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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MASANOBU IGUCHI

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Appeal 2011-005558  
Application 11/664,307  
Technology Center 3700

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Before TONI R. SCHEINER, LORA M. GREEN, 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 8-21 and 25-30, directed to a catheter. The claims have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

Claims 8-21 and 25-30 are pending and on appeal. Claims 1-7 and 22-24 have been canceled (App. Br. 2).

The Specification discloses a catheter with “an outer peripheral portion in the form of a tube” and an internal wall dividing the catheter into two lumens, wherein “axially extending linear contrastradiography sections of radiopaque material are formed at . . . intersection points between the outer peripheral section and the wall, the peripheral extent of the respective contrastradiography sections being different” (Spec. 3). This configuration is depicted in Figure 3 of the Specification, reproduced below:

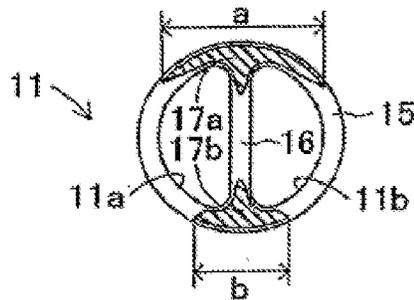


Fig. 3

Figure 3 is a cross-sectional view of an embodiment of the catheter main body 11 (a tube formed of a soft polymer resin) with “a cylindrical outer peripheral section 15 with a substantially diametrically extending wall 16 to divide the outer peripheral section 15 internally into . . . two lumens, a main lumen 11a and a sublumen 11b” (*id.* at 7). “Where the outer peripheral section 15 and the wall 16 intersect, linear contrastradiography sections 17a and 17b . . . are provided in the catheter body so as to extend in the longitudinal direction of the catheter main body 11. In addition, “the linear contrastradiography sections 17a and 17b are arranged within the outer peripheral section 15 not to be exposed at the surface thereof” (*id.* at 13).

In other words, the catheter has two radiopaque stripes (of different widths, a and b) running along the longitudinal axis of the catheter where the edges of the internal wall meet the cylindrical portion of the tube.

According to the Specification, because of the placement of the contrastradiography stripes at the intersection of the edges of the wall with the tube, “it is possible to confirm the position of the double lumen catheter 10 by radiography” (*id.* at 12), “to distinguish [between] the main lumen 11a and the sublumen 11b on the basis of the differen[t]” widths of the stripes (*id.* at 13), and “to confirm that medicinal fluids are passing through the main lumen 11a and the sublumen 11b, respectively” through the sections without the radiopaque agent (*id.*). In addition, because the contrastradiography stripes “are arranged within the outer peripheral section 15 not to be exposed at the surface thereof, it is possible to prevent deterioration or stripping thereof . . . [and] the useful life of the double lumen catheter 10 can be increased” (*id.*).

Claim 8 is representative:

8. A catheter, which comprises:  
a catheter main body including an outer peripheral section and an internal wall having a first end and a second end, the catheter main body defining first and second lumens extending along a longitudinal axis of the catheter main body, wherein the first and second ends of the internal wall each intersect the peripheral section of the catheter main body at a respective first intersection area and a respective second intersection area; and  
first and second contrastradiography sections disposed at least within the outer peripheral section and the first and second intersection areas, the first and second contrastradiography sections defining respective first and second different peripheral extents, and being positioned to assist in distinguishing the first lumen from the second lumen during imaging of the catheter main body.

The Examiner relies on the following evidence:

Becker et al.	US 4,469,483	Sep. 4, 1984
Bosley	US 5,289,831	Mar. 1, 1994
Chee et al.	US 5,542,937	Aug. 6, 1996

Claims 8-14, 16-19, 21, 25, 26, 28, and 29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Bosley and Becker.

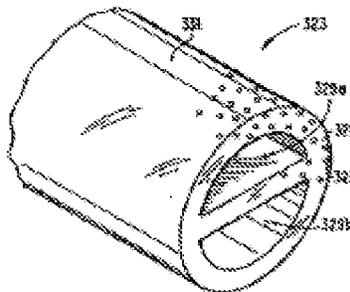
Claims 15, 20, 27, and 30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Bosley, Becker, and Chee.

