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EXAMINER
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BETSY SWANN

Appeal 2015-001481
Application 12/577,112
Technology Center 3700

Before JENNIFER D. BAHR, LINDA E. HORNER, and BRANDON J. WARNER, *Administrative Patent Judges*.

HORNER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Betsy Swann (Appellant) seeks our review under 35 U.S.C. § 134 of the Examiner's decision rejecting claims 20–32, which are all of the pending claims. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

CLAIMED SUBJECT MATTER

Appellant's claimed subject matter relates to "methods and apparatuses for endometrial ablation and intrafallopian tube contraceptive devices." Spec., para. 1. Claims 20 and 25 are independent. Claim 25, reproduced below, is illustrative of the subject matter on appeal.

> 25. A sterilization device comprising:
>
> a sheath having a proximal end and a distal end;
>
> a shaft slidably disposable within the sheath; and
>
> an ablation element connected to the shaft to ablate uterine tissue, the ablation element comprising an electrode array portion and a pair of non-conductive portions, the ablation element being expandable to conform to a uterus such that each non-conductive portion occupies a different corner region of the expanded ablation element in contact with a different ostium of a pair of fallopian tubes such that the electrode array portion does not come into contact with the ostia.

Independent claim 20 is directed to a method of sterilizing reproductive tissue, and similarly recites, in pertinent part:

> expanding the ablation element to conform to the uterus with the pair of non-conductive portions occupying a pair of corner regions of the expanded ablation element adjacent a pair of ostia of a pair of fallopian tubes such that the electrode array does not contact the ostia.

EVIDENCE

The Examiner relied upon the following evidence:

Ryan	US 2005/0182397 A1	Aug. 18, 2005
Tran	US 2005/0274384 A1	Dec. 15, 2005
Payne	US 2008/0154256 A1	June 26, 2008

REJECTIONS

Appellant appeals from the Final Action, dated November 19, 2013 ("Final Act."), which includes the following rejections:

1. Claim 25 under 35 U.S.C. § 103(a) as unpatentable over Payne and Ryan.
2. Claims 20–24 and 26–32 under 35 U.S.C. § 103(a) as unpatentable over Payne, Ryan, and Tran.

ANALYSIS

First Ground of Rejection

Independent claim 25 calls for an "ablation element being expandable to conform to a uterus such that each non-conductive portion occupies a different corner region of the expanded ablation element in contact with a different ostium of a pair of fallopian tubes *such that the electrode array portion does not come into contact with the ostia*." Appeal Br. 17 (Claims App.) (emphasis added).

The Examiner found that Payne discloses:

> [A]n ablation element (RF head 303 in figures 10E and 11A) connected to the shaft (as shown in figures 10E and 11A) to ablate uterine tissue (see page 9 [0115]), the ablation element comprising an electrode array (on the RF applicator - see page 1 [0007]) and a pair of non-conducting portions (non-conductive regions 344 as best shown in figure 11B) which are each positioned adjacent a tubal ostium for a fallopian tube (see page 9 [0115] which discloses that the RF applicator head 303 (which includes the pair of nonconductive portions 344) is positioned at a tubal ostium 110).

Final Act. 6–7. The Examiner acknowledged that "Payne does not . . . disclose that the ablation element is expandable to conform to a uterus with

each non-conductive portion occupying a different corner region of the expanded ablation element in a different ostium of a pair of fallopian tubes such that the electrode array does not come into contact with the ostia." *Id.* at 7. However, the Examiner found:

> Ryan discloses an ablation device 10 which includes a distendable bladder 102 which is inflated to conform to a body cavity such as a uterus (page 2 [0029]) whereas shown i.e. in figures 1–2, at least one resistive element is coupled to the outer surface of the bladder (116a–c in figures 1–2) but *any number of resistive elements can be used and they could be positioned at <u>any</u> desired location on the outer surface of the balloon* (page 3 [0032]).

Id. (emphasis added). The Examiner determined:

> It would have been obvious to one having ordinary skill in the art, at the time of the invention, to modify the device of Payne so that the ablation element is expandable to conform to a uterus, as in Ryan, in order to allow for sufficient contact between the device and the endometrial lining so that the maximum amount of coverage is possible (page 1 [0005]). Furthermore, it also would have been obvious *to modify the device of Payne so that each non-conductive portion occupies a different corner region of the expanded ablation element in a different ostium of a pair of fallopian tubes such that the electrode array is not in contact with the ostia, as in Ryan, in order to allow for targeted heating/ablation* (page 1 [0005]).

