UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MICHAEL P. BOUTILETTE, JAMES E. WINDHEUSER, and OSCAR CARRILLO

Appeal 2007-0845
Application 10/268,135
Technology Center 3700

Decided: May 14, 2007

Before ERIC GRIMES, NANCY J. LINCK, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a rapid exchange catheter. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

Treatment of disorders involving the biliary, hepatic, and pancreatic ducts can be aided by directly visualizing the treated area with an

endoscope (Specification 1). "[T]he duct itself must be navigated using a catheter" (*id.*).

Once the endoscope reveals an area requiring treatment, "a different catheter is typically required, necessitating a catheter exchange. A catheter exchange typically involves removing the first catheter from the endoscope, over the guide wire, and advancing a second catheter over the guide wire to the desired treatment site" (*id.*). In addition, guide wires may need to be exchanged, "for example, when a first guide wire is too large to fit through a desired body duct, or otherwise lacks the characteristics desired for a particular application" (*id.* at 2).

"To maintain the position of the guide wire and/or catheter, a physician typically must grasp the proximal end of the guide wire and/or catheter with one hand and perform the corresponding exchange with the other. This is difficult, and often results in movement of the guide wire and/or catheter" (*id.*). "If the guide wire moves during such a procedure, the guide wire may need to be re-directed through the body ducts to the target site, which is often a difficult and time consuming task" (*id. at 1*).

The Specification discloses a rapid exchange catheter having a guide wire lumen with a channel that opens to the outside of the catheter (*id.*). The catheter has a guide wire ramp that extends into the guide wire lumen channel (*id.* at 2-3). In application, the guide wire ramp deflects the guide wire out of the catheter, allowing the physician to "at all times maintain his grasp on an exposed portion of the guide wire 36 to maintain it in position without the need for guide wire extenders" (*id.* at 8).

DISCUSSION

1. CLAIMS

Claims 1-6, 8-12, and 20 are on appeal. Claims 13-19 are also pending but have been withdrawn from consideration by the Examiner.

Claim 1 is representative and reads as follows:

> 1. A rapid exchange catheter comprising:
>
> a guide wire lumen extending through the catheter, a channel portion of the guide wire lumen including a channel opening the channel portion to an outside thereof, wherein a width of the channel is less than a maximum width of the channel portion; and
>
> a guide wire ramp formed of a portion of a wall of the catheter separated from an adjacent portion of the catheter wall by a slit extending proximally from an edge of the channel to create a substantially angled tip at a point at which the slit meets the channel and wherein the angled tip extends into the channel to permit a guide wire to pass therethrough in a first direction and to force out of the channel a guide wire traveling through the channel portion in a second direction opposite the first direction.

Thus, claim 1 is directed to a catheter having a guide wire lumen extending through it. The guide wire lumen includes a channel that has an opening to the outside of the catheter.

The catheter also has a guide wire ramp formed from a portion of a wall of the catheter. The ramp is formed by a slit extending proximally from an edge of the channel. The slit creates a substantially angled tip where the slit meets the channel. The angled tip extends into the channel in a manner that permits a guide wire to pass into the channel through the ramp when

traveling in one direction, but forces a guide wire traveling in the opposite direction out of the channel.

2. REFERENCES

The Examiner relies on the following reference as evidence of unpatentability:

Jang	US 5,554,118	Sep. 10, 1996

3. ANTICIPATION

Claims 1-6, 8-12, and 20 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Jang (Answer 3). The Examiner finds that Figures 3, 5, 6, 14, 15 and 17-20 disclose all of the structural elements of claim 1 (Final Rejection 3).

Appellants concede that "[t]he side port 34, shown in Fig. 5 of Jang, seems to include an angled structure extending part-way into the lumen 20" (Br. 5).[1] Appellants argue, however, that

> Jang includes no description of the angled structure and clearly includes no description of a slit as separating this structure "from an adjacent portion of the catheter wall" as claimed - i.e., a slit extending proximally from an edge of the channel to create a substantially angled tip at a point at which the slit meets the channel.

(*Id*.)

Appellants urge that Jang does not describe the angled structure as being connected to the wall 30, and that "even assuming the angled structure is part of the wall 30, the cross-sectional figures in Jang provide no indication that it includes an angled tip and there is no description of such a tip" (Br. 6). Appellants further urge that Figures 3 and 6 "are inconsistent

[1] Appeal Brief filed July 5, 2006.

with one another, it is unclear whether the angled structure is bent as shown in Fig. 3 only when stressed (e.g., by a guide wire inserted through the side port 34)" (*id.*).

