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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
MATNEY, BROOKE MARIE

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lhowd@its.jnj.com
gsanche@its.jnj.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LEONARD A. VAN STOLEN and CORNELIUS VAN WEE

Appeal 2011-005879
Application 11/715,304
Technology Center 3700

Before FRANCISCO C. PRATS, STEPHEN WALSH, and
JOHN A. EVANS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to a balloon catheter that can be used with an endoscope. The Examiner entered a rejection for obviousness.

We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1, 2 and 4-8 stand rejected and appealed (App. Br. 2). Claim 1, the only independent claim, illustrates the appealed subject matter and reads as follows (emphasis added):

1. A balloon catheter for use with an endoscope, comprising:

> a flexible shaft having a proximal end and a distal end; the shaft having an inner member and an outer tubular body; the outer body surrounding at least a portion of the inner member and defining an inflation lumen; the outer body having at least one reinforcing member extending longitudinally along at least a portion of the outer body;
>
> a balloon defining an interior and being made of translucent balloon material which is substantially inelastic; the balloon having an inflatable portion extending between a proximal and distal balloon portion, *each proximal and distal balloon portion being affixed to the flexible shaft*;
>
> wherein the balloon is affixed to the flexible shaft near its distal end; and the inflatable portion includes a cylindrical working portion arranged between a proximal and distal tapering portion; the balloon in an initial configuration being deflated, pleated and wrapped around the flexible shaft;
>
> a hub affixed to the proximal end of the shaft and defining at least an inflation port; such that the inflation lumen communicates between the hub and the balloon;
>
> wherein the proximal and distal tapering portions each define an angle with respect to the longitudinal axis, and the angle defined by the proximal tapering portion is steeper than the angle defined by the distal tapering portion.

The sole rejection before us for review is the Examiner's rejection of claims 1, 2, and 4-8 are under 35 U.S.C. § 103(a) as obvious over Danforth,[1] Burnham,[2] and Leone[3] (Ans. 3-7).

OBVIOUSNESS

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .

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[1] Danforth et al., U.S. Patent No. 4,881,547 (issued November 21, 1989).
[2] Burnham, U.S. Patent No. 5,496,292 (issued March 5, 1996).
[3] Leone et al., U.S. Patent No. 6,468,244 B1 (issued October 22, 2002).

> After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

In this case, the Examiner found that Danforth taught or suggested a balloon catheter having all of the features required by claim 1, except for making the balloon from translucent material, and except for including a reinforcing member longitudinally along at least a portion of the outer body of the shaft (*see* Ans. 3-5). To remedy those deficiencies, the Examiner cited Burnham and Leone as evidence that an ordinary artisan would have considered it obvious to include those features on a catheter such as that described by Danforth (*see id.* at 5-6).

Appellants argue, among other things, that Danforth "does not teach 'each proximal and distal balloon portion being affixed to the shaft'" as required by claim 1 (App. Br. 8).

The Examiner responds that, "[f]or clarification, Examiner considers the shaft to be taught by the combination of housing 21 and stiffening element 44. As can be seen in Fig. 3B, the proximal and distal balloon portions are affixed to the combination of housing 21 and stiffening element 44" (Ans. 8).

We are not persuaded that a preponderance of the evidence supports the Examiner's finding.

We note, as the Examiner points out, that Figure 3B of Danforth, as well as Figures 3A and 3D, show a stiffening element 44 disposed adjacent to balloon 40 of Danforth's catheter.

Even assuming for argument's sake, however, that stiffening element 44 can be considered part of the catheter's flexible shaft, the Examiner does not point to any particular feature in any of those figures, nor does the Examiner point to any clear or specific teaching in Danforth's underlying disclosure, supporting the finding that balloon 40 is actually affixed to optional stiffening element 44.

The fact that element 44 is depicted adjacent to the balloon in Figure 3B does not, in our view, demonstrate that the balloon is affixed to that element. For example, in Figure 3E the guidewire 30 and balloon 40 are depicted as being adjacent, yet Danforth describes the guidewire as being unattached to the balloon (*see* Danforth, col. 6, ll. 32-36 ("Both the lumen **23** in housing **20** and the lumen created by wrapping balloon **40** are of sufficient caliber to permit unimpaired longitudinal and rotational movement of the guidewire **30** within the confines of the catheter.")).

As to the actual relationship of the stiffening element to the balloon, Danforth states:

> FIG. 3B illustrates the housing **21**, communicating channels **45**, and balloon **40** from above. The balloon is shown in an unwrapped deflated condition. **FIG. 3B** also illustrates an optional feature of the catheter, specifically, a stiffening element **44** disposed longitudinally along the length of the balloon to provide additional column strength to the balloon

(*Id.* at col. 6, ll. 4-10.) Thus, while Danforth discloses that the stiffening element 44 may be disposed longitudinally along the length of the balloon, Danforth simply does not state that the stiffening element is affixed to the balloon.

Danforth later discusses the function of the stiffening element:

> In this circumstance, the column strength of the guidewire contributes to the column strength of the catheter. On inflation of the balloon, the guidewire and catheter part. The addition of an optional stiffener **44**, as illustrated in **FIGS**. **3A**, **3B** and **3D** contributes to the column strength of the balloon.

(*Id.* at col. 7, ll. 14-19.)

As is evident, Danforth again fails to state that the stiffener 44 is affixed to the balloon. While it may be true that stiffener 44 contributes to the columnar strength of the balloon, the guidewire also performs that function, and, as noted above, the guidewire is undisputedly not affixed to the balloon.

Accordingly, we are not persuaded that a preponderance of the evidence supports the Examiner's finding that Danforth describes a balloon catheter in which a distal portion of the balloon is affixed to the catheter's flexible shaft, as claim 1 requires. As the Examiner has therefore not adequately explained how or why Danforth, Burnham, and Leone teach or suggest a balloon catheter having all of the features of claim 1, we reverse the Examiner's obviousness rejection of claim 1, and its dependents, over those references.

REVERSED

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