

Neurent Medical Inc. & Neurent Medical Ltd.
v.
Aerin Medical Inc.

IPR2024-00277 (US 11,241,271)

IPR2024-00278 (US 11,033,318)

IPR2024-00282 (US 11,766,286)

PATENT OWNER'S DEMONSTRATIVE EXHIBIT

The relationship between the '271, '318, and '286 Patents

All patents claim priority to the same Parent and Provisionals

Related U.S. Application Data

continuation of application No. 15/686,265, filed on Aug. 25, 2017, now Pat. No. 10,335,221, which is a continuation of application No. 15/272,007, filed on Sep. 21, 2016, now Pat. No. 9,788,886, which is a continuation of application No. 14/754,087, filed on Jun. 29, 2015, now Pat. No. 9,452,010, which is a continuation of application No. 14/319,087, filed on Jun. 30, 2014, now Pat. No. 9,072,597, which is a continuation-in-part of application No. 13/495,844, filed on Jun. 13, 2012, now Pat. No. 8,936,594.

- (60) Provisional application No. 61/603,864, filed on Feb. 27, 2012, provisional application No. 61/496,930, filed on Jun. 14, 2011.

Ex-1001-286 at [60], [63]

'286 is a continuation of the '318

Related U.S. Application Data

- (63) Continuation of application No. 16/412,982, filed on May 15, 2019, now Pat. No. 11,033,318, which is a
(Continued)

Ex-1001-286 at [63]

Invalidity Grounds – '318 and '286 Patents

Ground	35 U.S.C. Section	Claims	References
I	103	1, 4, 5, 9, 10, 12, 13, 15-17	Edwards-'535 + Stern
II	103	6	Edwards-'535 + Stern + Patel
III	103	9, 10	Edwards-'535 + Stern + Edwards-'886
IV	103	1, 4-6, 12, 13, 15-17	Makower + Stern
V	103	9, 10	Makower + Stern + Edwards-'886

318 Petition at 10

Ground	35 U.S.C. Section	Claims	References
I	103	1-3,7-9	Edwards-'535 + Stern
II	103	8	Ground I + Edwards-'886
III	103	1-4, 7-9	Makower + Stern + Edwards-'535
IV	103	8	Ground III + Edwards-'886
V	103	1-3,7-9	Ground I + Liang
VI	103	8	Ground I + Liang + Edwards-'886
VII	103	1-4,7-9	Ground III + Liang
VIII	103	8	Ground III + Liang + Edwards-'886

286 Petition at 8

Invalidity Grounds – '271 Patent

Ground	35 U.S.C. Section	Claims	References
I	103	1-3, 6-12, 16	Edwards-'535 + Kong + Stern
II	103	4	Edwards-'535 + Kong + Stern + Edwards-'886
III	103	1-3, 6-12, 16	Edwards-'535 + Liang + Stern
IV	103	4	Edwards-'535 + Liang + Stern + Edwards-'886

271 Petition at 8

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

The parties' experts

Patent Owner's Expert – Dr. Bikson



Petitioners' Experts – Drs. Martin and DelGaudio



Pertinent Disputes

Patents / Claims / Grounds	Dispute
'271, '318, and '286 Patents [All Claims and Grounds]	Whether Stern teaches “multiple pairs of bipolar radiofrequency electrodes” / “bipolar electrode pairs”
'318 and '286 Patents [All Claims and Grounds]	Whether Stern teaches “multiple radiofrequency output channels”
'271 Patent [All Claims and Grounds]	Whether Stern teaches “two rows of bipolar electrode pairs”
'271 Patent [All Claims and Grounds]	Whether a POSITA would have been motivated to combine Edwards-535 with Stern’s “two rows”
'271, '318, and '286 Patents [Dependent Claims]	Whether the prior art renders obvious the dependent claims of the '271, '318, and '286 patents

1[d]	an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;
1[e]	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; and

318 Petition at 103

1[a]	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;
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271 Petition at 98

'318 and '286 Patents – Claim 1

'318 Patent

1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:
a handle;
a shaft extending from one end of the handle;
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;
an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;
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; and
multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.

Ex-1001-381 at clam 1

'286 Patent

1. A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:
a handle;
a shaft extending from one end of the handle;
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;
multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;
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; and
at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

Ex-1001-286 at clam 1

'271 Patent – Claim 1

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.

Ex-1001-271 at clam 1

Dispute #1: Whether Stern Teaches “multiple pairs of bipolar radiofrequency electrodes” / “bipolar electrode pairs”

[All Patents, Claims, and Grounds]

“multiple pairs of bipolar radiofrequency electrodes” / “bipolar electrode pairs”

'318 Patent

1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:
a handle;
a shaft extending from one end of the handle;
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;
an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;
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; and
multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.

Ex-1001-381 at clam 1

'286 Patent

1. A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:
a handle;
a shaft extending from one end of the handle;
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;
multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;
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; and
at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

Ex-1001-286 at clam 1

'271 Patent

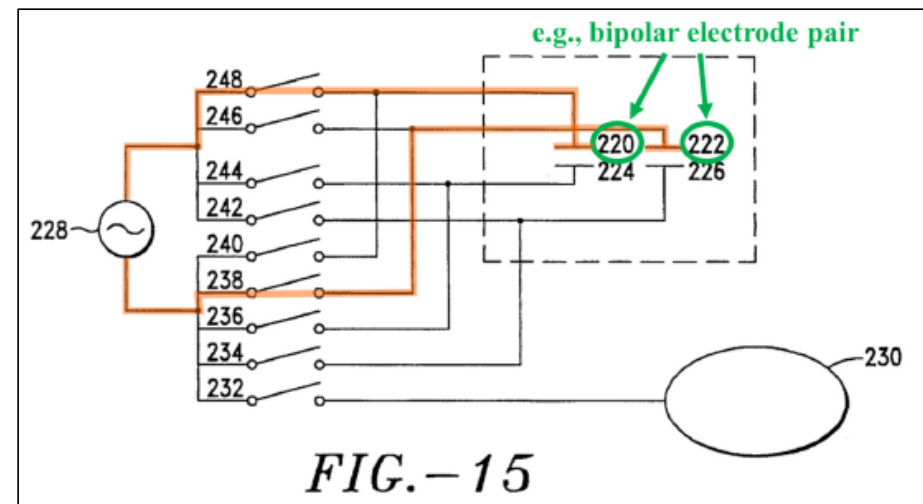
1. A method for treating a nasal airway to reduce mucus production, the method comprising:
contacting a treatment element of a nasal airway treatment device directly with nasal mucosa of the nasal airway, wherein the treatment element comprises two rows of bipolar electrode pairs;
applying radiofrequency 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.

Ex-1001-271 at clam 1

Petitioners' Argument

Stern teaches an array of multiple *pairs of bipolar radiofrequency electrodes* disposed along the treatment surface of the treatment element.

Stern's Figure 15 shows that the circuitry to operate bipolar pairs includes four electrodes 220, 222, 224 and 226 and various switches that determine the type of bipolar configuration depending on which switch(es) are closed. Ex.1033-Stern, 12:41-45. As an example, "[i]f switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222." *Id.*, 12:65-13:2.



318 Petition at 34-36; *see also*
271 Petition at 38-41; 286 Petition at 35-36

The experts agree on the definition of a “pair” of bipolar electrodes



Patent Owner's Expert

60. Consistent with the '318 patent's description, a POSITA would have understood a “pair” of bipolar radiofrequency electrodes to be two electrodes located near each other that have opposite polarities. (Ex-1001 at 23:7-11, 49:7-9, 49:18-24, 49:35-37, 49:46-54.)

Ex-2001-Bikson, ¶ 60



Petitioners' Expert

Q Okay. So you -- it's fair to say -- is it fair to say a bipolar electrode pair is two electrodes with different polarities such that current can flow between them?

A Yes.

Q Okay. And -- and when you say different polarities, what do you mean by that? Like a positive and a minus?

A Yes. That's one way to think of it, yes.

Ex-2008-Martin at 200:7-15

The experts agree the claims require more than one “pair”



Q. How does that show a -- how does that show multiple bipolar electrode pairs?

A. It's just one pair.

Q. So the last thing you drew there on this piece of paper, where it's just a row of two electrodes, that's just one pair; correct?

A. One pair, yeah.

Q. That's not electrode pairs plural; correct?

A. Correct.

Ex-2003-Martin at 286:2-11

A. Well, I guess to say "multiple pairs" is redundant. If you say "pairs," it's already plural. So that would mean if you have multiple pairs, that would be four electrodes.

Ex-2003-Martin at 244:14-17

Stern: no pairs when all switches are open

None of the electrodes have opposite polarities, no current can flow between them



62. Stern describes its electrodes as “an array of separate electrodes.”

(Ex-1033-Stern at 2:26-29, 2:39-40, 2:59-60.) Depending on which switches are closed, any of electrodes 220, 222, 224, and 226 in Figure 15 can be a monopolar electrode. (*Id.* at FIG. 15, 12:46-55.) Similarly, depending on which switches are closed, any of electrodes 220, 222, 224, and 226 can be a positive electrode or a negative electrode. (*Id.* at FIG. 15, 12:55-13:2.)

63. None of the electrodes in Stern’s Figure 15 have opposite polarities

when all the switches are open, and thus there are no bipolar electrode “pairs” in Figure 15 when all the switches are open. (Ex-1033-Stern at FIG. 15, 12:37-13:2.) Rather, a bipolar electrode “pair” is formed in Stern’s Figure 15 only when certain switches are closed. (Ex-1033-Stern at FIG. 15, 12:37-13:2.)

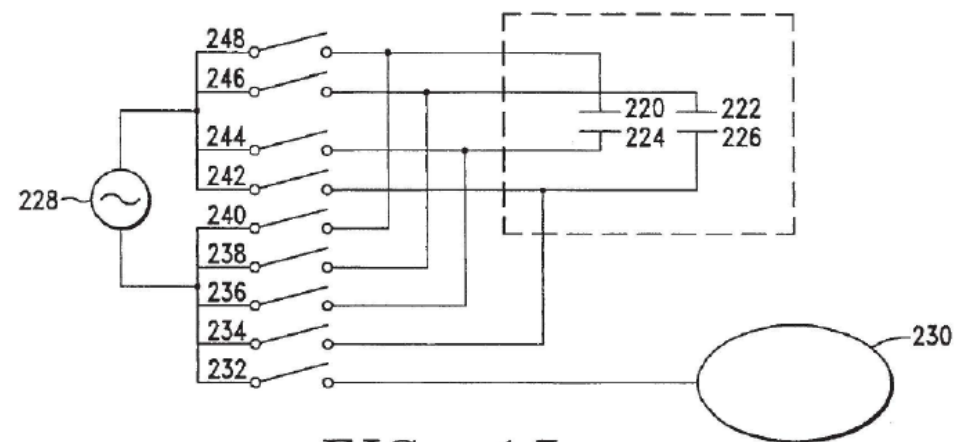


FIG. - 15

Ex-1033-Stern at FIG. 15

Ex-2001-Bikson, ¶¶ 62-63

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

An electrode “pair” is formed by closing switches



Q. So if I understand you correctly, it's your opinion that certain electrodes in Stern's figure 15 can become paired by closing particular switches. Is that accurate?

