

**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

PATENT OWNER'S SUR-REPLY

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	PETITIONERS FAILED TO SHOW THE CHALLENGED CLAIMS ARE OBVIOUS.	1
A.	Ground 1: Petitioners Failed To Show Edwards-535 In View Of Stern Renders Claims 1, 4-5, 9-10, 12-13, And 15-17 Obvious.....	1
1.	Petitioners Failed To Show Edwards-535 In View Of Stern Teaches “multiple pairs of bipolar radiofrequency electrodes.”	1
(a)	Petitioners’ Reply Is Premised On A Strawman Argument.....	2
(b)	Stern Does Not Teach A Device Comprising Multiple Pairs.	3
2.	Petitioners Failed To Show Edwards-535 In View Of Stern Teaches “multiple radiofrequency output channels.”	6
(a)	Patent Owner’s Interpretation Of “Radiofrequency Output Channel” Is Consistent With The Intrinsic Evidence And Dr. Martin’s Own Interpretation.....	6
(b)	There Is No Dispute Stern Teaches Only One Radiofrequency Output Channel Under The Correct Interpretation.....	9
(c)	Petitioners’ And Dr. Martin’s New Definitions Of “Radiofrequency Output Channel” Are Incorrect.	9
(d)	Petitioners And Dr. Martin Failed To Show Stern Teaches “multiple radiofrequency output channels” Even Under Their New Definitions.....	14
3.	Petitioners Failed To Show Edwards-535 In View Of Stern Teaches “wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels.”	15

4.	Petitioners Failed To Show Edwards-535 In View Of Stern Renders Dependent Claims 4-5, 9-10, 12-13, And 15-17 Obvious.....	15
(a)	Claim 5.....	15
(b)	Claim 9 – Element 9[a].....	17
(c)	Claim 9 – Element 9[b].....	19
(d)	Claim 15.....	21
(e)	Claim 17.....	22
B.	Ground 2: Petitioners Failed To Show Edwards-535 In View Of Stern And Patel Renders Dependent Claim 6 Obvious.....	23
C.	Grounds 3-5.....	25
1.	Petitioners Failed To Show Makower In View Of Stern Renders Claim 6 Obvious.	25
III.	DR. MARTIN'S REPLY TESTIMONY IS NOT CREDIBLE.....	27
IV.	PATENT OWNER'S POSITA DEFINITION IS CORRECT.....	28
V.	CONCLUSION	29

TABLE OF EXHIBITS

Exhibit No.	Description
2001	Declaration of Dr. Marom Bikson
2002	Curriculum Vitae of Dr. Marom Bikson
2003	Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin
2004	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
2005	Exhibit 6 to the Deposition of Dr. Gregory T. Martin
2006	Exhibit 7 to the Deposition of Dr. Gregory T. Martin
2007	Exhibit 8 to the Deposition of Dr. Gregory T. Martin
2008	Transcript of the February 20, 2025, Deposition of Dr. Gregory T. Martin

I. INTRODUCTION

Petitioners Neurent Medical Inc. and Neurent Medical Ltd.'s (collectively, "Petitioners") Reply primarily relies on a new, 92-page declaration from Petitioners' expert, Dr. Martin. That Petitioners require 92 additional pages of expert testimony confirms Petitioners failed to prove obviousness in the first instance. Further underscoring Petitioners' failure to establish a *prima facie* case of obviousness is Petitioners' improper attempt to raise brand-new modifications to, and combinations of, the asserted prior art not raised in their Petition. Nevertheless, like the Petition, Petitioners' Reply and Dr. Martin's new declaration also fail to show the claims are obvious. Accordingly, the Board should confirm the patentability of the Challenged Claims.

II. PETITIONERS FAILED TO SHOW THE CHALLENGED CLAIMS ARE OBVIOUS.

A. Ground 1: Petitioners Failed To Show Edwards-535 In View Of Stern Renders Claims 1, 4-5, 9-10, 12-13, And 15-17 Obvious.

1. Petitioners Failed To Show Edwards-535 In View Of Stern Teaches "multiple pairs of bipolar radiofrequency electrodes."