Id. at 7–8 (emphasis added).

Appellant argues that the Examiner's proposed modification of Payne's device so that the electrode array of the expanded ablation element does not contact the ostia is "contrary to the teaching of <u>*Payne*</u>" and "is the result of impermissible hindsight." Appeal Br. 11. In particular, Appellant asserts that "<u>*Payne*</u> requires the electrode pairs 340a–340d to be positioned

within the tubal ostium in order to perform its intended function of ablating the uterine tissue within the tubal ostium 110." *Id.* (boldface omitted). According to Appellant, "*Payne* is explicit that the electrodes are placed at the tubal ostium in order to ablate uterine tissue within the tubal ostium 110." Reply Br. 3; *see id.* at 2 (pointing to paragraph 115 of Payne). For the reasons that follow, we agree with Appellant that the Examiner's proposed modification of Payne's device based on the teachings of Ryan is not supported by adequate reasoning based on rational underpinnings. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Payne discloses a device, and corresponding method of using said device, for female sterilization that includes "RF applicator head **303** . . . [with] an electrode carrier having one or more bipolar electrodes." Payne, para. 114. Payne discloses that "RF applicator head **303** is introduced transcervically into the uterine cavity and *positioned at a tubal ostium **110**,*" wherein "[t]ransmitting RF energy through the RF applicator head **303** *ablates the uterine tissue **106, 108** and the tissue within the tubal ostium **110**.*" *Id.* at 115 (emphasis added). According to Payne, "[f]ollowing the destruction of the tissue at the tubal ostium **110,** the healing response occludes the tubal ostium **110** and the adjacent portion of the fallopian tube **104** resulting in sterilization." *Id.* Thus, Payne's sterilization device uses electrodes for targeted ablation of tubal ostium tissue so that scarring occludes the fallopian tube.

Ryan discloses device 100 for ablating a body cavity, such as a uterus, including distendable bladder 102 "designed such that, when in the inflated

state, . . . distendable bladder [102] substantially approximates the interior of the body cavity." Ryan, para. 29. Device 100 includes "multiple resistive elements **116*a***, **116*b***, **116*c*** . . . positioned at desired locations about the outer surface of . . . distendable bladder [102]." *Id.*, para. 32. Ryan further discloses "that any number of resistive elements could be used, and that they could be placed at any desired location on the outer surface of the [distendable bladder 102]." *Id.*

We are persuaded by Appellant that the Examiner has failed to articulate adequately why one having ordinary skill in the art would have been led to modify the expanded ablation element in the device of the proposed combination of Payne and Ryan such that the electrodes of the expanded ablation element do not contact the tubal ostia. Although Ryan evidences that electrodes *could* be placed at any desired location on an expandable ablation device (Ryan, para. 5), this is an insufficient explanation of a *reason* to modify Payne's device, which specifically targets tubal ostia tissue for ablation, such that the electrodes do not contact the tubal ostia, as called for in claim 25. For these reasons, we do not sustain the rejection of claim 25 under 35 U.S.C. § 103(a) as unpatentable over Payne and Ryan.

Second Ground of Rejection

Claims 20–24 and 26–32 are subject to the second ground of rejection as being unpatentable over Payne, Ryan, and Tran. As noted *supra*, independent claim 20, similar to claim 25, calls for expanding the ablation element such that the electrode array does not contact the ostia. Claims

21–24 depend from claim 20. Claims 26–32 depend from independent claim 25.

The rejection of claims 20–24 and 26–32 relies upon the same proposed combination of Payne and Ryan that we found deficient in the analysis of claim 25 discussed *supra*. *See* Final Act. 3–6, 8–10. The Examiner did not rely on any disclosure of Tran, nor articulate any additional reasoning, that would remedy this deficiency. Accordingly, we do not sustain the rejection of claims 20–24 and 26–32, under 35 U.S.C. § 103(a) as unpatentable over Payne, Ryan, and Tran.

DECISION

The decision of the Examiner to reject claims 20–32 is REVERSED.

REVERSED