A. Correct, yes.

Q. So in Stern's figure 15 the electrode pair is formed only when certain switches are closed; is that correct?

A. Well, in my mind, the "pair" implies that they have opposite polarity; right? That current is flowing between them.

Q. And until you close the switches, that doesn't happen; right?

A. Correct, yeah.

101. Stern's Figure 15, which I have reproduced below, depicts that the circuitry that controls the bipolar pairs and includes four electrodes 220, 222, 224 and 226. The figure includes switches that determine the type of bipolar configuration depending on which switches are open and which are closed. *Id.*, 12:41-45 (“within the bipolar mode...the switches allow for the selective application of RF energy to various combinations of electrodes.”). Stern teaches examples in which electrodes can be paired by closing particular subsets of switches. *Id.*, 12:7-24, 12:37-13:2. For instance, “[i]f switch 248 and switch 238 are closed there will be bipolar operation between the electrodes 220 and 222.” *Id.*, 12:65-13:2.

Ex-1002-Martin, ¶ 101;
see also Ex-2001-Bikson, ¶ 63

Ex-2003-Martin at 254:11-255:3

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Stern fails to disclose multiple “pairs” of bipolar electrodes

At any given time, Stern’s device comprises at most one “pair”

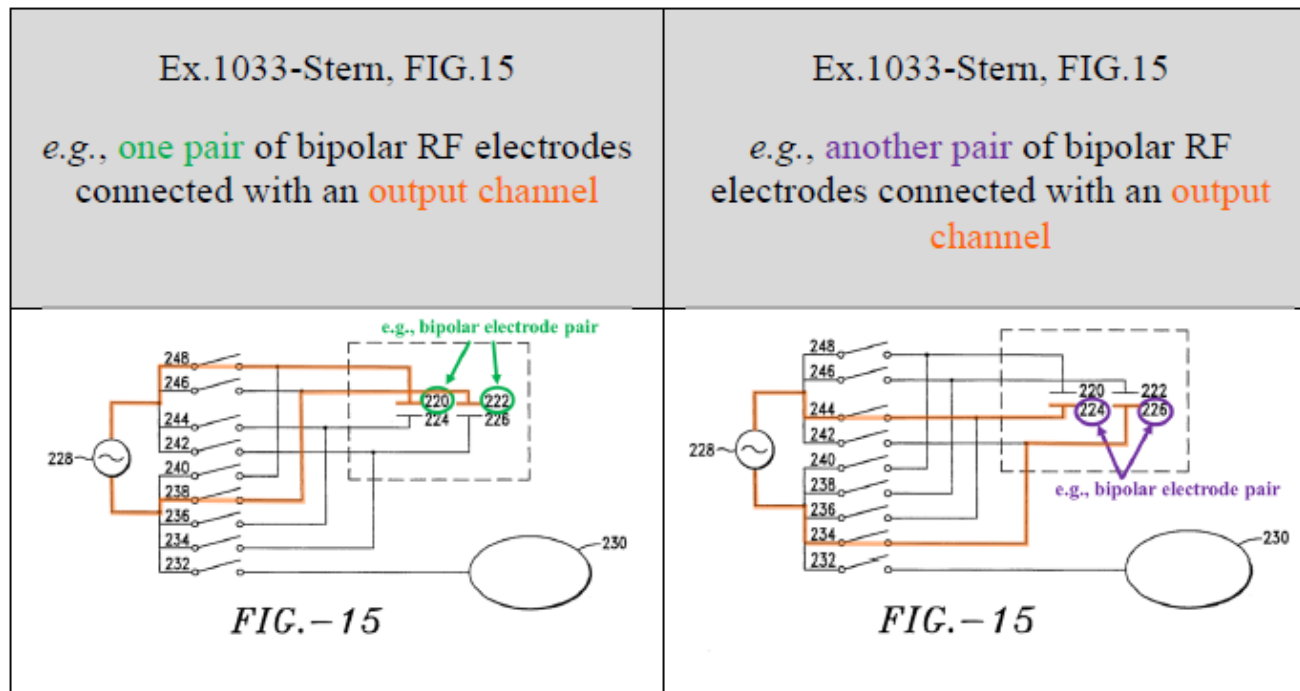


64. To form “multiple pairs of bipolar radiofrequency electrodes” in Stern’s Figure 15, three or more of Figure 15’s switches must be closed at the same time. However, Stern does not teach this. Instead, Stern teaches that its device is configured to have at most a single pair of bipolar electrodes. Specifically, Stern teaches at most closing one of switches 242, 244, 246, and 248 and one of switches 234, 236, 238, and 240 to form a single pair of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2.) This teaching is consistent with Stern’s teaching that its electrodes “are independently and sequentially energized.” (*Id.* at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern’s electrodes “independently and sequentially,” at most two of Stern’s switches would be closed at a time.

Ex-2001-Bikson, ¶ 64

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitions: two different configurations of one “pair”



318 Petition at 43; *see also id.* at 35-36, 42-43;
286 Petition at 35-36, 42; 271 Petition at 39-40

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Stern confirms only one “pair”

ment. That is, it provides monopolar operation. On the other hand, if the switch **232** is opened and if pairs of switches, with one of the pair being selected from the switches **242, 244, 246 and 248** and the other being selected from switches **234, 236, 238 and 240**, are operated in proper conjunction, the electrodes **220, 222, 224 and 226** will provide a bipolar 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**.

Ex-1033-Stern at 12:55-13:2

64. To form “multiple pairs of bipolar radiofrequency electrodes” in Stern’s Figure 15, three or more of Figure 15’s switches must be closed at the same time. However, Stern does not teach this. Instead, Stern teaches that its device is configured to have at most a single pair of bipolar electrodes. Specifically, Stern teaches at most closing one of switches 242, 244, 246, and 248 and one of switches 234, 236, 238, and 240 to form a single pair of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2.) This teaching is consistent with Stern’s teaching that its electrodes “are independently and sequentially energized.” (*Id.* at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern’s electrodes “independently and sequentially,” at most two of Stern’s switches would be closed at a time.

Ex-2001-Bikson, ¶ 64



Stern confirms only one “pair”

It is a further object of the present invention to provide that the electroconductive expandable member includes a thin bladder having an array of separate electrodes on one surface and further having a temperature sensor such as a thermistor associated with each separate electrode in order 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-Stern at 2:26-35

Once the device **124** and the controller **156** are connected, the RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature up to a desired level.

Ex-1033-Stern at 10:48-52

64. To form “multiple pairs of bipolar radiofrequency electrodes” in Stern’s Figure 15, three or more of Figure 15’s switches must be closed at the same time. However, Stern does not teach this. Instead, Stern teaches that its device is configured to have at most a single pair of bipolar electrodes. Specifically, Stern teaches at most closing one of switches 242, 244, 246, and 248 and one of switches 234, 236, 238, and 240 to form a single pair of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2.) This teaching is consistent with Stern’s teaching that its electrodes “are independently and sequentially energized.” (*Id.* at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern’s electrodes “independently and sequentially,” at most two of Stern’s switches would be closed at a time.

Ex-2001-Bikson, ¶ 64



A POSITA would not have formed more than one pair at a time

Q Okay. So, yes, Stern -- in your opinion, Stern does address the problem of uneven heating; is that correct?

A Correct.

Ex-2008-Martin at 170:21-171:3

Q Okay. And the difference in the amount of energy that flows between the green electrodes and the purple electrodes can vary based on, I think you said, the impedance of the medium between the electrodes; is that right?

A And the geometry, the size of the electrodes, the surface area, the material of the electrodes, the internal resistance in the circuitry.

Ex-2008-Martin at 29:12-20



Q I guess, can differences in the amount of current flowing between the various electrodes lead to differences in the temperature rise at various points in the patient's tissue?

A The answer to that is going to depend on a lot of factors, where the electrodes are, all the electrical properties, all the thermal properties, but, yes, it is possible.

Q Okay. And would you call that uneven heating?

A Well, it depends on -- it's -- it could induce an uneven temperature distribution.

Ex-2008-Martin at 50:2-15

A POSITA would not have formed more than one pair at a time

Petitioners' Expert



Q Okay. So it's fair to say that if this schematic of figure 15 were to be implemented in an actual device, it's fair to say you wouldn't know in advance where the current's going to flow if all four electrodes were activated at the same time?

A I should amend that to say you don't know where the current's going to flow.

Ex-2008-Martin at 25:11-20

Patent Owner's Expert



Q I'm just closing four switches. That's all I'm doing. I'm closing switch 248, 246, 236, and 234.

In that scenario are there multiple bipolar electrode pairs?

A I don't think you would do that, because if you did that you would lose control. You would not have the -- the independent control that you desire. And so it's not something that you would do.

Ex-1084-Bikson at 250:20-251:7

Petitioners' argument: "pairs" do not have to be active at the same time

a. "Multiple pairs of bipolar radiofrequency electrodes" need not be delivering energy "at the same time"

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.1084-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 the claims are interpreted to require bipolar pairs that are delivering energy "at the same time." POR, 19, 25. The Board should reject PO's arguments.

318 Reply at 3; *see also*
286 Reply at 3; 271 Reply at 4

Petitioners mischaracterize Patent Owner's position



Q Okay. And so my question going back to the claim on Page 16, will a device that's not delivering any radiofrequency energy have two rows of bipolar electrode pairs?

A A device that is not delivering any electrical energy can have two rows of bipolar electrode pairs.

Ex-1084-Bikson at 100:17-101:1

Q But it has to show that you would deliver energy through multiple pairs at the same time?

A I don't think that's the way I described it in my report.

Ex-1084-Bikson at 106:9-13

Petitioners' argument: "combination of pairs ... utilized together" means multiple pairs at the same time

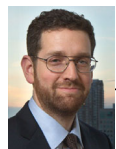
The embodiment of FIG. 15 not only provides a choice between monopolar and bipolar operation but also provides flexibility within the bipolar operation so that any pair or any combination of pairs of electrodes may be utilized together.

Ex-1033-Stern at 13:39-43

Even under PO's incorrect interpretation, Stern teaches activating multiple bipolar electrode pairs "at the same time." For example, Stern states that "*any combination of pairs* of electrodes [shown in Figure 15] may be *utilized together*" and therefore expressly contemplates activating all electrodes at one time. Ex.1033-Stern, 13:39-43. This is similar to the '318 patent's description. Ex.1001-USP318, 24:45-55. Ex.1083-Reply-Decl., ¶22.

318 Reply at 5; *see also*
286 Reply at 5; 271 Reply at 5-6

When read in isolation, the cited sentence is at best ambiguous



Q Okay. But I guess in the combination of pairs, it's your opinion that Stern is saying activate one pair of electrodes and then activate a second set of electrodes, correct?

A Stern is saying that you can at one point choose to activate a single pair of electrodes. You could then open the switches. It's then possible to activate another different pair of electrodes.

Ex-1084-Bikson at 112:4-12

Q Okay. And Stern teaches that you could use that combination of pairs together, correct?

A Stern writes, "bipolar operations that any pair or any combination of pairs of electrodes may be utilized together."

But as I've explained, what Stern is about is just selecting a single pair, and then you can disconnect.

Q And be energized through a pair?

A You could start over and select a different pair and energize that pair, yes.

Ex-1084-Bikson at 115:17-116:6

It is improper to read the prior art in isolation

755 F.2d 898

United States Court of Appeals,
Federal Circuit.

EWP CORPORATION, and La Societe
Trefilunion, Plaintiffs-Appellees,

v.

