

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.
Patent Owner

Case IPR2024-00278
U.S. Patent No. 11,033,318

PETITIONERS' DEMONSTRATIVES FOR ORAL ARGUMENT

Neurent Medical Inc. et al. v. Aerin Medical Inc.

IPR2024-00277; IPR2024-00278; IPR2024-00282

April 23, 2025

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Agenda

1

Technology and Prior Art Overview

2

Stern Discloses the claimed electrode pairs

- Stern discloses multiple bipolar electrode pairs
- Stern discloses “two rows” of bipolar electrode pairs
- A POSITA would have been motivated to arrange bipolar RF electrodes in Edwards-’535 in two rows

3

Stern Discloses “multiple RF output channels”

4

Patent Owner’s Definition of a POSITA Is Incorrect and Irrelevant to Any Disputed Issue

Technology and Prior Art Overview

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Bipolar Radiofrequency (RF) Energy Was Known

Critical ReviewTM in Biomedical Engineering, 38(1):53-63 (2019)

Biophysics

Dieter Hoernig
Department of Physics
University of California, San Diego

Biophysics of Radiofrequency Ablation

ABSTRACT: Radiofrequency (RF) ablation is a treatment modality that kills unwanted tissue by heat. Studies with cardiac tissue and in vivo models have shown that the biophysical mechanisms of RF ablation are complex and involve the formation of a coagulum. This coagulum is a result of the high temperature and the electric field. The coagulum is a result of the high temperature and the electric field. The coagulum is a result of the high temperature and the electric field.

KEY WORDS: Radiofrequency ablation, biophysics, coagulum, electric field, high temperature.

1. BACKGROUND

Radiofrequency (RF) ablation is a treatment modality that kills unwanted tissue by heat. Studies with cardiac tissue and in vivo models have shown that the biophysical mechanisms of RF ablation are complex and involve the formation of a coagulum. This coagulum is a result of the high temperature and the electric field. The coagulum is a result of the high temperature and the electric field.

ABBREVIATIONS

CT, computed tomography

Direction of RF current

Na⁺ → ← Cl⁻

← Cl⁻ K⁺ →

Na⁺ →

United States Patent (19) (11) Patent Number: **5,562,720**

Stern et al. (45) Date of Patent: **Oct. 8, 1996**

[54] **BIPOLAR MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD**

[75] Inventors: Roger A. Stern, Capistrano, Vincent N. Sullivan, San Jose; Benjamin L. Richman, Santa Cruz; Loren L. Roy, Northridge; Robert L. Marlow, Thomas D. Stringer, both of San Jose, all of Calif.

[73] Assignee: Vesta Medical, Inc., Palo Alto

[21] Appl. No.: 315,216

[22] Filed: Oct. 6, 1994

Related U.S. Application Data

Primary Examiner: Lee S. Cohen
Attorney, Agent, or Firm: William B. Walker

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"Hyperthermia: Overview Using Microwave Antennas", invited lecture, Thomas F. Ryan, M.D., Thermoradiotherapy, C. T. Conklin, M.D., "Devices Replacing The Ross-Brown", Trends, Michael Dolan.

"Endometrial Ablation", Therapeutic Hysteroscopy: Indications and Techniques, pp. 148-153, W. N. Barcock et al., "Uterine Resectoscopes for Endometrial Ablation and Resection", Karl Storz.

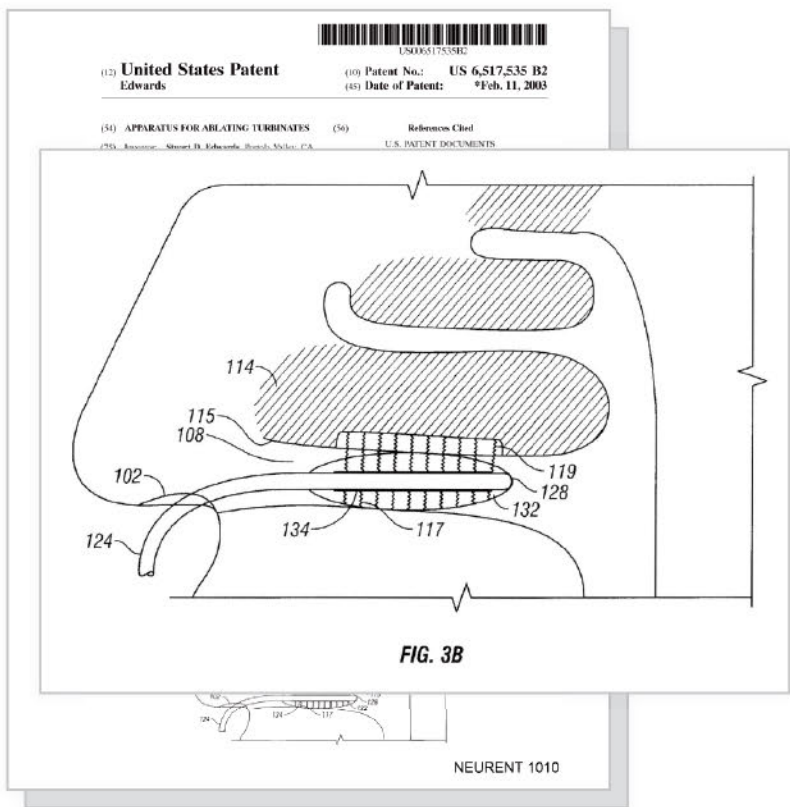
(List continued on next page.)

FIG. -17

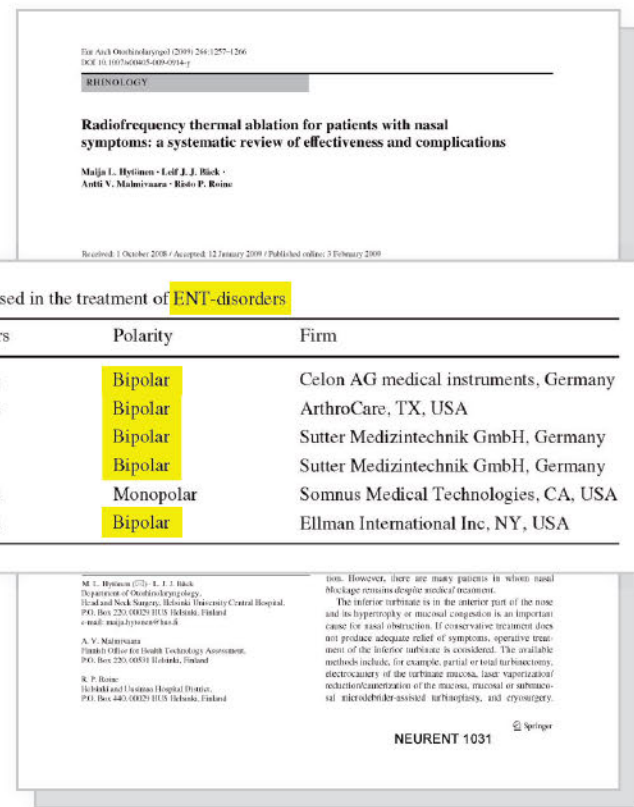
Ex.1051, 54; '277 Petition, 8-9; '278 Petition, 11; '282 Petition, 9; '277 Ex.1004, ¶¶29; '278 Ex.1002, ¶¶29; '282 Ex.1002, ¶¶29

Ex.1033, Fig.17; '277 Petition, 12; '278 Petition, 114; '282 Petition, 11; '277 Ex.1004, ¶¶38-40; '278 Ex.1002, ¶¶38; '282 Ex.1002, ¶¶41

Bipolar RF Energy Devices Were Used to Treat Nasal Tissue



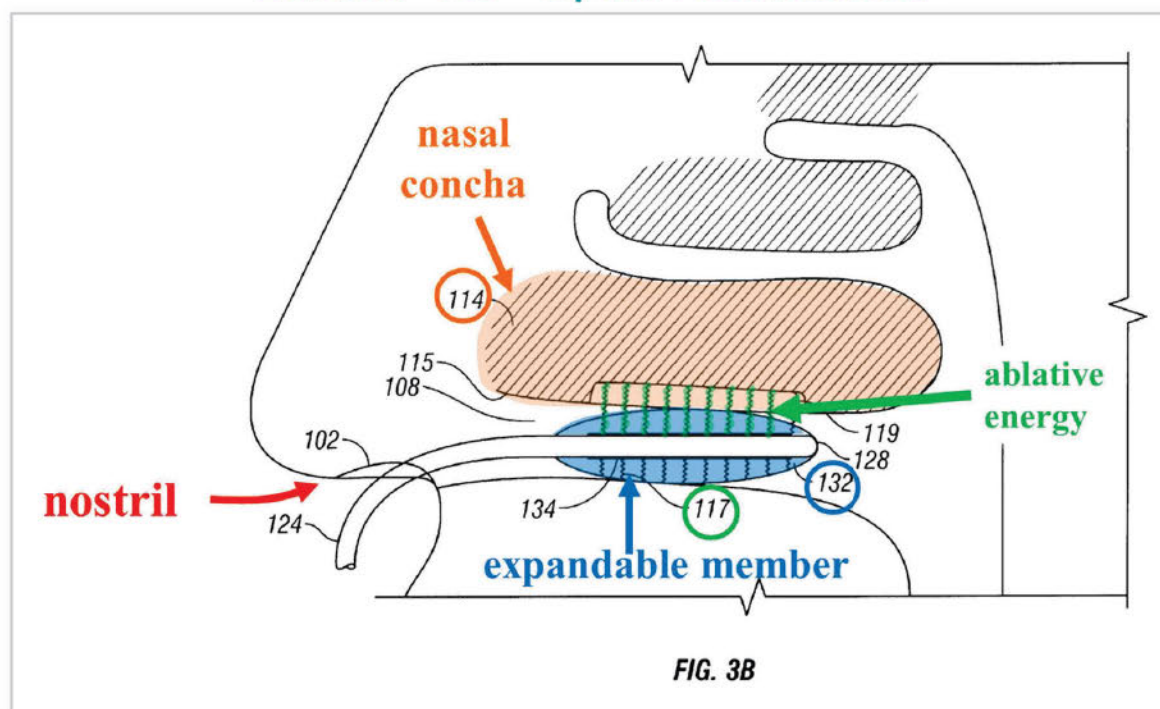
Ex.1010, Fig.3B, 10:30-32, 10:52-61; '277 Petition, 35; '278 Petition, 33; '282 Petition, 33-34; '277 Ex.1002, ¶184; '277 Ex.1004, ¶167; '278 Ex.1002, ¶196; '282 Ex.1002, ¶¶105-106



Ex.1031, 1258, Table 1; '277 Petition, 17-18; '282 Petition, 13; '277 Ex.1002, ¶45

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

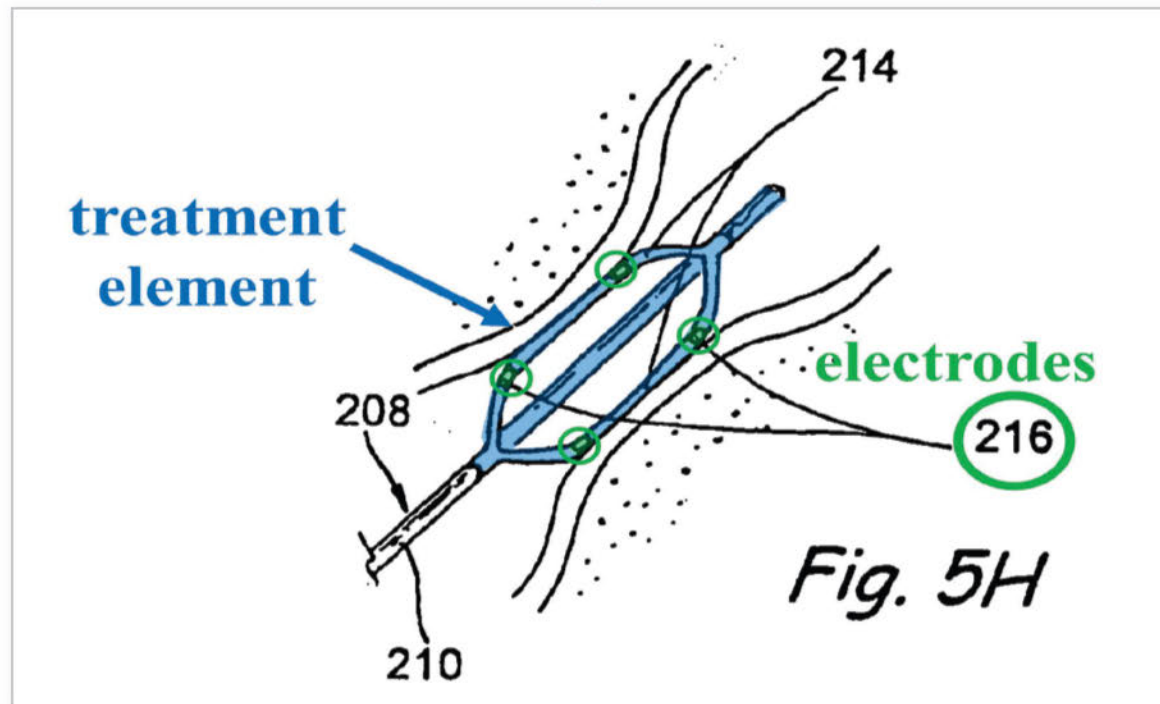
Edwards-'535 – Bipolar Nasal Ablation



'277 Petition, 35-37; '278 Petition, 32-34; '282 Petition, 33-34; '277 Ex.1002, ¶¶84-91;
'277 Ex.1004, ¶¶66-67; '278 Ex.1002, ¶¶95-97; '282 Ex.1002, ¶¶105-107

