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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FRANK J. BUNICK and JEN-CHI CHEN

Appeal 2015-004093
Application 11/691,839
Technology Center 1600

Before MELANIE L. McCOLLUM, JEFFREY N. FREDMAN, and KRISTI L. R. SAWERT, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134 involving a process for preparing a dosage form. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

"The present invention relates to coating for pharmaceutical dosage forms wherein the coatings form at least a continuous shell portion having a first composition and at least one discontinuous shell portion that is

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[1] Appellants identify the Real Party in Interest as McNeil-PPC, Inc., a wholly owned subsidiary of Johnson & Johnson (*see* Br. 2, Appellants' Brief lacks page numbers. We number the pages sequentially starting with the "Appeal Brief" header page).

compositionally different and located within the continuous shell portion" (Spec. 1:3–6).

The Claims

Claims 24–26, 33–35, and 40–43 are on appeal. Claim 24 is representative and reads as follows:

> 24. A process for preparing a dosage form, comprising:
> a) forming a compressed core containing at least one pharmaceutical active ingredient in a compression tableting machine; and
> b) coating the compressed core with a coating composition comprising a dispersion of:
> gelatin, and
> alginate,
> wherein the solids content of the alginate is controlled so as to provide a desired appearance, wherein if the alginate has a solids content greater than the solids content of gelatin, a coating having raised particle regions is formed and if the alginate has a solids content less than the solids content of the gelatin, a coating having depressed particle regions is formed.

The Issue

The Examiner rejected claims 24–26, 33–35, and 40–43 under 35 U.S.C. § 103(a) as obvious over Sowden,[2] Dong,[3] MacQueen,[4] and Tonnesen[5] (Final Act. 4–12).

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[2] Sowden et al., US 2003/0219484 A1, published Nov. 27, 2003 ("Sowden").
[3] Dong et al., *Alginate/ gelatin blend films and their properties for drug controlled release*, 280 J. Membrane Sci. 37-44 (2006) ("Dong").
[4] MacQueen et al., US 6,399,670 B1, issued June 4, 2002 ("MacQueen").
[5] Tonnesen et al., *Alginate in Drug Delivery Systems*, 28 Drug Dev. and Industrial Pharmacy 621–630 (2002) ("Tonnesen").

The Examiner finds Sowden teaches "an immediate release dosage form comprising a solid core and a shell surrounding the core . . . by injecting flowable material into a molding chamber" (Ans. 5). The Examiner finds Sowden teaches suitable gelling polymers include alginate and gelatin and Sowden has an embodiment where "the flowable material is taught as comprising gelatin as the gelling polymer" (Ans. 5–6).

The Examiner acknowledges that "Sowden does not teach a combination of gelatin and alginate as the coating material." (*Id.*).

The Examiner finds that "Dong teaches film compositions comprising mixtures of alginate and gelatin . . . and Dong teaches that it is well known that blending gelatin can be done to improve the performance of the polymer material, thus providing motivation for blending gelatin with alginate" (Ans. 6).

The Examiner finds that "due to the insolubility issue of these particles, the resulting texture of a tablet coated with this insoluble alginate particle matrix would comprise depressions and/or raised areas according to how much alginate is used" (Ans. 9).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Sowden, Dong, MacQueen, and Tonnesen render the process of claims 24–26 obvious?

Findings of Fact

1. Sowden teaches "a dosage form providing immediate release of an active ingredient. The dosage form comprises a solid core and a shell surrounding the core" (Sowden ¶ 2).

2. Sowden teaches the "core may [be] prepared by any suitable method, including for example compression or molding" (Sowden ¶ 35) and that the "core typically comprises active ingredient" (Sowden ¶ 108).

3. Sowden teaches the "shell is applied to the core by spraying, dipping, enrobing, or molding . . . Optionally, the shell or readily soluble shell portion of the present invention may further comprise one or more thickeners, and various adjuvants and/or excipients" (Sowden ¶ 211).

4. Sowden teaches that "[e]xamples of such thickeners include but are not limited to hydrocolloids. . . Examples of suitable hydrocolloids (also referred to herein as gelling polymers) such as alginates . . . Additional suitable thickening hydrocolloids include low-moisture polymer solutions such as mixtures of gelatin and other hydrocolloids" (Sowden ¶¶ 222–223).

