

UNITED STATES PATENT AND TRADEMARK OFFICE

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

Ex parte STEVEN H. SELMAN

Appeal 2008-0967
Application 10/201,164
Technology Center 3700

Decided: May 13, 2008

Before, DONALD E. ADAMS, DEMETRA J. MILLS, and
LORA M. GREEN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Representative claims follow.

16. A method for relieving the symptoms of a patient suffering with a prostatic disorder comprising:

(a) administering to the patient an effective amount of a photosensitive composition delivered by direct injection to the patient's prostate tissue such that the effective amount of photosensitive composition accumulates in the prostatic tissue at a point in time prior to irradiation of the prostatic tissue with an apparatus for diagnosing or treating prostatic tissue comprising a catheter for insertion through the patient's prostatic urethral lumen when the patient's prostate contains no effective amount of the photosensitive composition, the catheter having a proximal end and a distal end, the catheter comprising at least one axially extending opening therethrough for receiving a light delivery means;

(b) inserting the catheter through the patient's urethra;

(c) inserting the light delivery means through the catheter;

(d) determining the position of the light delivery means relative to the prostatic tissue and surrounding tissue of the patient to ensure that the distal end of the light delivery means is adjacent the prostatic tissue;

(e) irradiating the prostatic tissue by delivering light energy through the distal end of the light delivery means to the prostatic tissue; the light energy being delivered for a predetermined time and at a predetermined wavelength sufficient to effectively treat the prostatic tissue, the light delivery means distributing the light energy substantially evenly, whereby the light energy is transmitted to the patient's prostate; and

(f) removing the catheter and the light delivery means from the urethra of the patient.

18. The method of claim 16, wherein a first balloon is operatively connected to the distal end of the catheter, which method further comprises delivering a suitable quantity of fluid material into the first balloon prior to insertion of the light delivery means into the catheter.

19. The method of claim 16, wherein a coaxially extending transparent or second translucent balloon is placed adjacent the distal end of the catheter for receiving a transparent or translucent material; which

method further comprises delivering a suitable quantity of the transparent or translucent material into the second balloon prior to irradiating the prostatic tissue.

20. The method of claim 16, wherein the distal end of the catheter further comprises a stop means; which method further comprises positioning the stop means adjacent the patient's bladder and sphincter muscle to ensure placement of the catheter with the urethra at a point spaced apart from the sphincter muscle and bladder of the patient.

Cited References

Hascoet et al.	US 5,234,004	Aug. 10, 1993
Makower et al.	WO 93/15664	Aug. 19, 1993

Windahl et al., *The Lancet*, "Photodynamic therapy of localized prostatic cancer", vol. 336, p. 1139 (Nov. 3, 1990).

Grounds of Rejection

1. Claims 16, 17, 25 and 26 stand rejected under 35 U.S.C. § 103(a) as obvious over Windahl in view of Makower.
2. Claims 18-20 stand rejected under 35 U.S.C. § 103 as obvious over Windhal in view of Makower and Hascoet.

DISCUSSION

Background

"This invention relates generally to the medical field and, more particularly, to the use of photodynamic therapy to treat prostatic tissues, and to the use of transurethral photodynamic therapy to treat malignant transformation of the prostate tissue, such as obstructive carcinoma of the prostate and inflammatory conditions of the prostate. The present invention

involves treatment of a patient with prostatic disorders using a photosensitive composition which accumulates in the prostatic tissue.”
(Spec. 1.)

In addition,

[v]arious types of prostatic tissue become hypertrophied or increased in size, which increase does not necessarily involve malignant transformation. While the causes of such hypertrophy of the tissue are numerous, until the present invention, the treatments of such hypertrophied tissue have various limitations. In particular, benign prostatic hypertrophy (BPH) causes enlargement of the prostate gland and/or constriction of the urethra. Benign prostatic hypertrophy is a relatively common disorder in older males. Another type of prostate disorder is cancer of the prostate, such as obstructive carcinoma of the prostate. Still another type of prostate disorder is prostatitis. Prostatitis is an inflammatory condition due to an infective pathogen, such as a bacterium or other microbe. Often prostatitis does not respond well to antibiotic treatment. In chronic or severe cases of prostatitis, abscesses can form and destroy prostatic tissue.

(Spec. 1.)

1. Claims 16, 17, 25 and 26 stand rejected under 35 U.S.C. § 103(a) as obvious over Windahl in view of Makower. We select claim 16 as representative of the rejection before us since Appellants have not separately argued the claims. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner finds that

Windahl et al teach a method as claimed except the particular administration route of the photosensitive substance; the balloon; and treatment of non-cancerous tissue ... Makower et al teach a method such as claimed ... for placing the treatment device in the prostatic urethra; ... for insertion of the laser fiber and determining the position thereof; ... for irradiating the

tissue; ... for application of the photodynamic compound to the treatment area directly; ... for removal of the cannula with the optical fiber after the treatment is completed; ...for the use of balloons on the shaft; ... for the use of a balloon on the tip (tip is extended as in figure 11); ...for treatment of benign prostatic hypertrophy) except for the explicit requirement that the light delivery means distribute the light substantially evenly.

(Ans. 3.)

The Examiner concludes that

[i]t would have been obvious to the artisan of ordinary skill to employ the administration route of Makower et al in the method of Windahl et al, since this would photosensitize less peripheral tissue and to a lesser degree; to employ the treatment on benign prostate hypertrophy, since PDT is an appropriate treatment modality for this disorder, as taught by Makower et al or to employ the spherical radiator of Windahl et al in the method of Makower et al, since this would provide uniform irradiation and thus prevent over treatment of some areas and under treatment of others, thus producing a method such as claimed.

(*Id.* 3-4.)

