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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* GEORGE BOURNE, MICHAEL MADDEN,  
ARTHUR R. MADENJIAN, DOREEN RAO, MARCIA BUISER,  
JIANMIN LI, RAYMOND RACKLEY, and BARRY N. GELLMAN<sup>1</sup>

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Appeal 2017-009790  
Application 14/082,274  
Technology Center 1600

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Before DEMETRA J. MILLS, RICHARD M. LEBOVITZ, and  
MICHAEL J. FITZPATRICK, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness and new matter. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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<sup>1</sup> Appellant, is the Applicant, Boston Scientific Scimed, Inc., which, according to the Brief, is the real party in interest. App. Br. 2.

STATEMENT OF CASE

The following claim is representative.

14. A method for bulking mammalian tissue comprising the steps of:

introducing a bulking agent to the mammalian tissue, the bulking agent comprising: a carrier, and a plurality of substantially spherical polyvinyl alcohol particles dispersed within the carrier, the substantially spherical polyvinyl alcohol particles comprising surface pores covering up to 80% of the total surface area of the particles and the carrier aiding delivery of the substantially spherical polyvinyl alcohol particles to a site to be bulked; and

coating the mammalian tissue with the substantially spherical polyvinyl alcohol particles.

46. A method for bulking mammalian tissue comprising: inserting an inflation device within a portion of a mammal;

inflating the inflation device, thereby creating a void in the tissue; and

at least partially filling the void with a bulking agent that comprises a carrier and a plurality of polymeric particles dispersed within the carrier, wherein the plurality of polymeric particles comprise surface pores covering up to 80% of the total surface area of the particles.

*Cited References*

Van Bladel et al. ("Van Bladel")	US 5,813,411	Sept. 29, 1998
Bley et al. ("Bley")	US 5,855,615	Jan. 5, 1999
Vanderhoff et al. ("Vanderhoff")	US 6,214,331 B1	Apr. 10, 2001
Yao et al. ("Yao")	US 6,268,405 B1	July 31, 2001
Goupil et al. ("Goupil")	US 6,652,883 B2	Nov. 25, 2003

Johnson et al. ("Johnson")	US 7,185,657 B1	Mar. 6, 2007
Bourne et al. (Bourne '400")	US 8,394,400 B2	Mar. 12, 2013
Bourne et al. ("Bourne '071")	US 8,586,071 B2	Nov. 19, 2013

*Grounds of Rejection*

1. Claims 14–17 and 34–49 are rejected under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement.
2. Claims 14, 15, 17, 34, 35, 38–40, and 42–45 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Van Bladel, Vanderhoff, and Yao.
3. Claim 16 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Van Bladel, Vanderhoff, Yao, and Bley.
4. Claims 36, 37, 41, and 49 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Van Bladel, Vanderhoff, Yao, and Goupil.
5. Claims 46–48 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Johnson in view of Van Bladel, Vanderhoff, and Yao.
6. Claims 14, 15, 17, 34–36, 38, and 46–48 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–6 of U.S. Patent No. 8,586,071 B2 in view of Vanderhoff and Yao.
7. Claim 16 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–6 of U.S. Patent

No. 8,586,071 B2 in view of Vanderhoff and Yao as applied to claims 14, 15, 17, 34–36, 38, and 46–48 above and further in view of Bley.

8. Claims 39, 40, and 42–45 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–6 of U.S. Patent No. 8,586,071 B2 and Vanderhoff and Yao as applied to claims 14, 15, 17, 34–36, 38, and 46–48 above and further in view of Van Bladel.
9. Claims 37, 41, and 49 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–6 of U.S. Patent No. 8,586,071 B2 and Vanderhoff and Yao as applied to claims 14, 15, 17, 34–36, 38, and 46–48 above and further in view of Goupil.
10. Claims 14, 15, 17, 34, 35, 36, 38–40, and 46–48 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of U.S. Patent No. 8,394,400 B2 in view of Vanderhoff et al. and Yao.
11. Claim 16 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of U.S. Patent No. 8,394,400 B2 in view of Vanderhoff and Yao as applied to claims 14, 15, 17, 34–36, 38, and 46–48 above and further in view of Bley.
12. Claims 37, 41, and 49 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of U.S. Patent No. 8,394,400 B2 and Vanderhoff and Yao as applied to

claims 14, 15, 17, 34–36, 38, and 46–48 above and further in view of Goupil.

