

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte

HENRY J. PEPIN, MARTIN R. WILLARD, PU ZHOU,
and GREG KAMPA

Appeal 2008-4210
Application 10/146,980
Technology Center 3700

Decided: October 10, 2008

Before DEMETRA J. MILLS, ERIC GRIMES, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an intravascular catheter, which the Examiner has rejected on grounds of obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

Background

“Diagnostic catheters and guide catheters are commonly used to facilitate the diagnosis and treatment of vascular diseases such as coronary artery disease and peripheral vascular disease” (Spec. 1). The Specification notes that “[s]uch catheters commonly include a braid reinforcement layer disposed between an inner layer and an outer layer. The braid reinforcement provides torsional rigidity, column strength, kink resistance, as well as radiopacity” (*id.*). According to the Specification, “conventional braid reinforcement materials such as stainless steel are not MRI (magnetic resonance imaging) compatible due to ferro-magnetic properties” (*id.*).

Statement of the Case

The Claims

Claims 1-4 and 8-32 are on appeal. We will focus on claims 1 and 14 which are representative and read as follows:

1. An intravascular catheter comprising an elongate shaft that is entirely non-magnetically responsive and at least partially radiopaque, the elongate shaft including a reinforcement layer comprising non-magnetically responsive radiopaque metal wires;

wherein the elongate shaft includes an inner layer and an outer layer with the reinforcement layer disposed therebetween, the inner layer comprising a lubricious polymer; and

wherein the reinforcement layer comprises a wire braid and extends from near a distal tip of the shaft to a proximal portion of the shaft.

14. An intravascular catheter comprising an elongate shaft that is entirely non-magnetically responsive and at least partially radiopaque, the elongate shaft including a

reinforcement layer consisting of a non-magnetically responsive radiopaque metal, the reinforcement layer extending from near a distal tip of the shaft to a proximal portion of the shaft.

The Issues

The Examiner relies upon the following prior art references to show unpatentability:

Nita et al.	US 5,951,539	Sep. 14, 1999
Gillies et al.	US 6,272,370 B1	Aug. 7, 2001
Pacetti et al.	US 2003/0135114 A1	Jul. 17, 2003

- The rejections as presented by the Examiner are as follows:
- A. Claims 1 and 14-32 stand rejected under 35 U.S.C. § 103(a), as being obvious over Gillies and Nita (Ans. 3).
 - B. Claims 2-4 and 8-13 stand rejected under 35 U.S.C. § 103(a), as being obvious over Gillies, Nita, and Pacetti (Ans. 4).

A. 35 U.S.C. § 103(a) rejection over Gillies and Nita

The Examiner argues that “within the broadest reasonable interpretation, Gillies et al. disclose a tri-coaxial cable within an elongate shaft consisting of wires and two concentric shielding materials and an inner layer (col. 22 lines 12-65)” (Ans. 6). The Examiner further “construes the aforementioned configuration to be equivalent to a reinforcement structure” (*id.*).

Appellants argue that “the reinforcement layer is a layer of the shaft. Gillies fails to disclose such a reinforcement layer in a shaft of an intravascular catheter” (App. Br. 7). Appellants further contend that “the

shielding member of Gillies is disclosed as a structure that should introduce minimal effect on the flexibility of the catheter shaft” (*id.* at 8).

Appellants argue that “Nita fails to disclose those elements of claims 1, 14, 15 and 16 that are missing from Gillies” (*id.*).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Would an intravascular catheter with a reinforcement layer comprising a wire braid, positioned between an inner, lubricious layer and an outer layer, and extending from the distal tip to the proximal portion of the shaft have been obvious from the combination of Gillies and Nita?

Findings of Fact (FF)

1. Gillies teaches that the “microcatheter **1** can also be made from any of the well-known soft, biocompatible plastics used in catheter fabrication such as Percuflex” (Gillies, col. 25, ll. 44-46).

2. Gillies teaches that “[g]uidewires are usually made of radio-opaque material so that their precise location can be identified during a surgical procedure” (Gillies, col. 22, ll. 12-14).

