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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MATTHEW JOHN KACZANOWSKI,
THOMAS DANIEL WILLIAMS, KURT FRANKLIN TROMBLEY, and
NANCY LEE REDMAN-FUREY

Appeal 2017-004999
Application 12/769,293[1]
Technology Center 1600

Before JEFFREY N. FREDMAN, ELIZABETH A. LAVIER, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

LAVIER, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellants seek review of the Examiner's rejections of claims 1, 3, and 5–11. We have jurisdiction under 35 U.S.C. § 6(b). For the reasons set forth below, we AFFIRM.

BACKGROUND

The Specification relates to a "means to contain or reduce the degradation of 5-amino-2-hydroxybenzoic acid" in pharmaceutical

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[1] Appellants state the real party in interest is Warner Chilcott Company, LLC. Appeal Br. 1.

compositions. Spec. ¶ 5. Another name for 5-amino-2-hydroxybenzoic acid is 5-amino-salicylic acid. *See id.* ¶ 4.

Claim 1 is illustrative:

> 1. A kit comprising:
>
> (a) at least one unit dosage form comprising:
>
> (i) a safe and effective amount of 5-amino-2-hydroxybenzoic acid; and
>
> (ii) a reducing sugar;
>
> (iii) an amount of 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid at no more than about 0.15% wt/wt when the kit is exposed to a temperature of 25°C ± 2°C at 60% ± 5% relative humidity for 12 months, a temperature of 30°C ± 2°C at 65% ± 5% relative humidity for 12 months, or a temperature of 40°C ± 2°C at 75% ± 5% relative humidity for 6 months; and
>
> (b) a desiccant,
>
> wherein the desiccant is present in an amount sufficient to maintain said 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid at no more than about 0.15%wt/wt a concentration of a degradant that accumulates in the unit dosage form at no more than about 0.15% wt/wt when the kit is exposed to a temperature of 25°C ± 2°C at 60% ± 5% relative humidity for 12 months, a temperature of 30°C ± 2°C at 65% ± 5% relative humidity for 12 months, or a temperature of 40°C ± 2°C at 75% ± 5% relative humidity for 6 months, wherein the degradant is 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid.

Appeal Br. 16 (Claims Appendix).

APPEALED REJECTIONS

1. Claims 1, 3, and 7–11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rhodes[2] and Nisshin.[3] Non-Final Act. 3; *see* Final Action 2.

2. Claims 1, 3, and 5–11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rhodes, Nisshin, and Jackisch.[4] Non-Final Act. 4; *see* Final Action 2.

DISCUSSION

A. Rejection 1

The Examiner finds that Rhodes teaches a composition comprising 5-amino-salicylic acid (5-ASA)[5] and lactose, a reducing sugar. Non-Final Action 3 (citing Rhodes 23, Example VI). The Examiner turns to Nisshin for the teaching of adding a desiccant, such as silica gel, to the 5-ASA compositions of Rhodes, to avoid browning of the compositions associated with exposure to moisture. *See id.* (citing Nisshin ¶¶ 2, 3, 12, 14).[6]

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[2] Rhodes et al., WO 83/00435, published Feb. 17, 1983.
[3] Takanori et al., JP 1998015032A, published Jan 20, 1998 (English machine translation). The Examiner and Appellants refer to this reference as "Nisshin," after the applicant, Nisshin Flour Milling Co. Ltd. For consistency, we follow suit.
[4] Jackisch et al., US 5,114,003, issued May 19, 1992.
[5] As noted above, 5-amino-salicylic acid is another name for 5-amino-2-hydroxybenzoic acid. *See* Spec. ¶ 4. Rhodes uses the abbreviation "5-ASA." Rhodes 1:7–8.
[6] The Examiner states that JP 58-501174, cited at Nisshin ¶ 2, "is the RHODES reference," thereby relying on a secondary reference that specifically cites to the primary reference. Non-Final Action 3.

