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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* AMIT GOVIL,  
MICHAEL L. JONES, and PAUL LUBOCK

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Appeal 2019–001866  
Application 14/272,075  
Technology Center 1700

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Before MICHAEL P. COLAIANNI, GEORGE C. BEST, and  
DEBRA L. DENNETT, *Administrative Patent Judges*.

DENNETT, *Administrative Patent Judge*.

DECISION ON APPEAL<sup>1</sup>

Pursuant to 35 U.S.C. § 134(a), Appellant<sup>2</sup> appeals from the  
Examiner’s decision to reject claims 17–23 and 34–40 of Application

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<sup>1</sup> In our Decision, we refer to the Specification filed May 7, 2014 (“Spec.”) of Application 14/272,075 (“the ’075 Application”); the Final Office Action dated February 7, 2018 (“Final Act.”); the Appeal Brief filed July 26, 2018 (“Appeal Br.”); the Examiner’s Answer dated November 2, 2018 (“Ans.”); and the Reply Brief filed December 28, 2018 (“Reply Br.”).

<sup>2</sup> We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies SenoRx, Inc., C.R. Bard, Inc., and BD (Becton, Dickinson and Co.) as the real parties in interest. Appeal Br. 3.

14/272,075.<sup>3</sup> *See* Final Act. 1; Appeal Br. 1. We have jurisdiction under 35 U.S.C. § 6.

For the reasons set forth below, we REVERSE.

## BACKGROUND

The '075 Application relates to methods for forming porous bioabsorbable implants for cavities in soft tissue. Spec. ¶ 2. The '075 Application describes that such cavities result from biopsy or lumpectomy procedures. *Id.* The '075 Application describes that the implant remains at the biopsy or lumpectomy procedure site for a sufficient period of time to facilitate tissue in-growth within the body cavity. *Id.* at ¶ 27.

Claims 17 and 36 are representative of the '075 Application's claims and are reproduced below from the Claims Appendix of the Appeal Brief with key limitations emphasized.

17. A method for forming a porous implant suitable for a cavity from which tissue has been removed, comprising:
  - a. mixing soluble alginate and a radiopaque imaging agent with water to form an alginate-imaging agent solution;
  - b. incorporating a gas or a pore forming agent into the alginate-imaging agent solution;
  - c. transferring the alginate-imaging agent solution with the gas or the pore forming agent into a solidified body mold having a desired shape with an outer surface;

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<sup>3</sup> The Examiner's Office Action Summary identifies claim 24 as pending and rejected. Final Act. 1. Claim 24, however, has been canceled. Appeal Br. 29.

- d. removing the water from the solidified body; and
  - e. *dipping the solidified body into a conversion solution to convert the outer surface to a less soluble alginate creating a composition comprising the outer surface having less soluble alginate and a core having more soluble alginate.*
36. A method for forming a porous implant suitable for a cavity from which tissue has been removed, comprising:
- a. mixing soluble alginate and a radiopaque imaging agent with water to form an alginate-imaging agent solution;
  - b. incorporating a gas into the alginate-imaging agent solution;
  - c. transferring the alginate-imaging agent solution with the gas into a mold to form a solidified body having a desired shape;
  - d. removing the water from the solidified body; and
  - e. *dipping the solidified body into a conversion solution to convert only part, and not all, of the solidified body to a less soluble alginate, such that the solidified body has a surface region of the less soluble alginate and an interior region remains composed of a more soluble alginate.*

Appeal Br. 28, 29 (Claims App.).

