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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FREDRIK HODIN
and JORGEN LUNDIN

Appeal 2018-004998
Application 12/808,315
Technology Center 1700

Before KAREN M. HASTINGS, MICHAEL P. COLAIANNI, and GEORGE C. BEST, *Administrative Patent Judges*.

BEST, *Administrative Patent Judge*.

DECISION ON APPEAL

The Examiner finally rejected claims 13–17, 19, 22, 27–32, 34, 36–50, 52, and 53 of Application 12/808,315 under 35 U.S.C. § 103(a) as obvious. Final Act. (July 12, 2017). Appellant[1] seeks reversal of these rejections pursuant to 35 U.S.C. § 134(a). We have jurisdiction under 35 U.S.C. § 6.

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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 Swedish Match North Europe AB. Appeal Br. 3.

An oral hearing in this appeal was held on September 12, 2019. A transcript of that hearing will be placed into the '315 Application's prosecution history when it becomes available.

For the reasons set forth below, we ***reverse***.

BACKGROUND

The '315 Application describes snuff or snus comprising tobacco or non-tobacco material and magnesium carbonate. Spec. 1. According to the Specification, both tobacco and non-tobacco snuff or snus products need to be stored under conditions that maintain "a sufficiently high and fairly constant pH during the entire storage period." *Id.* The pH must be maintained at a fairly high level "to increase the amount of unprotonized nicotine which is absorbable by the mucous membrane. At increased pH[,] bacterial growth is also prevented." *Id.* Sodium carbonate is the most common pH regulating material used in the formulation of moist snuff products. *Id.* Although sodium carbonate is cheap and easy to handle, it does not convey upon the moist tobacco products a sufficiently long shelf life. *Id.*

The '315 Application's Specification describes the use of magnesium carbonate as a pH maintenance agent. *Id.* at 2. According to the Specification, magnesium carbonate—which is less soluble in water than sodium carbonate—service as a carbonate depot, slowly releasing carbonate ions to maintain a stable pH. *Id.*

Claims 13 and 28 are representative of the '315 Application's claims and are reproduced below from the Claims Appendix of the Appeal Brief.

13. A moist oral tobacco snuff or snus product, comprising:
    a pouch containing loose tobacco;
    water;

admixed magnesium carbonate; and

a pH-regulator selected from the group consisting of sodium carbonate, sodium bicarbonate, sodium hydroxide, potassium carbonate, potassium bicarbonate, potassium hydroxide, and phosphates, or any combination thereof, wherein the water is present in an amount of from about 30 to 60% by weight of the oral tobacco snuff or snus product; and wherein the admixed magnesium carbonate and the pH regulator are present in an amount sufficient to maintain the pH of the moist oral tobacco snuff or snus product between a pH of 8 to 9 after storage at room temperature for at least 90 days.

Appeal Br. 22.

28. An oral non-tobacco snuff or snus product, comprising:

a pouch containing loose non-tobacco bulk plant fiber material;

a pH-regulator selected from the group consisting of sodium carbonate, sodium bicarbonate, sodium hydroxide, potassium carbonate, potassium bicarbonate, potassium hydroxide, and phosphates, or any combination thereof; and

admixed magnesium carbonate, wherein the oral non-tobacco snuff or snus product does not contain any tobacco, and where the admixed magnesium carbonate and the pH regulator are provided in an amount sufficient to maintain the pH of the oral non-tobacco snuff or snus product between a pH of 8 to and 9 after storage at room temperature for at least 90 days.

Appeal Br. 23.

REJECTIONS

On appeal, the Examiner maintains the following rejections:

1. Claims 13–17, 19, 22, 27–32, 34–36, 52, and 53 are rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hansson,[2] Adusumilli,[3] Ciolino,[4] and NDSN.[5] Answer 3.
2. Claims 41–44 are rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Hansson, Adusumilli, and Holton.[6] Answer 7.
3. Claims 13, 15–17, 22, and 38–40 are rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Holton and Adusumilli. Answer 8.