RELIANCE UNIVERSAL INC., and Exposaic
Industries, Inc., Defendants-Appellants.

differences are irrelevant. A reference must be considered for everything it *teaches* by way of technology and is not limited to the particular *invention* it is describing and attempting to protect. On the issue of obviousness, the combined teachings of the prior art as a whole must be considered.

318 Sur-Reply at 4; 271 Sur-Reply at 6; 286 Sur-Reply at 4

796 F.2d 443

United States Court of Appeals,
Federal Circuit.

BAUSCH & LOMB, INC., Appellant,

v.

BARNES-HIND/HYDROCURVE, INC., and
Barnes-Hind International, Inc., Appellees.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art.

Stern resolves any potential ambiguity in Patent Owner's favor

It is a further object of the present invention to provide that the electroconductive expandable member includes a thin bladder having an array of separate electrodes on one surface and further having a temperature sensor such as a thermistor associated with each separate electrode in order 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-Stern at 2:26-35

Once the device **124** and the controller **156** are connected, the RF electrodes are separately, independently and sequentially energized with thermistor temperature feedback to bring the endometrial temperature up to a desired level.

Ex-1033-Stern at 10:48-52

64. To form “multiple pairs of bipolar radiofrequency electrodes” in Stern’s Figure 15, three or more of Figure 15’s switches must be closed at the same time. However, Stern does not teach this. Instead, Stern teaches that its device is configured to have at most a single pair of bipolar electrodes. Specifically, Stern teaches at most closing one of switches 242, 244, 246, and 248 and one of switches 234, 236, 238, and 240 to form a single pair of bipolar electrodes. (Ex-1033-Stern at 12:55-13:2.) This teaching is consistent with Stern’s teaching that its electrodes “are independently and sequentially energized.” (*Id.* at 2:31-33, 2:49-53, 10:48-52, 17:54-55.) To energize Stern’s electrodes “independently and sequentially,” at most two of Stern’s switches would be closed at a time.

Ex-2001-Bikson, ¶ 64



Stern resolves any potential ambiguity in Patent Owner's favor

ment. That is, it provides monopolar operation. On the other hand, if the switch **232** is opened and if pairs of switches, with **one of the pair being selected from the switches 242, 244, 246 and 248** and the other being selected from switches **234, 236, 238 and 240**, are operated in proper conjunction, the electrodes **220, 222, 224 and 226** will provide a bipolar 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**.

Ex-1033-Stern at 12:55-13:2

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Ex-2001-Bikson, ¶ 64



Stern resolves any potential ambiguity in Patent Owner's favor

In specific instances, it would be more precise to provide a more even heating of a uterus or other body organ if the electrode could have a controlled return path for the current. In such instances, if particular pairs of electrodes were chosen in a bipolar arrangement to receive RF energy, the return path could be controlled selectively by a physician who is performing a visual inspection by means of an x-ray, ultrasound, or other detection device.

Ex-1033-Stern at 12:25-32

Q I guess, can differences in the amount of current flowing between the various electrodes lead to differences in the temperature rise at various points in the patient's tissue?

A The answer to that is going to depend on a lot of factors, where the electrodes are, all the electrical properties, all the thermal properties, but, yes, it is possible.

Q Okay. And would you call that uneven heating?

A Well, it depends on -- it's -- it could induce an uneven temperature distribution.

Ex-2008-Martin at 50:2-15



Dispute #2: Whether Stern Teaches
“multiple radiofrequency output channels”
[’318 and ’286 Patents, All Claims and Grounds]

“multiple radiofrequency output channels”

'318 Patent

1. A device for delivering energy to a nasal airway to improve nasal airflow, the device comprising:
a handle;
a shaft extending from one end of the handle;
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration, wherein the treatment element comprises a tissue treatment surface;
an array of multiple pairs of bipolar radiofrequency electrodes disposed along the treatment surface of the treatment element;
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; and
multiple sensors on the tissue treatment surface, wherein the multiple sensors are selected from the group consisting of impedance sensors, electrodes and thermocouples.

Ex-1001-381 at clam 1

'286 Patent

1. A device for delivering energy to a nasal airway to treat rhinitis, the device comprising:
a handle;
a shaft extending from one end of the handle;
a treatment element coupled with a distal end of the shaft, sized to be inserted into a nostril, and configured to change from a first configuration to a second configuration to contact nasal mucosa lining the nasal airway;
multiple pairs of bipolar radiofrequency electrodes disposed on the treatment element;
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; and
at least one impedance sensor configured to measure impedance in the multiple pairs of bipolar radiofrequency electrodes.

Ex-1001-286 at clam 1

Petitioners' Argument

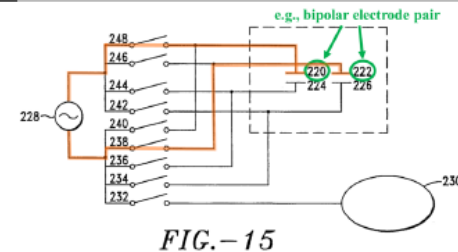
multiple radiofrequency output channels (e.g., shown in Figure 15 in Stern).

Ex.1033-Stern, FIG.15. Ex.1002-Decl., ¶123-124, 126.

Figure 15 of Stern shows circuitry capable of supplying energy to selected bipolar pairs via a “switching means” where each bipolar pair is wired to its own output channel. Ex.1033-Stern, 2:49-53, 3:12-29, Clm.1, FIG.15. Ex.1002-Decl., ¶124, 127.

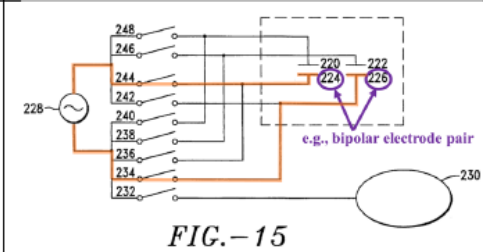
Ex.1033-Stern, FIG.15

e.g., one pair of bipolar RF electrodes connected with an output channel



Ex.1033-Stern, FIG.15

e.g., another pair of bipolar RF electrodes connected with an output channel



318 Petition at 41-44; *see also*
286 Petition at 40-43

The experts agree on the definition of “radiofrequency output channel”



Patent Owner's Expert

69. I understand that Dr. Martin testified at his deposition that the term “radiofrequency output channel” means “an output from a radiofrequency generator.” (Ex-2004 at 318:12-19; *id.* at 318:20-319:9, 319:17-320:2, 327:3-4, 329:21-22.) I agree with Dr. Martin.

Ex-2001-Bikson, ¶ 69



Petitioners' Expert

Q. Okay. So you understand a radiofrequency output channel to be an output from a radiofrequency generator; is that correct?

A. Yes.

Q. So I guess in analyzing the '286 patent, in your analysis of the term "radiofrequency output channel," is it fair to say that the meaning you apply to that term is an output from a radiofrequency generator?

A. Yes

Ex-2004-Martin at 318:15-19, 319:17-320:2

The experts' interpretation is consistent with the intrinsic evidence

The device **530** comprises a flexible wire or cable **542** electrically connected to an adaptor **544**. The adaptor **544** can be used to connect the device **530** to a remote generator (not shown). The adaptor **544** may allow transmission of treatment energy between a remote generator and the device **530**.

FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device arranged in a multi-channel configuration.

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.

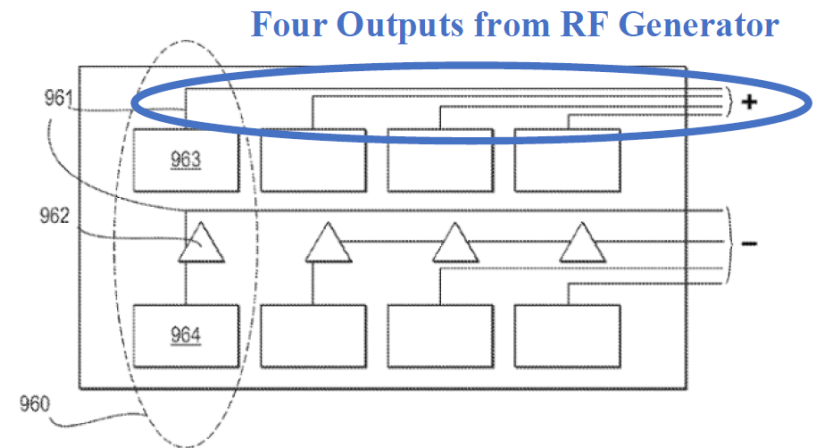


FIG. 39

Ex-1001-318 at FIG. 39

Ex-1001-318 at 28:61-66, 48:42-44, 48:63-65

318 Sur-Reply at 7-9; 286 Sur-Reply at 7-9

Number of “channels” depends on number of outputs from generator

70. The number of radiofrequency output channels depends on the number of outputs from the radiofrequency generator.

Ex-2001-Bikson, ¶ 70

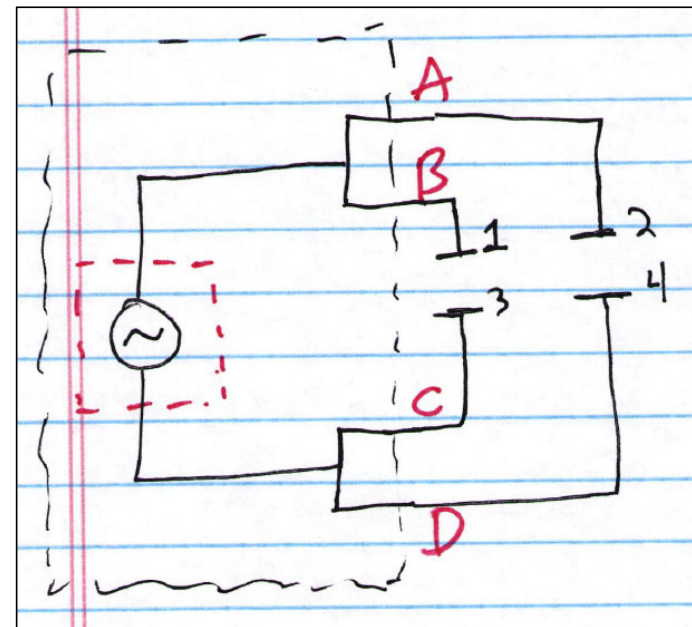


Q. So I believe you testified earlier that if you assume that that red dashed rectangle designates the radiofrequency generator, that in that case this circuit would have only one radiofrequency hub or channel; is that correct?

A. Correct.

Q. If you assume that the black dotted rectangle around the circle is the -- designates the radiofrequency generator, in that case how many radiofrequency output channels would you say that this circuit has?