As demonstrated in Patent Owner's Response ("POR"), Petitioners failed to show Edwards-535 in view of Stern teaches "multiple pairs of bipolar radiofrequency electrodes" because Stern teaches a device configured to have at most a *single pair* of bipolar radiofrequency electrodes. (POR at 15-20.) Nothing in Petitioners' Reply demonstrates otherwise.

(a) Petitioners' Reply Is Premised On A Strawman Argument.

Petitioners assert in their Reply that “[Patent Owner] argues that Stern does not disclose this limitation because its pairs are not active ‘at the same time.’” (Reply at 3.) Petitioners mischaracterize Patent Owner’s argument.

As Patent Owner explained in the POR, there is no dispute that a “pair” of bipolar radiofrequency electrodes comprises two electrodes located near each other that have opposite polarities. (POR at 16-17; Ex-2003 at 254:20-22, 256:4-6, 263:19-264:16; Ex-2001-Bikson, ¶60; Ex-2008 at 200:7-15.) There is also no dispute a bipolar electrode “pair” is formed in Stern’s Figure 15 only when certain switches are closed. (POR at 17; Ex-2003 at 254:11-255:3, 265:20-266:18; Ex-2001-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 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.*)

Claim 1 does not require simultaneous activation of multiple pairs, but it does require a device configured to have multiple pairs. (Ex-1001 at claim 1.) Patent Owner’s argument is based on how Stern’s particular device is configured, irrespective of whether Stern’s electrodes are turned on. (POR at 15-20.) Indeed, Patent Owner’s expert, Dr. Bikson, confirmed this several times during his

deposition—despite Petitioners' counsel's repeated efforts to get him to say otherwise. (Ex-1084 at 100:17-102:2, 104:20-105:9, 105:21-106:13; *id.* at 95:11-96:1, 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.

(b) Stern Does Not Teach A Device Comprising Multiple Pairs.

Patent Owner demonstrated in the POR that Stern teaches a device that, at any given time, comprises at most one pair of electrodes. (POR at 19.) This is consistent with the Petition, which relies on two examples where Stern is configured to have only one pair of electrodes. (Petition at 35-36, 42-43.)

In the Reply, Petitioners now assert that Stern teaches a device configured to 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 point to Dr. Martin's interpretation of this sentence where he concludes, based solely on his *ipse dixit*, that a POSITA “would have understood that when pairs of electrodes are used together, they are active ‘at the same time.’” (Ex-1083-Martin, ¶22.)

Petitioners' interpretation is wrong. When read in isolation, the above sentence from Stern is at best ambiguous. A POSITA could have (and would have) read the above sentence as teaching that any combination of pairs of electrodes may be utilized together ***sequentially*** (*i.e.*, one pair at a time). (Ex-1084 at 110:7-112:12, 113:21-114:9, 115:17-116:20; *id.* at 131:13-21.) The problem for Petitioners is that it is improper to read portions of the prior art in isolation. According to the Federal Circuit, “[a] reference must be considered for everything it teaches.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985); *see also Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F. 2d 443 (Fed. Cir. 1986) (“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”). Here, when Stern is properly read in its entirety, any potential ambiguity is resolved ***in Patent Owner's favor***.

First, Stern expressly teaches that its electrodes are “***independently and sequentially energized***.” (Ex-1033-Stern at 2:31-33, 2:49-53, 10:48-52, 17:54-55; Ex-2001-Bikson, ¶64; Ex-1002-Martin, ¶¶177, 206.) As Dr. Bikson explained, 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.)

Second, Stern expressly teaches closing ***one*** of switches 242, 244, 246, and 248 and ***one*** of switches 234, 236, 238, and 240 to form ***one pair*** of bipolar

electrodes at a time. (Ex-1033-Stern at 12:55-13:2; Ex-2001-Bikson, ¶64.) Stern does not teach closing three or more switches at the same time. (*Id.*)