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

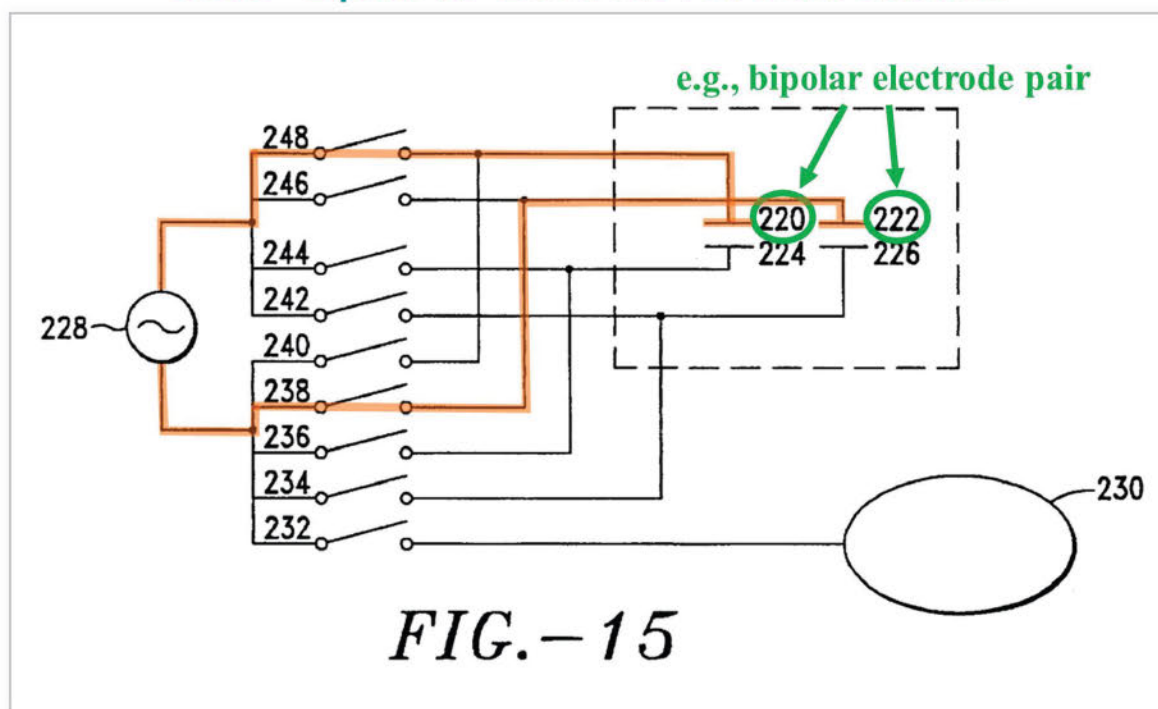
Makower – Nitinol Bipolar Nasal Ablation



'278 Petition, 82; '282 Petition, 67-68;
'278 Ex.1002, ¶¶20-272; '282 Ex.1002, ¶¶238-239

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

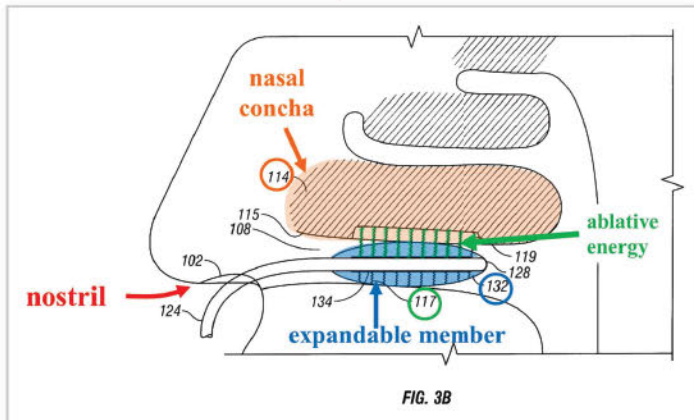
Stern – Bipolar RF Electrode Pairs and Channels



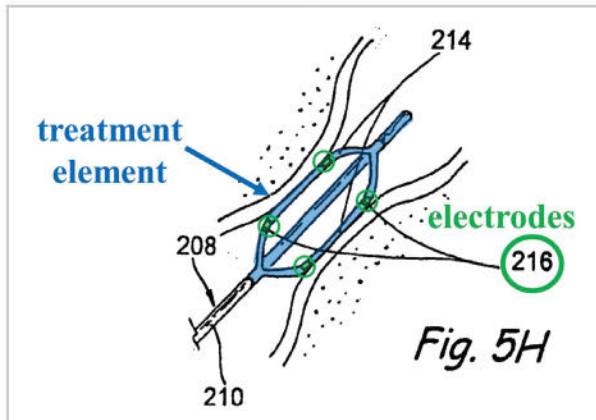
'277 Petition, 38-41; '278 Petition, 34-36; '282 Petition, 35-36; '277 Ex.1002, ¶¶92; '277 Ex.1004, ¶¶70-74; '278 Ex.1002, ¶¶98-101; '282 Ex.1002, ¶¶108-111

Bipolar RF Energy Applied to Nasal Tissue + Bipolar RF Control

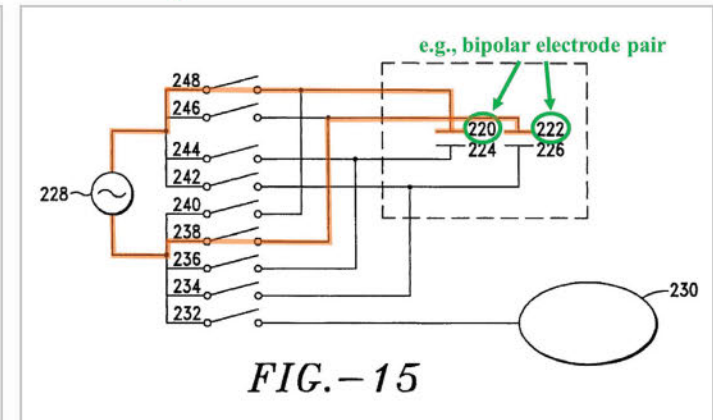
Edwards-'535 – Bipolar Nasal Ablation



Makower – Nitinol Bipolar Nasal Ablation



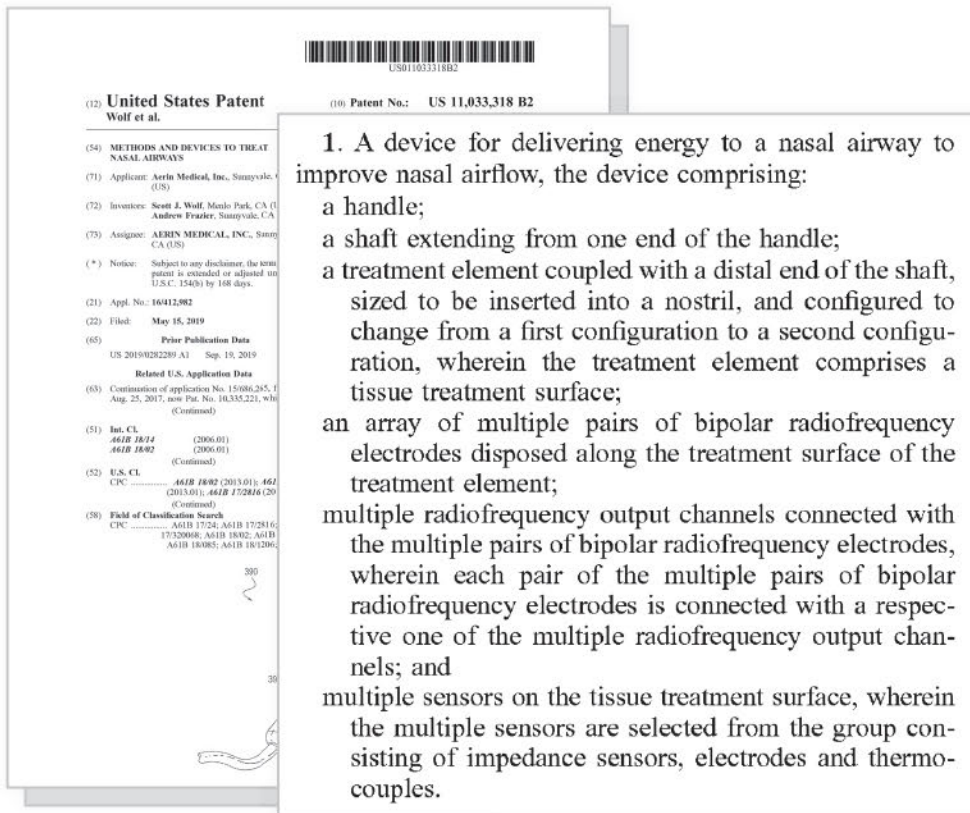
Stern – Bipolar RF Electrode Pairs and Channels



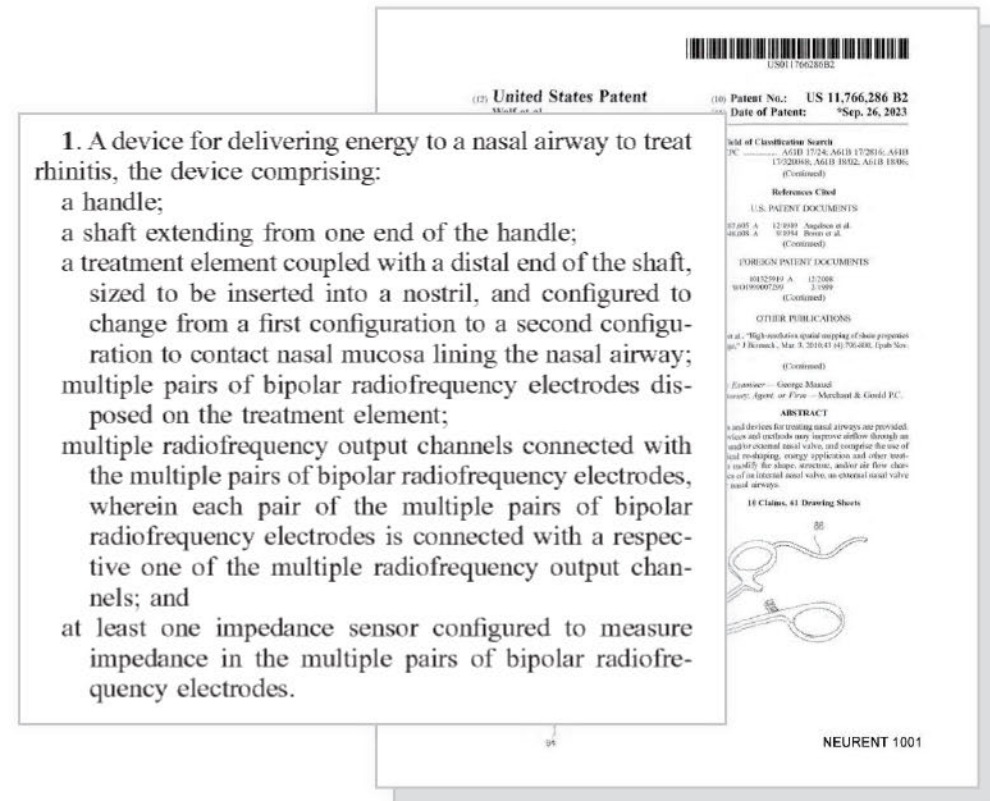
'277 Petition, 41-49; '278 Petition, 36-41; 282 Petition, 36-40; '277 Ex.1002, ¶¶93-94; '277 Ex.1004, ¶¶75-97; '278 Ex.1002, ¶¶102-122; '282 Ex.1002, ¶¶112-133

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Representative Independent Claims—'318 and '286 Patent



'278 Petition, Ex.1001-'318 Patent, Claim 1



'282 Petition, Ex.1001-'286 Patent, Claim 1

Challenged Claims

Representative Independent Claim—'271 Patent

US 11,241,271 B2

(12) United States Patent
Wolf et al.

(10) Patent No.: US 11,241,271 B2
(45) Date of Patent: Feb. 8, 2022

(54) METHODS OF TREATING NASAL AIRWAYS
(71) Applicant: Aeris Medical Inc., Austin, TX (US)
(72) Inventors: Scott J. Wolf, Menlo Park, CA (US); Andrew Frasier, Sunnyvale, CA (US)
(73) Assignee: Aeris Medical Inc., Sunnyvale, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 305 days. This patent is subject to a terminal disclaimer.