13. Claims 42–45 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–21 of U.S. Patent No. 8,394,400 B2 and Vanderhoff and Yao as applied to claims 14, 15, 17, 34–36, 38, and 46–48 above and further in view of Van Bladel.
14. Claims 14, 15, 34, 35, 41, and 49 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–26 of U.S. Patent No. 7,611,542 B2 and further in view of Yao.
15. Claim 16 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–26 of U.S. Patent No. 7,611,542 B2 and Yao as applied to claims 14, 15, 34, 35, 41, and 49 above and further in view of Bley.
16. Claims 17, 38–40, and 42–45 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–26 of U.S. Patent No. 7,611,542 B2 and Yao as applied to claims 14, 15, 34, 35, 41, and 49 above and further in view of Van Bladel.
17. Claims 36 and 37 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–26 of U.S. Patent No. 7,611,542 B2 and Yao as applied to claims 14, 15, 34, 35, 41, and 49 above and further in view of Goupil.
18. Claims 46–48 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–26 of U.S. Patent

No. 7,611,542 B2 and Yao as applied to claims 14, 15, 34, 35, 41, and 49 above and further in view of Johnson.

19. Claims 14, 15, 17, 38–45, and 49 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–27 of U.S. Patent No. 7,131,997 B2 in view of Yao and Van Bladel.

20. Claim 16 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–27 of U.S. Patent No. 7,131,997 B2, Yao, and Van Bladel as applied to claims 14, 15, 17, 38–45, and 49 above and further in view of Bley.

21. Claims 34, 35, and 36 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–27 of U.S. Patent No. 7,131,997 B2, Yao, and Van Bladel as applied to claims 14, 15, 17, 38–45, and 49 above and further in view of Vanderhoff.

22. Claims 36 and 37 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–27 of U.S. Patent No. 7,131,997 B2, Yao, and Van Bladel as applied to claims 14, 15, 17, 38–45, and 49 and further in view of Goupil.

23. Claims 46–48 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1–27 of U.S. Patent No. 7,131,997 B2, Yao, and Van Bladel as applied to claims 14, 15, 17, 38–45, and 49 above and further in view of Johnson.

## FINDINGS OF FACT

The Examiner's findings of fact are set forth in the Answer at pages 2–43.

## PRINCIPLES OF LAW

In making our determination, we apply the preponderance of the evidence standard. *See, e.g., Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

“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).

Moreover, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).

### *New Matter, 112, first paragraph Rejection 1*

Claims 14–17 and 34–49 are rejected under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement.

The Examiner withdrew this rejection in the Answer. Ans. 43.

### *Obviousness-type Double Patenting Rejections 6-23*

Rejections 6–23 as set forth in the Grounds of Rejection above are not argued by Appellants in the Brief or Reply Brief, and therefore are summarily affirmed. Arguments not made are waived.

*Obviousness Rejections (Rejections 2–4)*

Claims 14, 15, 17, 34, 35, 38–40, and 42–45 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Van Bladel, Vanderhoff, and Yao. Claim 16 is rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Van Bladel, Vanderhoff, Yao, and Bley. Claims 36, 37, 41, and 49 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Van Bladel, Vanderhoff, Yao, and Goupil.

These three rejections are based upon the same primary combination of references Van Bladel and Vanderhoff. The dispositive issue for each of the rejections is whether the primary references teach or suggest the claim limitation that, “the substantially spherical polyvinyl alcohol particles comprising surface pores covering up to 80% of the total surface area of the particles.” Claim 14.

The Examiner finds that

teachings of Van Bladel are related to a method of treating urinary disorders utilizing physiologically acceptable composition including a plurality of hydrogel particles (Abstract). The composition is injected into tissues adjacent to a selected tissue structure thereby deforming the selected tissue structure.

Ans. 3.