DISCUSSION

Rejection 1. The Examiner rejected claims 13–17, 19, 22, 27–32, 34–36, 52, and 53 as unpatentable over the combination of Hansson, Adusumilli, Ciolino, and NDSN. Answer 3.

Appellant presents four arguments for reversal of this rejection: (1) and Adusumilli is non-analogous art, Appeal Br. 19, (2) at this merely does not teach or suggest "admixed magnesium carbonate" in combination

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[2] US 2005/0061339 A1, published March 24, 2005.

[3] US 2004/0037879 A1, published February 26, 2004.

[4] Laura A. Ciolino et al., *The Relative Buffering Capacities of Saliva and Moist Snuff: Implications for Nicotine Absorption*, 25 J. Anal. Toxicol. 15 (2001).

[5] National Drug Strategy Network, *New Questions About Snuff Tobacco Industry* (1994).

[6] US 2007/0186941 A1, published August 16, 2007.

with other elements of the pending claims, *id.* at 9–12, (3) the cited references do not teach or reasonably suggest adding the admixed magnesium carbonate and pH regulator in an amount sufficient to maintain the pH of the snuff or snus product between 8 and 9 after storage room temperature 90 days, *id.* at 12–14, and (4) the claimed invention achieves unexpected results sufficient to overcome the prima facie case of obviousness set forth in the Final Action and Answer, *id.* at 15–18. We address each of these arguments below.

First, we take up Appellant's argument that Adusumilli is non-analogous art. A reference is available for use in a § 103(a) rejection only if it is analogous art. *In re Kahn*, 441 F.3d 977, 986–87 (Fed. Cir. 2006); *In re Oetiker*, 977 F.3d 1443, 1447 (Fed. Cir. 1992). A reference is analogous art only if it either (1) is in the field of the inventor's endeavor or (2) is reasonably pertinent to the particular problem with which the inventor was concerned. *Oetiker*, 977 F.3d at 1447.

In this case, we only consider the first prong of the test. Appellant argues that the inventors' field of endeavor is defined by the following statement in the Specification: "The current invention pertains to a tobacco product or a non-tobacco snuff product comprising a magnesium carbonate." Appeal Br. 19 (quoting Spec. 1).

The Examiner does not provide a substantive response to this argument. *See* Answer 8–10.

Notwithstanding the Examiner's failure to respond to Appellant's argument, we are not persuaded that the Examiner reversibly erred by finding that Adusumilli is analogous art.

"The Supreme Court's decision in *KSR International Co. v. Teleflex, Inc.*, . . . directs us to construe the scope of analogous art broadly." *Wyers v.*

Master Lock Co., 616 F.3d 1231, 1238 (Fed. Cir. 2010). The test for determining an applicant's field of endeavor "requires the PTO to determine the appropriate field of endeavor by reference to explanations of the invention's subject matter in the patent application, including the embodiments, function, and structure of the claimed invention." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

The Specification's describes the dual purpose for maintaining a fairly-high, constant pH during storage: increasing the amount of nicotine which is readily observable by the mucous membrane and preventing bacterial growth. Spec. 1. The Specification further states:

> At a basic pH, nicotine of a tobacco product is more readily absorbed by the mucous membrane. . . . Stability of the pH in the basic region is directly correlated to and a prerequisite for storage ability. Below 7, and insubstantial amount of nicotine is released from the tobacco-containing product, whereas a too basic pH may cause damage to the mucous membrane.

Id. at 4.

Based upon the Specification's emphasis on the availability of nicotine for absorption, we find that the inventors' field of endeavor is oral nicotine delivery devices.

Adusumilli, which describes an oral dosage formulation comprising nicotine for use as a nicotine replacement therapy, falls within this field of endeavor. Adusumilli's describes an oral dosage formulation that releases nicotine in the oral and/or buccal cavity. Adusumilli ¶ 7.

We, therefore, are not persuaded to reverse the rejection based upon Appellant's non-analogous art argument.

Second, Appellant argues that the rejection should be reversed because "Adusumilli does not teach or reasonably suggest '<u>admixed</u>

magnesium carbonate' in combination with the other elements of the pending claims." Appeal Br. 9–12 (bolding omitted).

