

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte OSCAR CARRILLO,
JAMES E. WINDHEUSER,
and
M. KEVIN RICHARDSON,
Appellants

Appeal 2008-4891
Application 11/366,739¹
Technology Center 3700

Decided: September 5, 2008

Before CAROL A. SPIEGEL, DONALD E. ADAMS, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Application 11/366,739 ("the 739 application," the disclosure of which is cited herein as "Spec."), *Rapid Exchange Catheter with Depressable Channel*, filed 2 March 2006, is a continuation of application 10/298,313, filed 15 November 2002. The real party in interest is Scimed Life Systems, Inc. (Appeal Brief under 37 C.F.R. § 41.37, filed 16 October 2007 ("App. Br."), 2)

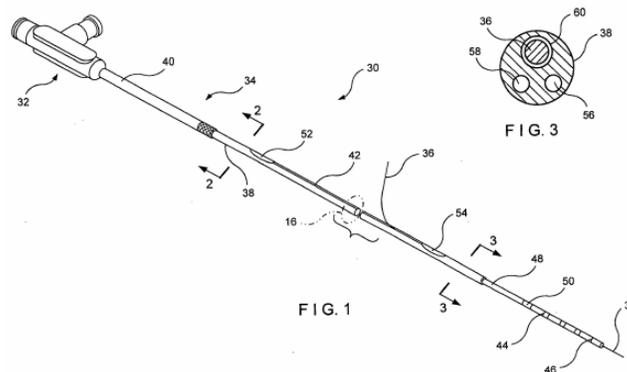
I. Statement of the Case

This is an appeal under 35 U.S.C. § 134 from an Examiner's final rejection of all pending claims, claims 1-21. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

The subject matter on appeal, as explained in the 739 specification (Spec. ¶ 5),

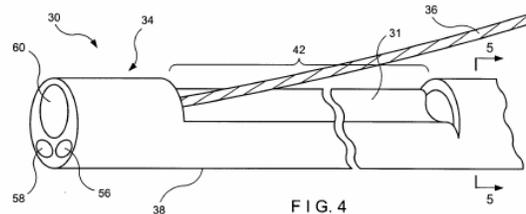
. . . is directed to a rapid exchange catheter extending from a proximal portion which remains outside of a patient's body during use to a distal portion which, during use, is located within a body lumen adjacent to a target area to be treated, wherein the proximal and distal portions are coupled by a medial portion. The catheter comprises a guide wire lumen extending longitudinally through the distal portion and a guide wire receiving channel formed by an outer surface of the medial portion, wherein the guide wire lumen is open to a distal end of the channel.

Figure 1 shows a rapid exchange catheter 30 comprising a tubular shaft 38 with proximal end 40, distal end 46, and depressible portion 42 between ends 52, 54 in a medial portion of shaft 38. Shaft 38, shown in cross-section in Figure 3, contains guide wire lumen 60 for inserting guide wire 36 and ancillary lumens 56, 58, e.g., for inserting another device or injecting a dye. (Spec. ¶¶ 20 and 29). Figures 1 and 3 are shown below.



{Figure 1 of the 739 application shows a perspective view of a catheter including a rapid exchange channel. Figure 3 is a cross-sectional view of the catheter with guide wire of Figure 1 distal to the depressible portion.}

"[P]artially circumferential slits . . . are formed in an outer wall of the catheter 30 at the depressable ends 52, 54 so that openings are formed to the guide wire lumen 60 at the depressable portion ends 52, 54" (Spec. ¶ 20). As illustrated in Figure 4, when depressible portion 42 is depressed, the outer wall of the catheter integral with guide wire lumen 60 between depressible ends 52, 54 moves inward toward an opposite side of the guide wire lumen 60 forming an opening or channel for inserting guide wire 36 into the guide wire lumen 60. Figure 4 is shown below.