(21) Appl. No.: 16/514,316
(22) Filed: Jul. 17, 2019
(65) Prior Publication Data: US 2019/0336166 A1 Nov. 7, 2019

Related U.S. Application Data
(63) Continuation of application No. 15/296,455, filed on May 16, 2017, now Pat. No. 10,398,489, which is a (Continued)

(51) Int. Cl. A61B 18/14 (2006.01); A61B 18/02 (2006.01) (Continued)
(52) U.S. Cl. CPC 86/34 (2013.01); A61B 18/02 (2013.01); A61B 18/1206 (2013.01); (Continued)

(58) Field of Classification Search CPC A61B 17/2814; A61B 17/2808; A61B 18/02; A61B 18/06; A61B 18/08; (Continued)

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5,316,408 A 9/1994 Stern et al. (Continued)

FOREIGN PATENT DOCUMENTS
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Primary Examiner — George Marnett
(74) Attorney, Agent, or Firm — Merchant & Gould P.C.

ABSTRACT
A device is described for treating a nasal airway by modifying a property of a nasal tissue or of near a nasal valve of the airway, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in the nasal airway. Various embodiments include an elongate shaft, a bipolar radiofrequency delivery member extending from one end of the shaft, and a handle attached to the elongate shaft at an opposite end from the radiofrequency delivery member. The radiofrequency delivery member is used to be inserted into a nose and configured to at least temporarily deform the nasal tissue and deliver radiofrequency energy. The radiofrequency delivery member includes two rows of protruding electrodes disposed on a tissue contact surface, and the device is configured to deliver radiofrequency energy from one row of electrodes to the other row of electrodes.

16 Claims, 41 Drawing Sheets

1. A method for treating a nasal airway to reduce mucus production, the method comprising:

contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

removing the treatment element from the nasal airway, wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue; and

wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

'277 Petition, Ex.1001-'271 Patent, Claim 1

Stern Discloses the Claimed Electrode Pairs

IPR2024-00277; IPR2024-00278; IPR2024-00282

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Stern Discloses Both:

- multiple bipolar electrode pairs
 - “bipolar electrode pairs” – IPR2024-00277
 - “multiple pairs of bipolar radiofrequency electrodes” – IPR2024-00278, IPR2024-00282
- “two rows” of bipolar electrode pairs
 - “two rows of bipolar electrode pairs” – IPR2024-00277
 - “the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes” – IPR2024-00278

E.g., '277 Petition, 38-41; '278 Petition, 34-36; '282 Petition, 35-36; '277 Ex.1002, ¶¶92; '277 Ex.1004, ¶¶70-74; '278 Ex.1002, ¶¶98-101; '282 Ex.1002, ¶¶108-111

Stern Discloses Multiple Bipolar Electrode Pairs

United States Patent (19)

Stern et al.

(11) Patent Number:

5,562,720

(45) Date of Patent:

Oct. 8, 1996

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5,443,463, and a continuation in part of Ser. No. 135,004,
Oct. 14, 1995, 60/028,004.

[31] Int. Cl.⁶ A61N 1/00
[52] U.S. Cl. 607/58, 607/59, 606/22,
606/41
[51] Field of Search 607/58, 607/59, 606/22,
606/33, 14, 27-40, 41, 48-50

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4 Claims, 19 Drawing Sheets

Stern Discloses Multiple Bipolar Electrode Pairs



- | | | |
|------|--|--|
| [54] | BIPOLAR MONOPHASE AC ELECTROMETRIC
ACTIVATION DEVICE AND METHOD | 3193033 10/1990 Germany
W03/027255 10/1997 WFO
W03/032623 10/1998 WFO |
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| [56] | Assignee: Biotra Medical, Inc., Palo Alto | |
| [57] | Appl. No. 331926 | |
| [58] | Filed: Oct. 8, 1994 | |

Related U.S. Application Data

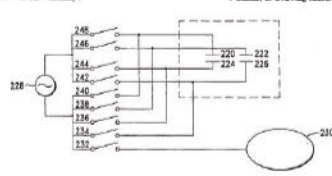
- [illegible]

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| 3,750,655 | 10/727 | Stuenkel |
| 3,784,328 | 2/174 | Rosen |

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| 0497057 | 1/1991 | European Pat. Off. |
| 2522801 | 1/1984 | France |
| 2679456 | 1/1993 | France |
| 832711.1 | 6/1985 | Germany |
- 4 Claims, 19 Drawing Sheets



NEURENT 1033

It is a further object of the present invention to provide a system of selective delivery of either monopolar RF energy to a single electrode or bipolar RF energy to chosen pairs of an array of separate electrodes which are used to bring the endometrial temperature to a desired level.

Ex.1033-'720 Patent, 2:36-40; '277 Petition, 38-39; '278 Petition, 34-35; '282 Petition, 35; '277 Ex.1002, ¶92; '277 Ex.1002, ¶70; '278 Ex.1002, ¶¶98-100; '282 Ex.1002, ¶¶108-110

Stern Discloses Multiple Bipolar Electrode Pairs

United States Patent [19] **Patent Number:** 5,562,720
Stern et al. [45] **Date of Patent:** Oct. 8, 1996

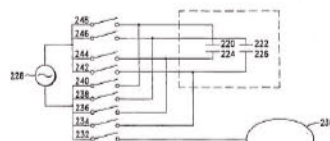
[54]	BIPOLAR MONOPHASE AC ELECTROMETRIC ACTIVATION DEVICE AND METHOD	3193033 10/1990 Germany W03/027255 10/1997 WFO W03/032623 10/1998 WFO
[55]	EXTRACTORS	OTHER PUBLICATIONS "Hypertension Overview Using Monomode Arterial", "Invasive Lung", Thomas P. Ryan, M.D. Thermatec Technology, C. C. Coggins, M.D. "Hypertension: The Role of the", Terrell, Michael Dolan. "Essential Arterial", "Therapeutic Hypertension: Indications and Techniques", pp. 163-67, W. B. Saunders et al. "Lumen Resonance for Inertial Arterial and Resonance", Karl Eise.
[56]	Assignee: Yota Medical, Inc., Palo Alto	
[57]	Appl. No. 3193216	
[58]	Filed: Oct. 8, 1994	

Retained U.S. Application Data

[63] *Continuation in part of* Ser. No. 5,473,667, May 1, 1992, *Int. Cl.* No. G01D 23/27, 23/30, and a *reformation in part of* Ser. No. 5,466,645, Apr. 14, 1993, *Int. Cl.* No. 5,467,655, Apr. 14, 1993, *Int. Cl.* No. G01D 23/27, 23/30, 23/38, 23/39, 23/40, 23/41, 23/42, 23/43, 23/44, 23/45, 23/46, 23/47, 23/48, 23/49, 23/50, 23/51, 23/52, 23/53, 23/54, 23/55, 23/56, 23/57, 23/58, 23/59, 23/60, 23/61, 23/62, 23/63, 23/64, 23/65, 23/66, 23/67, 23/68, 23/69, 23/70, 23/71, 23/72, 23/73, 23/74, 23/75, 23/76, 23/77, 23/78, 23/79, 23/80, 23/81, 23/82, 23/83, 23/84, 23/85, 23/86, 23/87, 23/88, 23/89, 23/90, 23/91, 23/92, 23/93, 23/94, 23/95, 23/96, 23/97, 23/98, 23/99, 23/100, 23/101, 23/102, 23/103, 23/104, 23/105, 23/106, 23/107, 23/108, 23/109, 23/110, 23/111, 23/112, 23/113, 23/114, 23/115, 23/116, 23/117, 23/118, 23/119, 23/120, 23/121, 23/122, 23/123, 23/124, 23/125, 23/126, 23/127, 23/128, 23/129, 23/130, 23/131, 23/132, 23/133, 23/134, 23/135, 23/136, 23/137, 23/138, 23/139, 23/140, 23/141, 23/142, 23/143, 23/144, 23/145, 23/146, 23/147, 23/148, 23/149, 23/150, 23/151, 23/152, 23/153, 23/154, 23/155, 23/156, 23/157, 23/158, 23/159, 23/160, 23/161, 23/162, 23/163, 23/164, 23/165, 23/166, 23/167, 23/168, 23/169, 23/170, 23/171, 23/172, 23/173, 23/174, 23/175, 23/176, 23/177, 23/178, 23/179, 23/180, 23/181, 23/182, 23/183, 23/184, 23/185, 23/186, 23/187, 23/188, 23/189, 23/190, 23/191, 23/192, 23/193, 23/194, 23/195, 23/196, 23/197, 23/198, 23/199, 23/200, 23/201, 23/202, 23/203, 23/204, 23/205, 23/206, 23/207, 23/208, 23/209, 23/210, 23/211, 23/212, 23/213, 23/214, 23/215, 23/216, 23/217, 23/218, 23/219, 23/220, 23/221, 23/222, 23/223, 23/224, 23/225, 23/226, 23/227, 23/228, 23/229, 23/230, 23/231, 23/232, 23/233, 23/234, 23/235, 23/236, 23/237, 23/238, 23/239, 23/240, 23/241, 23/242, 23/243, 23/244, 23/245, 23/246, 23/247, 23/248, 23/249, 23/250, 23/251, 23/252, 23/253, 23/254, 23/255, 23/256, 23/257, 23/258, 23/259, 23/260, 23/261, 23/262, 23/263, 23/264, 23/265, 23/266, 23/267, 23/268, 23/269, 23/270, 23/271, 23/272, 23/273, 23/274, 23/275, 23/276, 23/277, 23/278, 23/279, 23/280, 23/281, 23/282, 23/283, 23/284, 23/285, 23/286, 23/287, 23/288, 23/289, 23/290, 23/291, 23/292, 23/293, 23/294, 23/295, 23/296, 23/297, 23/298, 23/299, 23/300, 23/301, 23/302, 23/303, 23/304, 23/305, 23/306, 23/307, 23/308, 23/309, 23/310, 23/311, 23/312, 23/313, 23/314, 23/315, 23/316, 23/317, 23/318, 23/319, 23/320, 23/321, 23/322, 23/323, 23/324, 23/325, 23/326, 23/327, 23/328, 23/329, 23/330, 23/331, 23/332, 23/333, 23/334, 23/335, 23/336, 23/337, 23/338, 23/339, 23/340, 23/341, 23/342, 23/343, 23/344, 23/345, 23/346, 23/347, 23/348, 23/349, 23/350, 23/351, 23/352, 23/353, 23/354, 23/355, 23/356, 23/357, 23/358, 23/359, 23/360, 23/361, 23/362, 23/363, 23/364, 23/365, 23/366, 23/367, 23/368, 23/369, 23/370, 23/371, 23/372, 23/373, 23/374, 23/375, 23/376, 23/377, 23/378, 23/379, 23/380, 23/381, 23/382, 23/383, 23/384, 23/385, 23/386, 23/387, 23/388, 23/389, 23/390, 23/391, 23/392, 23/393, 23/394, 23/395, 23/396, 23/397, 23/398, 23/399, 23/400, 23/401, 23/402, 23/403, 23/404, 23/405, 23/406, 23/407, 23/408, 23/409, 23/410, 23/411, 23/412, 23/413, 23/414, 23/415, 23/416, 23/417, 23/418, 23/419, 23/420, 23/421, 23/422, 23/423, 23/424, 23/425, 23/426, 23/427, 23/428, 23/429, 23/430, 23/431, 23/432, 23/433, 23/434, 23/435, 23/436, 23/437, 23/438, 23/439, 23/440, 23/441, 23/442, 23/443, 23/444, 23/445, 23/446, 23/447, 23/448, 23/449, 23/450, 23/451, 23/452, 23/453, 23/454, 23/455, 23/456, 23/457, 23/458, 23/459, 23/460, 23/461, 23/462, 23/463, 23/464, 23/465, 23/466, 23/467, 23/468, 23/469, 23/470, 23/471, 23/472, 23/473, 23/474, 23/475, 23/476, 23/477, 23/478, 23/479, 23/480, 23/481, 23/482, 23/483, 23/484, 23/485, 23/486, 23/487, 23/488, 23/489, 23/490, 23/491, 23/492, 23/493, 23/494, 23/495, 23/496, 23/497, 23/498, 23/499, 23/500, 23/501, 23/502, 23/503, 23/504, 23/505, 23/506, 23/507, 23/508, 23/509, 23/510, 23/511, 23/512, 23/513, 23/514, 23/515, 23/516, 23/517, 23/518, 23/519, 23/520, 23/521, 23/522, 23/523, 23/524, 23/525, 23/526, 23/527, 23/528, 23/529, 23/530, 23/531, 23/532, 23/533, 23/5

[illegible]

4 Claims, 19 Drawing Sheets



NEURENT 1033

trodes. The step of controlling said radio frequency energy can include selectively providing bipolar energy to selective pairs of said plurality of electrodes.

