UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PETER CHRISTENSEN BAKER and RICHARD TREADWELL

Appeal 2017-010030
Application 13/160,858[1]
Technology Center 3700

Before ULRIKE W. JENKS, JOHN E. SCHNEIDER, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method and system for delivery of high frequency acoustic energy to a target site in a body cavity, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

STATEMENT OF THE CASE

"Effective and long-lasting reduction of mucus and accumulated inflammatory debris and reduction in the growth of biofilms within the nasal passages, sinuses and their drainage systems, remain challenging despite the

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[1] Appellants identify the real party in interest as Otogenix, Inc. (Appeal Br. 2.)

proliferation of treatment options." (Spec. 5.) "Nasal irrigators for application of both solutions and aerosols are well known and are used to relieve symptoms of sinusitis and rhinitis, such as nasal congestion." (Spec. 2.) "Application of ultrasound directly or indirectly to the nasal passages, or to tissue in the nasal passages, has also been proposed." (*Id.* at 3.)

"The use of high intensity focused ultrasound (e.g., HIFU) is well known for ablation or remodeling of various types of tissue." (*Id.* at 4.) In some electrosurgical systems, "[w]hen a high frequency voltage is applied, tissue in proximity to the electrode is ablated, severed, or modified." (*Id.* at 4–5.) Appellants' invention is directed at "providing improved methods and systems for delivery of fluids and aerosols and ultrasound energy to tissue surfaces, cavities and obstructed sites in passages, lumens or cavities such as nasal passages, sinuses and sinus ostia." (*Id.* at 5.)

Claims 1, 2, 5–8, 11–18, and 20–30 are on appeal. Claims 1 and 17[2] are representative and read as follows:

1. A system for delivery of high frequency acoustic energy to a target site at a tissue or at an obstruction within a body cavity or lumen, comprising:

an insertion wand sized and configured for insertion into a body cavity or lumen;

an acoustic energy delivery member associated with the insertion wand for contacting tissue and conveying high frequency acoustic energy directly to the target site,

a distal end of the insertion wand having a plurality of ports, including a fluid delivery port and an aspiration port, circumscribing a central portion of the distal end; and

a fluid source that delivers fluid via the fluid delivery port to the target site in a pulsatile flow,

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[2] We have added paragraphing for ease of reading.

wherein the acoustic energy delivery member includes a wire member that delivers acoustic energy extendable from the central portion of the distal end of the insertion wand to a position external to the insertion wand and distal to the plurality of ports.

(Appeal Br. 16.)

17. A method for delivering high frequency acoustic energy to a target site, comprising

positioning an insertion wand in proximity to the target site, a distal end of the insertion wand having a plurality of ports, including a fluid delivery port and an aspiration port,

circumscribing a central portion of the distal end; positioning an acoustic energy delivery member associated with the insertion wand at the target site in contact with tissue;

applying high frequency acoustic energy directly to the target site through the acoustic energy delivery member; and

delivering fluid to the target site via the fluid delivery port using a pulsatile flow, wherein the acoustic energy delivery member includes a wire member that delivers high frequency acoustic energy and is extendible from the central portion of the distal end of the insertion wand to a position external to the insertion wand and distal to the plurality of ports, and

positioning the acoustic energy delivery member at the target site includes extending the wire member from the insertion wand.

(Appeal Br. 18.)

The following grounds of rejection by the Examiner are before us on review:

(1) Claims 1, 2, 7, 8, 11, 17, 18, 25–27, and 30 under 35 U.S.C. § 103(a) as unpatentable over Nita,[3] Deem,[4] Vaska,[5] and Haefner,[6]

(2) Claims 12, 14, 15, and 28 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Coleman,[7]

(3) Claims 5, 6, and 20–24 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Maguire,[8]

(4) Claim 13 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Laugharn,[9] and

(5) Claims 16 and 29 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Chang.[10]

DISCUSSION

The Rejection of Claims 1, 2, 7, 8, 11, 17, 18, 25–27, and 30

The Examiner finds that Nita teaches a system and method for delivering acoustic energy to a target site within a body cavity, where the system includes an insertion wand, and acoustic energy delivery member associated with that wand for contacting tissue, a fluid delivery port, and a

