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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ROBERT RIOUX and DAVID J. SAUVAGEAU

Appeal 2011-006255
Application 11/316,501
Technology Center 3700

Before TONI R. SCHEINER, JEFFREY N. FREDMAN, and
ERICA A. FRANKLIN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 33-45 and 47-55, directed to an echogenic apparatus for use in performing medical procedures. The claims have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Claims 33-45 and 47-55 are pending and on appeal; claims 1-32 and 46 have been canceled (App. Br. 2).

The Specification discloses “a vessel occlusion apparatus [which] includes an elongate shaft with an expandable member [e.g., a balloon] carried on a distal end portion of the shaft” (Spec. ¶ 6), wherein the wall of the expandable member contains a plurality of fluid pockets (*id.* at ¶¶ 6, 22, 23). In addition, the Specification discloses an elongate tubular delivery member, wherein the wall of the tubular member contains a plurality of fluid pockets (*id.* at ¶ 26). In either case, the pockets are filled with an echogenic gas or a radiopaque liquid which allows the wall of the balloon or tubular member to be ultrasonically or fluoroscopically imaged during a medical procedure (*id.* at ¶¶ 33, 37).

Figure 4 of the Specification, reproduced below, depicts fluid pockets in the wall of a balloon:

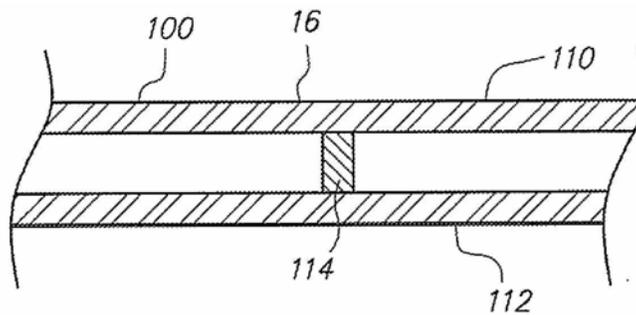


FIG. 4

Figure 4 depicts fluid pockets which extend along a length of a balloon wall 100. In this particular embodiment, the fluid pockets are “created by securing a first sheet 110 of material to a second sheet 112 of material using an adhesive 114 at selected locations” (*id.* at ¶ 23).

Claims 33 and 35 are representative of the subject matter on appeal:

33. A vessel occlusion apparatus, comprising:
an elongate shaft having a fluid delivery lumen; and
an expandable member carried on a distal end portion of the shaft, the expandable member comprising a body defining an interior region, the interior region in communication with the fluid delivery lumen, the body formed of a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of fluid pockets between the first sheet and the second sheet,
wherein the fluid pockets are fluidically isolated from any fluid lumens.

35. An apparatus for use in a medical procedure, comprising:
an elongate tubular delivery member having a proximal portion, a distal portion, and a lumen extending between the proximal and distal portions, wherein the distal portion of the tubular member is formed of a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of fluid pockets between the first sheet and the second sheet,
wherein the fluid pockets are fluidically isolated from any fluid lumens.

The Examiner relies on the following evidence:

Bosley	US 5,289,831	Mar. 1, 1994
O'Boyle	US 5,609,606	Mar. 11, 1997
Green et al.	US 5,807,327	Sep. 15, 1998
Zappala	US 6,364,855 B1	Apr. 2, 2002
Schroeder et al.	US 2005/0075723 A1	Apr. 7, 2005
Lim et al.	US 6,946,173 B2	Sep. 20, 2005

The claims stand rejected as follows:

I. Claims 33, 34, 36, 37, 40, 41, and 43 under 35 U.S.C. § 103(a) as unpatentable over Lim, Bosley, and Zappala (Ans. 4-5);