Ex.1033, 3:38-40; '277 Petition, 38; '278 Petition, 34-35; '282 Petition, 35;
'277 Ex.1002, ¶92; '277 Ex.1004, ¶70; '278 Ex.1002, ¶99; '282 Ex.1002, ¶109

PO's Expert Agrees that Stern Discloses Delivering RF Energy Through Different Pairs



Dr. Marom Bikson

PO's Declarant

- Q.** Sure. You agree Stern has at least two different pairs of bipolar electrodes, correct?
- A.** I think we've discussed that Stern allows you to select one pair of electrodes. And then if you return to the situation where the switches were open, you can select then another single, **different pair**.

* * *

- Q.** But there are two pairs, correct?
- A.** If you were to—we talked about a first case where you had one pair. We talked about a second case where you also had one pair. **If you were to then add those up, you would get to the number two.**

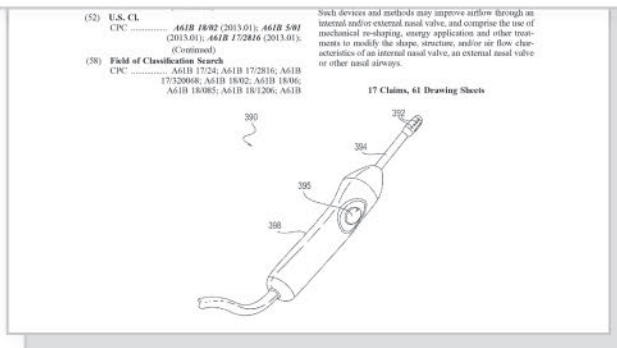
'278 Petition, Ex.1084, 113:3-10, 115:6-11; '277 Reply, 3; '278 Reply, 3; '282 Reply, 3

Stern's Disclosure Is Parallel to Disclosure in Challenged Patent

'318 Patent



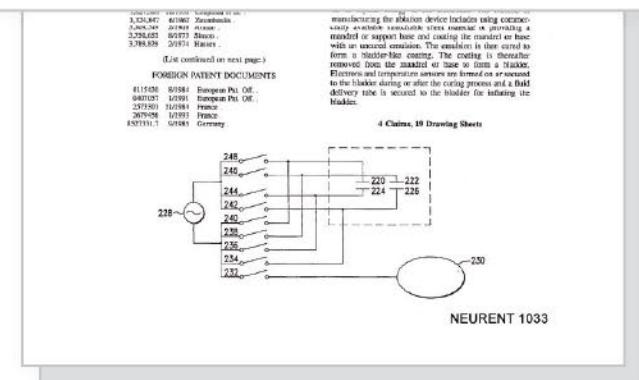
In some embodiments of treatment devices comprising an array or **multiple pairs of electrodes**, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For



Stern



4. The method according to claim 3 wherein the step of controlling said radio frequency energy includes selectively providing **bipolar energy to selected pairs** of said plurality of electrodes.



Patent Owner Argues Multiple “bipolar pairs” Are Required to Deliver Energy Through Three or More Switches

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
Petitioners,

v.

AERIN MEDICAL, INC.,
Patent Owner.

Case IPR2024-00282
U.S. Patent No. 11,766,286

PATENT OWNER'S SUR-REPLY

Bikson, ¶63; Ex-2008 at 202:14-203:4, 204:4-6.) Thus, for Stern's Figure 15 device to comprise “multiple pairs of bipolar radiofrequency electrodes,” as claimed, **three or more of Stern's switches must be closed.** (POR at 18-19; Ex-2001-Bikson, ¶64.) Stern does not teach this. (*Id.*) Rather, Stern teaches a device that, **at any given time**, comprises at most one pair of electrodes. (*Id.*)

'277 Sur-Reply, 4; '278 Sur-Reply, 2; '282 Sur-Reply, 2

Patent Owner Argues Multiple “bipolar pairs” Are Required to Deliver Energy Through Three or More Switches

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.,
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AERIN MEDICAL, INC.,
Patent Owner.

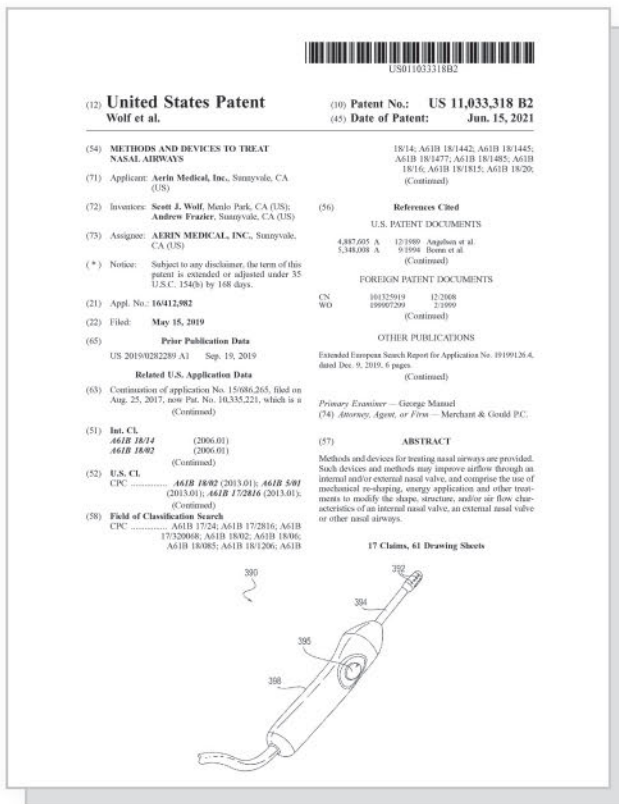
Case IPR2024-00282
U.S. Patent No. 11,766,286

PATENT OWNER'S SUR-REPLY

96:1, 125:9-126:1, 237:10-238:18; Ex-2008 at 17:2-18:13.) Petitioners fail to identify how their proposed combination teaches a device configured to have multiple pairs, as Stern teaches a device that, **at any given time**, comprises at most one pair of electrodes.

'278 Sur-Reply, 3; '282 Sur-Reply, 3; *see also* '277 Sur-Reply, 4

Stern's Disclosure Compared with the Disclosure of the Challenged Patents



Ex.1001-318 Patent, Claim 1

an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;

In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For

In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.

Ex.1001-'318 Patent, 24:45-49, 48:63-65; '278 Reply, 4; see also '277 Reply, 5; '282 Reply, 4

Stern's Disclosure Compared with the Disclosure of the Challenged Patents

to provide a feedback temperature for each electrode. The plurality of separate electrodes are independently and sequentially energized and controlled with thermistor temperature feedback control to bring the endometrial temperature to a desired level.

Ex.1033, 2:31-33; '277 Sur-Reply, 6; '278 Sur-Reply, 4; '282 Sur-Reply, 4

It is a further object of the present invention to provide a system of selective delivery of either monopolar RF energy to a single electrode or bipolar RF energy to chosen pairs of an array of separate electrodes which are used to bring the endometrial temperature to a desired level.

Ex.1033, 2:36-40; '277 Petition, 38-39; '278 Petition, 34-35; '282 Petition, 35; '277 Ex.1002, ¶192; '277 Ex.1004, ¶170; '278 Ex.1002, ¶¶98-100; '282 Ex.1002, ¶¶108-110

In some embodiments of treatment devices comprising an array or multiple pairs of electrodes, each pair of electrodes (bipolar) or each electrode (monopolar) may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately. For

Ex.1001-'318 Patent, 24:45-49

In some embodiments, each pair of electrodes may have a separate, controlled electrical channel to allow for different regions of the treatment element to be activated separately.

Ex.1001-'318 Patent, 48:63-65; '278 Reply, 4; see also '277 Reply, 5; '282 Reply, 4

Patent Owner Did Not Respond to Cited Evidence

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL, INC.

Patent Owner.

Case No. IPR2024-00282

U.S. Patent No. 11,766,286

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

have multiple pairs at the same time. (Reply at 5.) Petitioners' argument is based on a single sentence in Stern stating that "any combination of pairs of electrodes may be utilized together." (*Id.* (quoting Ex-1033-Stern at 13:39-43).) Petitioners

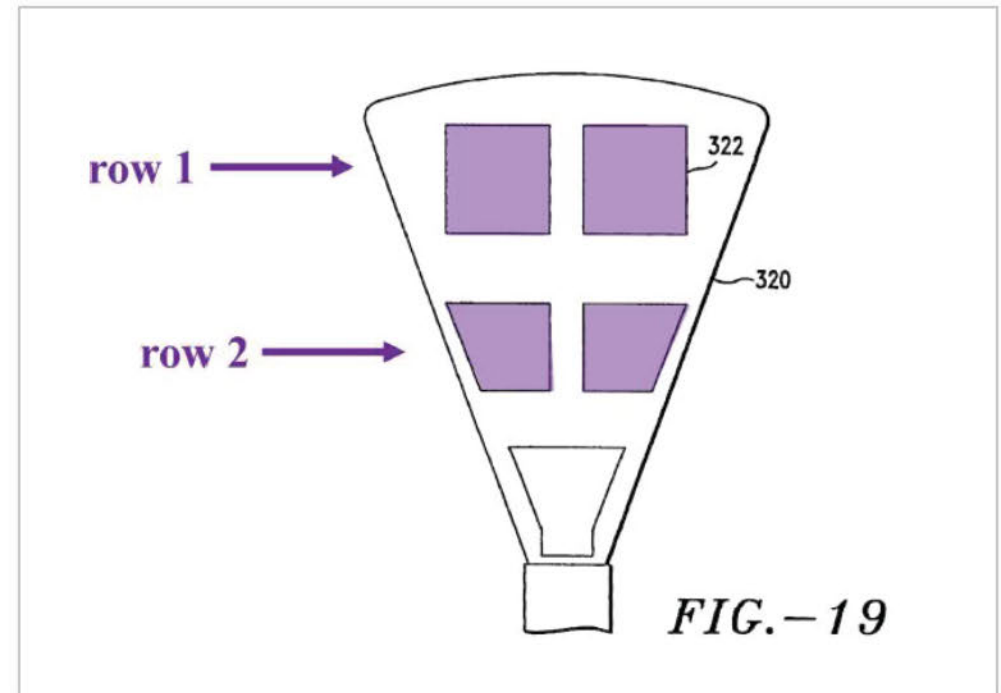
'277 Sur-Reply, 5; '278 Sur-Reply, 3; '282 Sur-Reply, 3

Stern discloses "pairs" of bipolar electrodes nine separate times, and there is no dispute that Stern discloses at least two different pairs of bipolar electrodes. Ex.1033-Stern, 2:36-40, 3:38-40, 12:20-22, 12:22-24, 12:29-33, 13:27-31, 13:31-38, 13:39-42, 20:6-9; Ex.1082-Bikson-Tr., 107:16-108:9, 109:4-12, 112:4-12, 113:3-116:20. PO nevertheless argues, incorrectly, that it can avoid Stern's teachings if

'277 Reply, 4; '278 Reply, 3; '282 Reply, 3

Stern Discloses “two rows” of Bipolar Electrode Pairs

- Claim 1, '271 Patent:
 - “two rows of bipolar electrode pairs”
- Claim 15, '318 Patent:
 - “the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes”



'277 Petition, 38-41; '278 Petition, 66-67; '277 Ex.1002, ¶¶92; '277 Ex.1004, ¶¶70-74; '278 Ex.1002, ¶¶212-217

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Patents Explain Bipolar Electrode Pairs Are Not in a Single Row

Claim Language

Claim 1, '271 Patent:

wherein the treatment element comprises two rows of bipolar electrode pairs;

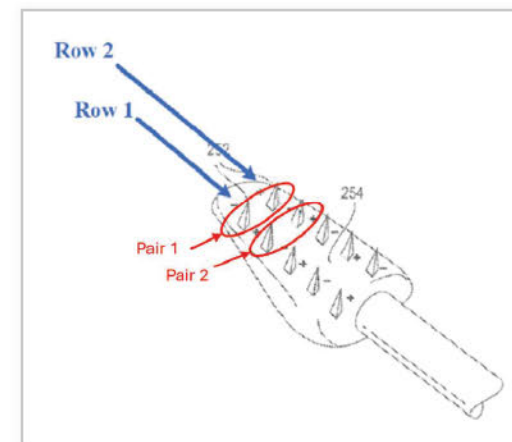
Claim 15, '318 Patent:

15. The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.

Ex.1001-'271 Patent, Claim 1; Ex.1001-318 Patent, Claim 15

Patent Specification

tissue. In some embodiments, the protruding electrodes may include two rows of electrodes, where the energy delivery member comprises a bipolar radio frequency delivery member, and where radio frequency energy travels from one row of electrodes to the other row of electrodes.



