

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DANIEL K. HALLOCK
and DARYL C. JAMGOTCHIAN

Appeal No. 1999-2540
Application 08/770,411

ON BRIEF

Before COHEN, McQUADE and GONZALES, Administrative Patent Judges.

McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Daniel K. Hallock et al. appeal from the final rejection of claims 1 through 15, all of the claims pending in the application.¹ We reverse.

¹Claims 1, 2, 5, 6, 10 and 13 have been amended

(continued...)

THE INVENTION

The invention relates to an apparatus and method for cooled, radio frequency generated ablation of heart tissue.

Claims 1 and 6 are illustrative and read as follows:

1. A radio frequency generator and pump apparatus for cooled ablation for ablating tissue in the wall of the heart of a patient, an ablation catheter comprising a flexible elongate member having proximal and distal extremities, an ablation electrode formed of a conductive material and carried by the distal extremity, said ablation electrode having a cavity therein, an electrical conductor carried by the flexible elongate member and coupled to the ablation electrode, a radio frequency generator coupled to said electrical conductor, said flexible elongate member having a liquid carrying lumen extending from the proximal extremity to the distal extremity and opening into the cavity of the ablation electrode, a pump coupled to the liquid lumen for supplying a cooling liquid to the lumen and to the cavity of the ablation electrode and automatic control means for controlling the operation of the radio frequency generator and the pump to supply pre-cooling, cooling and post-cooling in

¹(...continued)

subsequent to final rejection. The examiner and the appellants appear to agree that claims 2 and 5 as so amended do not accurately reflect what was intended by the appellants. See page 3 in the examiner's answer, Paper No. 10, and page 1 in the appellants' reply brief, Paper No. 12. The discrepancies should be resolved upon return of the application to the technology center. In the meantime, we have assumed for purposes of this appeal that claims 2 and 5 read as shown in the appendix to the reply brief.

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succession without interruption to the ablation electrode to
maintain the ablation electrode at a temperature to prevent

excessive heating of the ablation electrode and in the wall of the heart when the ablation electrode is in contact with the wall of the heart.²

6. A method for performing ablation of tissue in the wall of the heart of a patient utilizing a radio frequency generator and a pump apparatus and an ablation catheter comprising a flexible elongate member having proximal and distal extremities, an ablation electrode carried by the distal extremity, said electrode being formed of a conductive material and having a cavity therein and an electrical conductor carried by the flexible elongate member and coupled to the ablation catheter in which the ablation catheter has first and second lumens extending from the proximal to the distal extremity and in communication with the cavity in the electrode and a cooling liquid, the method comprising introducing the ablation catheter into the heart and into contact with the wall of the heart of the patient, supplying radio frequency energy to the ablation electrode to ablate tissue in the wall of the heart, terminating the application of radio frequency energy to the ablation electrode and operating the pump apparatus to supply continuously without interruption a cooling liquid through said first lumen and to the ablation electrode to pre-cool the ablation electrode prior to the application of radio frequency energy, to cool the electrode during the application of radio frequency energy and to cool the electrode after the application of radio frequency energy and removing the ablation catheter from the

²The preambles of claim 1 and of claims 2 and 5 (see n.1, supra) are somewhat garbled. Based on the underlying specification and the bodies of these claims, we understand the preambles as calling for the combination of a radio frequency generator, a pump apparatus and an ablation catheter. We also understand the references in claims 1, 2 and 5 to pre-cooling, cooling and post-cooling in light of the specification (and also in light of the corresponding limitations in claims 6, 10 and 13) as denoting cooling which respectively takes place before, during and after the application of the radio frequency energy.

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patient.

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THE PRIOR ART

The references relied upon by the examiner as evidence of obviousness are:

Neilson et al. (Neilson)	5,330,518	July
19, 1994		
Imran et al. (Imran)	5,348,554	Sept. 20,
1994		

THE REJECTION

Claims 1 through 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Imran in view of Neilson.

Attention is directed to the appellants' main and reply briefs (Paper Nos. 9 and 12) and to the examiner's final rejection and answer (Paper Nos. 5 and 10) for the respective positions of the appellants and the examiner with regard to the merits of this rejection.