The Examiner urges that it is clear from viewing Figure 5 that "Jang does disclose these limitations. Jang teaches a catheter (10) having a slit (34) extending from an edge of channel (20), creating an angled tip (as seen by the bent in portion of the catheter at slit 34) formed of the catheter wall" (Answer 4). As to whether the angled portion of the catheter is bent only when stressed, the Examiner points out that "Applicant does not positively recite that the angled structure of the Applicant's invention is permanently angled" (*id.*).

Appellants respond that, in Figure 3, "[t]he side port 34 does not contact either the proximal opening 32 or the distal end 16 (i.e., the edges of the guidewire lumen 20), and thus never extends proximally from an edge of the guidewire lumen 20" (Reply Br. 3). Thus, Appellants argue,

> using the Examiner's definitions, Jang neither discloses nor suggests "a guide wire ramp formed of a portion of a wall of the catheter separated from an adjacent portion of the catheter wall by *a slit extending proximally from an edge of the channel* to create a substantially angled tip at a point at which the slit meets the channel," as recited in claim 1.

(*Id.*)

"Description for the purposes of anticipation can be by drawings alone as well as by words." *In re Mraz*, 455 F.2d 1069, 1072, 173 USPQ 25, 27 (CCPA 1972) (quoting *In re Bager*, 47 F.2d 951, 953, 8 USPQ 484, 486 (CCPA 1931)). Thus, "the teachings of patent drawings, even as to features unexplained by the specification," may be used to demonstrate the presence

of claimed elements in the prior art. *Mraz*, 455 F.2d at 1072, 173 USPQ at 27.

Moreover, it is well settled that "claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Sneed*, 710 F.2d 1544, 1548, 218 USPQ 385, 388 (Fed. Cir. 1983) (citation omitted).

We agree with the Examiner that Jang describes a catheter having a slit extending proximally from an edge of a guide wire lumen channel, creating a substantially angled tip where the slit meets the channel.

Figures 3, 5, 6, 14, and 15 of Jang disclose a catheter having an elongated aperture 34 that opens the catheter's guide wire lumen to the exterior. Figures 17 through 20 designate the aperture as item 234. In our view, one of ordinary skill in the art would reasonably interpret the term "slit" to encompass the elongated aperture.

In Figure 3, for example, the elongated aperture extends from a distal end terminating at the guide wire lumen wall, to a proximal end that terminates at the angled structure that extends into the aperture. Thus, the aperture, or slit, extends proximally from an edge of the guide wire lumen channel, as required by claim 1.

Figure 3 shows that the angled portion of the catheter in the aperture 34 is part of the same structure as the guide wire lumen wall 30, and is therefore contiguous with the lumen wall. The angled portion of the wall is depicted as having a tip.

Thus, we agree with the Examiner that Jang's catheter meets claim 1's requirement of a guide wire ramp formed of a portion of the catheter wall separated from another portion of the catheter wall by a slit extending proximally to create a substantially angled tip.

We also agree with the Examiner that claim 1 does not require the angled portion of the guide wire ramp to be permanently angled. Moreover, by describing a guide wire exchange procedure that "deflects the ramp 62 radially outward to allow the guide wire 36 to pass thereunder" (Specification 9), Appellants' Specification clearly contemplates embodiments in which the guide wire ramp is not permanently angled.

Appellants argue that "in each drawing showing the angled structure, a gap is left between the angled structure and an inner surface of the wall 30" (Br. 6). Thus, Appellants argue, the conclusion that Jang's angled structure

> forms a ramp forcing a guidewire 50 out of the lumen 20 is speculative. . . . [A]lthough Jang includes no description of what happens as a proximal end of a guidewire moves proximally within the lumen 20 past the side port 34 (i.e., if the catheter of Jang were loaded distal end first as is generally done) it appears likely that the guide wire would continue through the lumen 20 past this angled structure into the proximal portion of the lumen 20. Nothing in Jang contradicts this reading and it is respectfully submitted that only speculation suggests any other reading.

(*Id.*)

The Examiner points (Answer 4) to Jang's disclosure that

> [t]he side port 234 . . . is adapted to permit insertion or removal of a guidewire therethrough. Preferably, the side port 234 is configured such that a guidewire passing through the side port 234 may easily extend distally through the guidewire lumen

> 220, *but is adapted to discourage a guidewire passing through the side port 234 from extending proximally through the guidewire lumen 220 from the side port 234.*

(Jang, col. 14, l. 66, to col. 15, l. 7, emphasis added.)