{Figure 4 of the 739 application is a perspective, partially cross-sectional view of a catheter having a depressible guide wire lumen.}

Claims 1 and 12 illustrate the subject matter on appeal and read (Claims Appendix, App. Br. 11-14):

1. A rapid exchange catheter comprising:
a guide wire lumen; and
first and second slits separated from one another longitudinally along a portion of the catheter forming a depressible portion of a wall of the catheter therebetween, the depressible portion being movable between a depressed configuration in which an inner surface of the depressible portion is moved radially inward toward an inner surface of an

opposite side of the guide wire lumen and a non-depressed configuration.

12. A rapid exchange catheter comprising:
a guide wire lumen;
a depressable portion of a wall of the catheter which, when in a depressed configuration, forms a guide wire receiving channel with an opening from the guide wire receiving channel to the guide wire lumen at a first end thereof, wherein, when the depressable portion is in a non-depressed configuration, an outer surface of the depressable portion forms a substantially continuous surface with adjacent portions of the catheter wall.

Claims 1-21 stand rejected as unpatentable under 35 U.S.C. § 102(b) over either Miraki² or Teirstein³ (FR⁴ 2-3; Ans.⁵ 3-7).

Appellants have not argued the separate patentability of any dependent claim. Further according to Appellants, claim 20 is allowable for at least the reasons discussed above with regard to claims 1 and/or 12 (App. Br. 6 and 9; Reply Br. 6 and 10). Therefore, we decide this appeal on the basis of claims 1 and 12. 37 C.F.R. § 41.37(c)(1)(vii).

II. Discussion

A. Legal standard

Anticipation requires a prior art reference to describe every limitation in a claim -- either expressly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). However, the law of anticipation does not require

² U.S. Patent 5,324,269, *Fully Exchangeable Dual Lumen Over-the-Wire Dilation Catheter with Rip Seam*, issued 28 June 1994, to Manouchehr Miraki ("Miraki").

³ U.S. Patent 5,468,225, *Rapid Exchange Catheter*, issued 21 November 1995, to Paul S. Teirstein ("Teirstein").

⁴ Final Office Action mailed 16 May 2007 ("FR").

⁵ Examiner's Answer mailed 31 January 2008 ("Ans.").

that the reference teach what the Appellants teach in their specification, but only that the claims on appeal "read on" something disclosed in the reference. *See Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 772 (Fed. Cir. 1983). For example, a mechanical device is anticipated by a prior art device of like construction and capable of performing the same function. *In re Walch*, 87 F.2d 511 (CCPA 1937).

B. Rejection over Miraki

1. Miraki

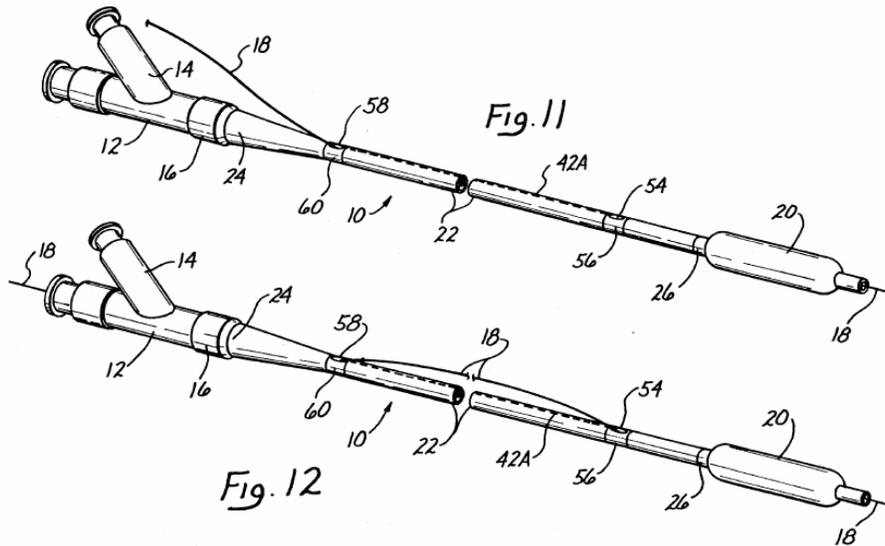
Miraki discloses a

. . . dual lumen over-the-wire balloon catheter provided with a longitudinal rip seam extending along a majority of the length of its guidewire lumen from its proximal opening or adjacent thereto to a position adjacent its distal end or its dilation balloon to facilitate the removal or exchange of the catheter assembly without docking a guidewire extension (Miraki 1:12-19).