Ex.1001-'271 Patent, 8:21-25; '277 Reply, 8; '277 Ex.1083, ¶130; '277 Ex.1097, ¶131

Patents Explain Bipolar Electrode Pairs Are Not in a Single Row

Claim Language

Claim 1, '271 Patent:

wherein the treatment element comprises two rows of bipolar electrode pairs;

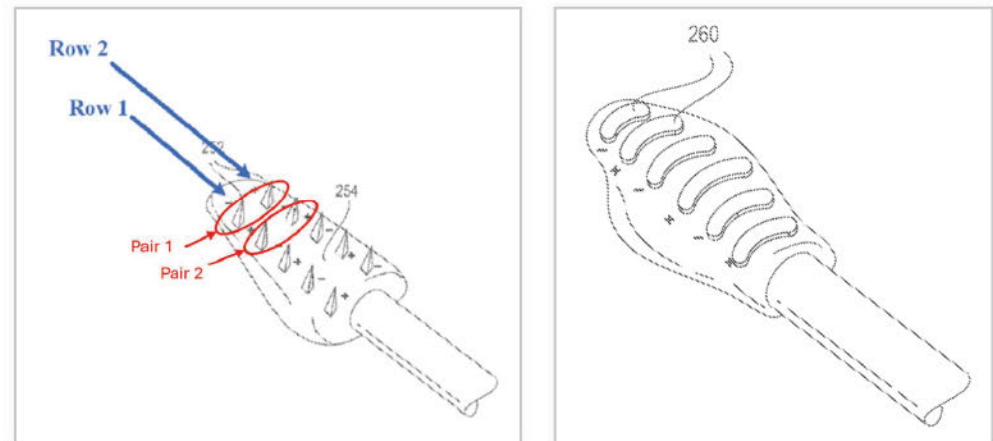
Claim 15, '318 Patent:

15. The device of claim 1, wherein the multiple pairs of bipolar radiofrequency electrodes comprise two rows of electrodes.

Ex.1001-'271 Patent, Claim 1; Ex.1001-318 Patent, Claim 15

Patent Specification

FIG. 8G illustrates another embodiment of a treatment element comprises one, two or many pairs of bipolar electrodes 260. As opposed to FIG. 8F, where the pairs of electrodes are arranged side-by-side, the embodiment of FIG. 8G arranges the pairs of electrodes along the length of the treatment element. The electrodes of FIG. 8G are also



Ex.1001-'271 Patent, 23:56-59; '277 Reply, 8; '277 Ex.1083, ¶130; '277 Ex.1097, ¶131

Prior Art Discloses “two rows” Even Under Patent Owner’s Improperly Narrow Interpretation / Construction

United States Patent (79) Stern et al. Patent Number: 5,562,720 Date of Patent: Oct. 8, 1996

151 Patent Number: 5,562,720
152 Date of Patent: Oct. 8, 1996

154 REGULAR MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD

155 INVENTORS: Roger A. Sierra, Capistrano; Vincent R. Sullivan, San Jose; Roxanne L. Richmond, Santa Cruz; Larus E. Roy, Northridge; Robert L. Markos, Thousand Oaks; Douglas D. Stricker, both of San Jose, all of Calif.

156 Assignee: Vesta Medical, Inc., Palo Alto

157 Appl. No. 315,244

158 Filed Oct. 6, 1994

Related U.S. Application Data

159 Continuation-in-part of Ser. No. 077,207, May 1, 1993, by No. 5,277,203, and a continuation-in-part of Ser. No. 4,683, Apr. 14, 1993, by No. 5,443,003, and a continuation-in-part of Ser. No. 060,601, filed Apr. 30, 1995, by No. 5,443,003, and a continuation-in-part of Ser. No. 350,098, Oct. 3, 1995, abandoned.

160 Int. Cl. A61N 5/06

161 U.S. CL. 607/908, 607/909, 607/912, 607/914

162 Field of Search 607/908, 909, 607/912, 607/913, 34, 37-40, 41, 44, 50

163 References Cited

U.S. PATENT DOCUMENTS

3,227,200 10/11/1966 Charnin et al.
3,224,842 6/19/67 Zwickel
3,300,540 5/19/68 Auer
3,300,652 9/22/68 Auer
3,300,629 2/19/69 Auer

(List continued on next page.)

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01/540 9/1984 European Pat. Off.
04/270 7/1991 European Pat. Off.
23/380 11/1984 France
20/940 9/1991 France
82/231.7 9/1983 Germany

4 Claims, 19 Drawing Sheets

FIG. 1033

A POSITA Would Have Been Motivated to Modify Edwards-'535 Electrode Arrangement in View of Stern

1. Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.
2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.
3. Two rows is an obvious arrangement of parts.
4. Other *KSR* rationales.

'277 Petition, 41-49; '278 Petition, 67; '277 Reply, 16-20; '278 Reply, 28-30

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'277 Petition, 41-49; '278 Petition, 67; '277 Reply, 16-20; '278 Reply, 28-30

1. Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.

(12) United States Patent
Edwards

(39) Patent No.: US 6,517,535 B2
(45) Date of Patent: *Feb. 11, 2003

(54) APPARATUS FOR ABLATING TURBINATES

(75) Inventor: Stuart D. Edwards, Perle Valley, CA (US)

(73) Assignee: Gyrus ENT LLC, Bedford, IN (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(b), and is subject to the twenty-year patent term provision of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 09/437,306

(22) Filed: Nov. 9, 1999

(65) Prior Publication Data

US 2000/010101 A1 Jul. 13, 2000

Related U.S. Application Data

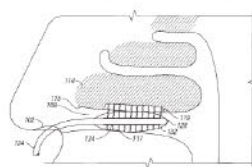
(63) Continuation of application No. 08/753,063, filed on Nov. 19, 1996, now abandoned, which is a continuation-in-part of application No. 08/758,330, filed on Nov. 19, 1996, now Pat. No. 5,746,234, and a continuation-in-part of application No. 08/724,776, filed on Nov. 19, 1996, now Pat. No. 5,740,420, which is a continuation-in-part of application No. 08/601,766, filed on May 22, 1996, now abandoned, which is a continuation-in-part of application No. 08/552,796, filed on May 22, 1996, now abandoned, which is a continuation-in-part of application No. 08/289,499, filed on Jan. 24, 1994, now Pat. No. 5,392,730.

(51) Int. Cl. A61B 18/18

(52) U.S. Cl. 606/41, 607/101, 128/008

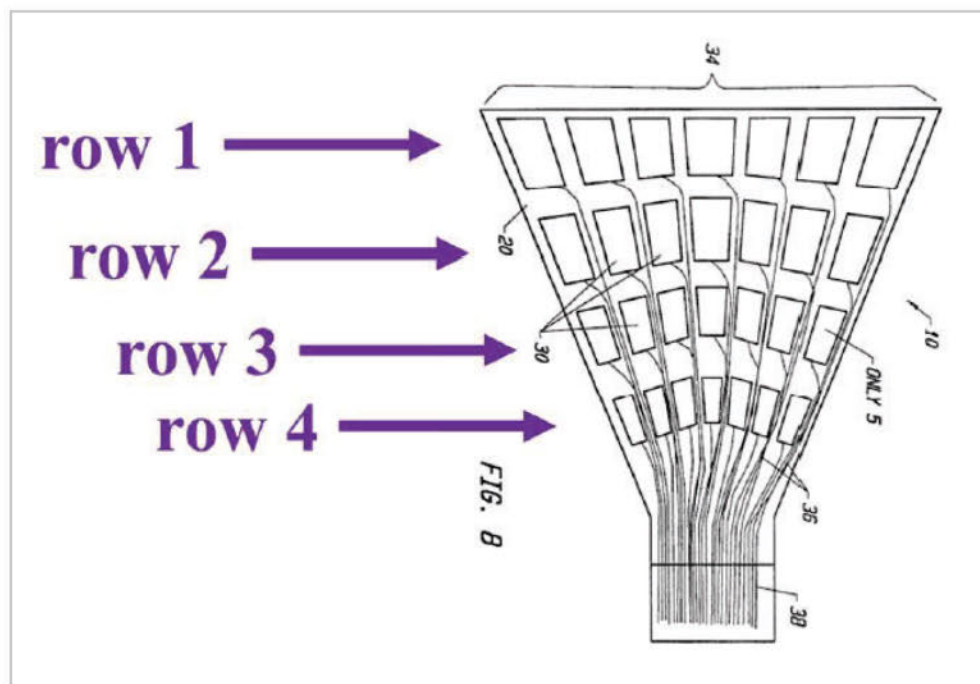
(53) Field of Search 606/27-31, 61, 606/42, 45-50, 607/100-105, 99, 115, 116, 604/114

10 Claims, 14 Drawing Sheets

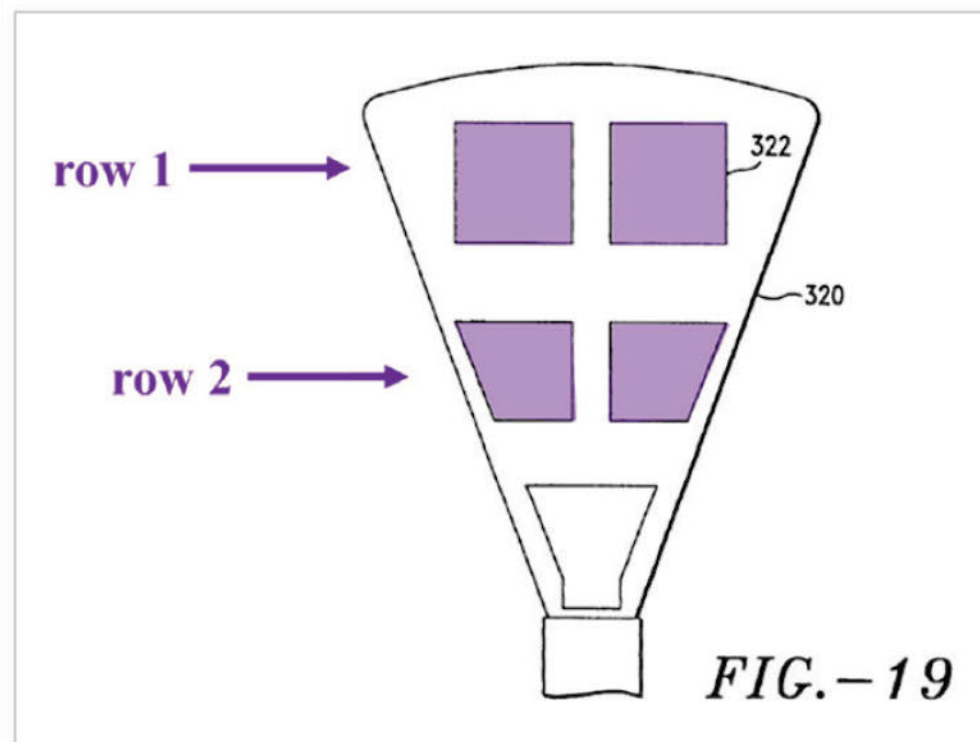


1. Edwards-'535 itself identifies a reference that has bipolar RF electrodes arranged in multiple rows.

Baker



Stern



Ex.1011, Fig. 8; Ex.1033, Fig.19; '277 Petition, 47; '277 Ex.1002, ¶194; '277 Ex.1004, ¶¶194-95

2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.

Petitioners,

v.

AERIN MEDICAL INC.,
Patent Owner.

Case No. IPR2024-00277
U.S. Patent No. 11,241,271

REPLY DECLARATION OF DR. JOHN DELGAUDIO

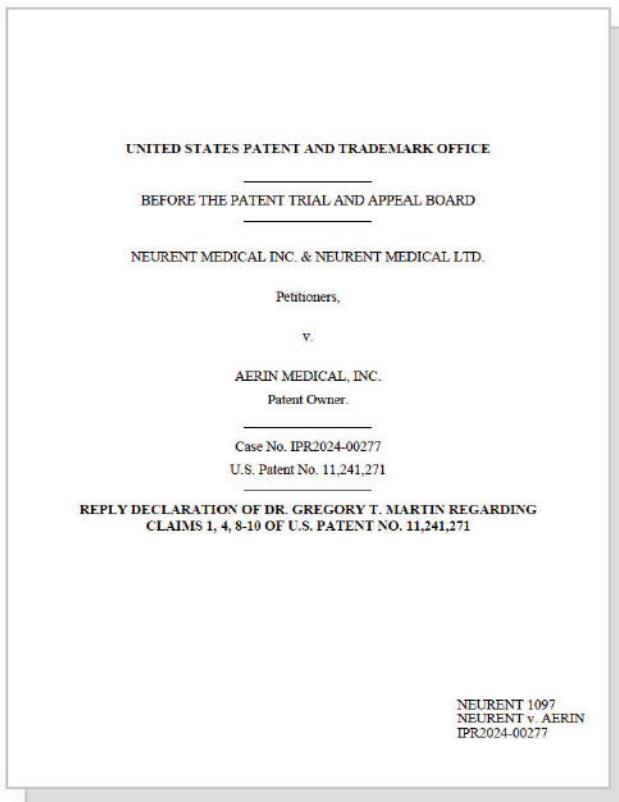
NEURENT 1083
NEURENT v. AERIN
IPR2024-00277

For example, when treating a smaller portion of a turbinate (or a turbinate of a smaller patient), one row of electrodes may be sufficient to provide the desired even heating and precise control, but when treating a larger portion or a larger patient, two or more rows may be preferred to give control over a larger area of the anatomy.

