

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte
ROBERT A. GANZ, BRIAN D. ZELICKSON, and ROGER A. STERN

Appeal 2008-0010
Application 10/370,645
Technology Center 3700

Decided: March 25, 2008

Before DONALD E. ADAMS, LORA M. GREEN,
and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 80-101 and 103-131. We have jurisdiction under 35 U.S.C. § 6(b). Claims 80, 100, and 116 are the independent claims on appeal, and read as follows:

80. A method of ablating mucosal tissue in an esophagus, comprising:
 - providing an energy delivery device;
 - positioning at least a portion of the energy delivery device at a mucosal tissue surface of the esophagus;
 - delivering sufficient energy from the energy delivery device to the mucosal tissue surface to create a lesion in the mucosal tissue, while controlling a depth of the lesion.
100. A method of treating a tissue site in an esophagus, comprising:
 - providing a dilation and ablation catheter having a balloon member;
 - providing an energy delivery device having a plurality of RF electrodes positioned on an outside surface of the balloon member;
 - positioning at least a portion of the energy delivery device at a mucosal surface of the tissue site in the esophagus;
 - expanding the balloon member in the esophagus;
 - delivering sufficient energy from the energy device to create a lesion with a controlled depth in the mucosal tissue.
116. A method for treating a tissue site in the esophagus, comprising:
 - providing an energy delivery device that includes a plurality of RF electrodes, a width of each RF electrode and a spacing between adjacent RF electrodes being selected to control a depth of ablation in mucosal layer of the esophagus;
 - positioning at least a portion of the energy device at the tissue site in the esophagus;
 - delivering sufficient energy from the energy delivery device to create a desired ablation depth in the mucosal layer.

The Examiner relies on the following references:

Kelleher	US 6,112,123	Aug. 29, 2000
Edwards	US 6,405,732 B1	Jun. 18, 2002
Hovda	US 6,053,172	Apr. 25, 2000

We reverse.

DISCUSSION

Claims 80-95, 97, 99, 100-105, 107, 110, 111, 113, 116-121, 123, 126, 127, and 129 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Edwards and Kelleher.

Edwards is cited for teaching treating a tissue site in the esophagus, but, according to the Examiner, “neglects to *expressly* disclose targeting esophageal mucosal layers.” (Ans.¹ 3.) According to the Examiner, however, Edwards “repeatedly mentions targeting the sphincter wall,” which includes the mucosal layer (*id.*).

Kelleher, according to the Examiner, discloses “an example of targeted ablation of the esophageal mucosal layer using a device analogous to that in Edwards.” (*Id.*) Thus, the Examiner concludes, “this makes obvious the Applicant’s claimed methods.” (*Id.*)

The burden is on the Examiner to set forth a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The Supreme Court has recently emphasized that “the [obviousness] analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and

¹ All references to the Answer are to the Examiner’s Answer mailed January 30, 2007.

creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). However, in order to facilitate review of the obviousness determination, the “analysis should be made explicit.” *Id.* at 1741.

Appellants argue the Examiner has not addressed the limitation that at least a portion of the energy delivery device be positioned at the mucosal surface of the esophagus (Br. 8). In the treatment method of Edwards, Appellants assert, the lesion is not made on the mucosal surface of the esophagus, but is made to the muscle tissue 1-5 mm beneath the mucosal surface, which is created by injecting a needle electrode into the esophageal tissue or uses nerve pathways to create lesions within the muscle tissue (*id.* at 6). According to Appellants, “Edwards specifically avoids damage or destruction of mucosal tissue.” (*Id.*) Kelleher, Appellants assert, cites significant problems associated with ablation of tissue in the lower esophagus, such as obtaining uniform ablation over the entire tissue surface (*id.* at 7). Kelleher, however, uses electrolyte assisted ablation, and the electrode is spaced away from the tissue surface (*id.*). Thus, Appellants assert, “the Examiner has not presented evidence that one having ordinary skill in the art would have been led to combine the relevant teachings of Edwards and Kelleher to arrive at the claimed invention nor how such a combination might work.” (*Id.* at 8.)