Appellants argue that this passage demonstrates only that "the side port 234 is configured to prevent, during insertion of a guidewire into the guidewire lumen 220, a distal tip of the guidewire from being routed proximally through the guidewire lumen 220" (Reply Br. 3).

We do not find Appellants' argument persuasive. In our view, claim 1 is broad enough to encompass the side port described by Jang. Claim 1 requires the ramp "to permit a guide wire to pass therethrough in a first direction and to force out of the channel a guide wire traveling through the channel portion in a second direction opposite the first direction." As pointed out by the Examiner, Jang explicitly states that the side port 234 "is adapted to discourage a guidewire passing through the side port . . . from extending proximally through the guidewire lumen . . . from the side port" (Jang, col. 15, ll. 4-7).

Thus, Jang's side port 234 is configured such that a guide wire inserted into the port may pass into the guide wire lumen in a distal direction, but cannot move into the lumen in the opposite, proximal direction. Because Jang's side port discourages passage of a guide wire in a proximal direction, Jang's side port in effect forces the guide wire out of the guide wire lumen channel, which is all that claim 1 requires. Because Jang describes this configuration of the side port explicitly (Jang col. 14, l. 66, through col. 15, l. 8), we do not agree with Appellants that this conclusion is speculative.

We note that Jang's drawings depict a gap between the angled structure and an inner surface of the wall 30. However, "it is well established that patent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue." *Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc.*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000); *In re Wright*, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977) ("Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.").

Appellants do not point to, and we do not see, any portion of Jang describing precise proportions of the aperture and angled section of the catheter, such that one of ordinary skill would conclude that the gap depicted in the drawings would permit passage of a guide wire in both directions along the guide wire lumen. Rather, as discussed *supra*, Jang explicitly states that the side port is configured to permit passage of a guide wire in a distal direction from the side port 234, but not a proximal direction.

We also note that several of Jang's drawings, for example Figure 3, depict a guide wire passing underneath the angled tip structure. However, as discussed *supra,* the instant Specification discloses a guide wire exchange procedure that "deflects the ramp 62 radially outward *to allow the guide wire 36 to pass thereunder*" (Specification 9) (emphasis added).

Thus, the fact that a guide wire may pass underneath Jang's ramp when deployed in a distal direction does not necessarily mean that the ramp will fail to force a guide wire out of the guide wire lumen when the wire is passed in a proximal direction. This conclusion is consistent with Jang's

explicit disclosure, discussed *supra*, that the side port containing the angled portion of the lumen wall is configured to discourage passage of a guide wire into the guide wire lumen in a proximal direction.

Because Jang describes a catheter meeting all of the limitations in claim 1, we affirm the anticipation rejection of claim 1.

Appellants base their arguments regarding the patentability of claims 2-6 and 8-10 on the limitations of claim 1 (Br. 7). Claims 2-6 and 8-10 therefore fall with claim 1.

Appellants argue that claim 11

> recites limitations substantially similar to those of claim 1, including "a guide wire ramp formed of a portion of a wall of the catheter separated from an adjacent portion of the catheter wall by a slit extending proximally from an edge of the channel to create a substantially angled tip at a point at which the slit meets the channel, wherein the angled tip extends into the channel portion."

(Br. 7.)

Appellants urge that, therefore, "claim 11 is allowable for at least the reasons stated above with reference to claim 1" (*id.*). Appellants further urge that "[b]ecause claim 12 depends from, and, therefore includes all of the limitations of claim 11, . . . this claim is also allowable" (*id.*).

Similar to their arguments regarding claim 11, Appellants urge that claim 20 recites a guide wire ramp substantially similar to that recited in claim 1, and that therefore "claim 20 is allowable for at least the reasons stated above with reference to claim 1" (Br. 7-8).

We are not persuaded by these arguments. As discussed *supra*, we agree with the Examiner that Jang describes a catheter having a guide wire ramp meeting the limitations of claim 1. Jang therefore also describes a

catheter having a guide wire ramp structure meeting the limitations in claims 11 and 20.

Thus, we affirm the anticipation rejection of claims 11 and 20 over Jang. Because Appellants' arguments regarding claim 12 are based on the limitations of claim 11, claim 12 falls with claim 11.

SUMMARY

We affirm the Examiner's rejection of claims 1-6, 8-12, and 20 under 35 U.S.C. § 102(b) as being anticipated by Jang.

AFFIRMED

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PATRICK J. FAY, ESQ.
FAY KAPLUN & MARCIN, LLP
SUITE 702
150 BROADWAY
NEW YORK NY 10038