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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* SHUN-POR LI, HANSPETER NAEF, FRANK BUNICK and  
DER-YANG LEE<sup>1</sup>

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Appeal 2015-005365  
Application 11,534,845  
Technology Center 1600

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Before DEMETRA J. MILLS, ERIC B. GRIMES, and DEVON ZASTROW  
NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to a solid dosage form. The Examiner entered final rejections for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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<sup>11</sup> Appellants identify the Real Party in Interest as McNeil-PPC, Inc., a wholly owned subsidiary of Johnson & Johnson, a New Jersey corporation. App. Br. 2.

## STATEMENT OF THE CASE

### *Background*

The Specification discloses “a dosage form comprising at least one active ingredient, a first compressed portion, and a second compressed portion, said first and second compressed portions being surrounded by or least covered in part[] by a shell, wherein the shell is at least translucent, preferably substantially transparent such that at least some light can pass directly therethrough.” Spec. 2:10–14.

### *The Claims*

Claims 1, 2, 5–9, 11, 14, 16, 17, and 26 are on appeal. Claim 1, the sole independent claim, is illustrative and reads as follows:

1. A solid dosage form comprising:
  - one or more shell portions;
  - at least two compressed portions having at least one surface area, a horizontal and a vertical axis; and
  - at least one light transmitting coating that is provided between the at least two compressed portions and covering at least one surface of each compressed portions,
  - wherein the light transmitting coating is at least translucent along at least one axis of the at least two compressed portions;
  - wherein the light transmitting coating comprises gelatin and a water soluble dye; and wherein the one or more shell portions comprises an ultraviolet dye.

App. Br. Claims Appx. 1.<sup>2</sup>

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<sup>2</sup> The pages of Appellants’ brief are not numbered. We cite herein to the pages as if consecutively numbered beginning on the page bearing the title “Appeal Brief.”

*The Issues*

The following rejections are before us to review (Ans. 2, 6):

A. The Examiner rejected claims 1, 2, 5–9, 11, 13, 14, 16, 17, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Swoden '508,<sup>3</sup> Daher,<sup>4</sup> and Barreto.<sup>5</sup>

B. The Examiner rejected claims 1, 2, 5–9, 11, 13, 14, 16, 17, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Sowden '559,<sup>6</sup> Swoden '508, and Barreto.

The issues presented are: Does a preponderance of the evidence of record support the Examiner's conclusion that the combinations of Swoden '508, Daher, and Barreto; and Sowden '559, Swoden '508, and Barreto suggest the composition of claim 1?

*Findings of Fact*

1. Swoden '508 teaches

a dosage form comprising at least one active ingredient, a first core, and a second core, said first and second cores being surrounded by a shell, wherein the shell comprises one or more openings and provides for modified release of at least one

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<sup>3</sup> Harry S. Swoden, et al., WO 2004/028508 A1, published Apr. 8, 2004 (“Swoden '508”). (We note the Examiner and Appellants referred to this publication in briefing as “Sowden '508.” We refer to the publication using the name as printed.)

<sup>4</sup> Lawrence J. Daher, et al., U.S. Pat. No. 6,077,540, issued June 20, 2000 (“Daher”)

<sup>5</sup> Marcos A. Barreto, US 2005/0099475 A1, published May 12, 2005 (“Barreto”)

<sup>6</sup> Harry S. Sowden, et al., US 2004/0146559 A1, published July 29, 2004 (“Sowden '559”)

active ingredient upon contact of the dosage form with a liquid medium, at least one of the first or second cores being distal to the opening or openings.

Swoden '508 at 6:14–19.

2. Swoden '508 teaches “[e]ach core is completely surrounded by, or embedded in, the shell. A portion of the shell, referred herein as the ‘interior wall’ separates the first and second cores.” *Id.* at 12:5–7.
3. Swoden '508 teaches “[t]ypically, a core comprises a solid, for example, a core may be a compressed or molded tablet . . .” *Id.* at 11:11–12.
4. Swoden '508 teaches that gelatin is a polymer suitable for use in creating cores. *Id.* at 42:23–43:8.
5. Swoden '508 teaches

In certain embodiments the dosage form comprises a first shell portion and a second shell portion that are compositionally different. As used herein, the term “compositionally different” means having features that are readily distinguishable by qualitative or quantitative chemical analysis, physical testing, or visual observation. For example, the first and second shell portions may contain different ingredients, or different levels of the same ingredients, or the first and second shell portions may have different physical or chemical properties, different functional properties, or be visually distinct . . . Examples of visual distinctions include size, shape, topography, or other geometric features, color, hue, opacity, and gloss.