A. Two.



Ex-2007

Ex-2004-Martin at 430:20-431:13 (discussing Ex-2007)

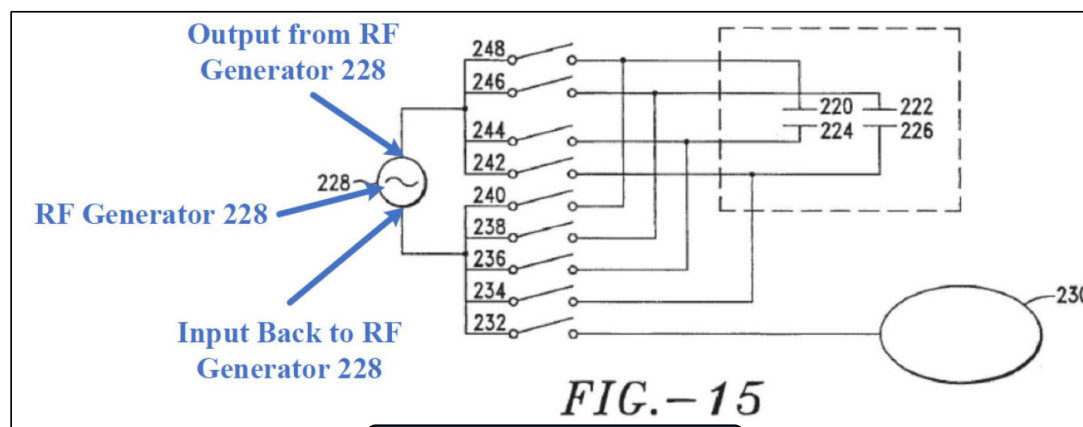
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Undisputed: Stern's generator has only one output (*i.e.*, one “output channel”)



79. Importantly, Stern's voltage source 228 (*i.e.*, the radiofrequency generator) has only one radiofrequency output channel. As shown in annotated Figure 15 below, voltage source 228 has only a single output and a single input. Thus, Stern teaches at most a single radiofrequency output channel.

Ex-2001-Bikson, ¶ 79



Ex-1033-Stern at FIG. 15

318 Reply at 6-14 (Petitioners failing to dispute); 286 Reply at 6-14 (same)

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

'318 and '286 patents: multiple “channels” prevents energy diversion

FIG. 39 is a block diagram depicting an array of electrodes of a nasal treatment device arranged in a multi-channel configuration. As described above, different target anatomies may have treatment surface areas of varying size and shape. Additionally, users operating a nasal treatment device may vary in skill, dexterity, and habits. Due to these variabilities, each electrode pair of the device may have varying degrees of contact with tissue of the target anatomy. For a configuration in which all pairs of electrodes are controlled by one main electrical channel, this may lead to varying magnitudes of treatment energy passing through each electrode pair. The pair(s) of electrodes that have a higher degree of contact with the tissue may experience higher magnitudes of impedance in their individual circuit. Since treatment energy takes the path of least resistance, this may lead to treatment energy being diverted to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact. Thus, it may be advantageous to control the treatment energy through each electrode to ensure repeatable treatments.

Ex-1001-318 at 48:42-62



80. Further, the '318 patent teaches that one of the benefits of the claimed multiple radiofrequency output channels is that they are separately controllable, which prevents the situation where, due to varying degrees of contact with the target tissue, treatment energy is “diverted” to pairs of electrodes that experience a relatively lower magnitude of impedance due to a relatively lower degree of tissue contact.” (Ex-1001 at 24:45-64, 48:42-49:4; *see also id.* at 49:65-50:2, 50:9-15.)

Ex-2001-Bikson, ¶ 80

Stern's single-channel design does not prevent energy diversion



However, Stern's Figure 15 does not offer the same "separate control" described in the '318 patent. If, for example, switches 248, 246, 236, and 234 were closed at the same time—which, to be clear, is not taught in Stern—then current would be diverted to whichever electrodes experience less impedance. The '318 patent discloses that this was a problem faced by single channel designs. (Ex-1001 at 48:50-59.)

Ex-2001-Bikson, ¶ 80; *see also*
318 Sur-Reply at 8-9;
286 Sur-Reply at 8-9

Petitioners' and Dr. Martin's smorgasbord of new Reply definitions

- “something that allows pairing between chosen electrodes to form a complete circuit” (Ex-1083-Martin, ¶ 36)
- “something that allows pairing between chosen electrodes to control a chosen pair[] of electrodes separately from another chosen pair” (*id.*, ¶ 39)
- “an energy connector between electrodes that allows for independent control of bipolar pairs” (*id.*, ¶ 40)
- “connects electrodes and provides the ability to independently control pairs of electrodes” (*id.*, ¶ 45)
- “a channel that carries the output ... from a radiofrequency generator to an electrode pair” (*id.*, ¶ 42)
- “multiple channels that are not necessarily connected directly to the voltage source or generator” (318 Reply at 10; 286 Reply at 11)

Dr. Martin's deposition testimony on "output channels"



A Well, again, as I said before, a radiofrequency output channel is a logical construct.

Q So with that clarification, does that impact in any way the number of radiofrequency output channels?

A So, again, I go back to -- the radiofrequency output channels is a logical construct. So it depends on how you want to define this construct.

Q And I believe you said that the, I guess, for lack of a better word, the number of radiofrequency output channels is kind of in the eye of the beholder; right?

A I might say in the eye of the designer, in the eye of the user.

Q Well, you just said different experts could come up with a different number of radiofrequency channels, didn't you?

A Depending on how the device is designed or intended to be used.

Ex-2008-Martin at 68:16-18, 85:22-86:6, 128:3-8, 151:16-22

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Dr. Martin wouldn't say how many "channels" Stern allegedly has



A That's -- I did not count them. I did not offer an opinion as to how many. It depends on how you would construct the device and actually implement this device. But could be two, could be four.

A I know there's -- there's more than one.

Ex-2008-Martin at 76:5-21

Dr. Martin's subjective interpretation is legally incorrect

417 F.3d 1342
United States Court of Appeals, Federal Circuit.

DATAMIZE, LLC, Plaintiff–Appellant,
v.
PLUMTREE SOFTWARE, INC., Defendant–Appellee.

“The scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual...”

318 Sur-Reply at 13-14; 286 Sur-Reply at 13-14

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Stern teaches one “channel” even under Dr. Martin’s new definitions



Q I guess, let me ask this a little bit of a different way. So, again, looking at Stern figure 15, the energy starts off in a single channel when it's output from the voltage source 228; right?

A Well, I don't know if I call that -- okay. Or it starts -- so the energy comes from the voltage source, yes.

Q So if I understand this figure correctly, all four electrodes share the radiofrequency energy from voltage source 228?

A Correct.

Ex-2008-Martin at 22:20-23:1, 124:21-125:6

e.g., two pairs of bipolar RF electrodes connected with respective RF output channels

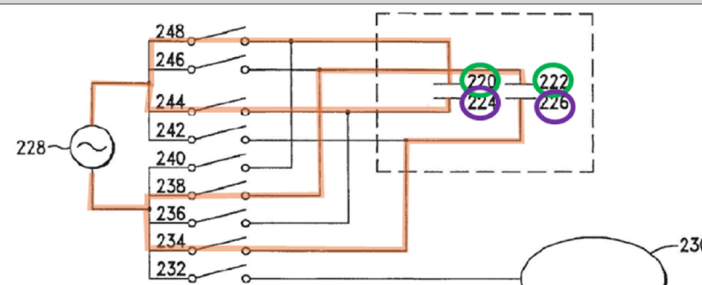


FIG. - 15

Ex-1083-Martin, ¶ 28

318 Sur-Reply at 14-15; 286 Sur-Reply at 14-15

Dispute #3: Whether Stern Teaches
“two rows of bipolar electrode pairs”
[’271 Patent, All Claims and Grounds]

“two rows of bipolar electrode pairs”

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.

Ex-1001-271 at claim 1

The claims require multiple “pairs” per row

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

Ex-1001-271 at claim 1

Patent Owner's Expert



75. The claim term “bipolar electrode pairs” is written in the plural, and thus requires multiple pairs. A row of only two electrodes is not a row of bipolar electrode pairs because a row of only two electrodes has at most a single pair (not multiple pairs). A row of bipolar electrode pairs requires at least three electrodes in the row.

Ex-2001-Bikson, ¶ 75

Petitioners' Expert



Q. So in other words to have multiple pairs, it sounds like you agree you need at least three electrodes?

A. Yeah.

Ex-2003-Martin at 244:22-245:4

The specification discloses multiple “pairs” per row



A So, for example, in my report on Page 30, I point to Figure 8F, which is from the patent. And there you can see a device which has two rolls -- two rows of bipole electrode pairs.

Ex-1084-Bikson at 101:4-7

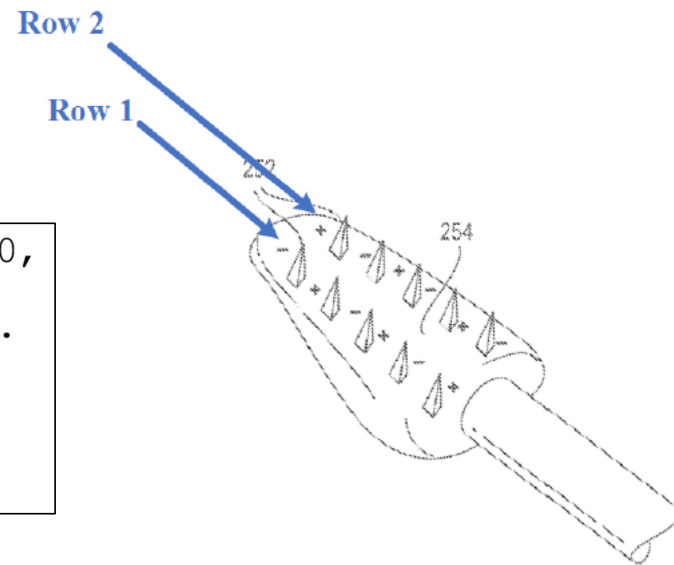


FIG. 8F

Ex-1001-271 at FIG. 8F

271 Sur-Reply at 8-9

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

“rows of electrodes” vs. “rows of electrode pairs”

US Patent No. 8,986,301 [related to the '271 patent]

1. A method of modifying at least one property of at least one tissue of or near a nasal valve of a nose, without using a surgical incision or an implant, to decrease airflow resistance or perceived airflow resistance in a nasal airway, the method comprising:

contacting an elongate treatment element of a treatment device with the at least one tissue inside the nasal airway, with sufficient force to at least temporarily deform the at least one tissue;

applying energy to the at least one tissue by transmitting radio frequency energy from a first row of electrodes to a second row of electrodes disposed vertically on the elongate treatment element; and

removing the elongate treatment element from the nostril.

Ex-2008-301 at claim 1

US Patent No. 11,033,318 [related to the '271 patent]

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

Ex-2009-318 at claim 15

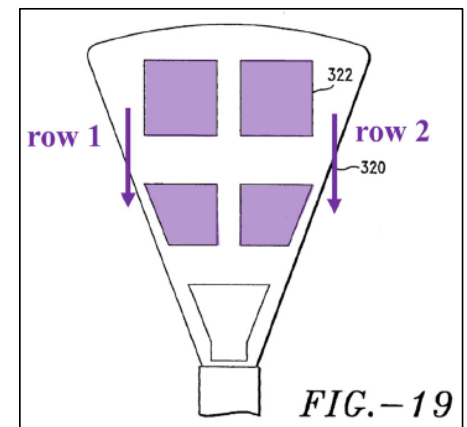
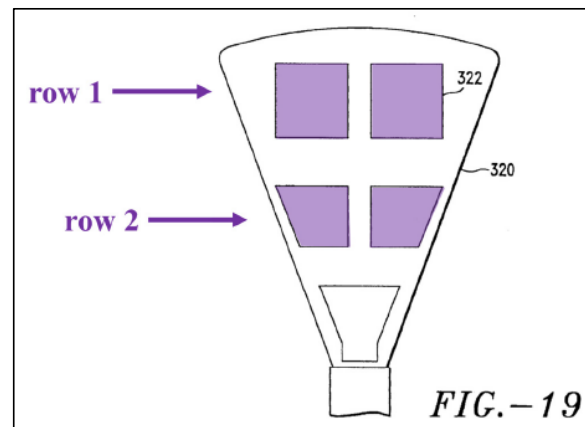
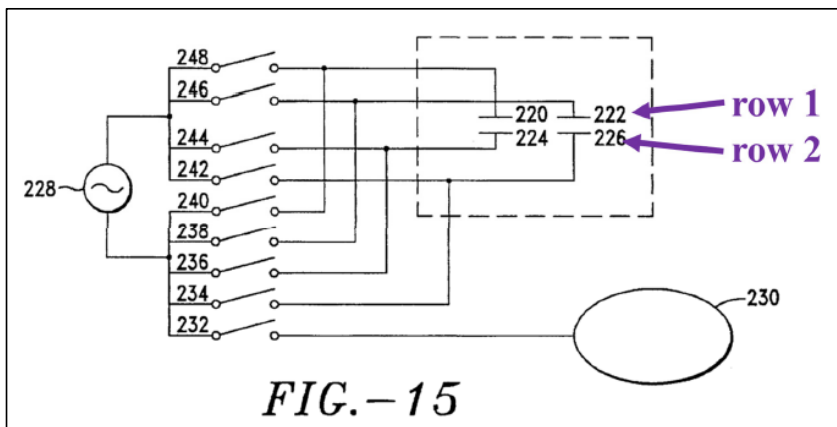
271 POR at 28-30

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

48

'271 Petition: Stern teaches “two rows of bipolar electrode pairs”

ii. Stern teaches wherein the treatment element comprises two rows of bipolar electrode pairs.

