channel blockers expressly suggested by Johnson (FF 1).

Conclusion of Law

The evidence of record support the Examiner’s conclusion that Johnson renders claims 1, 17, 21, and 27 claims obvious.

The evidence of record does not support the Examiner’s conclusion that Johnson renders claim 18 obvious.

SUMMARY

In summary, we affirm the rejection of claims claims 1, 17, 21, and 27 under 35 U.S.C. § 103(a) as obvious over Johnson. Claims 3–16, 22–26 and 28 fall with claims 1, 17, 21, and 27. 37 C.F.R. § 41.37(c)(1)(iv).
We reverse the rejection of claims 18–20 under 35 U.S.C. § 103(a) as obvious over Johnson.

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-IN-PART