Modifying Rhodes as taught in Nisshin would have been obvious because Nisshin "teaches silica gel would absorb the moisture and prevent the 5-aminosalicylic acid from degrading. One skilled in the art reasonably would have expected success because desiccants are widely used in connection with hydroscopic drugs in the pharmaceutical drug industry." *Id.* at 4. The Examiner further finds that "it is inherent that the prior art's 5-aminosalicylic acid compound would degrade to 5-[2-Formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid), because it is the same 5-aminosalicylic acid compound as claimed by Applicant." *Id.*

Appellants argue that they discovered that pharmaceutical compositions comprising 5-ASA and a reducing sugar (e.g., lactose), undergo degradation to form 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid, and that "[t]his degradation was completely unknown and is different from" those previously reported. Appeal Br. 4. Once they identified the degradant, Appellants "were able to determine an amount of desiccant necessary to maintain the degradant below about 0.15% wt/wt." *Id.* at 5. Appellants maintain that, because the problem of degradation to this particular type of degradation product (i.e., the formation of 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid) was unknown in the art, it could not have been obvious to use a desiccant to minimize or prevent the formation of that degradant (*see* Appeal Br. 8–9), and "the amount of desiccant needed to overcome [the problem] would not have been predictable" (*id.* at 12; *see also id.* at 13–14).

Claim 1 does not directly specify the amount of desiccant, but rather defines it indirectly in terms of maximum levels of the claimed degradant formed under certain conditions. However, and contrary to Appellants'

arguments (*see* Appeal Br. 5–8, 10; Reply Br. 2–3), the apparent fact that the degradation recited in claim 1 was not previously known in the prior art does not make the Examiner's rejection an improper application of the inherency doctrine. *Cf. Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 18 (1892) ("[N]othing is better settled in this court than that the application of an old process to a new and analogous purpose does not involve invention, even if the new result had not before been contemplated."). As discussed above, Nisshin teaches adding a desiccant to the 5-ASA compositions of Rhodes (which may include lactose[7]), to prevent browning.

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[7] Appellants assert that "[w]hile Rhodes does exemplify the use of lactose in combination with 5-aminohydroxybenzoic acid, such as in Example IV, Rhodes does not teach a person of ordinary skill that lactose must be present, as would be a requirement in a finding of inherency." Appeal Br. 7. This confuses the selection of express limitations in the prior art (i.e., lactose) with their inherent effects (i.e., formation of 5-[2-formyl-5-(hydroxymethyl)-lH-pyrrol-l-yl)-2-hydroxybenzoic acid). "[T]o rely on inherency to establish the existence of a claim limitation in the prior art in an obviousness analysis[,] the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art." *PAR Pharm. Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195–96 (Fed. Cir. 2014). Accordingly, Rhodes need not teach *only* lactose-containing formulations for inherency to apply. Rather, the issue here is whether the addition of a desiccant (as taught in Nisshin) to the 5-ASA formulations of Rhodes that *do* contain lactose would necessarily keep the formation of the recited degradant within the claimed ranges (which include zero, as the Examiner notes (*see* Ans. 3)). Appellants make other inherency-related arguments that are similarly not persuasive. For example, Appellants' argument that Nisshin does not teach or suggest that "<u>every</u> formulation containing 5-aminosalicyclic acid, no matter what the formulation, must include a desiccant" (Reply Br. 2; *see also* Appeal Br. 10), again confuses express elements selected from the prior art to form the obviousness rejection (i.e., desiccant) with the inherent effect of such a combination (i.e., whether it would maintain the recited degradant at or below the claimed levels).

The prevention of browning is a sufficient motivation to add a desiccant, whether or not one of ordinary skill in the art would have been aware of the problem of formation of 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid.