Third, as Dr. Martin testified, Stern's goal is to avoid uneven heating. (Ex-1083-Martin, ¶44; Ex-1033-Stern at 12:25-33; Ex-2008 at 170:12-171:13.) However, both parties' experts agree that utilizing multiple pairs at the same time in Stern's Figure 15 would *exacerbate* the problem of uneven heating—not help it. (Ex-2008 at 50:2-15; *id.* at 28:7-19, 29:3-11, 33:9-19; Ex-1084 at 253:6-254:4.)¹ Further, both parties' experts agree that utilizing multiple pairs at the same time in Stern's Figure 15 would result in a loss of control because “you don't know exactly where the current's going to flow.” (Ex-2008 at 24:21-25:21; *id.* at 23:7-21; Ex-1084 at 250:20-251:7 (“if you did that you would lose control.”).) Thus, a

¹ The amount of current that flows between the electrodes, which correlates to the amount of heating of the tissue between the electrodes, depends primarily on the impedance of the tissue between the electrodes. (Ex-2008 at 24:12-20, 26:8-27:3, 29:12-30:7, 31:1-32:14, 39:3-9, 41:15-42:5; Ex-1084 at 252:19-253:5, 255:10-19, 256:8-17.) Differences in impedance lead to different amounts of heating. (Ex-2008 at 42:10-43:3, 43:18-22, 44:14-20, 46:10-47:11.) Differences in impedance cannot be controlled—and are, in fact, expected—and thus the tissue between Stern's four electrodes will inevitably be heated *unevenly* if activated at the same time. (Ex-1084 at 248:5-11, 253:6-254:4, 257:10-14; Ex-2008 at 30:16-22.)

POSITA reading Stern would have known ***not*** to form multiple pairs in Figure 15.
(*Id.*)

Accordingly, Petitioners failed to show Edwards-535 in view of Stern teaches a device comprising “multiple pairs of bipolar radiofrequency electrodes.”

2. Petitioners Failed To Show Edwards-535 In View Of Stern Teaches “multiple radiofrequency output channels.”

As shown in the POR, Petitioners failed to show Edwards-535 in view of Stern teaches “multiple radiofrequency output channels” because Stern teaches at most a ***single*** radiofrequency output channel. (POR at 20-25.) Again, nothing in Petitioners’ Reply demonstrates otherwise.

(a) Patent Owner’s Interpretation Of “Radiofrequency Output Channel” Is Consistent With The Intrinsic Evidence And Dr. Martin’s Own Interpretation.

Petitioners assert that Patent Owner “improperly seeks to add the requirement that each ‘output channel’ must be connected directly to the voltage source in the radiofrequency generator.” (Reply at 6.) This is another strawman argument.

As explained in the POR, the plain and ordinary meaning of “radiofrequency output channel” is “an output from a radiofrequency generator.” (POR at 21; Ex-2001-Bikson, ¶69.) Dr. Martin ***confirmed*** this understanding during his original deposition. (Ex-2004 at 318:12-19; *id.* at 318:20-319:9, 319:17-320:2, 327:3-4,

329:21-22; *see also* Petition at 41 (referring to a “radiofrequency output channel” as an “energy output”).)²

Further, the POR demonstrated that the number of “radiofrequency output channels” depends on the number of outputs from the radiofrequency generator. (POR at 21-22; Ex-2001-Bikson, ¶70.) That is, “multiple radiofrequency output channels” requires multiple outputs from the radiofrequency generator. (*Id.*) Again, Dr. Martin **confirmed** Patent Owner’s understanding during his original deposition. (Ex-2004 at 430:2-431:13, 432:16-433:6 (discussing Ex-2007); *see also* Ex-2008 at 139:10-19, 141:14-142:22.)

Patent Owner’s interpretation of “radiofrequency output channel”—which, again, Dr. Martin agreed with—is consistent with the intrinsic evidence. The ’318 patent discloses a nasal treatment device that is coupled to a radiofrequency generator. (Ex-1001 at 28:61-66, 31:43-47, 34:31-44, 50:59-61.) The radiofrequency generator provides power to the electrodes in the treatment device. (*Id.*) Power is delivered to each pair of electrodes via “a separate, controlled electrical channel.” (*Id.* at 48:63-64; *see also id.* at 24:45-64.) Each of these separate, controlled electrical channels is depicted as a separate output from the

² As noted below, Dr. Martin now attempts to discredit his own prior sworn testimony.

radiofrequency generator (denoted with a “+” sign). (Ex-1001 at FIGS. 39-44; Ex-1084 at 177:2-14; Ex-2008 at 61:13-62:18.)