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[3] Nita, US 2004/0024402 A1, published Feb. 5, 2004.
[4] Deem et al., US 2007/0267011 A1, published Nov. 22, 2007. We note that the Examiner incorrectly refers to this reference as "Deam." (*See, e.g.*, Final Action 2.)
[5] Vaska et al., US 2004/0054363 A1, published Mar. 18, 2004.
[6] Haefner, US 2004/0204728 A1, published Oct. 14, 2004.
[7] Coleman, US 6,692,450 B1, issued Feb. 17, 2004.
[8] Maguire et al., US 2002/0019627 A1, published Feb. 14, 2002.
[9] Laugharn, Jr. et al., US 2008/0031094 A1, published Feb. 7, 2008.
[10] Chang et al., US 2006/0210605 A1, published Sept. 21, 2006.

fluid source that delivers fluid to the target site. (Final Action 2–3.) The Examiner recognizes that Nita does not disclose that the acoustic energy delivery member has a wire member that delivers the acoustic energy and is extendable from the wand to a position external to the wand. (*Id.* at 3.) The Examiner also recognizes that Nita does not disclose the wand having a plurality of ports that circumscribe a central portion of the distal end of the insertion wand and where the ports include an aspiration port. (*Id.*) The Examiner contends that it would have been obvious to modify Nita to include these structural limitations in light of the disclosure of Deem and Haefner. (*Id.*)

The Examiner additionally notes that Nita does not explicitly disclose that the acoustic energy is high frequency acoustic energy or that the fluid is delivered using pulsatile flow. (*Id.*) The Examiner contends that it would have been obvious to modify Nita to include these features in light of the teachings of Deem and Vaska. (*Id.*)

The Examiner finds that Deem discloses using a wire member to deliver acoustic energy into a nasal cavity and that this wire member is extendable from within the central portion of the wand to a position external thereto. (*Id.*) The Examiner further explains that Deem teaches that the acoustic energy can be high frequency acoustic energy. (*Id.*) The Examiner also finds that Deem discloses delivering fluid "by aerosol port which is a pulsatile flow." (*Id.*) The Examiner finds that Vaska discloses delivering fluid in a pulsatile flow and performs treatment with high frequency ultrasound. (*Id.*) According to the Examiner, Vaska's disclosure supports that "[p]ulse fluid is effective in performing [a] flushing action." (*Id.* at 4.)

The Examiner finds that Haefner discloses a wand whose distal end has "a plurality of ports, including an aspiration port, circumscribing a central portion of the distal end." (*Id.* at 3.)

The Examiner reasons that the features disclosed in Deem, Vaska, and Heafner discussed above are "effective and commonly use[d] in the field to perform treatment and cleaning of tissue and body fluid/debris" and, thus, it would have been obvious to modify Nita to include them. (*Id.* at 4.) The Examiner explains that the addition of a guide wire to deliver the high frequency acoustic energy that is extensible as claimed would have been obvious to include because such a guide wire would more easily get inside a body chamber to perform treatment. (Ans. 11–12.) The Examiner also notes that the addition of many holes circumferentially at the distal end of the wand would enable the device to deliver more dispersed fluid "to clean more area." (*Id.* at 12.) According to the Examiner, adding these elements to Nita would only require routine skill in the art and would have been added "for the intuitively obvious reason mentioned." (*Id.*)

Regarding the "pulsatile flow," the Examiner states that "the cleaning process utilizes water or fluid motion as ordinary artisans would instantly recognize[, and] Vaska discloses fluid leaking/pouring out of the membrane and onto the tissue." (Ans. 9.) According to the Examiner, "Vaska discloses sweep away bubble or provide a flushing action" and "[i]f the bubble can be swept away through the opening hole, then certainly debris or body fluid/blood on the tissue can be swept away by fluid/water coming out of the opening 462." (*Id.* at 9–10.) The Examiner asserts further that:

> using pulsating fluid for flushing is common knowledge from well-known everyday activities. For example, a clogged kitchen sink can be unclogged by turning on water and using a

> plunger to push the water down the drainage. This create a pulsatile fluid that have strong pressure to sweep away the trash that caused a clog in the drainage.

(*Id.* at 10.)