'277 Reply, 19-20; '277 Ex.1083, ¶ 47

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

2. Two rows of bipolar electrode pairs facilitates simple spatial resolution of the applied energy.



Ordered arrangements of electrodes (e.g., those in rows like in Stern) directly support that process by making it easy to determine (1) the location and proximity of electrodes that could be paired and (2) sense the characteristics of energy application local to such pairs. In more random arrangements, it would be

'277 Reply, 19-20; '277 Ex.1097, ¶ 44; '278 Reply, 29-30; '278 Ex.1083, ¶191

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

3. Two rows is an obvious arrangement of parts.

Edwards-'535 already discloses one row of electrodes, *see, e.g.*, Ex.1010-Edwards-'535, FIG.6, and thus adding another row of electrodes would have involved an obvious duplication of parts. *See, e.g., In re Harza*, 274 F.2d 669 (C.C.P.A. 1960). Ex.1002-Decl., ¶94; Ex.1004-Decl., ¶¶94-95.

'277 Petition, 48

Petition at 47-49, but not Petition at 43-47). Generally, increasing the quantity of a component in a device that functions in the same, predictable way is not patentable. *Tyco Healthcare Group LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 978 (Fed. Cir. 2014).

'277 Reply, 17

4. Other **KSR** rationales.

Additional Motivations to Combine

Straightforward and predictable combination

Combining known prior art elements according to known methods to yield predictable results

Substituting one known element for another to obtain predictable results

Using a known technique to improve similar devices in the same way

Applying a known technique to a known device ready for improvement

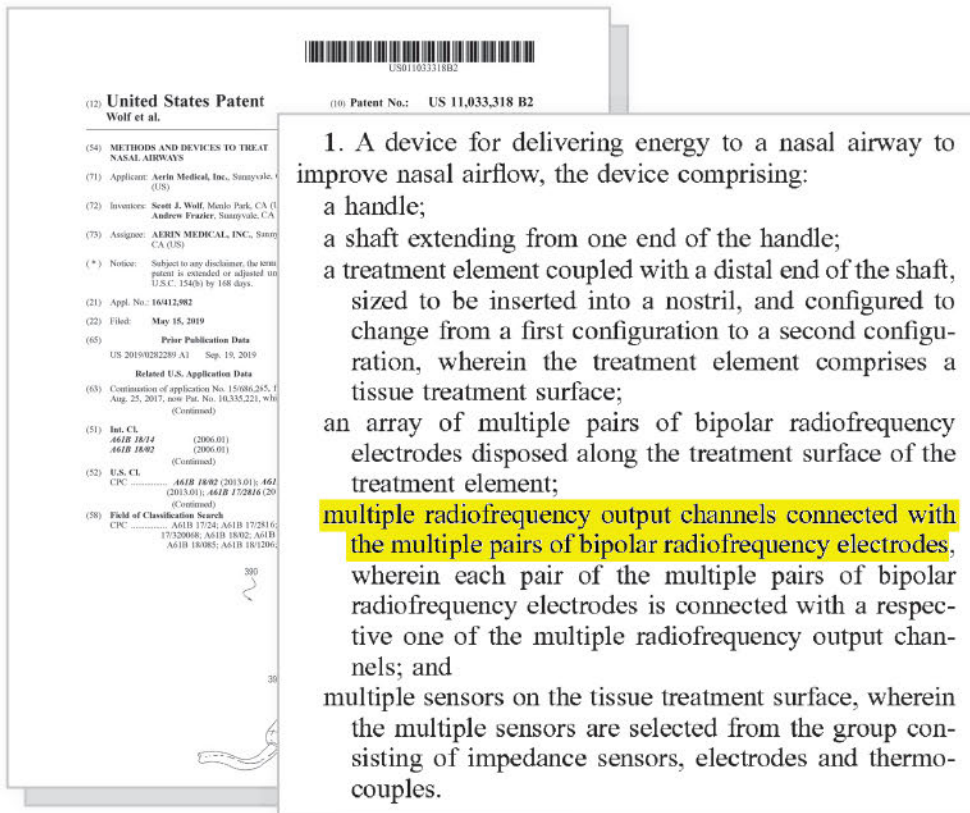
'277 Petition, 48-49; '277 Ex.1002, ¶ 94; '277 Ex.1004, ¶97

**Stern Discloses
“multiple radiofrequency output channels”**

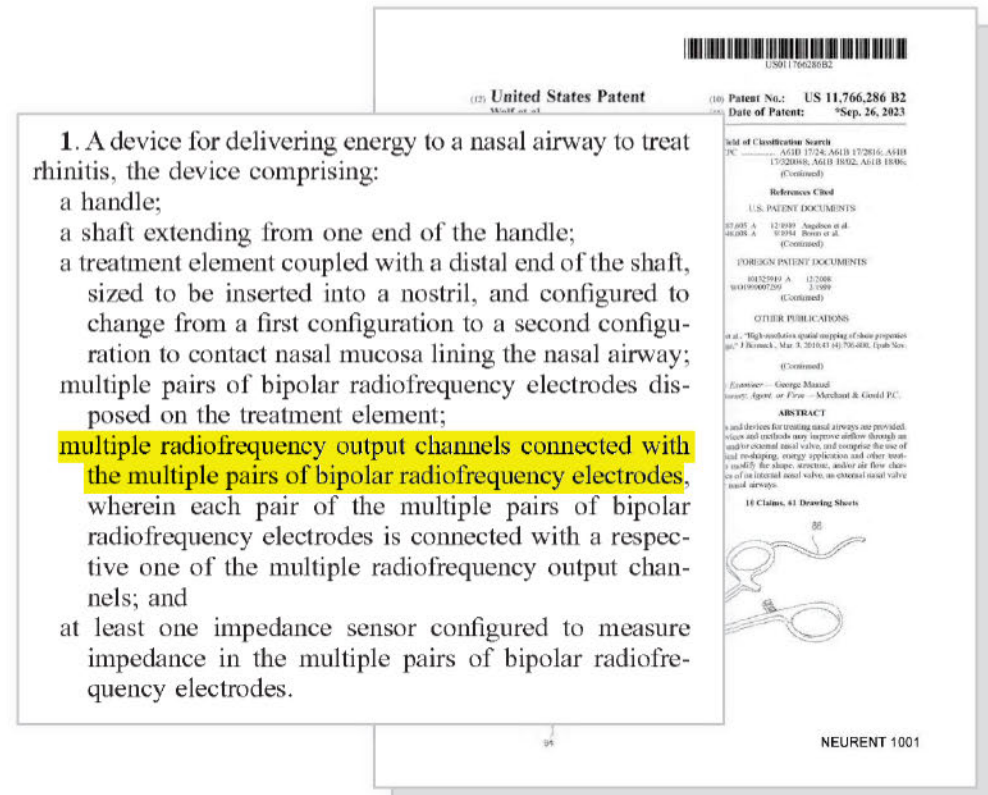
IPR2024-00278; IPR2024-00282

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Representative Independent Claims—'318 and '286 Patent

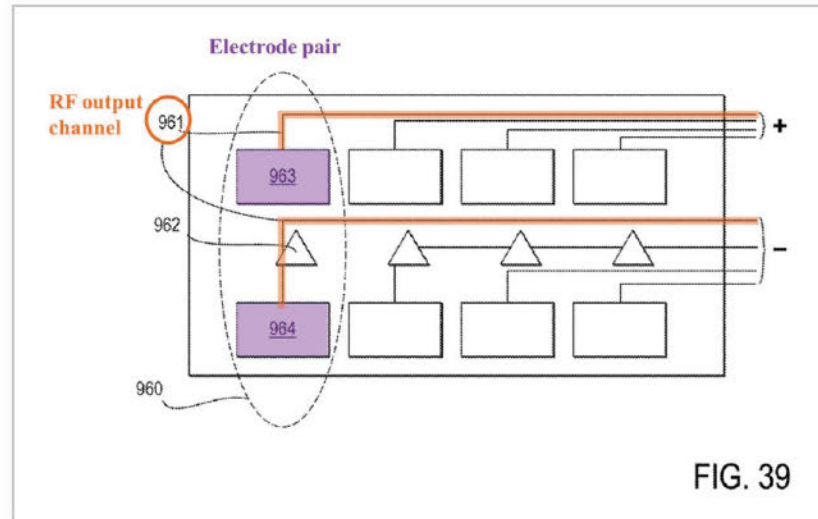
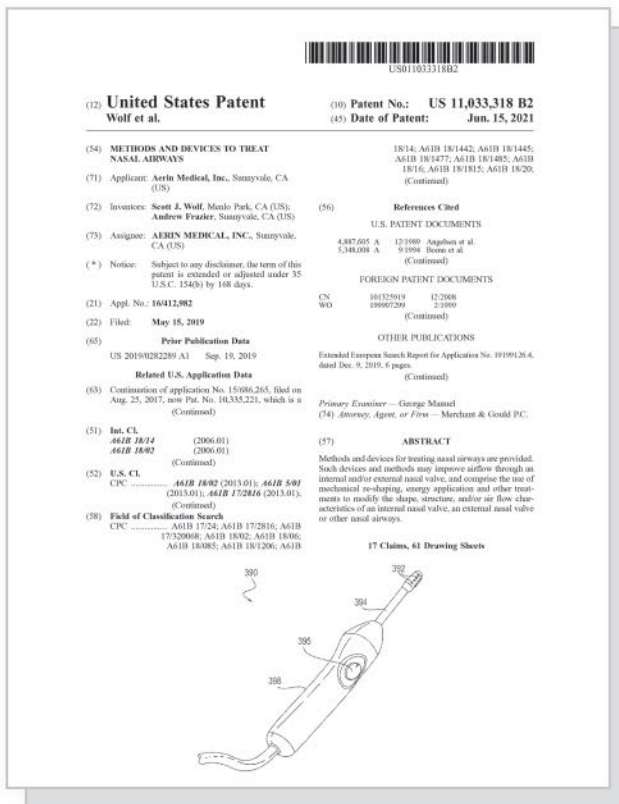


'278 Petition, 41-45; Ex.1001-'318 Patent, Claim 1



'282 Petition, 40-43; Ex.1001-'286 Patent, Claim 1

Patents Describe “output channels” as Individually Controllable Channels Delivering RF Energy to Electrodes

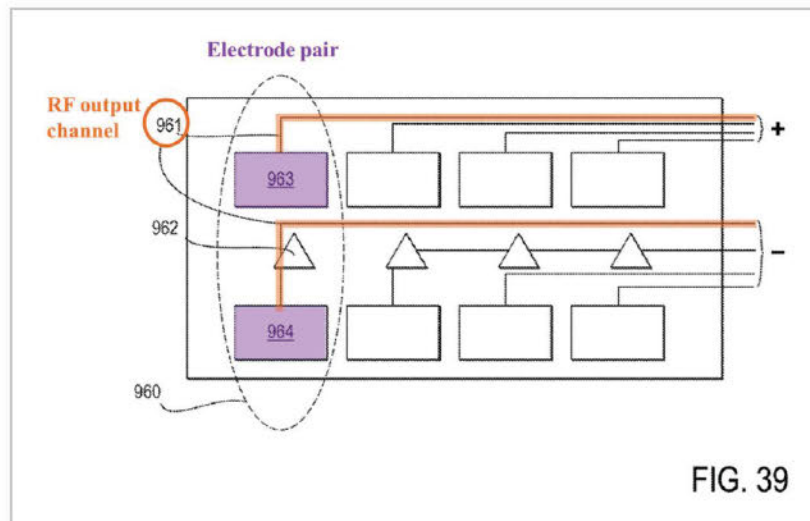
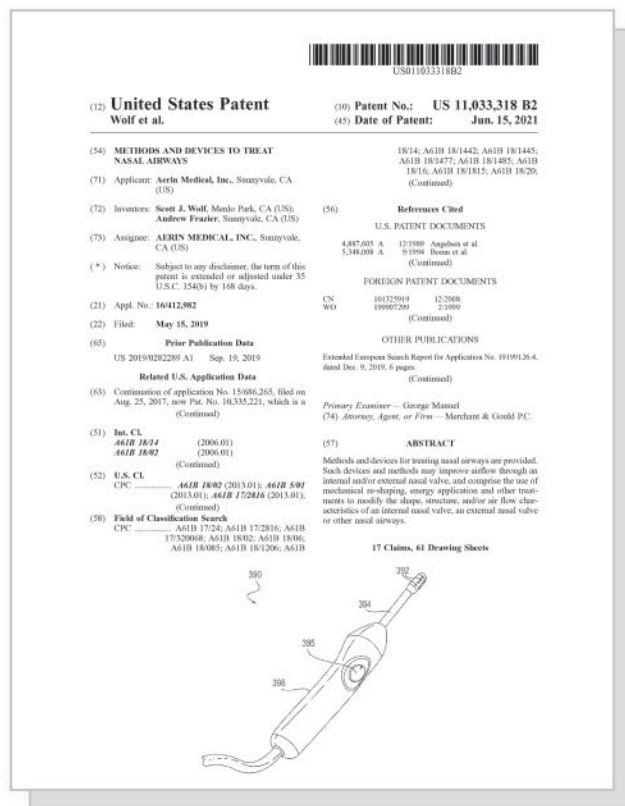


In some embodiments, each pair of electrodes may have a **separate, controlled electrical channel** to allow for different regions of the treatment element to be activated separately.

