

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 33

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANDREW D. SUTTON and
RICHARD A. JOHNSON

Appeal No. 1999-1731
Application 08/411,815

ON BRIEF

Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 24 through 34 and 46 through 56, which are all of the claims remaining in the application.

Representative Claims

Claims 24 and 46, which are illustrative of the subject matter on appeal, read as follows:

24. A process of preparing microcapsules, the process comprising the steps of:

(i) spray-drying a solution or dispersion of at least one wall-forming material in a liquid carrier into a gas in order to obtain gas- or vapor-filled microcapsules by evaporation of said liquid carrier, and

(ii) including at least one charge-altering material in or on said microcapsules to adapt said microcapsules for selective targeting to an area of a human or animal body. [Emphasis added.]

46. A method for generating an ultrasound image of a region of a human or animal body comprising the steps of:

(i) introducing to said region an ultrasound contrast agent formed by

(1) spray drying a solution or dispersion of at least one wall-forming material in a liquid carrier into a gas to obtain gas- or vapor-filled microcapsules by evaporation of said liquid carrier; and

(2) including at least one charge-altering material in or on said microcapsules to adapt said microcapsules for selective targeting to an area of a human or animal body;

(ii) exposing said ultrasound contrast agent to ultrasonic energy; and

(iii) creating an image from the reflection of the ultrasonic energy by said ultrasound contrast agent;

wherein said microcapsules selectively target the region of the human or animal body to be imaged. [Emphasis added.]

The References

The prior art references relied on by the examiner are:

Erbel et al. (Erbel)	5,137,928	Aug. 11, 1992
Galjch et al. (Galjch)	5,147,631	Sep. 15, 1992
Mathiowitz et al. (Mathiowitz)	5,271,961	Dec. 21, 1993
Unger	5,547,656	Aug. 20, 1996

The Issue

The issue presented for review is whether the examiner erred in rejecting claims 24 through 34 and 46 through 56 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Mathiowitz, Galjch, Erbel, and Unger.

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials:

- (1) the instant specification, including Figures 1 through 5, and all of the claims on appeal;
- (2) applicants' Main Brief (Paper No. 25) and the Reply Brief (Paper No. 27);
- (3) the Examiner's Answer (Paper No. 26); and
- (4) the above-cited prior art references.

On consideration of the record, including the above-listed materials, we reverse the

examiner's rejection under 35 U.S.C. § 103.

Discussion

The present invention relates to the preparation of ultrasound contrast agents comprising hollow microcapsules, and to the use of such microcapsules to enhance ultrasound imaging techniques. More specifically, the invention relates to a process of preparing microcapsules by spray-drying a wall-forming material into a gas in order to obtain hollow microcapsules, and including a charge-altering material in or on the microcapsules to adapt the microcapsules for selective targeting to an area of a human or animal body. The present invention also relates to a method of generating an ultrasound image of a region of a human or animal body by introducing the hollow microcapsules formed by the above process into the region to be imaged, exposing the microcapsules to ultrasonic energy, and creating an image from the reflection of the ultrasonic energy by the microcapsules.

Independent claim 24, drawn to a process of preparing microcapsules, and independent claim 46, drawn to a method for generating an ultrasound image, contain the following limitation:

including at least one charge-altering material in or on said microcapsules to adapt said microcapsules for selective targeting to an area of a human or animal body.

Having carefully reviewed the content of Mathiowitz, Glajch, Erbel, and Unger, we find that

the combined disclosures of cited references are insufficient to support a conclusion of obviousness of claims containing that limitation. We shall not belabor the record with extensive comment in this case. Rather, we refer to the position succinctly expressed in applicants' Appeal Brief, explaining why the above-cited references would not have led a person having ordinary skill in the art to claims 24 through 34 which include clause (ii) or to claims 46 through 56 which include clause (i)(2). For the reasons set forth in the Appeal Brief, we agree that claims 24 through 34 and 46 through 56 patentably distinguish over the cited prior art.

We also note the following as a matter of procedure. The § 103 rejection is said to be based on a combination of references (Answer, page 4, last paragraph). Nevertheless, in the Answer, the examiner does not include an explanation supporting this rejection in the manner outlined in § 706.02(j) of the Manual of Patenting Examining Procedure, entitled "Contents of a 35 U.S.C. 103 Rejection." Rather, the examiner bundles together four references which, in his opinion, individually suggest various elements of the claimed invention. The examiner discusses Mathiowitz, Glajch, Erbel, and Unger individually and sequentially; and concludes that those references would have led a person having ordinary skill in the art to the claimed invention. That is not enough. The examiner fails to set forth the difference or differences in any claim over the applied reference(s); the proposed modification of the applied reference(s) necessary to arrive at the claimed subject matter; and an explanation why one of ordinary skill in the art at the time the invention was made

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would have been motivated to make the proposed modification.

The procedural error is compounded, because the examiner has considerably overstated the significance of teachings found in Mathiowitz. The examiner's position to the contrary, notwithstanding, Mathiowitz does not disclose the preparation of protein microspheres by spray-drying. Mathiowitz does not disclose a method "which is basically the same as the instant method" (Answer, page 6, lines 2 and 3), but rather discloses the preparation of protein microspheres by a phase separation, solvent removal process. Nor does Mathiowitz disclose or suggest the step of including at least one charge-altering material in or on microcapsules to adapt the microcapsules for selective targeting to an area of a human or animal body. Accordingly, to the extent that the examiner characterizes Mathiowitz alone as constituting sufficient evidence to establish a prima facie case of anticipation or obviousness (Answer, page 6, lines 4 through 8), we disagree. The examiner has not established an adequate evidentiary basis on this record to shift the burden of proof to applicants under principles of law set forth in In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980); and In re Best, 562, F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

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For these reasons, we reverse the examiner's rejection of claims 24 through 34 and 46 through 56 under 35 U.S.C. § 103.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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