DISCUSSION

Imran, the examiner's primary reference, discloses an apparatus and method for cooled, radio frequency generated ablation of heart tissue. As described by Imran,

the present invention embodies a catheter for radio frequency ablation with a cooled electrode for use in a heart having a wall forming at least one chamber with blood therein. The catheter [11] is comprised of a flexible elongate member [12] having proximal and distal extremities [13 and 14]. An electrode [16] is mounted on the distal extremity of the flexible elongate member and has a cavity [17] therein. Means [a conductor 31 in communication with a radio frequency supply and controller 76] is provided which extends through the flexible elongate member from the proximal to the distal extremity for supplying radio frequency energy to the tip electrode. The flexible elongate member is provided with a first lumen [27] therein extending from the proximal extremity to the distal extremity and being in communication with the electrode. Means [pump 66] is provided for introducing a cooling liquid into the lumen. The means for introducing the cooling liquid into the lumen includes means for adjusting the pressure of the liquid in the lumen at the electrode so that it approximates the pressure of the blood in the chamber of the heart in which the distal extremity is disposed [column 2, lines 38 through 57].

Of additional interest is Imran's disclosure that in

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using the apparatus the cooling liquid is pumped to the electrode “[p]rior to the delivery of . . . radio frequency energy or at the same time” (column 4, lines 48 and 49). The cooling of the electrode permits the ablation procedure to be performed without boiling and coagulating blood on the electrode (which would undesirably increase its impedance) or unintended necrosis of the surface lining of the heart (see column 9, et seq.).

Upon argument by the appellants (see, for example, page 9 in the main brief), the examiner concedes that Imran does not expressly meet the post-cooling limitations in independent claims 1, 2, 5, 6, 10 and 13 (see n.2, supra). The examiner nonetheless concludes that “it would [have been] obvious to continue [Imran’s] cooling the tissue, particularly if the monitored temperature was still in excess of a desired value. In support of such an assertion, the Neilson et al reference was relied upon as a teaching of post energy delivery cooling” (answer, page 4).

Imran, however, provides no factual support for the

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examiner's conjecture that the temperature of the electrode might rise above a desired value upon termination of the radio frequency energy. This deficiency finds no cure in Neilson.

Neilson discloses "a urethral catheter for thermal treatment of BPH [benign prostatic hyperplasia] which is capable of selectively directing microwave energy toward tumorous prostatic tissue growth anterior and lateral to the urethra, while sparing the urethra and healthy tissue posterior to the urethra from thermal damage" (column 3, lines 5 through 11). The catheter includes a flexible shaft having a lumen for a microwave antenna and intake and exhaust lumens for a cooling fluid. Neilson teaches that "[a]t the conclusion of microwave thermal therapy treatment period, cooled water from the cooling system is continuously pumped through the intake and exhaust lumens for about 10 to about 120 minutes to reduce edema of the treated tissues, thereby eliminating the need to insert a post-thermal therapy drain catheter" (column 3, lines 63 through 68). The therapy procedure is discussed in detail at column 8, line 14

et seq.

It is not apparent, nor has the examiner cogently explained, why Neilson's disclosure of a microwave urethral catheter and its use in the treatment of prostatic tumors would have led the artisan to conclude that the temperature of the electrode in Imran's radio frequency heart catheter might rise above an undesirable level upon termination of the radio frequency energy. Moreover, the post-cooling step taught by Neilson to reduce edema in the prostate and eliminate the resulting need for a urinary drain catheter has no apparent relevance to Imran's heart tissue ablation procedure. In this light, we are satisfied that the combined teachings of Imran and Neilson would not have suggested supplying the apparatus and method disclosed by Imran with a post-cooling element and step of the sort recited in independent claims 1, 2, 5, 6, 10 and 13.

Accordingly, we shall not sustain the standing 35 U.S.C. § 103(a) of claims 1, 2, 5, 6, 10 and 13, or of claims 3, 4, 7 through 9, 11, 12, 14 and 15 which depend therefrom, as

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being unpatentable over Imran in view of Neilson.

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SUMMARY

The decision of the examiner to reject claims 1 through
15 is reversed.

REVERSED

	IRWIN CHARLES COHEN)	
	Administrative Patent Judge)	
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)) BOARD OF
PATENT)	
	JOHN P. McQUADE)	APPEALS
	Administrative Patent Judge)	AND
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INTERFERENCES)	
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	JOHN F. GONZALES)	
	Administrative Patent Judge)	

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