3. Gillies teaches that the “catheter **1** which might be used for retroperf[u]sion has a magnetic tip which allows it to be steered during nonlinear magnetic stereotaxis procedures” (Gillies, col. 25, ll. 36-39).

4. Gillies teaches that a “tri-coaxial cable (a cable with a center line conductor surrounded by two concentric layers of shielding material)” or a “shielded twisted wire cable (a cable with two twisted wires at the center surrounded by a concentric layer of shielding material)” can be

integrated into the catheter as a transmission module (Gillies, col. 27, ll. 29-50).

5. Gillies teaches that “the presence of conductive elements in the catheter also introduces increased electronic noise and the possibility of Ohmic heating, and these factors have the overall effect of degrading the quality of the MR image and raising concerns about patient safety” (Gillies, col. 22, ll. 42-46).

6. The Examiner concedes that “Gillies et al do not explicitly disclose a tungsten braid” (Ans. 3).

7. Figure 2 of the Specification is reproduced below:

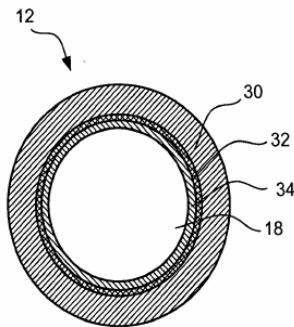


FIG. 2

“Figure 2 is a cross-sectional view taken along line 2-2 in Figure 1” where “Figure 1 is a plan view of an intravascular catheter” (Spec. 2:13-15).

8. The Specification teaches that “the elongate shaft 12 may be multi-layered. In this embodiment, the elongate shaft 12 may include an outer layer 30, a reinforcement layer 32, and an inner layer 34” (Spec. 4:10-12).

9. Nita teaches that “two or more spirally wound reinforcement ribbons or wires, preferably stainless steel, [are] typically placed between an

outer polymeric covering and an inner lubricious polymeric liner” (Nita, col. 7, ll. 42-45).

10. Nita teaches that “[d]esirable, because of cost, strength, and ready availability are stainless steels . . . and tungsten alloys” (Nita, col. 11, ll. 46-48).

11. Nita teaches that “each of the polymers discussed herein may be used in conjunction with radiopaque material or fillers” (Nita, col. 13, ll. 49-50).

12. Nita does not expressly teach the use of non-magnetically responsive radiopaque metal wires (*see* Nita, col. 11).

13. The word “layer” is defined as “[a] single thickness, coating or stratum spread out or covering a surface.”¹

A. Discussion of the 35 U.S.C. § 103(a) rejection over Gillies and Nita

We interpret the claims using the broadest reasonable interpretation. *See, e.g., In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (“[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.”). In *Trans Texas Holdings*, the Federal Circuit provided a clear description of how to construe claims, noting:

In *Phillips*, we held that while “the specification [should be used] to interpret the meaning of a claim,” courts must not “import[] limitations from the specification into the claim.” *Id.* at 1323. We specifically noted that it is improper to “confin[e] the claims to th[e] embodiments” found in the specification, as Trans Texas asks us to do.

¹ Webster’s II New College Dictionary 623 (1995).

In re Trans Texas Holdings Corp., 498 F.3d 1290, 1299 (Fed. Cir. 2007) (quoting *Phillips v. AWH Corp.* 415 F.3d 1303, 1323 (Fed. Cir. 2005)).

In the instant context, the analysis begins with the interpretation of the phrase “reinforcement layer” in claim 1, and particularly the word “layer”. While the Examiner correctly finds that Gillies teaches an intravascular catheter with an elongate shaft that is radiopaque, with inner and outer layers (FF 1-3), we find that several modes of claim interpretation militate against the interpretation of “reinforcement layer” as encompassing the transmission module of Gillies (FF 4-5).