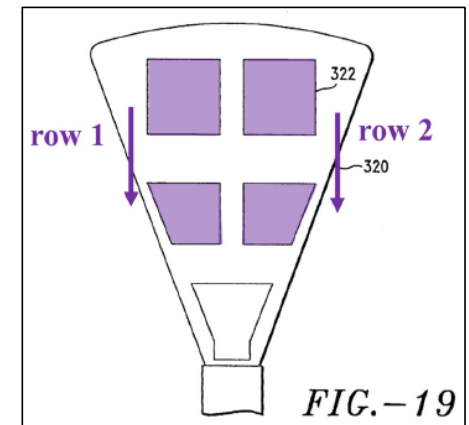
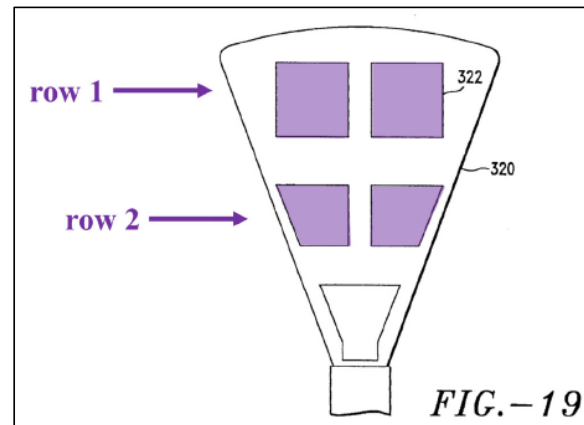
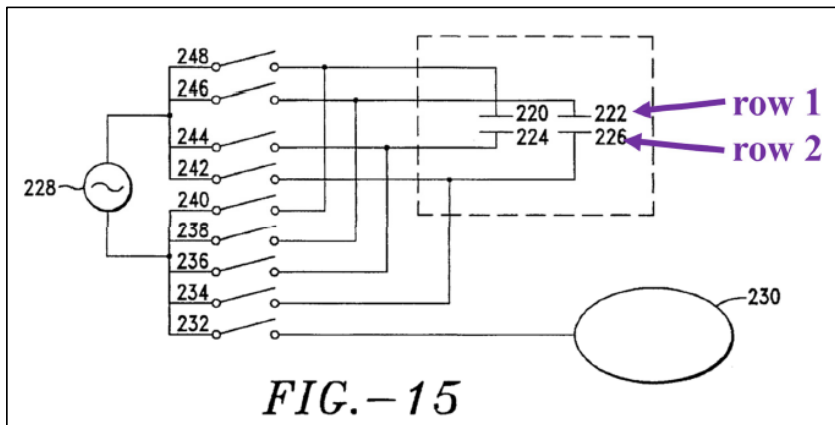


271 Petition at 38-41

Stern teaches two rows of one pair each – not rows of “pairs”



74. I disagree with Petitioners that Stern teaches “two rows of bipolar electrode pairs.” Even if Stern teaches a treatment element comprising “bipolar electrode pairs” (it does not), Stern teaches two rows of a single pair each—not two rows of pairs.



Ex-2001-Bikson, ¶ 74; 271 POR at 25-26

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petitioners' argument: multiple "pairs" per row excludes a preferred embodiment

The above arrangement has no pairs within a single row—pairs are formed across rows, not within them. That is, each row contains one electrode—half—of a given pair and no complete pairs. The preferred embodiment is therefore excluded under PO's interpretation that requires multiple pairs within a single row. The preferred embodiment does, however, satisfy an interpretation that simply requires multiple pairs in the two rows. Ex.1083-DelGaudio-Reply-Decl., ¶31; Ex.1097-Martin-Reply-Decl., ¶¶31-32.

271 Reply at 7-9

The claims are directed to embodiments that have multiple “pairs” per row

As Dr. Bikson explained, both row 1 and row 2 in Fig. 8F have multiple pairs of electrodes as enabled by the five electrodes in each row. (Ex-2001-Bikson, ¶79.) The Challenged Claims—which require each row to have multiple pairs of electrodes—are directed to this embodiment, not alternative embodiments where each row has only one pair of electrodes. (*Id.*)

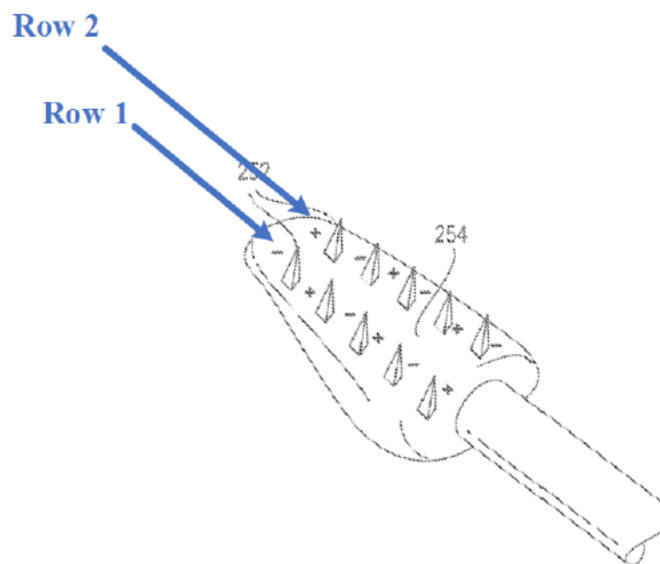


FIG. 8F

Dr. Bikson confirmed multiple “pairs” per row are required



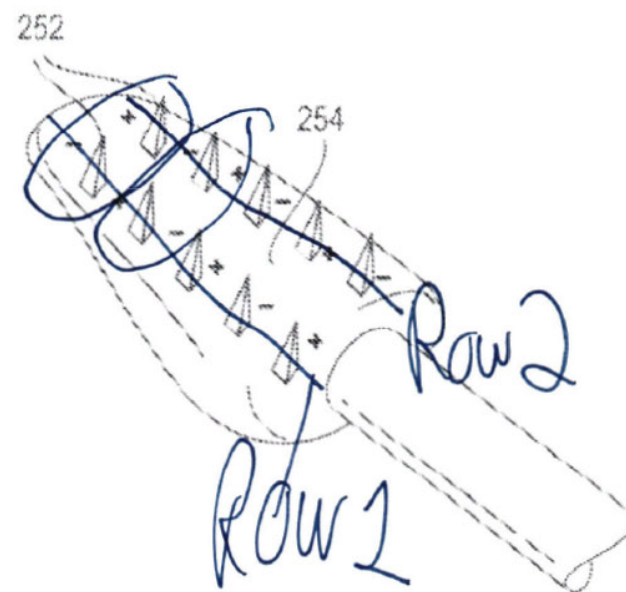
Q Do you see element A, it says, "wherein the treatment element comprises two rows of bipolar electrode pairs"?

A I see that.

Q Does the circled instances that you have in Exhibit C read on that requirement?

A No.

Ex-1084-Bikson at 241:13-19
(discussing Ex-1087)



Ex-1087

Petitioners' argument: "pairs" can encompass one pair

Second, even if the claim requires "pairs" in a single row, as PO argues, the Federal Circuit has repeatedly held that, in analogous circumstances, a plural term can be interpreted to require only one item. *Dayco Prod., Inc. v. Total Containment, Inc.*, 258 F.3d 1317, 1328 (Fed. Cir. 2001) (phrase "plurality of ... projections with recesses therebetween" does not require "three or more projections" because "the use of 'recesses' can be understood to mean a single recess where there are only two projections and more than one recess where there are three or more projections"); *Versa Corp. v. Ag-Bag Intern. Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) (phrase "means for creating air channels," plural, "does not imply that multiple channels are required"). Like the plural terms in *Dayco* and *Versa*, "pairs" in claim 1 can encompass one pair

271 Reply at 9-10

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

54

Plural terms presumptively require more than one

28 F.4th 254

United States Court of Appeals, Federal Circuit.

APPLE INC., Appellant

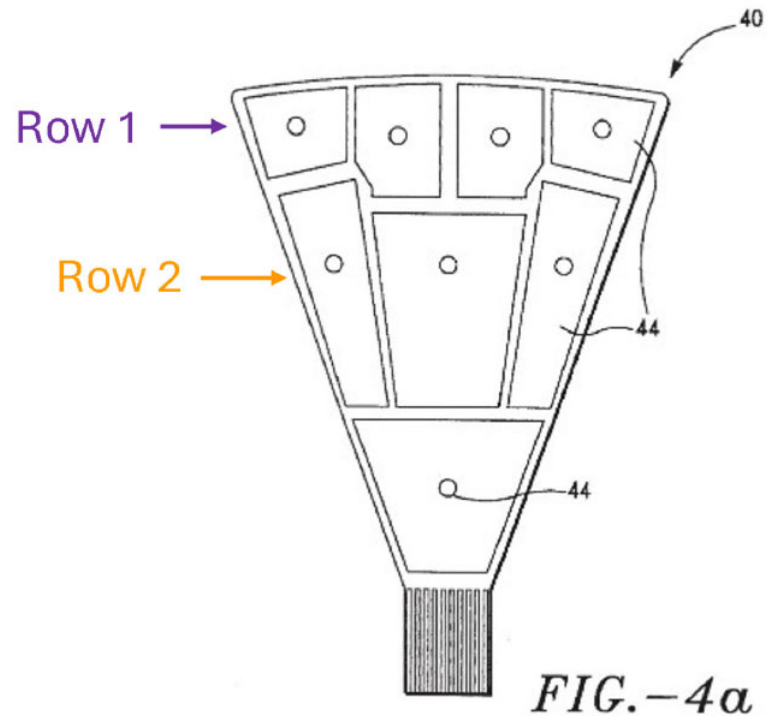
v.

MPH TECHNOLOGIES OY, Appellee

[9] [10] In accordance with common English usage, we presume a plural term refers to two or more items. See *Leggett & Platt, Inc. v. Hickory Springs Mfg. Co.*, 285 F.3d 1353, 1357 (Fed. Cir. 2002) (“[T]he claim recites ‘support wires’ in the plural, thus requiring more than one welded ‘support wire.’”