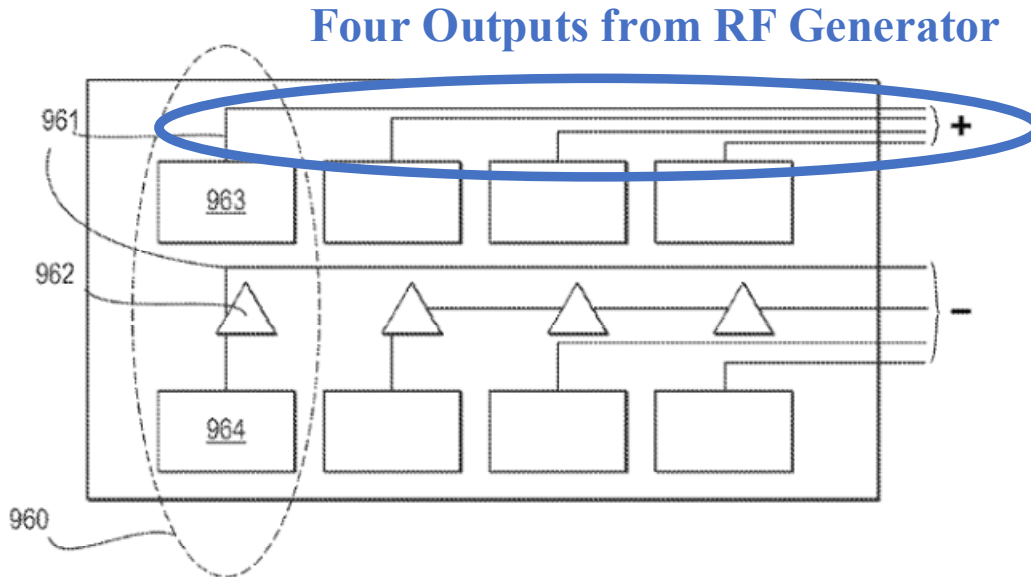


FIG. 39

(Ex-1001 at FIG. 39 (annotated).)³

Additionally, 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

³ While the '318 patent teaches that the input back to the radiofrequency generator may be shared (*id.* at 49:61-50:13, FIGS. 43-44), the '318 patent consistently shows that each of the outputs from the generator is separate. (*Id.* at FIGS. 39-44.)

contact.” (Ex-1001 at 24:45-64, 48:42-49:4; *id.* at 49:65-50:2, 50:9-15.) This functionality (i) cannot be accomplished without multiple outputs from the generator; and (ii) is neither disclosed by, nor achievable with, Stern’s Figure 15 configuration. (Ex-2001-Bikson, ¶80; Ex-1084 at 247:10-248:15, 250:20-251:7, 253:6-254:4.)

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

(b) There Is No Dispute Stern Teaches Only One Radiofrequency Output Channel Under The Correct Interpretation.

There is no dispute Stern teaches only one radiofrequency output channel under the correct interpretation (*i.e.*, “an output from a radiofrequency generator”).

Petitioner *does not dispute* that Stern’s radiofrequency generator 228 has only one output. (Reply at 6-14; *see also* Ex-2001-Bikson, ¶79; Ex-1002-Martin, ¶¶ 127, 128, 291; Ex-2004 at 335:10-336:16, 343:10-344:21, 429:22-431:5, 433:1-4; Ex-2008 at 124:21-125:6.) Because Stern’s radiofrequency generator 228 indisputably has only *one* output, Stern cannot teach “*multiple* radiofrequency output channels,” as claimed. (Ex-2001-Bikson, ¶79.)

(c) Petitioners’ And Dr. Martin’s New Definitions Of “Radiofrequency Output Channel” Are Incorrect.

Recognizing that Dr. Martin’s original definition of “radiofrequency output channel” is fatal to Petitioners, Petitioners and Dr. Martin provide no less than *six*

new definitions to try to fix Dr. Martin's prior testimony. (Ex-1083-Martin, ¶¶36, 39, 40, 42, 45; Ex-2008 at 55:20-56:4, 88:22-89:5, 100:18-101:2, 112:21-113:5, 129:12-19; Reply at 10.) Petitioners' and Dr. Martin's new definitions should be rejected because they are inconsistent with Dr. Martin's prior sworn testimony, with each other, and with the intrinsic evidence.