. . . Each of the alternative forms of rip seam **42** functions in essentially the same manner allowing the vascular physician to withdraw catheter **10** along guidewire **18** by peeling guidewire **18** through rip seam **42** (Miraki 7:44-48).

Figures 11 and 12 of Miraki depicts an embodiment wherein catheter 10 comprises a rip seam 42A extending longitudinally along a medial section of shaft 22 between side access ports 54 (distal) and 58 (proximal) in combination with a guidewire 18. In the combination shown in Figure 11, guidewire 18 is inserted through proximal side access port 58 into guidewire lumen 40 (not shown) of shaft 22 and exits through the distal tip of the catheter. In the combination shown in Figure 12, guidewire 18 is inserted through Y-connector 12 into guidewire lumen 40 (not shown) at the proximal end of catheter 10, emerges through proximal side access port 58

and reenters the guidewire lumen through distal side access port 54 in a semi-over-the-wire configuration before exiting through the distal tip of the catheter (Miraki 6:12-64; 8:57 - 9:8). Figures 11 and 12 are shown below.



{Figure 11 of Miraki is a partial fragmentary perspective view of an alternative embodiment of an exchangeable dual lumen catheter in combination with a guidewire.}

{Figure 12 of Miraki is a partial fragmentary perspective view of the alternative embodiment of Figure 11 illustrating an alternative, "semi-over-the-wire" guidewire placement.}

According to Miraki, each disclosed embodiment may be formed from surgically acceptable flexible materials (Miraki 9:9-12). Further according to Miraki, the proximal portion of tubular shaft 22 is preferably formed of a relatively high density material to provide added pushability and control in placing the catheter in a vascular pathway (body lumen), while the distal portion the shaft is preferably formed of a relatively low density material to provide enhanced flexibility and maneuverability (Miraki 9:12-21).

2. The Examiner's findings

As to claim 1, the Examiner found

Miraki discloses a rapid exchange catheter (10) comprising a guidewire lumen (40), first and second slits (54, 58 . . .) separated from one another longitudinally (see Figures 11-12) along a portion of the catheter forming a wall portion (area in between 54 and 58 and including the rip seam 42 and the area immediately around the rip seam), wherein this portion is functionally capable of being depressed and moved towards an opposite side of the guidewire lumen to a depressed configuration from a non-depressed configuration (Figures 11-12) (Ans. 3-4).

The Examiner further found "when the depressable portion is in a non-depressed configuration (functional limitation), an outer surface of the portion forms a substantially continuous surface with adjacent portions of the catheter wall (See Figures 11-12)" (Ans. 5). As to claim 12, the Examiner found Miraki is functionally capable of creating a guidewire receiving channel by pushing down on the depressible portion between slits 54 and 58 (Ans. 5). As to claim 20, the Examiner found (Ans. 8-9) that

[w]hen a guidewire is threaded through the distal slit (42) [sic, (54)], there will inherently be pressure put upon the depressable portion (area in between 58 and 54) which will create a channel that will lead to the guidewire lumen. The guidewire will pass from the channel to the guidewire lumen into the body.

3. Appellants' position

Appellants argue "nothing in Miraki suggests that, if the portion of the Miraki device lying between access ports 54 and 58 was depressed, it would assume a 'depressed configuration,' as recited in claim 1. It is at least equally plausible that this portion would spring back to its original state or

that it would rip apart along the rip seam 42" (Reply Br.⁶ 3-4). Appellants further argue that "there is nothing in Miraki to support the Examiner's assertion [that a 'slight depression of the depressable portion (area defined above) would result in the wall of the catheter forming a channel] and it is at least equally likely that the catheter of Miraki would be completely incapable of forming, in a depressed configuration, a guide wire receiving channel, as recited in claim 12" (Reply Br. 5). According to Appellants, "claim 20 is allowable for at least the reasons discussed above with regard to claims 1 and 12" (Reply Br. 6).