Appellant, on the other hand, contends that “the Examiner has failed to advance any factual basis to support the conclusion that it would have been obvious to one of ordinary skill in the art to administer to the patient an effective amount of photosensitive composition delivered by direct injection to the patient's prostate tissue.” (Br. 4.) The Appellant further argues the Examiner has not “advanced any factual basis to support the conclusion that the administering is such that the effective amount of photosensitive composition accumulates in the prostatic tissue.” (*Id.* at 4-5) Appellant

argues that this is because Windahl indicates that the prostatic tissue has been resected or removed and that Windahl does not directly inject prostatic tissue. (Br. 8.)

We are not persuaded by this argument. To the contrary we find the Examiner has presented evidence of direct injection into prostatic tissue of a photosensitive composition. Windahl describes photodynamic therapy of localized prostate cancer by injecting a photosensitive composition into the treatment area (prostatic cavity) and irradiating the cavity tissue with a laser. (Windhal, col. 1, 2nd ¶.) Makower also describes a photodynamic therapy may be applied to the prostate using a compound which is specifically targeted to particular cells and sensitive to selected light frequencies. (Makower 20: 1-10.) In view of this one of ordinary skill in the art would have understood that either the prostatic cavity or prostatic tissue could be injected with a photosensitive composition and subjected to photodynamic therapy.

In addition, Appellant argues that Makower fails to disclose that the light delivery means distributes the light substantially evenly to the prostate. (Br. 5.) The Examiner responds, arguing that Makower describes irradiating a spherical treatment area and that one of ordinary skill in the art would reasonably understand that this would administer the light substantially evenly to the patient's prostate. (Ans. 5; Makower 10:13-17.) We find no error in the Examiner's *prima facie* case of obviousness and no rebuttal argument put forth by Appellant to the Examiner's position.

In view of the above, the obviousness rejection is affirmed.

2. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Windahl in view of Makower and Hascoet. Each of claims 18-20 have been argued separately by Appellant and therefore we address each claim individually.

With respect to claims 18 and 20 the Examiner finds that Hascoet “teach the use of balloons as well as material opaque to the applied radiation.” (Ans. 4.) The Examiner concludes that

[i]t would have been obvious to the artisan of ordinary skill to employ balloons and a stop means as taught by Hascoet et al since this would secure the catheter (column 4, line 12-20) and protect the bladder (see column 11, lines 5-13 and column 14, line 13-26) and sphincter (see column 17, lines 27 to 30), as taught by Hascoet et al, thus producing a device such as claimed.

(Ans. 4.)

Appellant contends that Hascoet fails to teach the use of photosensitive compositions to treat prostatic tissue. (Br. 12.) However, the Examiner relies additionally on the disclosures of Windahl and Makower to meet this limitation discussed herein. Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). The test of obviousness is “whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention.” *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991). Thus, we are not persuaded by Appellant’s argument.

Appellant further argues that “Hascoet et al. does not teach the use of a balloon to more evenly deliver light into the affected area of the prostate” (Br. 11.)

The Examiner responds, arguing that it is the combination of references that is being relied on to meet this limitation. The Examiner contends that

Makower . . . teach the use of multiple balloons, both on the shaft (see page 12, lines 1 to 20, note especially lines 14 to 20), describing the locking function of the balloon and noting that the balloon can also serve a cooling function) and at the distal end thereof (see page 17, lines 21 to 26). Hascoet et al. teach the use of a cooling medium, which may be water, along the shaft of the catheter, (see column 14, lines 26 to 39) and the balloon connected to the distal end (element 22) can also be filled with a liquid medium through which the radiation cannot pass.

(Ans. 6.)

We initially note that claim 18 does not recite the intended use of the balloon as argued by appellant, “to more evenly deliver light into the affected area of the prostate.” (Ans. 9.) The issue then becomes, whether the combination of references teaches a first balloon connected to the distal end of a catheter which is fluid filled, as recited in claim 18. We agree with the Examiner that the evidence of record supports that one of ordinary skill in the art upon review of Windhal, Makower and Hascoet would have found it obvious to place a balloon adjacent the distal end of the catheter for receiving a transparent or translucent material and irradiating the tissue with a laser. The rejection of claim 18 is affirmed.

Appellant further argues that the cited references do not teach the limitations of claim 19. (Br. 11.) With respect to claim 19, we find the Examiner has presented evidence of a second balloon adjacent to the distal end of the catheter. For example, Makower describes a tip balloon (located adjacent to the end of the catheter). (Makower 17, ll. 14-26.) Hascoet describes a “rectal inflatable element 92 forming ballooned [sic] fixed around [a] rectal probe” which is adjacent to the distal end of the catheter. (Hascoet, col. 16, l. 67 to col 17, l. 8; Fig. 1.)

Appellant provides no further rebuttal argument to the evidence presented by the Examiner. In view of the above, the rejection of claim 19 is affirmed.

Appellant further argues that the cited references do not teach the stop means of claim 20. (Br. 11.) We find the Examiner has presented evidence of stop means, as claimed. Hascoet discloses that balloon means (stop means) lock the front end of the urethral probe in the bladder neck to “protect from the heat the sensitive tissues other than the tissues to be treated, such as the bladder and sphincter” (Hascoet, col. 11, ll. 5-13). (Hascoet, col. 4, ll. 12-20; col 14, ll. 13-25.) Hascoet further discloses a radioreflecting screen 22 (stop means) to protect tissues of the prostate. (Hascoet, col. 17, ll. 48-50; 55-62.)

Appellant provides no further rebuttal argument to the evidence presented by the Examiner. In view of the above, the rejection of claim 20 is affirmed.

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SUMMARY

The obviousness rejections are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a).

AFFIRMED

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