*Id.* at 22:3–17.

6. Daher teaches “a tablet core containing active ingredients and a continuous gelatin coating contributing from about 0.5% to about 5% by

weight of the tablet weight . . . [t]he coating composition contains gelatin, a surfactant, a drying agent, and water.” Daher at 1:33–44.

7. Daher teaches the disclosed “coating provides smooth continuous finish to the tablet, which provides pleasing aesthetics for the consumer, and is also perceived to facilitate swallowing.” *Id.* at 2:4–7.

8. Daher teaches “[i]f opaque and/or colored film coated tablets are desired, colorants and opacifiers are to be included in the coating composition to produce the desired effect.” *Id.* at 3:1–3.

9. Barreto teaches that its

system and method for implementing an edible, invisible ink provide a way to print information on pharmaceutical products or other substrates in a manner that is “invisible” to the naked eye when viewed under normal white light conditions. However, when exposed to ultraviolet (UV) light between approximately 254 and 400 nanometers (nm), the edible, invisible ink fluoresces in the visible light range (400-600 nm). The present edible, invisible ink may be safely used to print or otherwise mark on pharmaceutical substrates such as tablets, capsules, gel caps, pills, caplets, and other solid dosage forms; dental products and instruments; and or food products.

Products may be marked by the present edible, invisible ink with information such as, but not limited to, logos, names, bar codes, alphanumeric codes, text, watermarks, and other markings. Marking pharmaceuticals with information using invisible ink allows manufacturers and distributors to control fraudulent dispensing of drugs, control counterfeit production of drugs, and ensure that patients receive the correct medication, among other things.

Barreto at ¶¶ 54–55.

10. Sowden '559 teaches

a dosage form having an inner core and an outer shell, in which the inner core and outer shell have shapes which are substantially different. It is one feature of this invention that, in one embodiment, the core and shell have different numbers of planes of symmetry or reflection lines with respect to the same reference axis.

Sowden '559 at ¶ 12.

11. Sowden '559 teaches “[i]n another embodiment of the invention, the outer surface of the core displays written information, and the shell outer surface is transparent, semi-transparent or translucent.” *Id.* at ¶ 27.

12. Sowden '559 teaches

Dosage forms with high surface gloss are preferred by consumers due to their aesthetic elegance and perceived swallowability. The surface gloss of the shell depends upon a number of factors, including the shell composition, the method of forming the shell, and, if a mold is used, the surface finish on the mold.

*Id.* at ¶ 247.

*Principles of Law*

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability. If that burden is met, the burden of coming forward with evidence or argument shifts to the applicant.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

“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). “If a person of

ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

## DISCUSSION

### *A. Swoden '508, Daher, and Barreto.*

We adopt the Examiner’s fact finding and reasoning regarding the scope and content of the prior art (Ans. 2–12) and agree that claim 1 is rendered obvious by the combination of Swoden ’508, Daher, and Barreto. We address Appellants’ arguments below.

Appellants argue:

Sowden ’508 does not teach (i) a translucent coating, (ii) the adding of colorants, and (iii) having one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye . . . Daher et al. does not teach having one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye . . . Sowden ’559 does not disclose a dosage form that comprises a light transmitting coating that comprises gelatin and a water soluble dye. Moreover, Sowden ’559 does not teach having one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye . . . Barreto does not disclose or suggest a dosage form having one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye. Thus, it follows that the combination of Sowden ’508, Daher et al., Sowden ’559, and/or Barreto in the manner proposed in the Office Action, one would not arrive at the claimed invention recited in Claim 1, since none of these references disclose or suggest a solid dosage form that includes one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye.

