

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALEXEI MARKO,
IAN MCDougall, DOUGLASS YACKEL,
and MONTY BRUCE

Appeal 2007-3765
Application 10/160,826
Technology Center 3700

DECIDED: February 7, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS, and ERIC GRIMES,
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 8-14, 17, and 18.¹ The claims stand rejected as obvious over the prior art. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

¹ Claim 19 is also pending, but has been withdrawn from consideration. Claims 1-7, 15, and 16 have been canceled.

BACKGROUND

“Medical treatments involving ablation of the endometrium of the uterus are well known in the prior art. . . . Such ablation treatments typically involve either the direct or indirect application of heat or cold to the endometrial tissue . . . [thereby] cauterizing, or inducing necrosis of the endometrial lining” (Spec. 1: 11-18).

The Specification describes a thermal ablation apparatus “for causing necrosis of a body cavity or duct, specifically the uterus” (Spec. 6: 9-10).

The apparatus comprises:

- “a disposable portion of the apparatus comprising a sealed system consisting of a liquid within said sealed system, an elongated distal section with a flexible balloon (or bladder) attached to it, a proximal flexible balloon (or bladder), and a means for connection to a permanent non-disposable apparatus” (Spec. 6: 12-16);
- “a means for heating said liquid” (Spec. 6: 17); and
- “a permanent non-disposable apparatus comprising, a pneumatic pressurizing means for initiating flow of the liquid within said sealed system of the disposable portion of the apparatus, connection means for said disposable portion to permanent portion, and a controlling means for heating, pneumatic pressure, and time” (Spec. 6: 18-22).

According to the Specification, the apparatus “provide[s] a means of ensuring uniform treatment of the uterine cavity . . . by injecting a pre-heated, isothermal volume of liquid into the distal flexible bladder within [the] uterine cavity . . . [such that] at the time of injection into the uterus, all areas of the uterus are contacted with a uniform high temperature” (Spec. 7: 8-13).

Figure 2 of the present Specification is reproduced below:

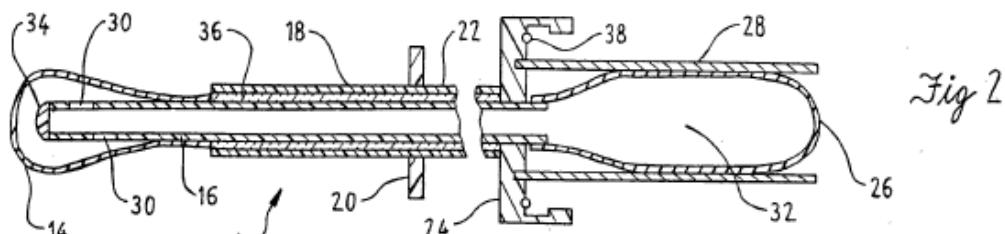


Figure 2 shows a cross sectional view of an embodiment of the portion of the apparatus comprising the sealed system. “Distal balloon 14 is bonded in a liquid tight manner to the distal end of catheter 16 . . . The distal end of catheter 16 further includes a plurality of liquid ports 30 located such that they are contained within distal balloon 14. . . . The proximal end of catheter 16 is bonded in a liquid tight manner to the proximal balloon such that a liquid tight system exists comprising distal balloon 14, catheter 16 and proximal balloon 26” (Spec. 10: 23 to 11: 1). Catheter 16 is “semi-rigid or rigid” (Spec. 10: 11). “The liquid tight system . . . is filled with liquid such that there exists only liquid 32 within the system and no significant volume of gas at room temperature and ambient pressure” (Spec. 11: 3-6).

DISCUSSION

The claims on appeal are directed to that portion of Appellants' apparatus comprising the sealed system, essentially a single-lumen catheter connecting two balloons, or bladders, in a liquid-tight manner.