## REJECTIONS

The Examiner maintains the following rejection:<sup>4</sup>

1. Claims 17–23 and 34–40 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement.<sup>5</sup>  
Final Act. 2–4.

## DISCUSSION

The Examiner finds that the Specification, as filed, and the parent Application 12/586,449 (“the ’449 Application”) lack written description support for all pending claims (17–23 and 34–40) reciting the partial conversions that follow “dipping the solidified body into a conversion solution,” a limitation found in the independent claims (claims 17 and 36). Final Act. 2–4; *see also* Appeal Br. 28, 29 (Claims App.). Regarding claim 17 specifically, the Examiner finds a lack of written description for “dipping the solidified body into a conversion solution to convert the outer surface to a less soluble alginate creating a composition comprising the outer surface having less soluble alginate and a core having more soluble alginate.” Final Act. 2. Regarding claim 36, the Examiner finds a lack of written description for: (i) “dipping the solidified body into a conversion solution to convert only part, and not all, of the solidified body to a less soluble alginate” and

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<sup>4</sup> Because this application is a continuation of an application filed before the March 16, 2013, effective date of the America Invents Act, we refer to the pre-AIA version of the statute.

<sup>5</sup> The Examiner omits dependent claim 23 from the statement of the rejection. Final Act. 2. Claim 23, however, includes the limitations recited in rejected independent claim 17. Accordingly, we view the Examiner’s omission of claim 23 from the statement of the rejection as a clerical error.

(ii) dipping “such that the solidified body has a surface region of the less soluble alginate and an interior region of a more soluble alginate.” *Id.* at 3, 4.

The Examiner finds that although the Specification describes instances in which the porosity of an outer surface may vary from the porosity of an interior surface, the described feature does not support claims directed to differences in the solubility of surfaces and regions. *Id.* at 2–3, 4 (citing Spec. ¶ 8). Likewise, the Examiner finds that the Specification’s description that “the introduction of the body to the conversion solution converts ‘at least part’ of the body to a less soluble alginate” is similarly unresponsive to claims 17 and 36. Final Act. 3 (citing Spec. ¶¶ 11, 24, 27); *see also* Final Act. 4. According to the Examiner, this disclosure “does not provide support for where the exterior is converted more so than the interior of the body.” Final Act. 4.

Appellant argues that the disputed limitations recited in claims 17 and 36 are supported by the Specification and Figure 4 of the application. Appeal Br. 13–22; 23–25. Appellant relies on these arguments for reversal of the rejection of the dependent claims. *Id.* at 22–23; 25.

Specifically, Appellant directs the reader to the following portions of the Specification: (1) “if the porous body is formed of alginate, the porous body is dipped into a solution of  $\text{CaCl}_2$ , where at least part of the sodium alginate is converted to the less soluble calcium alginate” (Spec. ¶ 23); (2) “[i]f the body contains sodium alginate, then as shown in Figure 4, the porous spherical body 29 is introduced into an aqueous  $\text{CaCl}_2$  solution 30 in container 31 at least part of the sodium alginate is converted to calcium alginate that quickly precipitates” (Spec. ¶ 24); (3) “[t]he formed implant structure of sodium alginate is introduced into a solution of calcium chloride

(0.5 to about 4% (wt.)) where at least part of the sodium alginate is converted to calcium alginate which precipitates” (Spec. ¶ 27); and (4) “Figure 4 is a schematic elevation view in section illustrating placing the dried porous body into a solution of CaCl<sub>2</sub> to convert the soluble alginate to a less soluble alginate” (Spec. ¶ 18). Appeal Br. 15, 17, 21, 24.

The sufficiency of an application’s written description is a question of fact. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). Appearance of a claim in the Specification in *ipsis verbis* does not guarantee that the written description requirement is satisfied. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002). At the same time, a failure to meet that standard does not require a finding that a claim fails to comply with the written description requirement. *In re Edwards*, 568 F.2d 1349, 1351–52 (Fed. Cir. 1978). All that is required is that the Specification demonstrate, with reasonable clarity, to a person of ordinary skill in the art that the inventor was in possession of the invention. *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008).

Appellant argues, *inter alia*, that the ordinarily skilled artisan at the time of invention would have understood that the more soluble alginate, e.g., sodium alginate, and the conversion solution, e.g., calcium chloride (0.5 to about 4% (wt.)), engage in a **precipitation reaction** to convert **at least part** of the more soluble alginate, e.g., sodium alginate, to a less soluble alginate, e.g., calcium alginate.