Because Nisshin teaches that a desiccant prevents browning, the amount of desiccant was known as a result-effective variable. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1297 (Fed. Cir. 2012) ("A recognition in the prior art that a property is affected by the variable is sufficient to find the variable result-effective."). Thus, optimization of the amount of desiccant to minimize browning would have been obvious within the ranges disclosed in Nisshin. *See In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."). And in this regard, Nisshin teaches 0.1–10 g desiccant per 25 g 5-ASA, or preferably 1–3 g desiccant per 25 g 5-ASA. Nisshin ¶ 14. The Examiner finds:

> NISSHIN had known of using desiccant to prevent degradation of 5-aminoaslicylic acid by moisture, wherein the prior art NISSHIN used 10 gram of desiccant for every 25 gram of 5-aminoaslicylic acid (see [0014]), which is more than the amount of desiccant used by Appellant (see Appellant's specification filed on 04/28/2010 at [0070]-[0073]), and would read on sufficient amount and would result in preventing any degradations by moisture, including Appellant's degradation at an amount of less than 0.15% as claimed by Appellant. Additionally, the amount of degradant would inherently be below about 0.15% wt/wt when using this same ratio amount in all of RHODE's 5-aminoaslicyclic acid compositions, unless proven otherwise. Note, Applicant is not claiming the degradant, since the degradant can be zero.

Ans. 2–3.

Appellants do not dispute the Examiner's finding that Nisshin's 10 g desiccant per 25 g 5-ASA exceeds the amounts of desiccant taught in the Specification's examples. *See* Reply Br. 3. Rather, Appellants point out that "Nisshin also discloses using 0.1 grams of desiccant for every 25 grams of 5-hydroxy-benzoic acid which is significantly less than that used by Applicant." *Id.* This is not persuasive, as a partial overlap in ranges is sufficient to establish obviousness. *See Peterson*, 315 F.3d at 1329 ("In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness."); *see also In re Aller*, 220 F.2d 454, 456–58 (CCPA 1955) ("[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation").

Appellants cannot overcome this prima facie case of obviousness by relying on the apparently previously-undiscovered degradation (i.e., of 5-ASA in the presence of a reducing sugar to form 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid), because Nisshin already would have provided the ordinarily skilled artisan with a motivation to add enough desiccant to avoid browning. As the upper end of Nisshin's range exceeds the amount of desiccant used in the exemplary formulations in the Specification, Nisshin teaches formulations that would necessarily limit 5-[2-formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid to

levels within the claimed tolerances.[8] *Cf. In re Montgomery*, 677 F.3d 1375, 1381 (Fed. Cir. 2012) ("[E]fficacy is inherent in carrying out the claim steps."). In other words, "the primary reference RHODES teaches the prior art had known of compositions comprising 5-ASA and lactose, wherein the secondary reference NISSHIN teaches a motivation to add a desiccant, which would inherently result in preventing the degradant to the level as claimed by Appellant." Ans. 10–11. Contrary to Appellants' argument (*see* Appeal Br. 12–13), the Examiner's rejection is not an exercise in impermissible hindsight, but one of common sense informed by the teachings of Nisshin and Rhodes. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (explaining that pursuing known options within technical grasp of ordinarily skilled artisan is "likely the product not of innovation but of ordinary skill and common sense").

Having considered all of Appellants' arguments, we are not persuaded that the Examiner erred in rejecting claim 1, for the reasons described herein and those of record. Appellants do not separately argue claims 3, and 7–11; these fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv). We affirm Rejection 1.

B. Rejection 2

Appellants assert that "the deficiencies of Rhodes and Nisshin are not remedied by Jackisch" (Appeal Br. 14), but otherwise offer no arguments in

[8] Contrary to Appellants' argument that the combination "is still not truly inherent" because it must be "exposed to a certain humidity and temperature" (Appeal Br. 7), claim 1's limitations are drawn to the components of the kit, not to storage under particular conditions.

regard to this rejection. As discussed above, Appellants have not persuaded us of any such deficiencies. Accordingly, we affirm Rejection 2.

CONCLUSION

The rejections of claims 1, 3, and 5–11 are affirmed.

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

AFFIRMED