We disagree with the Examiner's conclusion that the system of claim 1 and the method of claim 17 would have been obvious from the prior art relied on. As Appellants explain, Vaska's disclosed use of pulsed flow that results in a flushing action for the fluid or that "help[s] to sweep away bubbles" does not rely on the pulsed liquid per se to flush or sweep. (Appeal Br. 7–8; Reply Br. 2–3; Vaska ¶ 269.) Rather, the flushing/sweeping action is the result of the pulsed flow of fluid "inflating/deflating" a membrane. (*Id.*)

While Vaska teaches the pulsed fluid can be provided to cause the fluid to intermittently leak through the membrane (Vaska ¶ 269), in this regard, Vaska teaches that such leaked fluid may help to conduct energy or simply reduce or eliminate air gaps. Elimination of the air gap allows for energy transfer from the ablation element to the tissue to be maximized for most efficient treatment. (Vaska ¶¶ 267–268.) As Vaska explains, air bubbles can inhibit energy transfer and reduce the efficiency of ultrasound and RF ablation. (*See id.* ¶ 267). In short, contrary to the Examiner's position, the pulsed flow of Vaska is not described to be such that it is "pouring out"(Ans. 9) so as to sweep away anything of substance away rather than just taking up space where air bubbles may have previously been. Thus, we agree with Appellants that Vaska's teaching of pulsed flow does not provide a motivation to deliver the fluid of Nita in a pulsed flushing fashion to clean tissue/debris.

Moreover, the Examiner's position that it is known that pulsating fluid such as from a running faucet in a sink that is being plunged can clear away debris (Ans. 10) is insufficient to establish a reason why one of ordinary skill in the art would modify Nita to include pulsed flow. A prima facie case for obviousness requires "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). That pulsed flow might clear away debris from a sink does not explain why one of ordinary skill in the art would have modified Nita to include pulsed flow.[11] As Appellants explain, Nita's system for therapeutic ultrasound for ablating obstructions within blood vessels employs "reverse irrigation, wherein the irrigation fluid is injected through a guide catheter 240, travels to the distal head of the catheter 10, and then carries the tissue particles through the channel 74 in a reverse direction. (Appeal Br. 7; Nita ¶ 57.) The Examiner has not explained why one of ordinary skill in the art knowing that plunging a sink while running water thereby creating pulsed flow would have provided a reason to one of ordinary skill in the art to use pulsed flow of irrigation fluid in Nita's system, nor do we deem such a reason to be "instantly recogniz[able]" as asserted by the Examiner (Ans. 9.)

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[11] We note that the Examiner contended that delivery of fluid by aerosol, as taught by Deem "is a pulsatile flow." (Final Action 3.) The Examiner does not point to any evidence in the record to support such a finding, and we disagree with the Examiner's unsupported assertion. Aerosol sprays can provide for a consistent flow rate. Moreover, we do not find Deem suggests anywhere using aerosol application as a pulsatile flow. It simply describes aerosol delivery as one means to have toxin delivered to a target tissue to which acoustic energy may also be applied in order to achieve treatment benefit by the toxin. (*See, e.g.*, Deem ¶¶ 30, 77, 125.)

In light of the foregoing, we disagree with the Examiner that one of ordinary skill in the art would have found it obvious from the present record to modify Nita to add pulsed flow of the fluid to the irrigation fluid delivery described in Nita. Thus, we reverse the Examiner's rejection of claims 1, 2, 7, 8, 11, 17, 18, 25–27, and 30 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, and Haefner.

The remaining rejections of the claims by the Examiner rely on the Examiner's position concerning the obviousness of pulsed flow discussed above. Thus, for the same reasons just discussed, we reverse the other outstanding rejections of the claims by the Examiner.

SUMMARY

We reverse the rejection of claim 1, 2, 7, 8, 11, 17, 18, 25–27, and 30 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, and Haefner.

We reverse the rejection of claims 12, 14, 15, and 28 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Coleman.

We reverse the rejection of claims 5, 6, and 20–24 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Maguire.

We reverse the rejection of claim 13 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Laugharn.

We reverse the rejection of claims 16 and 29 under 35 U.S.C. § 103(a) as unpatentable over Nita, Deem, Vaska, Haefner, and Chang.

REVERSED