4. Analysis

We find the claimed depressible region formed between first and second slits reads on the rip seam area 42A between side access ports 54 (distal) and 58 (proximal) of catheter 10 shown in Miraki Figures 11 and 12. As noted by the Examiner (Ans. 8), Miraki's catheter is preferably made of a flexible material. Furthermore, the distal portion of the Miraki's catheter is preferably more flexible than the proximal end (Miraki 9:12-21). Therefore, we find that depressing a distal portion of rip seam area 42A, e.g., when threading guidewire 18 through distal access port 54 in a semi-over-the-wire configuration as shown in Figure 12 of Miraki, inherently forms the claimed depressible portion as recited in claims 1 and 12. None of the claims require any minimum degree of depression. Further, the guidewire 18 and catheter 10 combination depicted in Figure 12 shows rip seam area 42A in a non-depressed configuration after threading guidewire 18 through distal access port 54. Where, as here, the claimed and prior art products and processes are identical or substantially identical, the burden is on Appellants to prove

⁶ Reply Brief under 37 C.F.R. § 41.41 filed 31 March 2008 ("Reply Br.").

otherwise. *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977); *In re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990); *In re Fitzgerald*, 619 F.2d 67, 70 (CCPA 1980). Appellants' arguments do not persuade us otherwise.

Appellants admit it is plausible that if the portion of the Miraki device lying between access ports 54 and 58 was depressed, the portion would spring back to its original state (Reply Br. 3-4). Indeed, it appears more than plausible based on Miraki. One of ordinary skill in the art would not have reasonably expected the flexible shaft of the catheter, particularly at its distal end, to be so fragile that it would rip apart along the rip seam as a guidewire is being threaded through its guidewire lumen in a semi-over-the-wire configuration. Otherwise the guidewire-catheter combination would rip apart before/during insertion into a body lumen.

Finally, we note that Appellants have not provided additional arguments as to the subject matter of claim 20 other than those set forth for claims 1 and 12.

Therefore, we sustain the rejection of claims 1-21 under § 102(b) over Miraki.

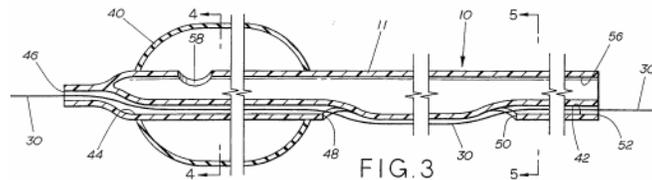
C. Rejection over Teirstein

1. Teirstein

Teirstein discloses a

. . . catheter which has two integral guidewire channels, one near the distal end of the catheter body, and one near the proximal end of the catheter body. Each guidewire channel is a lumen passing longitudinally through the catheter body, sized to allow the free passage of a guidewire. Each guidewire channel has two ports through which the guidewire enters and exits the respective guidewire channel (Teirstein 3:30-37).

Figure 3 of Teirstein depicts an embodiment of catheter 10 having a flexible elongated body 11, a distal end 36 and proximal end 38. Two hollow guidewire channels 42, 44 are formed in body 11 at its proximal and distal ends, respectively. Distal guidewire channel 44 has a distal guidewire entry port 46 and a first guidewire exit port 48 at its proximal end. Proximal guidewire channel 42 has a guidewire reentry port 50 at its distal end and a second guidewire exit port 52 at its proximal end. Guidewire 30 exits port 48 of distal guidewire channel 44, passes alongside catheter body 11, re-enters at re-entry port 50 of proximal guidewire channel 42, then finally exits catheter body 11 at exit port 52 (Teirstein 5:47- 6:1). Figure 3 is shown below.



{Figure 3 of Teirstein is a longitudinal view of an embodiment of a catheter having two integral guidewire channels, one near the distal end of the catheter body, and one near the proximal end of the catheter body.}

2. The Examiner's findings

As to claim 1, the Examiner found

Teirstein discloses a rapid exchange catheter (10) comprising a guidewire lumen (42,44), first and second slits (48,50 . . .) separated from one another longitudinally (see at least Figures 2-3) along a portion of the catheter forming a wall portion (area between 48 and 50), wherein this portion is functionally capable of being depressed and moved towards an opposite side of the guidewire lumen to a depressed configuration from a non-depressed configuration (Ans. 5).