First, Petitioners' and Dr. Martin's new definitions are inconsistent with Dr. Martin's prior sworn testimony. As noted above, Dr. Martin previously testified that the plain and ordinary meaning of "radiofrequency output channel" is "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.) Dr. Martin now asserts that his prior testimony was somehow "taken out of context." (Ex-1083-Martin, ¶41.) Dr. Martin's explanation makes little sense and is a *post hoc* attempt to salvage Petitioners' case. (*Id.*, ¶¶41-42.)

Second, Petitioners' and Dr. Martin's new definitions are inconsistent with each other. Dr. Martin testifies at various points in his reply declaration that a "radiofrequency output channel" is (i) "something that allows pairing between chosen electrodes to form a complete circuit"; (ii) "something that allows pairing between chosen electrodes to control a chosen pairs of electrodes separately from another chosen pair"; (iii) "an energy connector between electrodes that allows for independent control of bipolar pairs"; or (iv) something that "connects electrodes

and provides the ability to independently control pairs of electrodes.” (Ex-1083-Martin, ¶¶36, 39, 40, 45.)

At other points, Dr. Martin testifies that a “radiofrequency output channel” is just “a channel that carries the output from a radiofrequency generator to an electrode pair” or simply the wires connected to an electrode pair. (Ex-1083-Martin, ¶¶42, 49; Ex-2008 at 163:3-164:22, 168:14-20, 169:4-170:2.)

Petitioners, for their part, ignore Dr. Martin’s definitions and assert the plain and ordinary meaning of “radiofrequency output channels” is “multiple channels that are not necessarily connected directly to the voltage source or generator.” (Reply at 10.)

Petitioners’ and Dr. Martin’s smorgasbord of new definitions are inconsistent with each other. Do the claimed radiofrequency output channels have to allow pairing between chosen electrodes? Do they have to allow pairing separately from another chosen pair? Do they have to form a complete circuit? Are they just wires attached to electrodes? The answers to these questions remain unknown.

Third, Petitioners’ and Dr. Martin’s new definitions are inconsistent with the intrinsic evidence. The claims of the ’318 patent expressly recite “multiple radiofrequency *output* channels.” (Ex-1001 at claim 1.) However, Dr. Martin testified a “radiofrequency output channel” is no different than a “radiofrequency

channel.” (Ex-2008 at 114:10-21.) Similarly, Petitioners assert that “radiofrequency output channels” are just “multiple channels.” (Reply at 10.) Petitioners and Dr. Martin give no meaning to the term “output,” which is improper. *Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017); *Merck & Co., Inc. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). Patent Owner, on the other hand, **does** give meaning to the term “output.” (POR at 21-22.)

Further, the '318 patent teaches the claimed multiple radiofrequency output channels are separately controllable, which differs from single channel designs in that multiple electrode pairs can be activated at the same time without diverting energy to the electrodes that have the least impedance between them. (Ex-1001 at 24:45-64, 48:42-49:4.) But Dr. Martin interprets “multiple radiofrequency output channels” to encompass designs that admittedly fail to offer the “separate control” described in the '318 patent. (Ex-2004 at 442:11-19; Ex-2001-Bikson, ¶80; Ex-1084 at 247:10-248:15, 250:20-251:7, 253:6-254:4.)

Additionally, Dr. Martin asserts that the '318 patent describes “an output wire extending from the voltage source ... which further branches into multiple output channels.” (Ex-1083-Martin, ¶45.) But as Dr. Martin conceded during his deposition, nothing in the '318 patent discloses a single output wire branching off

into multiple output channels. (Ex-2008 at 98:10-16, 133:17-134:12, 135:2-136:18.)