Claims 8 and 12 are representative:

8. A device for facilitating necrosis of tissue comprising:
 - a distal flexible bladder;
 - a proximal flexible bladder;
 - a single lumen catheter joining said distal and proximal flexible bladders in a liquid-tight system,
 - a liquid sealed inside the system to flow between the two bladders; wherein the liquid volume is established to permit the distal bladder to substantially deflate when the liquid is moved out of the distal end; and
 - wherein the catheter has two opposing ends, one end opening into the proximal bladder and the other end opening into the distal bladder, the catheter extending continuously and normally open between its ends to define an unchangeable volume for the system liquid.
12. The device of claim 8 wherein the liquid is of a type wherein the liquid viscosity substantially decreases when heated.

The claims stand rejected as follows:

1. Claims 8-11, 14, 17, and 18 under 35 U.S.C. § 103(a) as unpatentable over Neuwirth² and Horzewski.³
2. Claims 12 and 13 under 35 U.S.C. § 103(a) as unpatentable over Neuwirth, Horzewski, and Smith.⁴

² International Patent Application WO 94/10948 of Neuwirth et al., published May 26, 1994.

³ U.S. Patent 5,470,322 to Horzewski et al., issued November 28, 1995.

⁴ U.S. Patent 5,133,708 to Smith, issued July 28, 1992.

Both of the Examiner's rejections are premised on a proposed combination of Neuwirth and Horzewski, so we will address the rejections together.

Neuwirth describes a dual lumen thermal ablation apparatus "wherein fluid is neither introduced nor withdrawn from the interior of the apparatus" (Neuwirth 16: 4-6). Neuwirth's Figure 5 is reproduced below:

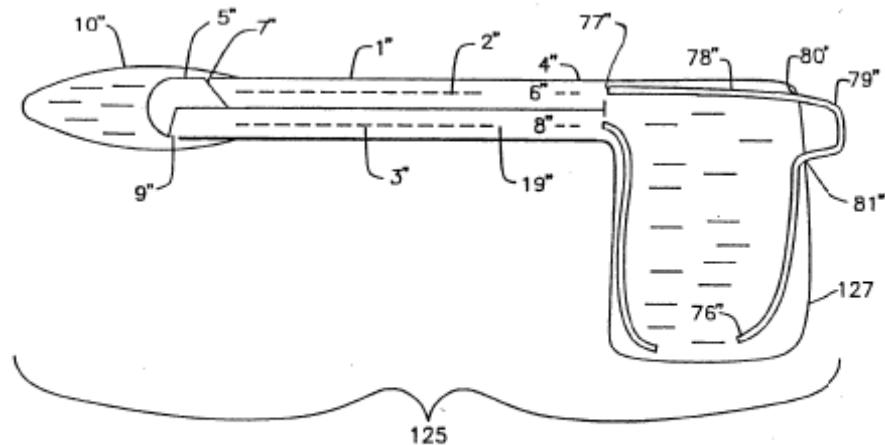


FIG. 5

Figure 5 shows a dual lumen 2", 3" "closed fluid apparatus 125 which is provided with a flexible fluid conduit 78" having an inlet port 76" and an outlet port 77". Inlet ports 76" and 77" are in fluid communication with the interior of distendable reservoir 127. A portion of fluid conduit 78" extends outside distendable reservoir 127 to form an external loop 79". The external surface of fluid conduit 78" forms a fluid tight seal at its points of exit 80" and 81" from [the] distendable reservoir" (Neuwirth 16: 12-20).