The Examiner responds that Appellants are very narrowly construing the Edwards patent (Ans. 10). According to the Examiner, “just because Edwards mentions preventing damage to the mucosa in a small two-line excerpt . . . [with] at least 10 object/embodiments does not mean that the excerpt applies universally.” (*Id.*) As to the positioning of the energy

device at the mucosal surface, the Examiner points to Figure 2a of Edwards, stating that the Figure does not differentiate between the anatomically adjacent mucosal and submucosal surfaces, asserting that the lesion could be easily construed as being within the mucosal layer (*id.* at 11).

We conclude that Appellants have the better argument. Claim 80 (as do claims 100 and 116, the other independent claims), requires 1) *“positioning at least a portion of the energy delivery device at a mucosal tissue surface of the esophagus; and 2) delivering sufficient energy from the energy delivery device to the mucosal tissue surface to create a lesion in the mucosal tissue, while controlling a depth of the lesion.* Thus, claim 80 requires that a portion of the energy delivering device be positioned at the tissue surface of the mucosa, and also requires that the device positioned at the surface of the mucosa deliver energy to the mucosa to create a lesion in the mucosal tissue.

Although Edwards has multiple embodiments, they are all directed to ablating tissue below the mucosal surface, and are performed such that the mucosal surface is not damaged (*see, e.g.*, Edwards, col. 12, ll. 40-41; col. 14, ll. 29-32; col. 16, ll. 31-39; col. 17, ll. 1-8). Thus, while the Examiner argues that Figure 2a can be construed as having the lesion within the mucosal layer, Edwards states that the Figure is drawn to producing lesions in a sphincter (Edwards, col. 7, ll. 41-48). Edwards teaches further as to Figures 12 and 13, drawn to treatment of the sphincter, that the needle electrode is introduced into the smooth muscle tissue of the sphincter wall (Edwards, col. 13, ll. 16-46). Thus the ordinary artisan when reading that teaching, coupled with the other portions of Edwards that teach that the mucosal surface is not damaged, would not construe Figure 2a as the energy

delivery device being positioned at the mucosal tissue surface of the esophagus, and then using the delivery device at the surface of the mucosal tissue to produce a lesion in the mucosal tissue. Moreover, while the Examiner asserts that Edwards mentions preventing damage to the mucosa in only one embodiment while disclosing at least ten objects/embodiments, the Examiner does not point to any portion of the disclosure of Edwards that introduces lesions at the mucosal surface through the use of a energy delivery device, where at least a portion of the device used to deliver energy is positioned at the mucosal tissue surface of the esophagus.

Finally, the Examiner has not explained how Kelleher remedies the deficiencies of Edwards, because, as explained by Appellants (Br. 7), Kelleher discloses an electrolyte assisted ablation, wherein the energy delivering electrode is spaced away from the tissue surface in the conducting medium (Kelleher, abstract, *see also*, col. 3, ll. 34-51). Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness as to independent claims 80, 100, and 116, and we are compelled to reverse the rejection.

Claims 95, 96, 98, 106, 108, 109, 112, 114, 115, 122, 124, 125, 128, 130, and 131 stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Edwards and Kelleher as further combined with Hovda.

The combination of Edwards and Kelleher is relied upon as set forth above (Ans. 8). Hovda is cited for addressing the limitation of using the device to perform esophageal tumor surgery (*id.*). Thus, as Hovda fails to remedy the deficiencies of the combination of Edwards and Kelleher, we are compelled to reverse this rejection as well.

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CONCLUSION

In summary, as we conclude that the Examiner has failed to set forth a prima facie case of obviousness, the rejection of claims 80-95, 97, 99, 100-105, 107, 110, 111, 113, 116-121, 123, 126, 127, and 129 under 35 U.S.C. § 103(a) over the combination of Edwards and Kelleher, and the rejection of claims 95, 96, 98, 106, 108, 109, 112, 114, 115, 122, 124, 125, 128, 130, and 131 under 35 U.S.C. § 103(a) over the combination of Edwards and Kelleher as further combined with Hovda, are reversed.

REVERSED

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