5. Dong teaches "the alginate/gelatin film was potentially useful in drug delivery systems" (Dong, abstract).

6. Dong teaches "blending is effective and convenient method to improve the performance of polymer materials. In the present study, we prepared alginate/ gelatin blend films" (Dong 38, col. 1).

7. Dong teaches "that blending is effective in improving the mechanical properties of the drug loaded films" (Dong 41, col. 1).

8. Tonnesen teaches "[a]lginates have a wide application as rate-controlling excipients in drug delivery systems, as a matrix for biomolecules, and as an excipient in pharmaceutical preparations for local administration" (Tonnesen 628, col. 2).

9. MacQueen teaches the "macroscopic texture may have any design, shape, or pattern on the surface of the coating" (MacQueen 9:37–38).

10. The Specification teaches:

> The raised regions are a result of a greater percentage of water evaporating from the portion with lower percent solids than from the portion with a higher percent solids upon drying. In another embodiment, polymeric particles for the discontinuous have a solids content less than the solids content of the continuous film-forming polymer, which are combined with one another to form a dispersion that can be used to provide a shell portion over a core having depressed particle regions.

(Spec. 10:16–22).

Principles of Law

> Where, as here, the claimed and prior art products . . . are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products.

In re Best, 562 F.2d 1252, 1255 (CCPA 1977) (citations and footnotes omitted).

Analysis

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 4–12; FF 1–10) and agree that the claims would have been obvious over Sowden, Dong, Tonnesen, and MacQueen.

Appellants contend that

> if one were to combine Sowden et al., Dong et al., MacQueen et al., and/or Tonnesen et al. as proposed, the result would be a process for preparing a film wherein a core is dispersed throughout the film, wherein the film comprises gelatin and alginate. As discussed above, the film of Dong et al. is not the same as a coating. This does not describe Applicants invention.
>
> Applicants respectfully submit that neither Sowden et al., Dong et al., MacQueen et al., Tonnesen et al. nor any combination thereof, disclose or suggest the novel feature recited in Claim 24, wherein the solids content of the alginate is controlled so as to provide a desired appearance, wherein if the alginate has a solids content greater than the solids content of gelatin, a coating having raised particle regions is formed and if the alginate has a solids content less than the solids content of the gelatin, a coating having depressed particle regions is formed.

(Br. 5–6)

We do not find this argument persuasive. The ordinary artisan forming Sowden's coating—comprising thickeners made up of "mixtures of gelatin and other hydrocolloids"—would have further relied on Sowden's teaching that alginate is such an "other hydrocolloid" (FF 3–4) to form a coating comprising gelatin and alginate. Dong further motivates this combination by teaching that the hydrocolloid mixture of alginate and gelatin results in improved mechanical properties (FF 7).

Once the artisan formed the coating with alginate and gelatin as suggested by Sowden and Dong, that coating would necessarily have comprised a solids content with greater or lesser amounts of alginate and gelatin, inherently yielding a "texture of a tablet coated with this insoluble

alginate particle matrix [that] would comprise depressions and/or raised areas according to how much alginate is used" (Ans. 8). That is, the ratio of these hydrocolloids would be controlled by whatever ratio would have been selected by the routine artisan. The Specification itself indicates that the ratio itself inherently results in either raised or depressed portions (FF 10).

Therefore, the Examiner reasonably cites *In re Spada,* 911 F.2d 705, 709 (Fed. Cir. 1990), for the proposition that the obvious coating of Sowden and Dong would thus necessarily result in a controlled ratio of gelatin to alginate, with the appearance based on this ratio representing an inherent property of the obvious resultant coating.

Appellants' also contend that "[c]laims 25 and 26 also include the noteworthy feature wherein the solids content of the alginate is controlled so as to provide a desired appearance" (Br. 6). We find this argument unpersuasive for the same reasons as given for claim 24 because the desired appearance simply represents an inherent property of the alginate/gelatin ratio, and no particular appearance is required by the claims.

Conclusion of Law

The evidence of record support the Examiner's conclusion that Sowden, Dong, MacQueen, and Tonnesen render the process of claims 24–26 obvious.

SUMMARY

In summary, we affirm the rejection of claims 24–26 under 35 U.S.C. § 103(a) as obvious over Sowden, Dong, MacQueen, and Tonnesen. Claims 33–35 and 40–43 fall with claim 24–26.

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