### ISSUE

Both rejections turn on the same issue: Has the Examiner established that it would have been obvious to place radiopaque stripes of different widths along the longitudinal axis of a double lumen catheter within the outer peripheral section of the catheter where the outer peripheral section intersects the catheter's internal wall, given the teachings of Bosley and Becker?

### FINDINGS OF FACT

1. Bosley discloses a double lumen catheter, which is formed of a composite material comprising "a formable matrix material having discrete sound reflective particles embedded therein" (Bosley, col. 2, ll. 36-40; col. 5, ll. 22-29). Figure 3 of Bosley is reproduced below:



**Fig.3**

Figure 3 is a cross-sectional perspective view of body member 323 of Bosley's double lumen catheter with lumen 329a and 329b disposed in catheter wall 331, and showing "a multitude of sound reflective particles" 327 embedded in matrix material 325 (*id.* at col. 14, ll. 59-64).

2. Bosley teaches that the composite material "still maintains the requisite flexibility . . . while providing echogenicity throughout the body of the device. In this way, the physician may observe a full image of the medical device in the patient" (Bosley, col. 5, ll. 34-38).

3. Bosley teaches that the echogenic composite may also include a radiopaque material, such as barium or tungsten, so that the catheter "is both sound reflective and radiopaque for use with either ultrasonic equipment or radiographic equipment" (Bosley, col. 5, ll.40-42; col. 6, ll.16-19). Bosley teaches that

These advantages may be incorporated without a significant modification to the fabrication technique presently being used. The reflective particles, and optionally the radiopaque material, are mixed into the matrix material prior to forming the device by, for example, extrusion in the case of most catheters. Thus, no additional post extrusion fabrication steps are required to provide the desired echogenicity and a high level of quality control may be maintained.

(*Id.* at col. 5, ll. 42-50.)

4. Becker discloses that "[o]ne serious problem that has limited the amount of radiopaque material that can be present in a catheter is the fact that if a radiopaque material such as barium sulfate is dispersed into the plastic catheter material, its physical properties such as ultimate tensile strength can be severely deteriorated" (Becker, col. 1, ll. 29-34). Becker

also teaches that “it is desirable for the interior of the catheter to be visible, so the catheter should have transparent sections” (*id.* at col. 1, 36-38).

5. Becker addresses both of these issues by providing a catheter with “a particular arrangement of radiopaque stripes . . . which exhibits improved x-ray visibility in all positions of the catheter” (Becker, col. 1, ll. 47-50).

[A] catheter made of silicone rubber or the like carries a pair of longitudinal stripes of radiopaque material, the stripes being positioned in diametrically opposed, spaced relation to each other about the circumference of the catheter and comprising a mixture of silicone rubber and the finely divided radiopaque material. The catheter also defines a pair of diametrically opposed, transparent, longitudinal segments positioned between the stripes for viewing the catheter interior. Typically the stripes containing radiopaque material occupy a total of 50° to 270° of the catheter circumference, and preferably 90° to 180°.

Because of the use of stripes of substantial width (typically at least 45° and preferably about 60° to 100°) and their diametric positioning, increased x-ray visibility is provided by the fact that from whatever position the catheter occupies the stripes are either seen from a substantially edge-on view, or seen in overlapping relationship. Thus x-rays passing laterally through the catheter will tend to either pass through both of the stripes in their diametrically opposed relation, or the x-rays will pass sideways through[] the stripes. In either event the x-rays pass through an increased amount of radiopaque agent, and thus the radiopaque stripes tend to be more visible on opposed x-ray film than stripes of radiopaque agent positioned in a different configuration.

Also, since the transparent, longitudinal segments are in opposed relation to each other, one can see through the catheter for easy viewing of the interior.

(*Id.* at col. 1, l. 60 - col. 2, l. 22.)

6. Becker's coextruded silicone catheter tubing is depicted in Figure 1, reproduced below:

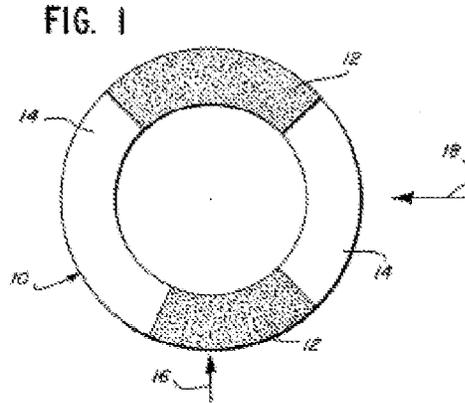


Figure 1 is a transverse sectional view of Becker's catheter tubing. "The respective angular widths of [radiopaque] sections 12 as shown are specifically shown to be 67° and 98°, while the transparent segments in this specific embodiment exhibit respective angular widths of 89° and 115°. However, it is understood that variations of these angles will be customary" (*id.* at col. 4, ll. 54-60).