Here, the term “information fields” is plural and, thus, presumably requires more than one field. Nothing in the phrase “partition containing information fields related to the connection” or surrounding claim language suggests otherwise.

Petitioners' new argument: Stern FIG. 4a teaches two rows of pairs



271 Reply at 13

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

56

Petitioners' new argument is untimely and wrong

Petition did not rely on FIG. 4a for “two rows”

FIG. 4a is *unipolar*, not *bipolar*

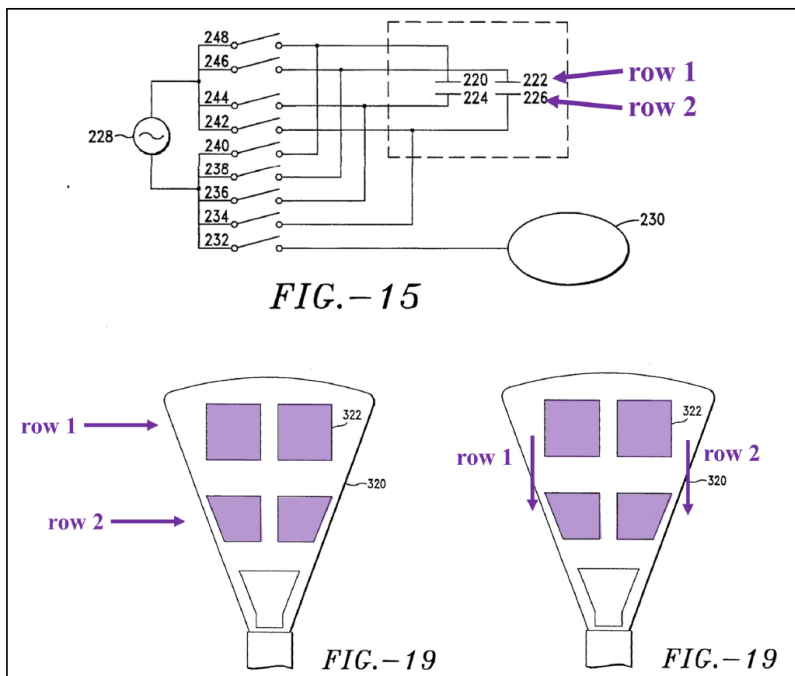


FIG. 5 is a schematic representation of the power source controller and the switch matrix for the multi-segment balloon discussed above in conjunction with, for example, FIG. 4.

FIG. 15 illustrates the use of four electrodes 220, 222, 224 and 226 and a voltage source 228 with the same patient grounding pad or patch or return electrode 230 as in, for example the FIG. 5 unipolar arrangement.

Ex-1033-Stern at 8:66-9:4, 12:47-49

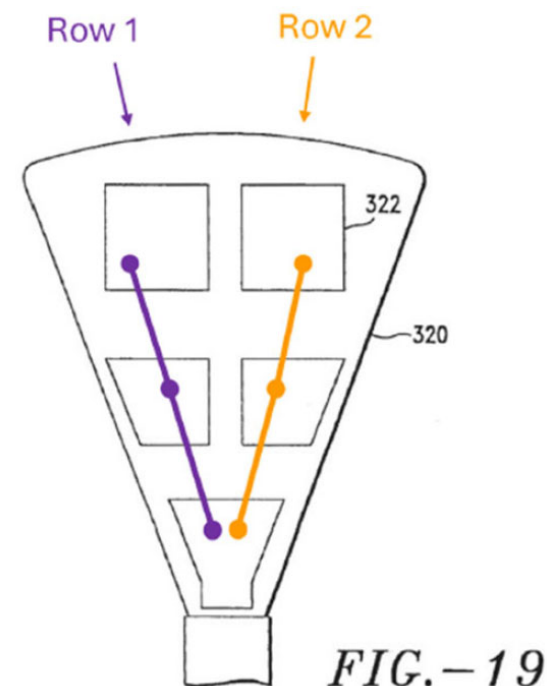
271 Petition at 41

271 Sur-Reply at 10-12

Petitioners' new footnote argument: Stern's fifth electrode

³ Stern discloses various other arrangements of electrodes that satisfy PO's interpretation. For example, the fifth electrode at the bottom of Figure 19 could be activated, providing a third electrode for each of the rows. Ex.1033-Stern, Figure 19; Ex.2003-Martin-Tr., 278:5-279:6. Ex.1081-Reply-Decl., ¶¶39-40; Ex.1097-Martin-Reply-Decl., ¶39.

271 Reply at 14 n. 3



Ex-1083-DelGaudio, ¶ 39

Petitioners' new footnote argument is untimely and wrong

- Petitioners' new footnote argument was not raised in the Petition. (Petition at 40-41.)
- Dr. Martin confirmed he had not even considered that Stern's FIG. 19 has a fifth electrode. (Ex-2003-Martin at 276:14-277:22.)
- Arguments raised in footnotes are improper. *In re ZTE Corp.*, 2022 U.S.P.Q.2D 438 at *6 (Fed. Cir. May 5, 2022).
- Petitioners improperly attempt to circumvent the reply word limit. 37 C.F.R. 42.6(a)(3).
- The fifth electrode in FIG. 19 is not in a "row" with the other electrodes in FIG. 19.
- Stern does not teach configuring a bipolar electrode pair with the fifth electrode in FIG. 19. (See *generally* Ex-1033-Stern.)

Dispute #4: Whether a POSITA Would Have Been Motivated to
Combine Edwards-535 with Stern's "two rows"
['271 Patent, All Claims and Grounds]

Legal Standards for Obviousness

Inc. v. The Toro Co., 848 F.3d 1358, 1367 (Fed. Cir. 2017). The Petitioner must also demonstrate “that a skilled artisan would have had reason to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.”

In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig., 676 F.3d 1063, 1068-69 (Fed. Cir. 2012); *see also Orexo AB v. Actavis Elizabeth LLC*, 903 F.3d 1265, 1271 (Fed. Cir. 2018) (holding that a finding of obviousness requires a showing “that a person of ordinary skill would have selected and combined and modified the subject matter of the references in the manner of the claimed invention, with a reasonable expectation of success.”).

271 POR at 14

1004-Martin, ¶ 95; Ex-2001-Bikson, ¶ 88.) To prove obviousness, the patent challenger must demonstrate “a motivation to pick out [the] references and combine them to arrive at the claimed invention.” *See, e.g., Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017).

271 POR at 36

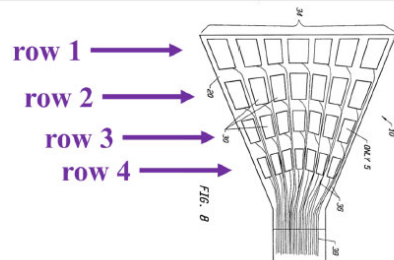
Petitioners' reasons to combine with Stern's "two rows"

(1) Edwards-535 instructs a POSITA to look to Baker's electrodes

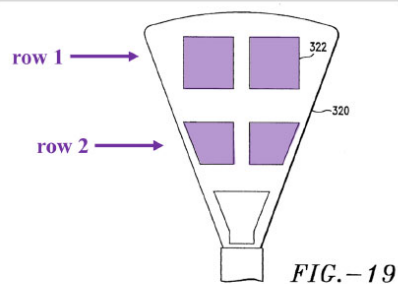
(b) Two Rows

A POSITA also would have been motivated to implement Edwards-'535's electrodes as **two rows** of bipolar electrodes as disclosed by Stern. Edwards-'535 instructs a POSITA to look to Baker for how to dispose electrodes on the surface of a membrane, Ex.1010-Edwards-'535, 8:26-33, and Baker, like Stern, also discloses electrodes in rows. Compare Ex.1011-Baker, FIG.8 with Ex.1033-Stern, FIG.19:

Ex.1011-Baker, FIG. 8 (showing rows of electrodes)



Ex.1033-Stern, FIG. 19 (same)



(2) Two rows facilitates simple energy application / control

A POSITA would have recognized that arranging electrodes in rows, as opposed to a more disorganized pattern or a single row, facilitates simple spatial resolution of the applied energy. As discussed above, Kong teaches that proper placement of the electrodes is paramount, and thus control of electrode pairs in rows enables targeting particular portions of tissue (e.g., the anterior, middle, and posterior of the inferior turbinate).

(3) Duplication 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.

Edwards-535 does not instruct a POSITA to look to Baker's electrodes

An example of a suitable surface for disposition on the membrane is described in application Ser. No. 08/319,373, "Thin Layer Ablation Apparatus", filed Oct. 6, 1994, which is incorporated by reference.

Ex-1010-Edwards-535 at 8:28-31



87. I note that Edwards-535's incorporation by reference passage does not incorporate the Baker Application in its entirety. (Ex-1010-Edwards-535 at 8:28-31.) Edwards-535 cites the Baker Application just for one limited example (*i.e.*, "An example of a suitable surface for disposition on the membrane"). (Ex-1010-Edwards-535 at 8:28-31.) The Baker Application's other teachings (*e.g.*, the Baker Application's electrode arrangement) are not incorporated by reference in Edwards-535. (*Id.*)

Ex-2001-Bikson, ¶ 87

86. Edwards-535's incorporation by reference passage has nothing to do with the Baker Application's electrodes or electrode arrangement. Edwards-535 discloses that the expandable member may be "an expandable porous membrane" that is "permeable to [an] electrolytic medium used to expand the member." (Ex-1010-Edwards-535 at 7:66-8:7.)

The Baker Patent similarly describes "an expandable member made of a material with a porous exterior surface," wherein an electrolytic solution is released through the porous exterior surface. (Ex-1011-Baker at Abstract; *see also id.* at 3:11-17, 3:33-37, claim 1, claim 17.) In view of the above, Edwards-535's incorporation by reference passage incorporates the Baker Application's description of a "porous exterior surface" for releasing an electrolytic solution, not the Baker Application's electrode arrangement.

Ex-2001-Bikson, ¶ 86

Two rows does not simplify anything – it adds complexity



Q. So if I understand you correctly, when you're mentioning in Paragraph 95 of the '271 declaration "simplified spatial resolution of the applied energy," basically what you're comparing is some sort of ordered arrangement compared to a random arrangement. Is that accurate?

A. I think that's one way to look at it, yes.

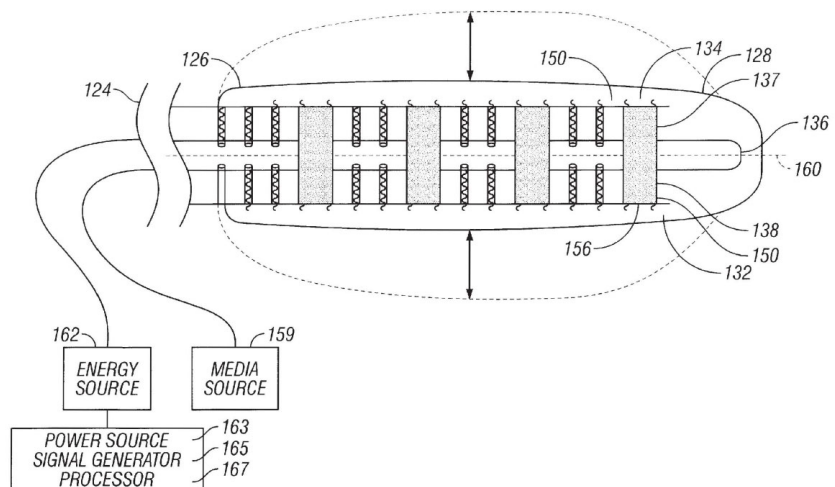
Ex-2003-Martin at 291:7-14



88. Second, I disagree with Petitioners' assertion that arranging electrodes in rows "facilitates simple spatial resolution of the applied energy." There are numerous (if not infinite) "ordered arrangements" for bipolar electrodes, of which Stern's electrode arrangement is merely one possibility. In bipolar operation, energy flows from a positive electrode to a negative electrode. The application of this energy can be controlled in many ways, such as varying the position or orientation of the device, varying which electrodes are activated (*e.g.*, electrodes that are closer together or further away, electrodes that have different orientations with respect to each other, etc.), varying the power, placing an insulating material near the electrodes, and the like. Using only two electrodes, or arranging the electrodes in a single row, provides the simplest way to control the applied energy. Other electrode arrangements do not simplify anything. Instead, they add complexity.