When given a chance to explain his new, conflicting definitions of “radiofrequency output channel” at his deposition, Dr. Martin repeatedly testified that a “radiofrequency output channel” is just a “logical construct.” (Ex-2008 at 65:20-21, 68:16-18, 70:21-22, 74:1-9, 83:21-22, 85:16-21, 104:12-14, 105:2-3, 113:6-12, 125:16-17, 127:7-8, 151:19-22.) According to Dr. Martin, the number of radiofrequency output channels “depends on how you want to define this construct” and is “in the eye of the user.” (*Id.* at 85:22-86:6, 151:16-22; *see also id.* at 127:11-128:8, 158:2-17.) Dr. Martin testified he used an imaginary dotted line to determine Stern discloses multiple radiofrequency output channels, but stated the imaginary line can be drawn different ways and the number of channels will differ depending on the line. (*Id.* at 66:14-19, 68:9-69:17, 70:17-71:9, 74:5-9, 75:6-17, 82:4-11, 86:7-13.)

Dr. Martin’s completely subjective, “a radiofrequency output channel is whatever I say it is” approach is legally untenable. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) (“The scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual”). Patent Owner’s interpretation, on the other hand, correctly

provides an objective basis for determining the number of “radiofrequency output channels,” and the Board should adopt Patent Owner’s interpretation.

(d) Petitioners And Dr. Martin Failed To Show Stern Teaches “multiple radiofrequency output channels” Even Under Their New Definitions.

Even if the Board adopts one of Petitioners’ and/or Dr. Martin’s many differing definitions of “radiofrequency output channel,” Petitioners still cannot show that Stern teaches “multiple radiofrequency output channels.”

Petitioners’ and Dr. Martin’s own annotated versions of Stern’s Figure 15 clearly depict *one radiofrequency output channel* that is *shared* by four electrodes:

**All Four Electrodes Connected To Single
Radiofrequency Output Channel**

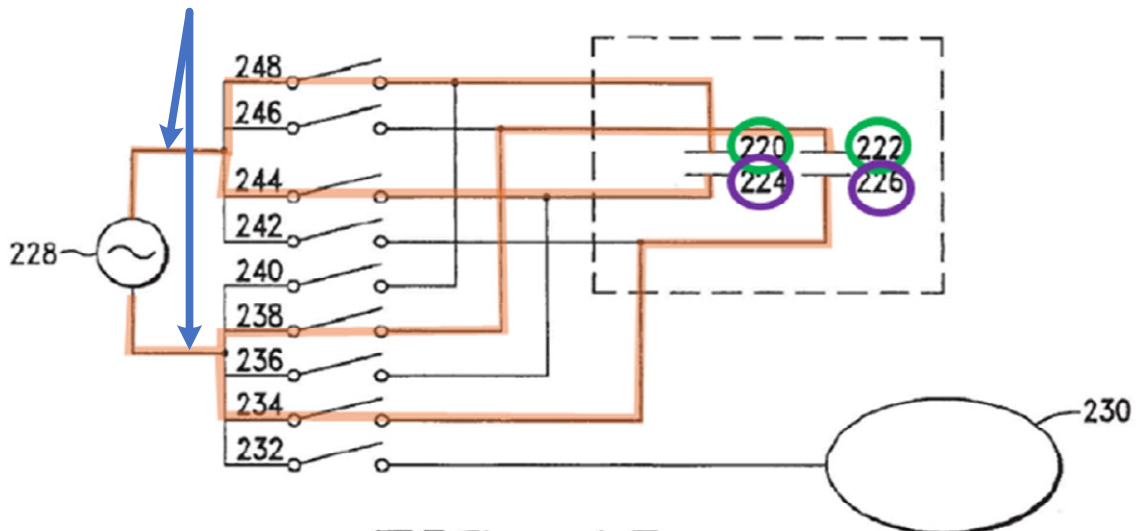


FIG. -15

(Ex-1083-Martin, ¶28 (annotated).)

Indeed, Dr. Martin admitted at his deposition that Stern's electrodes 220, 222, 224, and 226 share the radiofrequency energy from radiofrequency generator 228's *single output channel*. (Ex-2008 at 124:21-125:6; *id.* at 22:14-23:1, 121:16-122:1, 122:19-123:9.)

Thus, regardless of how the Board construes the term, the Board should find Edwards-535 in view of Stern fails to teach "multiple radiofrequency output channels."

3. Petitioners Failed To Show Edwards-535 In View Of Stern Teaches "wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels."