App. Br. 5–6.<sup>7</sup>

We are not persuaded that the Examiner erred in rejecting claim 1 over Swoden '508, Daher, and Barreto. As stated by the Examiner, Swoden '508 teaches a dosage form to carry active ingredients with two cores surrounded by a shell and separated by an interior wall. Ans. 2, FF 1–2. The core can be compressed and gelatin polymer can be used in the shell. Ans. 2–3, FF 3–4. Swoden '508 teaches that the two cores can be made visually distinct using opacity (e.g., made translucent). Ans. 3, FF 5. Daher teaches gelatin spray coatings and that such coatings provide pleasing aesthetics for the consumer and create a perception of eased swallowing. Ans. 4, FF 6–7. Daher further teaches the coating composition may be made opaque if desired. Ans. 4, FF 8. Barreto teaches edible, optically invisible ink that can fluoresce when exposed to ultraviolet light, which can be used on pharmaceutical products to verify correct medication and control fraudulent distribution. Ans. 5, FF 9.

Appellants' arguments regarding the features not taught by the individual references are unpersuasive as the Examiner's rejection is based on the *combined* teachings of Swoden '508, Daher, and Barreto. (*See* Ans. 2–6). We agree with the Examiner because nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. *In re Merck & Co. Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986); *see also In re Keller*, 642 F.2d

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<sup>7</sup> The pages of Appellants' brief are not numbered. We cite herein to the pages as if consecutively numbered beginning on the page bearing the title "Appeal Brief."

413, 426 (CCPA 1981) (finding “one cannot show nonobviousness by attacking references individually where, as here, the rejections are based on combinations of references” (citations omitted)). Thus, whether Swoden ’508, Daher or Barreto individually fails to teach a solid dosage form that includes one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye is not dispositive to the sufficiency of the rationale underlying the rejection. The Examiner sufficiently establishes that an ordinary artisan reading Swoden ’508, Daher, and Barreto would have reasonably expected that the teachings of Daher regarding clear and colored films could be applied to the teachings in Swoden ’508 regarding the dosage form. Ans. 6. In addition, the teachings of Barreto regarding an edible ink visible in the UV spectrum, which is taught for use in pharmaceuticals, would have provided a reason to one of skill in the art to create a solid dosage form that includes one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye. *Id.* Accordingly, we affirm the rejection of claim 1 over Swoden ’508, Daher, and Barreto. Claims 2, 5–9, 11, 13, 14, 16, 17, and 26 have not been argued separately and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

*B. Sowden ’559, Swoden ’508, and Barreto*

We adopt the Examiner’s fact finding and reasoning regarding the scope and content of the prior art (Ans. 2–12) and agree that claim 1 is rendered obvious by the combination of Sowden ’559, Swoden ’508, and Barreto. Applicants’ arguments, made once with respect to both rejections, are stated above.

We are not persuaded by Appellants' arguments regarding the failures of the individual teachings of Sowden '559, Swoden '508, or Barreto that the Examiner erred in rejecting claim 1 these references. We agree with the Examiner that Sowden '559 teaches a dosage form for carrying active ingredients with an inner core and an outer shell with two shapes, and that the shell portions of the core may be made visually distinct, such as translucent, and made to have different planes of symmetry. Ans. 7, FF 10–11. Sowden '559 further teaches that dosage forms with high surface gloss are preferred by consumers due to “their aesthetic elegance and perceived swallowability.” FF 12.

We agree with the Examiner that the teachings of Swoden '508 and Barreto (summarized above in FF 1–5, 9) combined with the teachings of Sowden '559 would inform one of skill in the art how to make a solid dosage form that includes one or more shell portions wherein the one or more shell portions comprises an ultraviolet dye. Ans. 7–12. Accordingly, we affirm the rejection of claim 1 over Sowden '559, Swoden '508, and Barreto. Claims 2, 5–9, 11, 13, 14, 16, 17, and 26 have not been argued separately and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejection of claims 1–2, 5–9, 11, 13–14, 16–17, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Swoden '508, Daher, and Barreto.

We affirm the rejection of claims 1–2, 5–9, 11, 13–14, 16–17, and 26 under 35 U.S.C. § 103(a) as being unpatentable over Sowden '559, Swoden '508, and Barreto.

TIME PERIOD FOR RESPONSE

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