This argument is not persuasive of the existence of reversible error. As the Examiner found, Hansson describes mixing the tobacco mass with a suitable buffer "such as e.g.[,] carbonate." Hansson ¶ 23. We discern no reversible error in the Examiner's finding, Answer 3–4, that Adusumilli describes magnesium carbonate as a useful buffer in an oral nicotine delivery product.

Third, Appellant argues that the rejection should be reversed because the cited references do not describe or suggest using magnesium carbonate at a pH regulator in an amount sufficient to maintain the pH of the product between a pH of 8–9 after room temperature stored for at least 90 days. Appeal Br. 12–15. The Examiner relied upon test data reported in Ciolino and NDSN as the basis for this finding. The Examiner, however, acknowledged that neither of these references report the length of storage before the pH of the products were determined. Answer 5. The Examiner, however, argues that "it would have been obvious that the pH of at least some of the products exceeded a pH of 8 after significant storage and distribution time." *Id.*

Because neither Ciolino nor NDSN expressly describe the claim limitation, the Examiner is relying upon the principal of inherency as the basis for the finding that the prior art describes or suggests the 90 day pH maintenance limitation. However, "[i]nherency . . . may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939).

Thus, the Examiner erred by finding that the prior art describes or suggests the 90 day pH maintenance limitation. This is reversible error.

Fourth, Appellant argues that the claimed combination achieves unexpected results. Appeal Br. 15–18. The Examiner determined that Appellant's evidence of unexpected results need not be considered because Appellant relies upon data that is not commensurate in scope with the claims "because the claims are directed to products stored at room temperature for 90 days while the declaration only provides data for products stored 28 days." Answer 10.

The Examiner's failure to consider the data in the Inventors' May 2, 2016 Declaration is reversible error. The Declaration specifically states that the products were stored for periods of up to 28 days at elevated temperatures before the pH was measured and that storage at these elevated temperatures was equivalent to storage for a longer time periods at room temperature. Declaration ¶¶ 8–10, Table 3, Table 4. The Examiner neither addresses these contentions nor presents evidence that the statements in the Declaration are incorrect. Thus, the Examiner should have considered whether or not the data presented by the Declaration is sufficient to overcome any prima facie case of obviousness that might have existed.

For the reasons set forth above, we determine that the Examiner reversibly erred in rejecting claims 13–17, 19, 22, 27–32, 34–36, 52, and 53 as obvious over the combination of Hansson, Adusumilli, Ciolino, and NDSN.

Rejection 2. The Examiner rejected claims 41–44 as unpatentable over the accommodation of Hansson, Adusumilli, and Holton. Answer 7. In doing so, the Examiner relies upon Hansson and Adusumilli as describing or suggesting each limitation in independent claims 13 and 28. *Id.* Claims 41–

44 depend, directly or indirectly, from either claim 13 or claim 28. Appeal Br. 25. As discussed above, we have determined that the Examiner reversibly erred in rejecting claims 13 or 28. We, therefore, also reverse the rejection of claims 41–44.

Rejection 3. The Examiner rejected claims 13, 15–17, 22, and 38–40 as unpatentable over the combination of Holton and Adusumilli. Answer 8. As discussed above, we have determined that the Examiner reversibly erred by failing to consider Appellant's evidence of unexpected results. We, therefore, reverse this rejection.

CONCLUSION

In summary:

Claims Rejected	Basis	Affirmed	Reversed
13–17, 19, 22, 27–32, 34–36, 52, and 53	§ 103(a) Hansson, Adusumilli, Ciolino, and National Drug Strategy Network		13–17, 19, 22, 27–32, 34–36, 52, and 53
41–44	§ 103(a) Hansson, Adusumilli, and Holton		41–44
13, 15–17, 22, and 38–40	§ 103(a) Holton and Adusumilli		13, 15–17, 22, and 38–40
Overall Outcome			13–17, 19, 22, 27–32, 34, 36–50, 52, and 53

REVERSED