In use, the closed fluid apparatus is inserted into a housing, as shown in Neuwirth's Figure 7, reproduced below:

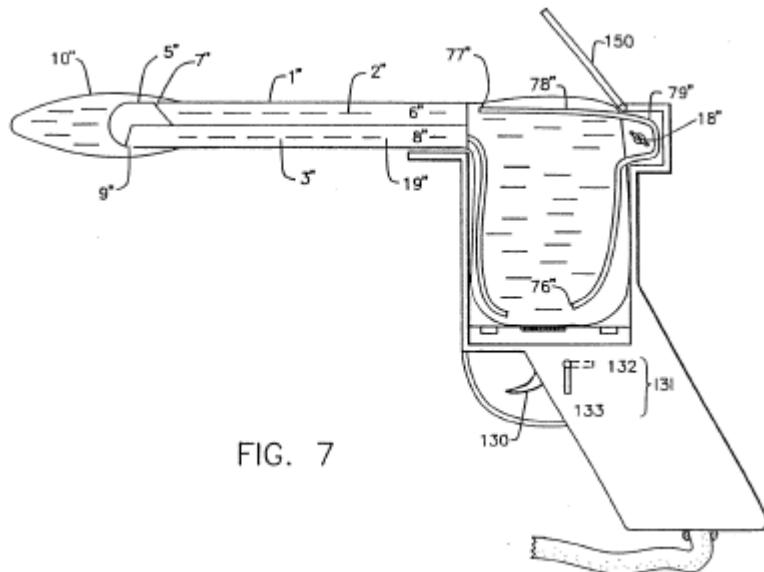


Figure 7 shows the closed fluid apparatus of Figure 5 inserted into a housing such that "peristaltic pump means 18" communicates with and impinges upon the outer surface of external fluid loop 79" so as to pump the fluid 19" in and out of [the] external fluid loop" (Neuwirth 16: 23-27), causing heated fluid from reservoir 127 to circulate through the closed system through lumen 2", into distendable bladder 10", and back to reservoir 127 through lumen 3".

There is no dispute that Neuwirth teaches all of the components of claim 8, except that Neuwirth "fails to disclose the claimed [] single-lumen catheter" (Br. 10), and instead, "requires at least a pair of lumens" (*id.*).

The Examiner cites Horzewski as teaching that "single-lumen catheters are more advantageous to use than multi-lumen catheters since the

[latter] are of larger diameter and require more space for the lumens" (Ans. 4). The Examiner argues that "it would have been obvious to one of ordinary skill in the art . . . to incorporate a single-lumen catheter in the Neuwirth . . . device to reduce the profile of the catheter and thus make it easier to manipulate within the body" (Ans. 4).

In our opinion, the Examiner has not established that one of ordinary skill in the art would have had a reason to combine the references relied on in the manner claimed. Unlike Neuwirth's catheter, Horzewski's catheter is intended for insertion "through bodily lumens such as blood vessels, nasal passages, urethral passages and the like" (Horzewski, col. 1, ll. 10-12), i.e., "long bodily passages which terminate in convoluted, closely bent or curved, or intricately branched regions prior to or at the site of the region where the presence of the functional tip of the catheter is required" (Horzewski, col. 1, ll. 44-48). Horzewski's disclosure is primarily directed to multi-lumen catheters capable of negotiating such passages. The mere fact that Horzewski mentions in passing that multi-lumen catheters are more problematic than single-lumen catheters under such conditions is not enough to suggest the conversion of Neuwirth's dual-lumen catheter to a single-lumen catheter, given the fact that Neuwirth's device and objectives are so dissimilar to Horzewski's.

Moreover, we agree with Appellants that the proposed modification of Neuwirth would not have been obvious to one skilled in the art because "[t]he proposed elimination of the dual-lumen catheter of Neuwirth in favor of a single-lumen catheter would require a substantial reconstruction and redesign of the elements shown in Neuwirth as well as a change in the basic

principle (fluid pumped into and out of the remote, inflated bladder 10) under which the Neuwirth construction was designed to operate” (Br. 12).

Smith was cited by the Examiner as evidence that that “it is old and well known in the art to use glycerin as an ablation fluid” (Ans. 4), but the reference does nothing to cure the underlying deficiency in the proposed modification of Neuwirth.

Accordingly, both rejections of the claims under 35 U.S.C. § 103(a) are reversed.

REVERSED

Ssc:

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