In other words, according to the Examiner, the depressible portion of a catheter wall recited in claim 1 reads on the portion of Teirstein's flexible elongated catheter body between ports 48 and 50 (Ans. 9). The Examiner maintains claim 1 "only requires that the catheter includes a guidewire lumen (Teirstein discloses 42 and 44 as guidewire lumen) and that the depressible portion is capable of being moved radially inward *toward* an inner surface of an opposite side of the guidewire lumen" (Ans. 9-10, original emphasis). In other words, according to the Examiner, depressing the portion of Teirstein's catheter between ports 48 and 50 moves the portion inward into alignment with the inner surfaces of guidewire lumens 42 and 44. As to claim 12, the Examiner found that "a slight depression" of the portion of Teirstein's catheter between ports 48 and 50 "would result in the wall of the catheter forming a channel" (Ans. 10). As to claim 20, the Examiner found

[w]hen a guidewire is threaded through the distal slit (48) (see Figure 3), there will inherently be pressure put upon the depressable portion (area in between 48 and 50) which will create a channel that will lead to the guidewire lumen. The guidewire will pass from the channel to the guidewire lumen and into the body (Ans. 10).

3. Appellants' position

Appellants argue "[o]ne skilled in the art would not determine that a catheter is depressible based only on the recitation that the catheter is longitudinally flexible" (Reply Br. 8). Appellants further argue recitation of a depressible portion movable to a depressed configuration "in which an inner surface of the depressible portion is moved radially inward toward an inner surface of an opposite side of the guide wire lumen" in claim 1

explicitly requires the guide wire lumen to be located under the depressible portion of the catheter (App. Br. 8; Reply Br. 8). As to claim 12, Appellants point out the depressible portion of the catheter, "when in a depressed configuration, forms a guide wire receiving channel with an opening from the guide wire receiving channel to the guide wire lumen at a first end thereof" (App. Br. 8-9; Reply Br. 9). According to Appellants, "claim 20 is allowable for at least the reasons discussed above with regard to claim 1" (App. Br. 9; Reply Br. 10).

4. Analysis

"During patent examination the pending claims must be interpreted as broadly as their terms reasonably allow." *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). Here, the broadest reasonable interpretation of "a depressable portion of a wall of a catheter" comprising a guide wire lumen wherein "the depressable portion being movable between a depressed configuration in which an inner surface of the depressable portion is moved radially inward toward an inner surface of an opposite side of the guide wire lumen" does not require the depressable portion of the catheter wall and the guide wire lumen to be integrated, opposing structures. Therefore, we agree with the Examiner that the depressible portion of claim 1 reads on a depressible portion of the Teirstein's catheter between ports 48 and 50 because this portion of Teirstein's catheter reasonably appears capable of being depressed along a radius, e.g., parallel to line 5-5 in Figure 3, inwardly toward an opposite side of guidewire lumen 42 or 44. In addition, the argument that a skilled artisan would not determine that catheter is depressible based solely on its longitudinal flexibility is conclusory and,

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therefore, entitled to little, if any, weight. *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

Similarly, the depressible portion of Teirstein's catheter between ports 48 and 50 reasonably appears capable of being depressed to form a guidewire receiving channel with an opening to the guidewire lumen (42 or 44) at a first end thereof, i.e., at ports 48 or 50.

Finally, we note that Appellants have not argued the patentability of claim 20 any differently from that of claims 1 and 12.

Therefore, we sustain the rejection of claims 1-21 under § 102(b)

III. Order

Upon consideration of the record, and for the reasons given, it is ORDERED that the decision of the Examiner rejecting claims 1-21 as unpatentable under 35 U.S.C. § 102(b) over Miraki is AFFIRMED;

FURTHER ORDERED that the decision of the Examiner rejecting claims 1-21 as unpatentable under 35 U.S.C. § 102(b) over Teirstein is AFFIRMED; and

FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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