The Examiner further finds that, “[a]lthough Van Bladel teaches that the particles contain pores, they do not teach pore sizes and if the pores are on the surface of the particles.” *Id.*

With respect to the limitation of “the substantially spherical polyvinyl alcohol particles comprising surface pores covering up to 80% of the total surface area of the particles,” the Examiner finds that

[A] person of ordinary skill in the art at the time of the invention to have modified the particles of Van Bladel modified with Vanderhoff by varying pore size in the range of below 125 micron and varying pore density from 10 pores/cm<sup>3</sup> to 10<sup>5</sup> pores/cm<sup>3</sup>, with a reasonable expectation of success because Yao teaches that pore density that ranges from 10 pores/cm<sup>3</sup> to 10<sup>5</sup> pores/cm<sup>3</sup> is useful for polyvinyl[] alcohol particles intended for soft tissue augmentation. Varying these parameters would have yielded particles that have surface pores covering an area that is at least close enough to the claimed surface area of up to 80% of the total surface area of the particles. Vanderhoff teaches the presence of pores in the particles but does not provide any guidance regarding pore density. Therefore, a person of ordinary skill would have been motivated to look to Yao for guidance on suitable pore densities of polyvinyl alcohol particles that are intended for bulking tissue. The claimed pore surface area of the particles is obvious over the prior art particles because there is no evidence of criticality of the claimed surface area.

Final Act. 8.

Appellants contend that, “the cited references alone and in combination fail to teach or suggest substantially spherical polyvinyl alcohol particles, which include surface pores covering up to 80% of the total surface area thereof.” App. Br. 10; Reply Br. 6.

#### ANALYSIS

We do not find that the Examiner has provided evidence to support a prima facie case of obviousness. In particular, the Examiner has failed to provide evidence in the cited prior art that shows substantially spherical

polyvinyl alcohol particles, which include surface pores covering up to 80% of the total surface area of the particles. The Examiner argues that varying the pore size and pore density parameters would have yielded particles that have surface pores covering an area that is at least close enough to the claimed surface area of up to 80% of the total surface area of the particles.  
Final Act. 8.

We are not persuaded by the Examiner's arguments. While Vanderhoff teaches particle pore sizes and Yao teaches particle pore densities, the Examiner has not pointed to a specific teaching in the cited references of particles that have surface pores covering an area that is at least close enough to the claimed surface area of up to 80% of the total surface area of the particles. The Examiner has not established with evidence, a clear relationship between pore density and covering a surface area up to 80% of the total surface area of the particles. Put another way, the Examiner has not established with evidence, that it was known in the art at the time of the invention that varying particle pore size and particle pore density would necessarily result in particles that have surface pores covering an area that is at least close enough to the claimed surface area of up to 80% of the total surface area of the particles.

The Examiner has not shown that any of the secondary references overcome the deficiencies of the primary combination of references.

Rejections 2-4 are reversed.

*Obviousness Rejection 5*

Claims 46-48 are rejected under pre-AIA 35 U.S.C. § 103(a) as being unpatentable over Johnson in view of Van Bladel, Vanderhoff, and Yao.

Appellants contend that, “[t]here is no mention in Johnson of spherical polyvinyl alcohol particles that include surface pores, and therefore Johnson does nothing to cure the above-noted deficiencies of Van Bladel, Vanderhoff and Yao with respect to claim 14.” App. Br. 11–12.

#### ANALYSIS

We do not find that the Examiner has provided evidence to support a prima facie case of obviousness. This rejection of representative claim 46 suffers from the same deficiency as the rejection of claim 14. The Examiner has not pointed to a specific teaching in the cited reference of particles that have surface pores covering an area that is at least close enough to the claimed surface area of up to 80% of the total surface area of the particles. Adding Johnson to this rejection does not make up the deficiencies of Van Bladel, Vanderhoff, and Yao indicated above.

Obviousness rejection 5 is reversed.

#### CONCLUSION OF LAW

The cited references do not support the Examiner’s obviousness rejections 2–5 as set forth in the grounds of rejection, which are reversed. The obviousness-type double patenting rejections 6–23 are affirmed. Because all claims remain rejected for obviousness-type double patenting, the rejection of the pending claims is 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)(1)(iv).

AFFIRMED