Ex.1001-'318 Patent, Fig.39, 48:63-65; '278 Reply, 8; '278 Ex.1083, ¶¶32-40; see also Ex.1001-'286 Patent, Fig.39, 49:10-12; '282 Reply, 8-9; '282 Ex.1083, ¶¶33-40

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Patents Describe “output channels” as Individually Controllable Channels Delivering RF Energy to Electrodes



As shown in FIG. 39, the nasal treatment device may include one or more thermocouples 962 and an RF output channel 961 assigned to each electrode pair for feedback. An

Ex.1001-'318 Patent, Fig.39, 48:63-65; '278 Reply, 8; '278 Ex.1083, ¶¶32-40; *see also* Ex.1001-'286 Patent, Fig.39, 49:10-12; '282 Reply, 8-9; '282 Ex.1083, ¶¶33-40

Stern Discloses the Same “output channels”

United States Patent (19)

Stern et al.

Patent Number: 5,562,720

Date of Patent: Oct. 8, 1996

154

REGULAR MONOPOLAR ENDOMETRIAL ABLATION DEVICE AND METHOD

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FIG. 15

The device of FIG. 15 provides an apparatus for both bipolar and monopolar application of RF energy with the choice of either bipolar or monopolar being made by control of the switches. Furthermore, not only are the modes selectable by controlling the switches but also within the bipolar mode, for instance, the switches allow for the selective application of RF energy to various combinations of electrodes.

E.g., Ex.1033, FIG.15, 12:38-45; '278 Petition, 42-44; '282 Petition, 41-43; '278 Ex.1002, ¶¶125-128; '282 Ex.1002, ¶¶136-138

DEMONSTRATIVE EXHIBIT - NOT EVIDENCE

40

Stern Discloses the Same "output channels"

United States Patent (79)
Stern et al.

Patent Number: 5,562,720
Date of Patent: Oct. 8, 1996

ABSTRACT
A bipolar, monopolar endometrial ablation device and method.

REFERENCES CITED

U.S. PATENT DOCUMENTS

4,682,300 10/1981 Chouinard et al.
5,253,442 6/1993 Zwickler
5,303,540 5/1994 Aronson
5,350,652 9/1995 Basso
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(List continued on next page.)

FOREIGN PATENT DOCUMENTS

01/540 01/1981 European Pat. Off.
04/270 07/1991 European Pat. Off.
22/330 11/1981 France
28/940 07/1991 France
82/231.7 07/1983 Germany

FIG. 15

operation. As an example, if switch 248 is closed as well as switch 236, then the current will pass from electrode 220 to electrode 224. In a similar manner, if switch 246 is closed as well as switch 234, there will be a bipolar operation with current flowing between electrodes 222 and 226. Clearly bipolar operation is not limited to these 220-224 and 222-226 pair couplings. If switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222.

E.g., Ex.1033, FIG.15, 12:61-13:2; '278 Petition, 42-44; '282 Petition, 41-43; '278 Ex.1002, ¶¶125-128; '282 Ex.1002, ¶¶136-138

DEMONSTRATIVE EXHIBIT - NOT EVIDENCE

Patent Owner's Expert Depicts the Same “output channels”



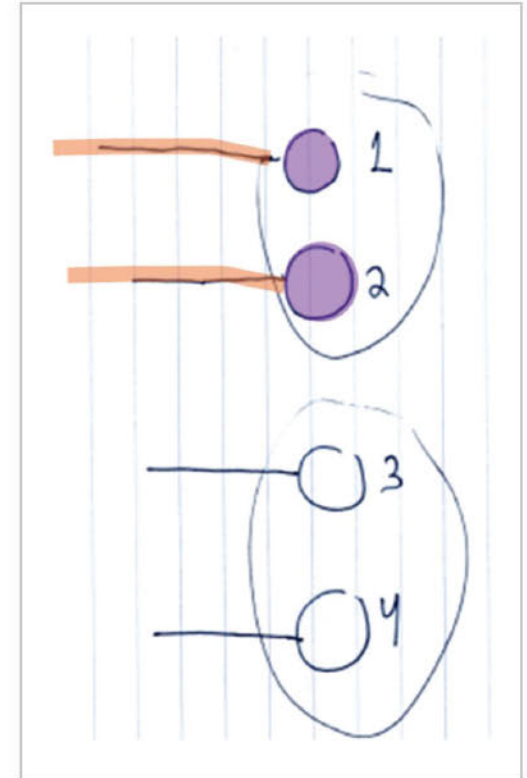
Dr. Marom Bikson

PO's Declarant

Q. Can you draw a device that has multiple radiofrequency output channels as required by [claim 1 of the '318 patent]?

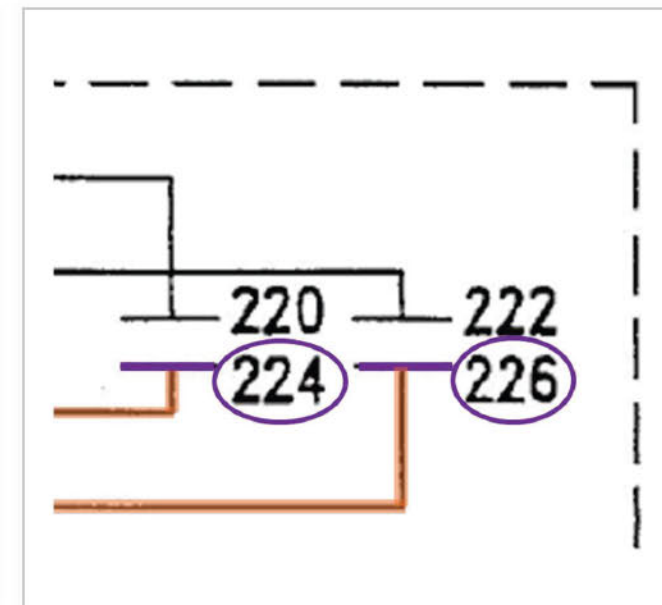
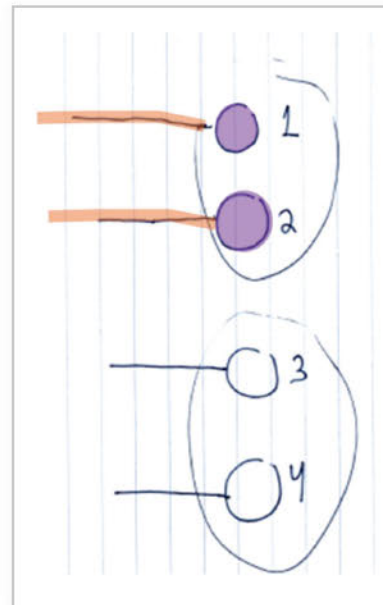
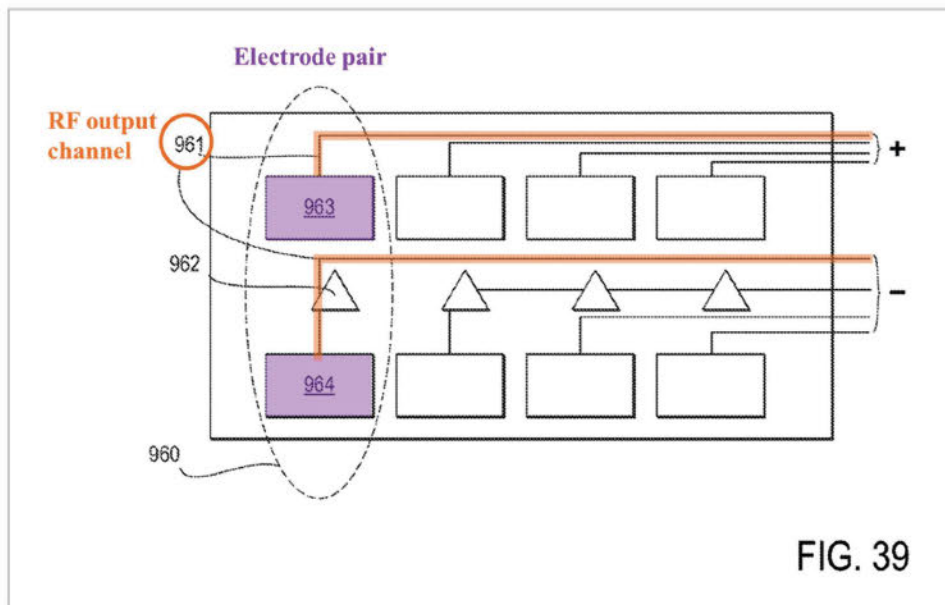
A. So, again, just hypothetically, I'm drawing four electrodes. I guess I can label them one, two, three, four.

And I'm drawing **wires** going to electrodes one and two. And I'm drawing **wires** going to electrode three and four. And I guess I'll put a circle around one and two and around three and four, so each — this is one bipole and this is another bipole. And the **wires coming to them would represent one channel and this would represent another channel.**



Ex.1084, 194:13-195:4; '278 Reply, 11-12; '282 Reply, 11-12

Challenged Patent, Patent Owner's Expert, and Stern Disclose the Same "multiple RF output channels"



Ex.1001-318 Patent, Fig. 39; Ex.1087-Bikson-Dep-Ex.E; Ex.1033, Fig. 15; '278 Reply, 14; '282 Reply, 14

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Challenged Patent, Patent Owner's Expert, and Stern Disclose the Same “multiple RF output channels”



Dr. Marom Bikson

PO's Declarant

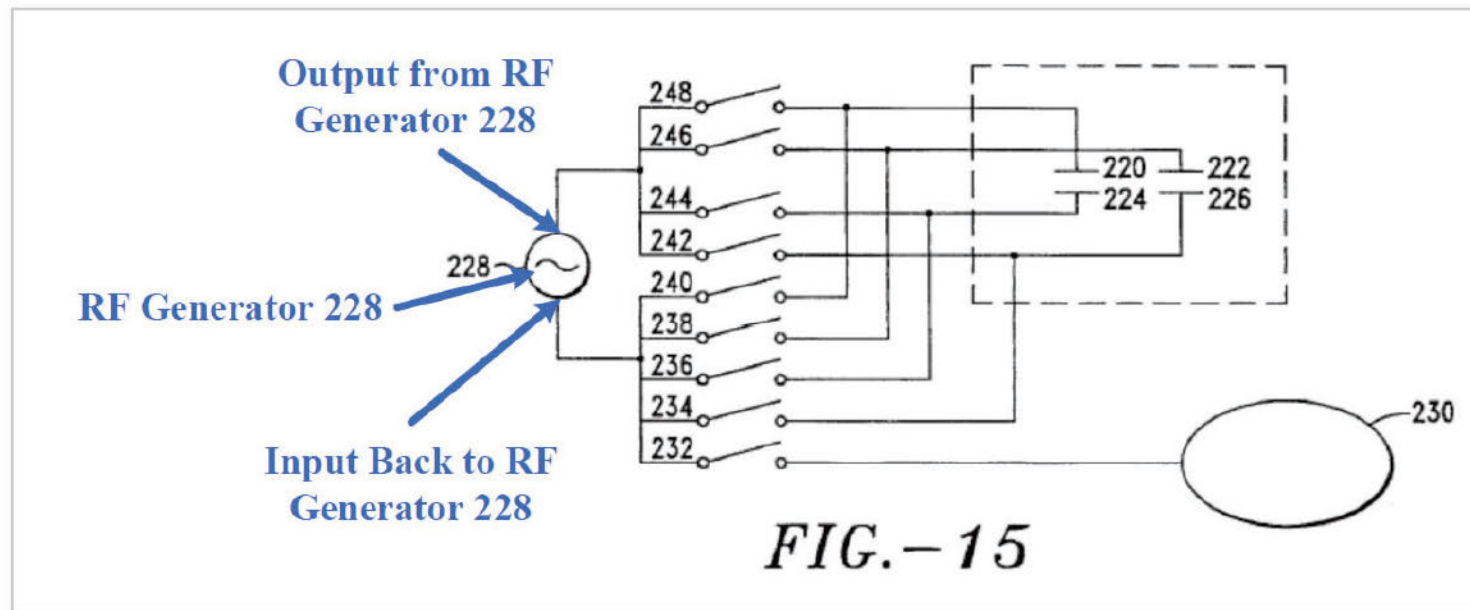
- Q.** But otherwise in the dashed box in Stern Figure 15, it also shows four electrodes and each electrode is connected to its own wire, correct?
- A.** The — it's correct that in Figure 15 from Stern you have four electrodes and each electrode is associated with a wire.
- Q.** Okay. And in your depiction in Bikson Exhibit E, that shows two pairs of bipolar electrodes with multiple radiofrequency output channels, correct?
- A.** That is what I intended to show, yes.