II. Claims 38 and 39 under 35 U.S.C. § 103(a) as unpatentable over Lim, Bosley, Zappala, and Schroder (Ans. 7).

III. Claim 42 under 35 U.S.C. § 103(a) as unpatentable over Lim, Bosley, Zappala, and O'Boyle (Ans. 7-8).

IV. Claim 44 under 35 U.S.C. § 103(a) as unpatentable over Lim, Bosley, Zappala, and Green (Ans. 8).

V. Claims 35, 47, 48, 51, and 52 under 35 U.S.C. § 103(a) as unpatentable over Bosley and Zappala (Ans. 5-6).

VI. Claims 49 and 50 under 35 U.S.C. § 103(a) as unpatentable over Bosley, Zappala, and Schroeder (Ans. 8-9).

VII. Claims 53-55 under 35 U.S.C. § 103(a) as unpatentable over Bosley, Zappala, and Green (Ans. 9).

FINDINGS OF FACT

1. Lim discloses a catheter balloon comprising “a first layer [33] formed of a polymeric material such as ePTFE coated or impregnated with a bondable material [35] . . . positioned against a second layer [34] and . . . heated to fusion bond together” (Lim, col. 6, ll. 8-13; col. 8, ll. 1-13).

2. Bosley discloses an “echogenic device to be sonically imaged” (Bosley, col. 7, ll. 38), e.g., “catheters, devices made from catheters, stents, pacing leads, introducers, pacemakers, ultrasonic rulers, . . . pumps, [and] balloons” (*id.* at col. 7, ll. 41-44).

3. Bosley's echogenic device is partially made up of a composite material comprising sound reflective particles, e.g., glass particles, embedded in a formable, pliable plastic matrix material which can be molded or extruded into a variety of shapes (*id.* at col. 7, ll. 49-63). Alternatively, the glass particles can be attached to the surface of the echogenic device using a medical grade adhesive, and coated with a layer of plastic material to provide a smooth outer surface (*id.* at col. 11, ll. 31-43).

4. Zappala discloses a urethral catheter which “features an inflatable balloon at the distal/bladder end and a central lumen containing a semisolid masma comprising a plurality of hypoechoic, gas filled microspheres” (Zappala, col. 2, ll. 54-57).

REJECTIONS I-IV

Rejections I-IV are based, in whole or in part, on the Examiner’s proposed combination of Lim, Bosley, and Zappala. As the same issue is dispositive for all four rejections, we will discuss them together.

Independent claim 33 is directed, in relevant part, to an occlusion apparatus with an elongate shaft having a fluid delivery lumen and an expandable member “formed of a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of fluid pockets between the first sheet and the second sheet, wherein the fluid pockets are fluidically isolated from any fluid lumens.”

The Examiner finds that Lim discloses a vessel occlusion apparatus with an expandable member, i.e., a balloon, “defining an interior region . . . in communication with [a] fluid delivery lumen” (Ans. 4), wherein the balloon is “formed of a first sheet of material secured to a second sheet of material using an adhesive” (*id.*). The Examiner acknowledges that Lim’s balloon does not include “a plurality of fluidically isolated [fluid] pockets” (*id.*). However, the Examiner finds that Bosley “teaches a catheter in which particles . . . can alternatively be attached to a surface with adhesive or embedded in its material . . . which can be placed between two layers . . . to allow the catheter to be sonically imaged” (*id.*). In addition, the Examiner finds that Zappala “teaches gas filled microspheres which are used to acoustically image a catheter” (*id.*).

The Examiner concludes that it would have been obvious for one of ordinary skill in the art “to use microspheres between the layers of the balloon of Lim et al. as in Bosley and to further use the gas filled microspheres of Zappala because Bosley and Zappala teach this to allow the catheter device to be sonically imaged” (*id.* at 4).

Appellants contend, in relevant part, that “even if . . . one of ordinary skill in the art would have been motivated to include the spheres of Bosley or the gas-filled spheres of Zappala in between the layers 33 and 34 taught by Lim . . . such a construction does not render obvious the claimed apparatus” (Reply Br. 2), at least because the applied prior art references do not teach or otherwise suggest “creating fluid pockets between first and second sheets of . . . [an expandable member] by using an adhesive at selected locations” (*id.*; *see also* App. Br. 8), as required by independent claim 33.