Ex-2001-Bikson, ¶ 88

Duplicating Edwards-535's parts does not result in Stern's two rows



$\times 2 \neq$

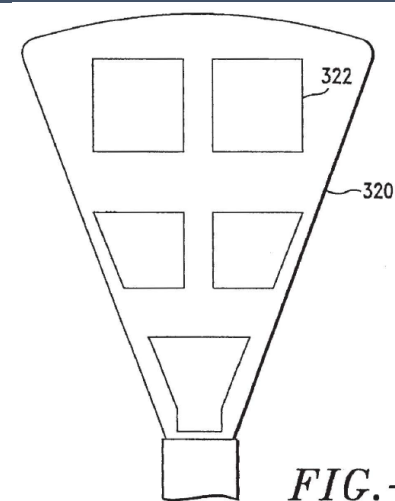


FIG.-19



FIG. 19, 14:14-42.) Duplicating Edwards-535's electrodes would have resulted in a single row of eight ring electrodes—not two rows of electrodes, or anything remotely resembling Stern's electrode arrangement.

Petitioners' argument: Patent Owner did not contest Petitioners' motivations

Thus, PO has not contested the overwhelming majority of reasons in the Petition regarding why a POSITA would have been motivated to arrange Edwards-'535's electrodes into two rows in view of Stern. Ex.1083-DelGaudio-Reply-Decl., ¶44; Ex.1097-Martin-Reply-Decl., ¶42.

271 Reply at 17-18

Patent Owner did contest Petitioners' motivations



88. Second, I disagree with Petitioners' assertion that arranging electrodes

in rows "facilitates simple spatial resolution of the applied energy." There are numerous (if not infinite) "ordered arrangements" for bipolar electrodes, of which Stern's electrode arrangement is merely one possibility. In bipolar operation, energy flows from a positive electrode to a negative electrode. The application of this energy can be controlled in many ways, such as varying the position or orientation of the device, varying which electrodes are activated (*e.g.*, electrodes that are closer together or further away, electrodes that have different orientations with respect to each other, etc.), varying the power, placing an insulating material near the electrodes, and the like. Using only two electrodes, or arranging the

electrodes in a single row, provides the simplest way to control the applied energy.

Other electrode arrangements do not simplify anything. Instead, they add complexity.

Using Stern's two rows of electrode pairs on Edwards-'535's expandable member 132 would have merely involved combining known prior art elements (Edwards-'535's apparatus 124 with Stern's electrodes and control scheme) according to known methods (*e.g.*, Stern's and Edwards-'535's selective control techniques) to yield predictable results (fine-tuned energy delivery and control).

Likewise, it would have involved simply substituting one known element (Edwards-'535's energy delivery device 134 on the surface of expandable member 132) for another (Stern's two rows of paired bipolar electrodes and control scheme) to obtain predictable results (finer control of energy delivery and temperature control). It also

271 Petition at 48-49

Ex-2001-Bikson, ¶ 88

Dispute #5: Whether the Prior Art Renders Obvious the Dependent Claims of the '271, '318, and '286 Patents

'318 Patent, Element 9[a] / '286 Patent, Element 7[a]

9. The device of claim 1, further comprising:
a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and
a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Ex-1001-318 at claim 9

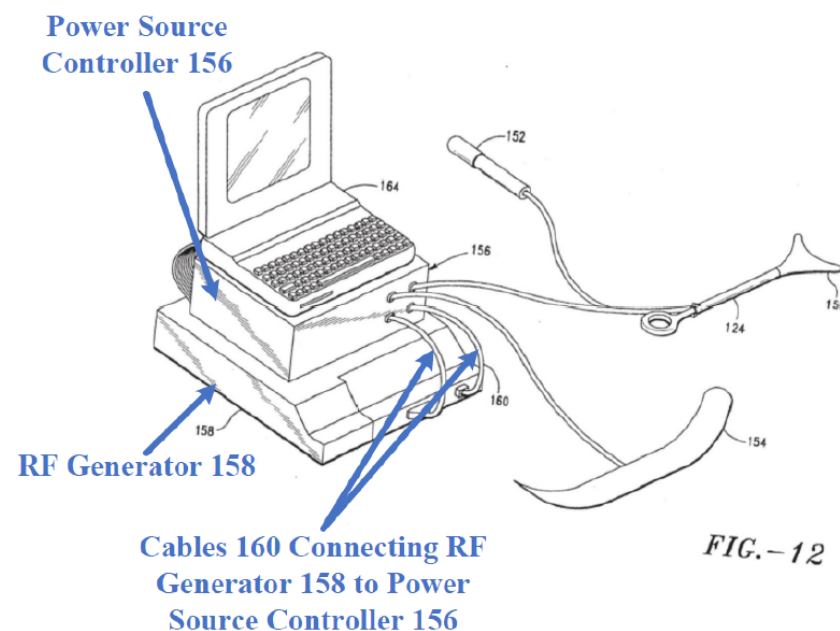
7. The device of claim 1, further comprising:
a radiofrequency generator configured to receive sensed signals from the at least one impedance sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and
a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Ex-1001-286 at claim 7

Prior art does not teach a generator configured to deliver energy “separately”



92. In any case, Stern fails to teach that its RF generator 158 is configured to “deliver radiofrequency energy separately.” Stern teaches an “RF generator 158” in the form of “a conventional electrosurgical power supply.” (Ex-1033-Stern at FIG. 12, 10:44, 10:54-55; *id.* at 2:50-51.) The RF generator 158 has a single “output,” which is provided to a separate power source controller 156 via electrosurgical interface cables 160. (*Id.* at FIG. 12, 10:42-46; *id.* at 2:49-53, 3:12-21, 9:14-17, 10:53-55, claim 1.) Switches in the power source controller 156 control which electrodes in the application device 124 receive radiofrequency energy. (*Id.* at 3:12-21, 8:66-67, 11:49-51, 12:21-24, 12:38-61, claim 1, FIG. 5, FIG. 12, FIG. 15.)



Petitioners' argument: Stern teaches energizing electrodes “separately”

Therefore, even though Stern discloses an “RF generator 158 [that] serves as the RF input power for the controller 156,” “[o]nce the device 124 and the controller 156 are connected, the RF electrodes are separately, independently and sequentially energized....” Ex.1033-Stern, 10:33-53. This discloses the claim limitation. See Ex.1001-USP318, FIG.22A. Ex.1083-Reply-Decl., ¶¶80-81.

318 Reply at 25; 286 Reply at 22-23

Petitioners fail to address what is claimed



91. Petitioners and Dr. Martin fail to address what is claimed. Challenged Claim 9 expressly recites that the “radiofrequency generator” is configured to deliver radiofrequency energy separately to each of the multiple radiofrequency output channels. (Ex-1001 at claim 9.) However, Petitioners and Dr. Martin fail to explain in their Challenged Claim 9 analysis how Edwards-535 in view of Stern teaches a “radiofrequency generator” configured to deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels

Ex-2001-Bikson, ¶ 91;
see also 318 Sur-Reply at
18; 286 Sur-Reply at 17

9. The device of claim 1, further comprising:
a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and
a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Ex-1001-318 at claim 9

'318 Patent, Element 9[b] / '286 Patent, Element 7[b]

9. The device of claim 1, further comprising:
a radiofrequency generator configured to receive sensed signals from the multiple sensors and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels in the form of a 460 KHz sinusoid wave; and
a cable coupled to the handle for plugging the handle into the radiofrequency generator.

Ex-1001-318 at claim 9

7. The device of claim 1, further comprising:
a radiofrequency generator configured to receive sensed signals from the at least one impedance sensor and deliver radiofrequency energy separately to each of the multiple radiofrequency output channels; and
a cable coupled to the handle for plugging the handle into the radiofrequency generator.

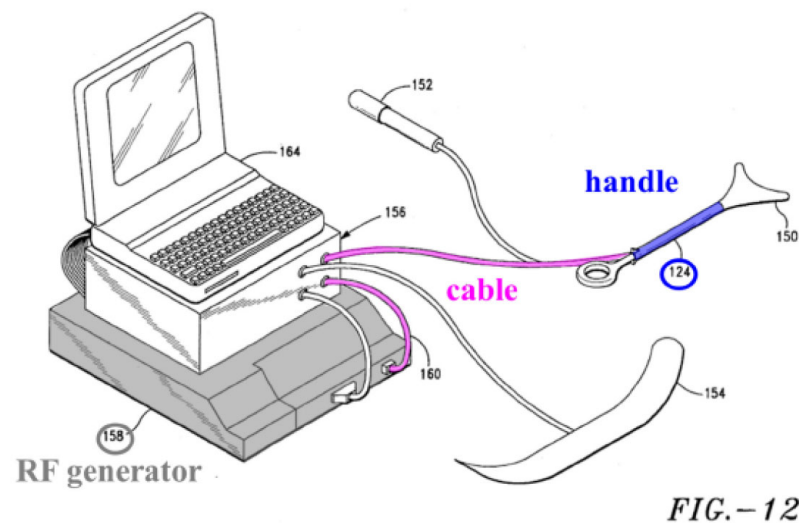
Ex-1001-286 at claim 7

Prior art does not teach the claimed “cable”



99. I disagree with Petitioners and Dr. Martin that Stern teaches a cable coupled to the handle of application device 124 for plugging the handle into the RF generator 158. As depicted in Petitioners’ and Dr. Martin’s annotated diagram above, Stern’s RF generator 158 is connected to a separate power source controller 156 via electro-surgical interface cables 160. (Ex-1033-Stern at FIG. 12, 10:36-49.) The handle of application device 124 is plugged into power source controller 156 via a different cable. (*Id.*) Thus, the cable coupled to Stern’s handle 124 is plugged into Stern’s power source controller 156—not into Stern’s RF generator 158 (*i.e.*, the alleged radiofrequency generator).

Ex-2001-Bikson, ¶ 99



318 Petition at 58; 286 Petition at 54

Petitioners' arguments: "a" does not require only one and the patents contemplate a generator and a separate control system

First, "a" does not require one and only one. *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008) ("a" means "one or more" in open-ended "comprising" claims). The fact that Stern's Figure 12 depicts a cable connecting the handle to power source controller 156, and an allegedly different cable connecting power source controller 156 to RF generator 158, is immaterial.