Appeal Br. 17 (citing Spec. ¶¶ 24, 27). Appellant argues that the Specification, as filed, depicts dipping the solidified body as submerging the

body in its entirety. Appeal Br. 21 (citing Spec. ¶¶ 18, 24; Fig. 4).

Appellant further argues

that a person of ordinary skill in the art would have understood that the precipitate, which is ‘a less soluble alginate[,]’ e.g., the calcium alginate, **would separate from** the conversion solution and **settle on the surface of** any of the solidified body that remains unconverted, i.e.[,] the original solidified body was composed of at least the more soluble alginate, e.g.[,] sodium alginate.

Appeal Br. 24.; *see also id.* at 19.

In response, the Examiner argues, *inter alia*, that the Specification “provides no discussion of distinguishing between the surface and the core of the porous body.” Ans. 7. The Examiner contends that the Specification “does not disclose the less soluble alginate allegedly settling on the surface of the solidified body, resulting in the claimed body having an outer shell and a more soluble core.” *Id.* at 8. According to the Examiner, neither does the Specification “imply where the converted outer surface happens to settle on the unconverted inner surface during the reaction in order to reach the claimed body configuration.” *Id.* The Examiner argues that the limitations in dispute are effectively impermissible negative limitations requiring that the core is not affected by the conversion solution. *Id.* at 6–7.

We, however, find that the skilled artisan, after viewing Figure 4 in context with the remainder of the Specification, would have understood the limitations in dispute. *See Ex parte Parks*, 30 USPQ2d 1234, 1236 (BPAI 1994) (favoring a more reasonable test of what the originally filed disclosure would have conveyed to one having ordinary skill in the art over a *per se* prohibition of negative limitations lacking written description support).

The Examiner provides no explanation of why one skilled in the art would fail to recognize that portions of a porous spherical or oval alginate body, which is submerged entirely in a conversion solution, would convert or precipitate at rates dependent on the portion's proximity to the conversion solution. Figure 4 of the Specification depicts such a spherical porous body submerged in its entirety in CaCl<sub>2</sub> conversion solution. Spec. ¶¶ 18, 24. The Specification, furthermore, describes that “the implant will be spherical or oval in shape.” *Id.* at ¶ 7. As Appellant persuasively argues, “one of ordinary skill in the art, who already has an understanding of precipitation reactions, would understand that the conversion solution **does not** convert the solidified body from the inside out, even if the body being converted is porous.” Reply Br. 8.

Thus, the original disclosure reasonably conveys to one skilled in the art that, as of the application filing date, the Appellant had possession of the subject matter “dipping the solidified body into a conversion solution to convert the outer surface to a less soluble alginate creating a composition comprising the outer surface having less soluble alginate and a core having more soluble alginate,” and “dipping the solidified body into a conversion solution to convert only part, and not all, of the solidified body to a less soluble alginate, such that the solidified body has a surface region of the less soluble alginate and an interior region remains composed of a more soluble alginate.” *See* Appeal Br. 28, 29 (Claims App.). Therefore, Appellant shows reversible error in the Examiner's finding that claims 17 and 36, and each of their respective dependent claims, lack written description.

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We reverse the rejection of claims 17–23 and 34–40 under 35 U.S.C. § 112, first paragraph, as lacking written description. *See* 37 C.F.R. § 41.37(c)(1)(iv).

### CONCLUSION

In summary:

| <b>Claims Rejected</b> | <b>35 U.S.C. §</b> | <b>Reference(s)/Basis</b> | <b>Affirmed</b> | <b>Reversed</b> |
|------------------------|--------------------|---------------------------|-----------------|-----------------|
| 17–23, 34–40           | 112                | 1 <sup>st</sup> paragraph |                 | 17–23, 34–40    |

REVERSED