7. Chee discloses a catheter wherein "[t]he materials making up the catheter are typically polymeric and may be either neat or filled. By 'filled' we mean that the polymers may contain radiopaque agents such as . . . barium sulfate" (Chee, col. 3, ll. 63-66). Thus, Chee is cumulative to Bosley in this respect.

#### PRINCIPLES OF LAW

[An invention] composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.

*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

## DISCUSSION

Claims 8-14, 16-19, 21, 25, 26, 28, and 29 stand rejected over Bosley and Becker, while claims 15, 20, 27, and 30 stand rejected as unpatentable over Bosley and Becker. The same issue is dispositive for both rejections, so we will discuss the rejections together.

The Examiner concedes that Bosley's double lumen catheter does not have discrete contrast radiography sections, but concludes that it would have been obvious to modify Bosley's catheter by placing stripes of radiopaque material where the internal wall intersects the outer peripheral section of the catheter (Ans. 4, 9), for two reasons. First, according to the Examiner, "the initial impression of [Bosley's] figure 3 shows the imaging material at the intersection point of the device" and this "suggest[s] a location for the material (at least more than any other location around the device) if only a limited amount of radiopaque material were being introduced, such as in Becker" (*id.* at 9). "Secondly, the Examiner views it as a matter of design choice" (*id.*), since "the stripes will have to be placed at some position around the exterior of the device of Bosley . . . [and] no matter where they are placed the stripes will assist in distinguishing the first and second lumens during imaging" (*id.* at 8).

Appellant contends, among other things, that "neither Bosley nor Becker teaches or suggests placing radiopaque material at specific positions on a double lumen device (i.e., the intersection between the internal wall and the peripheral section of the catheter main body) to distinguish the first lumen from the second lumen" (Reply Br. 10). Appellant contends that "placing the radiopaque material at the intersection areas is more than a design choice" (*id.* at 11).

This is a close case. As discussed above, Bosley discloses a double lumen catheter with radiocontrast material evenly dispersed throughout the catheter (FF3). While we disagree with the Examiner's assertion that Figure 3 of Bosley (or anything else in Bosley) suggests any discrete location for the material (*see* FF1), we do agree that it would have been obvious to use alternating stripes of radiopaque and transparent material on Bosley's double lumen catheter, because Becker explicitly discusses the disadvantages associated with dispersing radiopaque material throughout the catheter (FF4), and suggests these disadvantages can be avoided by co-extruding the catheter with alternating radiopaque and transparent stripes (FF5).

Nevertheless, we disagree with the Examiner that the specific placement of the radiopaque stripes required by the claims is simply a matter of inconsequential design choice. As discussed above, the Specification teaches that placing radiopaque stripes of different widths "within the outer peripheral section and the first and second intersection areas" (*see e.g.*, claim 8) makes it possible to more easily confirm the position of the double lumen catheter (Spec. 12), to distinguish between the two lumens (*id.* at 13), and to confirm that fluids are passing through the appropriate lumens (*id.*). Moreover, because the contrast radiography stripes "are arranged within the outer peripheral section 15 not to be exposed at the surface thereof, it is possible to prevent deterioration or stripping thereof . . . [and] the useful life of the double lumen catheter 10 can be increased" (*id.*).

The Examiner has not established that it would have been obvious to place radiopaque stripes of different widths along the longitudinal axis of a double lumen catheter within the outer peripheral section of the catheter

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where the outer peripheral section intersects the catheter's internal wall,  
given the teachings of the prior art.

#### SUMMARY

The rejection of claims 8-14, 16-19, 21, 25, 26, 28, and 29 as  
unpatentable over Bosley and Becker is reversed.

The rejection of 15, 20, 27, and 30 as unpatentable over Bosley,  
Becker, and Chee is reversed.

REVERSED

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