Second, the '318 patent does not indicate that the cable must *directly connect* the generator to the handle. As discussed in Section II.D.1., the patent explains that the generator may be separate from a control system "that delivers energy or control signals." Ex.1001-USP318, 16:27-31, 34:33-34, 5:25-30, 16:27-35, FIG.3. Therefore, the patent contemplates a control system between the generator and handle. Stern therefore teaches this limitation. Ex.1083-Reply-Decl., ¶¶86-87.

318 Reply at 27-28; 286 Reply at 24-25

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Need at least one claimed “cable” / Petitioners ignore the claimed embodiment

Petitioners’ argument ignores the express language of Claim 9. While it is true there could be two or more cables coupled to the handle for plugging the handle into the generator, the claim indisputably requires *at least one cable coupled to the handle for plugging the handle into the radiofrequency generator* to satisfy the claim. (Ex-1001 at claim 9.) Here, Stern does not teach even one cable coupled to the handle for plugging the handle into the radiofrequency generator. (Ex-2001-Bikson, ¶99.)

Further, while the ’318 patent may arguably describe an embodiment with a control system between the generator and handle, the *claimed embodiment* expressly requires that the handle is plugged into the generator, not a separate control system. (Ex-1001 at claim 9.) Patent Owner provided undisputed evidence that the cable coupled to the handle of Stern’s application device 124 is plugged into Stern’s power source controller 156—not into Stern’s generator 158, as claimed. (Ex-2001-Bikson, ¶99.)

318 Sur-Reply at 19-20; 286 Sur-Reply at 18-19

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

76

'318 Patent, Claim 6 / '286 Patent, Claim 4

6. The device of claim 4, wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.

Ex-1001-318 at claim 6

4. The device of claim 2, wherein the multiple segments are pre-shaped and comprise a shape-memory alloy material configured to expand to a desired size and shape.

Ex-1001-286 at claim 4

Petitions: Makower suggests making struts of nitinol

As discussed above for claim 4, Makower teaches that “strut members 214 may be collapsible and expandable.” Ex.1021-Makower, [0187]. Makower further explains that “any...elongate flexible devices of this invention may include design elements that impact performance features.” *Id.*, [0194]. This includes using “**shape memory alloys such as nitinol**” to “predictably deflect various sections of the catheter.” *Id.*; *see also id.*, [0149] (discussing nickel titanium alloy frame). Ex.1002-Decl., ¶318.

Because the strut members 214 deflect when expanded, a POSITA would have understood that Makower suggests making strut members 214 of a **shape memory alloy** to facilitate collapse and expansion. Ex.1002-Decl., ¶319.

318 Petition at 92; 286 Petition at 78-79

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Makower does not suggest making struts of nitinol

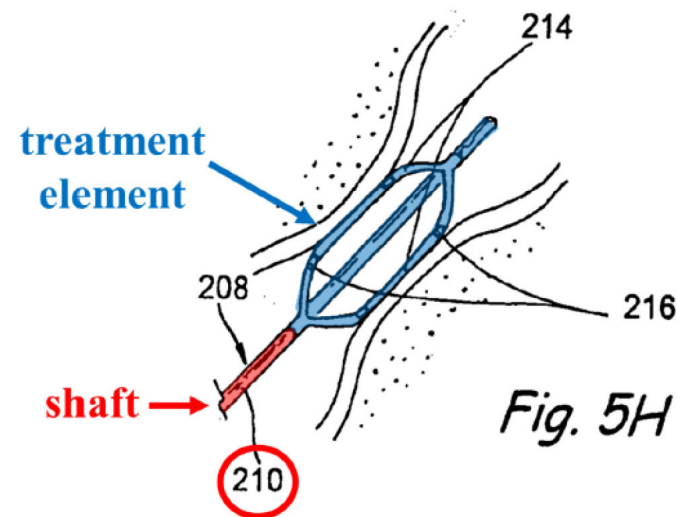
elements to predictably deflect various sections of the catheter (e.g., tension straps or wires, shape memory alloys such as nitinol, etc.).

Ex-1021-Makower at [0194]

Makower does not teach that its strut members 214 deflect the catheter. (*Id.* at FIG. 5H, [0187].) Thus, Makower's only description of "nitinol" is unrelated to the strut members 214.

Makower also expressly teaches that its strut members 214 are different than the catheter 210. (*Id.*)

Ex-2001-Bikson, ¶¶ 121-123



318 Petition at 81; 286 Petition at 67

Petitioners' argument: Makower teaches using same material for catheter and struts

Makower's disclosure that components other than the elongate flexible device shown in Figure 5H can be made from nitinol does not negate Makower's clear teaching to use the same material for the elongate flexible device, including its strut members 214. *Nextremity Solutions, Inc. et al v. Extremity Medical, LLC*, IPR2022-00802, Paper 35 (P.T.A.B July 26, 2023) ("Simply because one embodiment of [the prior art] teaches the limitation and one does not 'is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.'" (citations omitted)). Ex.1083-Reply-Decl., ¶71.

318 Reply at 22-23; 286 Reply at 20

Petitioners mischaracterize Makower's teachings

As to Petitioners' first argument, Makower *does not teach* using the same material for strut members 214 as for the catheter. (Ex-1021-Makower at [0194]; Ex-2001-Bikson, ¶¶120-123.) Makower references nitinol only with respect to the catheter. (*Id.*; see also Ex-1021-Makower at [0195] (discussing use of “shape memory materials” to make the catheter “steerable”).) Makower does not teach using nitinol—or any other shape-memory material—for anything other than the catheter. (*Id.*) It is undisputed that Makower's strut members 214 are different than the catheter. (Ex-2001-Bikson, ¶123.) Tellingly, Petitioners provide *no citation* to Makower to show Makower's supposed “clear teaching to use the same material.” (Reply at 23.)

318 Sur-Reply at 26; 286 Sur-Reply at 21-22

elements to predictably deflect various sections of the catheter (e.g., tension straps or wires, shape memory alloys such as nitinol, etc.).

Ex-1021-Makower at [0194]

such device inoperative for its intended purpose. Steerable catheters and scopes are well known in the art and may utilize mechanical steering assemblies (e.g., pull wires, hinges, etc.) or shape memory materials (e.g., nickel titanium alloys, shape memory polymers, etc.) to induce the device to undergo the desired bending or curvature after it has been inserted into the body. Examples of apparatus and

Ex-1021-Makower at [0195]

Petitioners' argument: Examiner applied the same mapping

the catheter.” Pet., 92 (citing Ex.1021-Makower, [0194]). This is the exact same mapping that the Examiner applied when it found that Makower anticipated this claim.⁵ Ex.1003-USP318FH, 509. Ex.1083-Reply-Decl., ¶¶69-70, 72.

318 Reply at 22; 286 Reply at 19

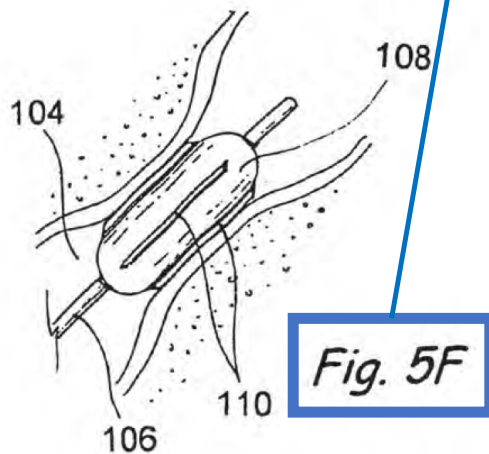
The Examiner did not apply the same mapping

Examiner's Mapping

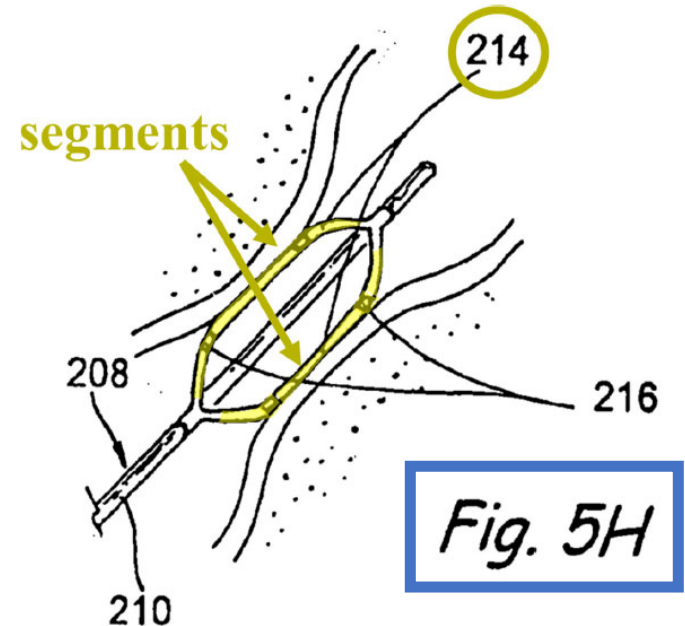
Regarding claims 15-17, the treatment element disclosed in Fig. 5F comprises a balloon

108 having multiple segments separated by radiofrequency electrodes 110 that is expandable from the first configuration to the second configuration. See paragraph [0088].

Regarding claim 18, Makower et al teach the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape. See paragraph [0194].



Petitioners' Mapping



318 Petition at 90; 286 Petition at 76-77

Ex-1003-318-Prosecution-History at 509;
Ex-2021-Makower at FIG. 5F

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

The Correct Definition of a POSITA

Petitioners' definition of a POSITA

VII. PERSON OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art (“POSITA”) at relevant times (2011-2021) 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.

318 Petition at 19-20; 286 Petition at 17; 271 Petition at 20-21

The correct definition of a POSITA



37. I disagree with part (2) of Petitioners' definition. Part (2) of Petitioners' definition encompasses within the definition of a POSITA persons who only have experience with the clinical use or testing of medical devices. But a POSITA in the field of the '318 patent would have had more experience than just clinically using medical devices or simply conducting tests with medical devices.

40. The correct definition of a POSITA is someone who has: (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 design and development of medical devices, including medical devices that deliver energy to tissue.

Dr. DelGaudio does not qualify as a POSITA



Q -- you don't have three years of design,
correct?

A No, I do not have three years of design

My declaration spells those things out to show
that I'm a person of ordinary skill in the art
because I'm an M.D. and I've been practicing for
three years with the clinical use of
energy-delivering devices in the nasal cavity.

Ex-2007-DelGaudio at 98:1-99:1, 131:18-22

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Neurent Medical Inc. & Neurent Medical Ltd.
v.
Aerin Medical Inc.

IPR2024-00277 (US 11,241,271)

IPR2024-00278 (US 11,033,318)

IPR2024-00282 (US 11,766,286)

PATENT OWNER'S DEMONSTRATIVE EXHIBIT

IPR2024-00277
IPR2024-00278
IPR2024-00282

PO's Demonstrative Exhibit

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the below date, I caused the foregoing to be served by electronic mail to the following:

David Cavanaugh
david.cavanaugh@wilmerhale.com

Gregory Lantier
gregory.lantier@wilmerhale.com

Alexis Cohen
alexis.cohen@wilmerhale.com

Joshua Stern
joshua.stern@wilmerhale.com

Alexander Nemtzow
alex.nemtzw@wilmerhale.com

Sarah Murphy
sarah.j.murphy@wilmerhale.com

Brian Lambson
Brian.Lambson@wilmerhale.com

WHNeurentIPRService@wilmerhale.com

Date: April 18, 2025

/s/ Heath J. Briggs
Heath J. Briggs