First, construing the claim phrase “layer” in light of the Specification, we find that Appellants’ Specification repeatedly identifies the claimed “reinforcement layer” as providing rigidity and surrounding the inner layer (FF 7, 8). Appellants’ Specification never suggests that a reinforcement layer can be a guidewire that does not surround the inner layer (FF 7).

Second, the Federal Circuit noted that “[u]nder *Phillips*, dictionary definitions are also pertinent. *See id.* at 1318 (‘[T]he court has observed that dictionaries … can be useful in claim construction.’).” *Trans Texas* at 1299. Here, the dictionary definitions of “layer” is “[a] single thickness, coating or stratum spread out or covering a surface” (FF 13). This definition would not reasonably include a “transmission module” as a layer, as argued by the Examiner (Ans. 6). The Examiner acknowledges that Gillies does not teach a tungsten braid (FF 6).

In our opinion, the proper interpretation of “layer” requires reading the term in light of the specification and in the context of its ordinary dictionary usage. We agree with Appellants that “the shielding layers

around the cable of Gillies cannot be considered a layer of the shaft. Therefore, Gillies does not disclose a reinforcement layer of a shaft of an intravascular catheter" (App. Br. 8). We therefore find that Gillies does not teach a "reinforcement layer" as required by claims 1 and 14, and the Examiner does not point to any disclosure in Nita to make up for this deficiency.

We reverse the rejection of claims 1 and 14-32 as obvious over Gillies and Nita.

B. 35 U.S.C. § 103(a) rejection over Gillies, Nita, and Pacetti

The Examiner contends that

Parcetti [sic] et al teach that an intravascular catheter consisting a tip portion where the tip has a magnetic susceptibility less than 1×10^{-4} and 1×10^{-5} (paragraph 0013). Therefore it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Nita et al's reinforced wire at the tip of Gillies et al's catheter and Parcetti [sic] et al's teaching of magnetic susceptibility limits for the intravascular catheter as shown in Gillies et al's device described above.

(Ans. 5.) The Examiner further argues that it "would have been obvious to one of ordinary skill in the art to have incorporated the aforementioned susceptibility limits in order for the magnetic tip to respond to the induced magnetic field, and which would not function otherwise" (*id.* at 6).

Appellants contend that "Pacetti does not disclose the elements of claim 2 that are missing from Gillies and Nita." (App. Br. 13).

In view of these conflicting positions, we frame the obviousness issue before us as follows:

Would an intravascular catheter with a non-magnetically responsive and radiopaque reinforcement layer that has a magnetic susceptibility less than 1×10^{-4} have been obvious from the combination of Gillies, Nita, and Pacetti?

Findings of Fact

14. Pacetti teaches a “guide wire which is safe, compatible and readily visible with MRI” (Pacetti 2, ¶ 0008).

15. Pacetti teaches that “the distal core section 12 is made of a metal or alloy material which has a volumetric magnetic susceptibility of less than about 280×10^{-6} ” (Pacetti 4, ¶ 0043).

B. Discussion of the 35 U.S.C. § 103(a) rejection over Gillies, Nita, and Pacetti

We find that while Pacetti discusses the use of guide wires in MRI (FF 14) as well as magnetic susceptibilities close to the claimed values (FF 15), Pacetti does not resolve the central element absent from the Gillies and Nita references, which is a reinforcement layer comprising a wire braid, positioned between an inner, lubricious layer and an outer layer. Pacetti simply teaches a guide wire that is compatible with MRI, but does not suggest any reinforced layer, much less a reinforcement layer comprising a wire braid, positioned between an inner, lubricious layer and an outer layer. We do not think it is sufficient to contend, without any evidence in the cited prior art of Gillies, Nita or Pacetti, that this limitation would have been obvious. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational

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underpinning to support the legal conclusion of obviousness"). Here, no such reasoning is present.

We reverse the rejection of claims 2-4 and 8-13 as obvious over Gillies, Nita, and Pacetti.

CONCLUSION

In summary, we reverse the rejections of claims 1-4 and 8-32 under 35 U.S.C. § 103(a).

REVERSED

cdc

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