We agree with Appellants. All the claims subject to Rejections I-IV require “a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of fluid pockets between the first sheet and the second sheet” (*see* claim 33). As discussed above, Lim discloses a bi-layer balloon with no fluid pockets (FF1); Bosley discloses echogenic glass particles that are either embedded in a moldable matrix material or attached to the surface of a device using an adhesive, and then coated with a layer of plastic material to provide a smooth outer surface (FFs 2, 3); and Zappala discloses gas-filled microspheres suspended in a “masma” (FF4). Thus, the Examiner has not established that any of the cited references (or the secondary references Schroeder, O’Boyle, or Green) discloses the structure required by the claims, in a balloon or otherwise, nor

has the Examiner explained why one of ordinary skill in the art would have had a reason to modify any of the devices of the cited art to include such a structure.

On this record, the Examiner has not established that it would have been obvious to form fluid pockets between the layers of Lim's bi-layer balloon by using an adhesive only at selected locations of the balloon, as required by the claims. Accordingly, Rejections I-IV are reversed.

REJECTIONS V-VII

Rejections V-VII are based, in whole or in part, on the Examiner's proposed combination of Bosley and Zappala. As the same issue is dispositive for all three rejections, we will discuss them together.

Independent claim 35 is directed, in relevant part, to an apparatus with an elongate tubular delivery member with a lumen, wherein the distal portion of the tubular member is "formed of a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of fluid pockets between the first sheet and the second sheet, wherein the fluid pockets are fluidically isolated from any fluid lumens."

The Examiner finds that Bosley discloses "an elongate tubular delivery member having a proximal portion, a distal portion, and a lumen . . . wherein the distal portion of the tubular member is formed of a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of pockets" which the Examiner concedes do not contain fluid (Ans. 5). Again, the Examiner finds that Zappala "teaches gas filled microspheres which are used to acoustically image a catheter" (*id.*).

The Examiner concludes that it would have been obvious for one of ordinary skill in the art “to use the micro spheres of Zappala in the device of Bosley because the particles of Bosley allow the catheter to be sonically imaged and Zappala teach[es] gas filled micro spheres to equivalently allow the catheter device to be sonically imaged” (*id.* at 6).

Appellants contend that neither reference discloses or suggests a distal portion of a tubular member “that is formed of a first sheet of material secured to a second sheet of material using adhesive at selected locations. Nor does either reference disclose or otherwise suggest creating a plurality of fluid pockets between the two sheets by using adhesive at selected locations” (App. Br. 10), as required by claim 35.

Again, we agree with Appellants. All the claims subject to Rejections V-VII require “a first sheet of material secured to a second sheet of material using an adhesive at selected locations, thereby creating a plurality of fluid pockets between the first sheet and the second sheet” (*see* claim 35). As discussed above, Bosley discloses echogenic glass particles that are either embedded in a moldable matrix material or attached to the surface of a device using an adhesive, and then coated with a layer of plastic material to provide a smooth outer surface (FFs 2, 3), while Zappala discloses gas-filled microspheres suspended in a “masma” (FF4). Thus, the Examiner has not established that either of the cited references (or secondary references Schroeder or Green) discloses the structure required by the claims, nor has the Examiner explained why one of ordinary skill in the art would have had a reason to modify any of the devices of the cited art to include such a structure. Accordingly, Rejections I-IV are reversed.

SUMMARY

I. The rejection of claims 33, 34, 36, 37, 40, 41, and 43 as unpatentable over Lim, Bosley, and Zappala is reversed.

II. The rejection of claims 38 and 39 as unpatentable over Lim, Bosley, Zappala, and Schroder is reversed.

III. The rejection of claim 42 as unpatentable over Lim, Bosley, Zappala, and O'Boyle is reversed.

IV. The rejection of claim 44 as unpatentable over Lim, Bosley, Zappala, and Green is reversed.

V. The rejection of claims 35, 47, 48, 51, and 52 as unpatentable over Bosley and Zappala is reversed.

VI. The rejection of claims 49 and 50 as unpatentable over Bosley, Zappala, and Schroeder is reversed.

VII. The rejection of claims 53-55 as unpatentable over Bosley, Zappala, and Green is reversed.

REVERSED

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