Ex.1084, 196:6-11; '278 Reply, 12-13; '282 Reply, 12-13

Patent Owner's Narrow Interpretation Is Contradicted by the Challenged Patents

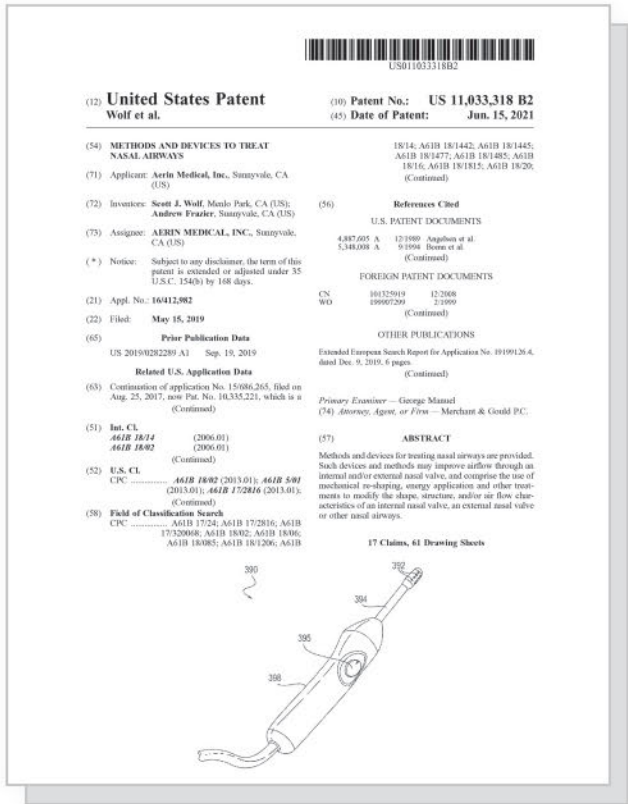
Accordingly, the correct interpretation of “radiofrequency output channel” is “an output from a radiofrequency generator.”

'318 Sur-Reply, 9; '282 Sur-Reply, 9



'318 POR, 24; '282 POR, 23

Patent Owner's Narrow Interpretation Is Contradicted by the Challenged Patents



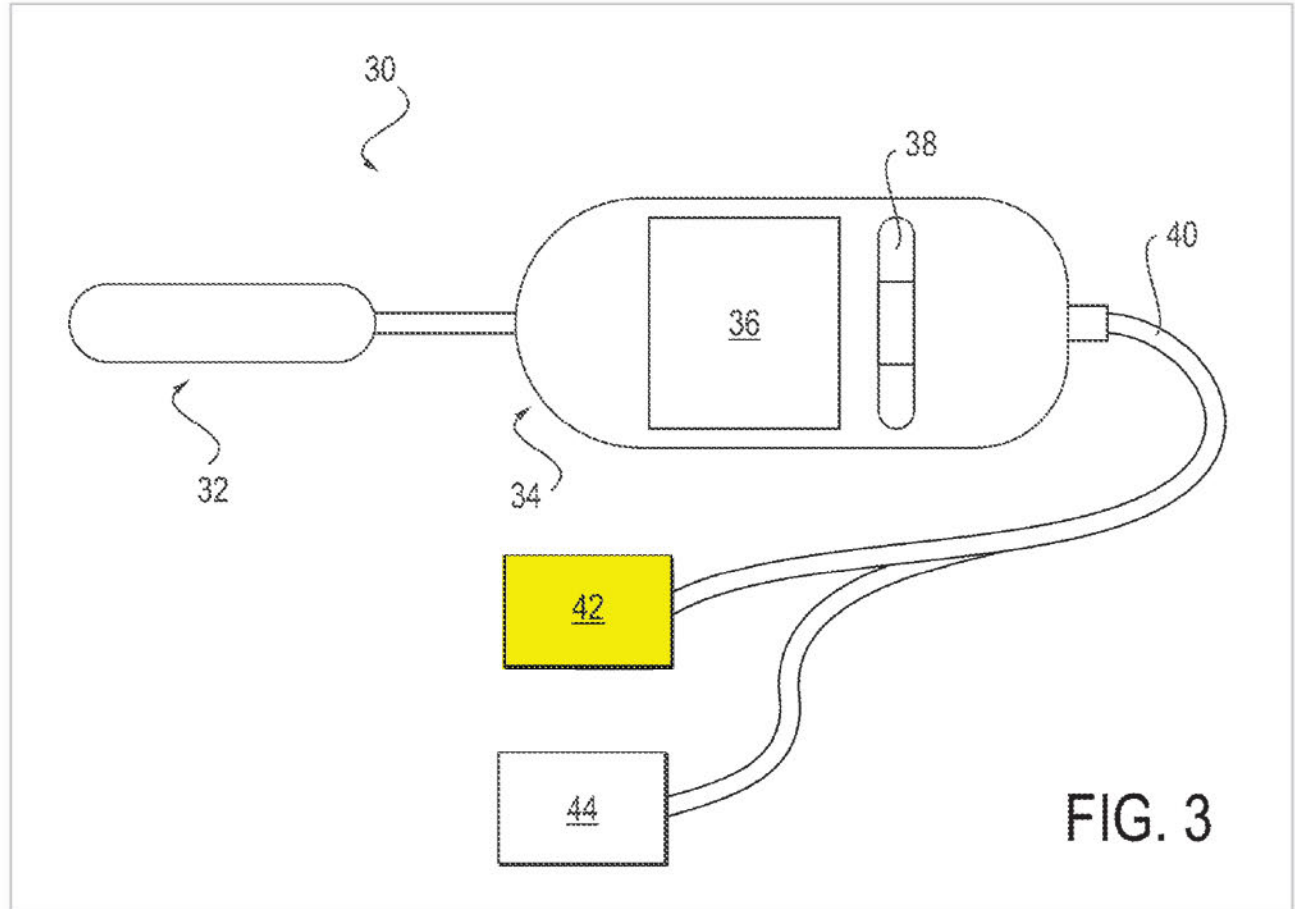
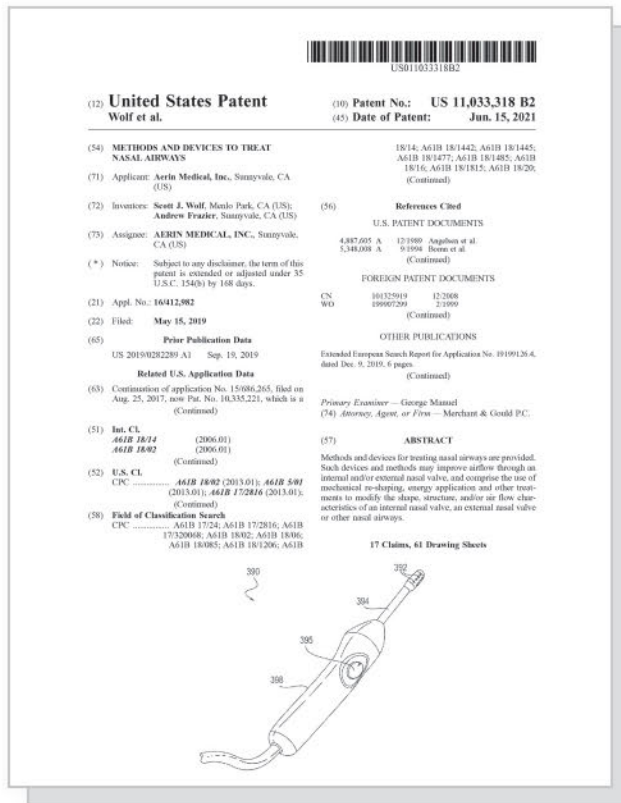
1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:

multiple radiofrequency output channels connected with the multiple pairs of bipolar radiofrequency electrodes, wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels;

'278 Petition, Ex.1001-'318 Patent, Claim 1; Ex.1001-286 Patent, Claim 1

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Patent Owner's Narrow Interpretation Is Contradicted by the Challenged Patents



Ex.1001-318 Patent, Fig. 3, 16:217-31; '278 Reply, 24-25; '282 Reply, 21-22; '278 Ex.1083, ¶¶ 77-79; '282 Ex.1083, ¶¶ 71-72

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

**Patent Owner's Definition of a POSITA Is
Incorrect and Irrelevant to Any Disputed Issue**

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioners' POSITA Definition Is Correct

Petitioners' Definition

A POSITA would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the clinical use, design, development, and/or testing of medical devices, including medical devices that deliver energy to tissue.

Less work experience may be compensated by a higher level of education, and vice versa.

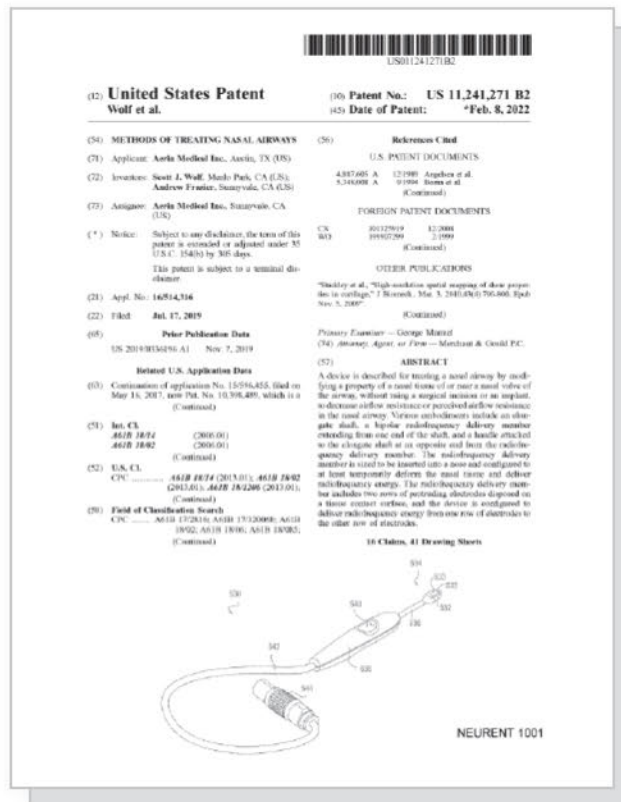
Patent Owner's Definition

A POSITA would have had (1) a Doctor of Medicine (M.D.) or at least a bachelor of science degree in engineering or a related discipline and (2) at least three years of experience in the ~~clinical use, design and~~[[,]] development, ~~and/or testing~~ of medical devices, including medical devices that deliver energy to tissue.

'277 Ex.1083, ¶16; '277 Reply, 28-31

Challenged Claims

Representative Independent Claim—'271 Patent



1. A method for treating a nasal airway to reduce mucus production, the method comprising:

contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;

applying radiofrequency energy with the bipolar electrode pairs through the nasal mucosa to a target tissue underlying the nasal mucosa for an amount of time to heat the target tissue; and

removing the treatment element from the nasal airway, wherein heating the target tissue with the applied radiofrequency energy modifies at least one property of the target tissue, and wherein the modified at least one property of the target tissue causes a reduction in mucus production in the nasal airway.

'278 Petition, Ex.1001-'271 Patent, Claim 1

Dr. DelGaudio and Dr. Martin Are POSITAs



Dr. John DelGaudio

*Chief of Rhinology, Sinus, and
Skull Base Surgery, Emory
University School of Medicine*

- Practicing otolaryngologist of over 30 years
- Former president of American Rhinologic Society
- Used RF energy devices in the nose for decades
- Routine consultant for medical device designers and manufacturers
- Designed disposable microdebrider device



Dr. Greg Martin

*Principal,
Tremont Consulting LLC*

- Ph.D. in mechanical engineering, MIT
- Designed and developed energy-based medical devices since 1998
- Senior Lecturer at Boston University
- Vice President of R&D for 4 different companies
- Chief Technology Officer for Hemedex, Inc.

'277 Ex.1002, Appendix A; '277 Ex.1004, Appendix A; '277 Reply, 25-28

None of Patent Owner's Arguments Rely on POSITA Definition



Dr. Marom Bikson

PO's Declarant

42. I met both parties' definitions of a POSITA as of the time of the invention of the Challenged Claims of the '271 patent. My opinions herein are the same regardless of which definition the Board applies.

'277 Petition, Ex.2001, ¶142; '271 Reply, 25

Date: April 21, 2025

Respectfully Submitted,

By: /David L. Cavanaugh/
David Cavanaugh
Reg. No. 36,476

CERTIFICATE OF SERVICE

I hereby certify that, on April 21, 2025, I caused a true and correct copy of:

- Petitioners' Demonstratives for Oral Argument

to be served on Patent Owner via electronic mail to:

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