As discussed above, Petitioners failed to show Edwards-535 in view of Stern teaches "multiple radiofrequency output channels." Thus, Petitioners have likewise failed to show that Edwards-535 in view of Stern teaches "wherein each pair of the multiple pairs of bipolar radiofrequency electrodes is connected with a respective one of the multiple radiofrequency output channels."

4. Petitioners Failed To Show Edwards-535 In View Of Stern Renders Dependent Claims 4-5, 9-10, 12-13, And 15-17 Obvious.

(a) Claim 5.

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Stern teaches "wherein at least one pair of the multiple pairs of bipolar

radiofrequency electrodes is coupled with each of the multiple segments.” (POR at 28-30.)

Petitioners respond that Stern teaches that each segment includes a pair of electrodes because Stern teaches that each conductive “segment” (singular) is electrically connected through “conventional leads” (plural) to a power source, and a “segment would need multiple leads for bipolar operation to connect multiple electrodes to the power source.” (Reply at 17 (citing Ex-1033-Stern at 8:56-57).)

Petitioners misconstrue Stern. Stern expressly teaches that each segment has two leads: one for an electrode and one for a thermistor. (Ex-1033-Stern at 8:49-9:6.) That is, Stern expressly teaches that each segment has only one electrode—not two. (Ex-2001-Bikson, ¶88.)

Recognizing the Petition failed to establish a *prima facie* case of obviousness, Petitioners argue in their Reply that, even if Stern does not teach that each of its segments includes a pair of electrodes, “it would have been obvious to a POSITA to combine two [of Stern’s] segments.” (Reply at 17.) This argument was not raised in the Petition (Petition at 51-53), cannot be raised for the first time in reply, and must be disregarded. 37 C.F.R. § 42.23(b); *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1002 (Fed. Cir. 2023) (“the Board is not permitted to entertain ‘[s]hifting arguments’ but must, instead, reject any ‘entirely new theory of *prima facie* obviousness absent from the petition’”). Petitioners’ belated

argument should also be disregarded because Petitioners have presented no evidence a POSITA would have been motivated to combine two of Stern's segments.

Petitioners also argue for the first time in their Reply that Patent Owner “does not dispute Edwards-’535 discloses segments that include two electrodes.” (Reply at 18-19.) However, the Petition expressly relied on Stern—not Edwards-535—as allegedly teaching the limitations of Claim 5, and Petitioners never argued Edwards-535 discloses a pair of electrodes coupled with each segment. (Petition at 51-53.) Indeed, the Petition expressly stated a POSITA would have been motivated to “segment Edwards-’535’s expandable member 132 *as taught by Stern*” and to “*use the electrode configuration of Stern* with Edwards-’535’s expandable member.” (*Id.* at 51-53 (emphases added).) Thus, regardless of whether Edwards-535 allegedly teaches a pair of electrodes coupled with each segment, Petitioners expressly proposed using Stern’s segments that include only one electrode per segment. (Ex-2001-Bikson, ¶88.)

(b) Claim 9 – Element 9[a].

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Stern teaches “a radiofrequency generator configured to ... deliver radiofrequency energy separately to each of the multiple radiofrequency output channels.” (POR at 30-34.)

In response, Petitioners argue that Stern discloses this limitation because Stern discloses “RF electrodes [that] are separately, independently and sequentially energized...” (Reply at 25 (quoting Ex-1033-Stern at 10:33-53).)

Petitioners’ argument, like the Petition itself, fails to address what is claimed. Claim 9 expressly recites the **radiofrequency generator** is configured to deliver radiofrequency energy separately to each of the multiple radiofrequency output channels. (Ex-1001 at claim 9; Ex-2001-Bikson, ¶ 91.) Whether Stern’s electrodes can be separately energized has no bearing on whether Stern teaches a **radiofrequency generator** configured to deliver radiofrequency energy separately to each of the alleged multiple radiofrequency output channels, as claimed. (Ex-2001-Bikson, ¶91.) Indeed, Patent Owner provided undisputed evidence that Stern’s radiofrequency generator is **not** configured to “deliver radiofrequency energy separately.” (*Id.*, ¶¶92-94.)

Once again recognizing the Petition failed to establish a *prima facie* case of obviousness, Petitioners argue that whether Stern discloses a separate RF generator 158 and controller 156 is “irrelevant” because a “POSITA would have been motivated to modify Edwards-’535’s generator to include the functionality of Stern’s controller.” (Reply at 26.) Again, this argument was not raised in the Petition. (Petition at 53-57.) At no point did Petitioners propose incorporating Stern’s controller 156 into Edwards-535’s generator. (*Id.*) Indeed, Petitioners

expressly argued that “Stern’s teachings would have been applied to Edwards-’535 *in the same way those teachings are used in Stern itself*,” and Stern clearly shows that controller 156 is separate from the generator 158. (*Id.* at 40 (emphasis added); Ex-2001-Bikson, ¶92.) The Board must disregard Petitioners’ belated attempt to re-write their proposed combination. *Corephotonics*, 84 F.4th at 1002. Petitioners’ belated argument should also be disregarded because Petitioners have presented no evidence a POSITA would have been motivated to incorporate Stern’s controller 156 into Edwards-535’s generator.

(c) Claim 9 – Element 9[b].

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Stern teaches “a cable coupled to the handle for plugging the handle into the radiofrequency generator.” (POR at 34-36.)

In response, Petitioners argue that “‘a’ does not require one and only one,” and “the [’318] patent contemplates a control system between the generator and handle.” (Reply at 27-28.)

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.)

Recognizing the Petition failed to establish a *prima facie* case of obviousness, Petitioners once again improperly attempt to re-write their Petition. According to Petitioners, “whether Stern discloses a separate RF generator and cable is irrelevant” because “Edwards-'535's generator would have been modified to include a cable to plug Edwards-'535's device into the generator.” (Reply at 28.) But the Petition expressly argued that “Stern's teachings would have been applied to Edwards-'535 *in the same way those teachings are used in Stern itself*” (Petition at 40 (emphasis added)), and Stern indisputably teaches the cable coupled to handle 124 is plugged into controller 156—not into generator 158. (Ex-2001-Bikson, ¶99; Ex-1033-Stern at FIG. 12, 10:36-49.) This is exactly what is shown in the below annotated figure, which was provided in the Petition:

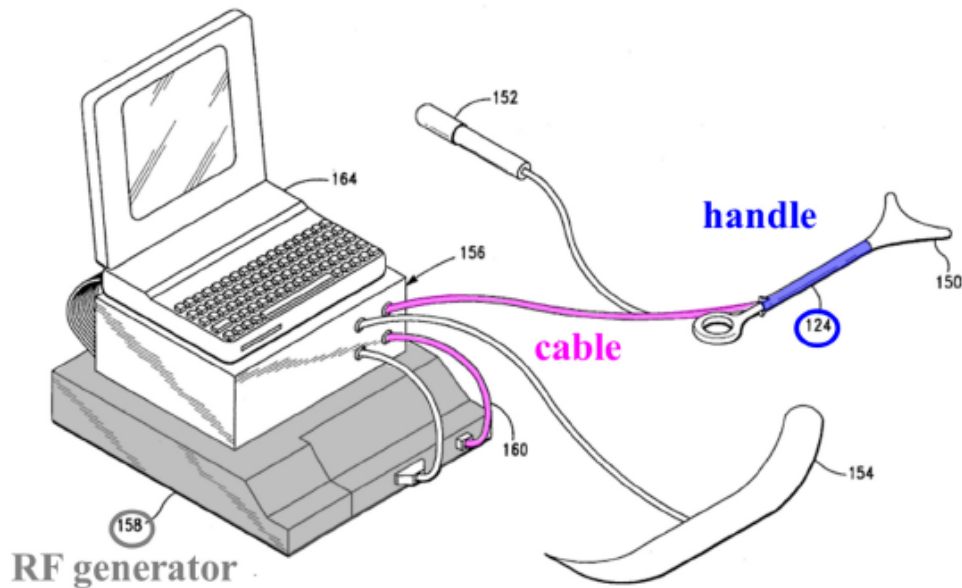


FIG. - 12

(Petition at 58 (annotations in original); *id.* (“Providing a handle with a cable ... *as taught by Stern* would have been obvious”) (emphasis added).) Petitioners are stuck with the argument they raised in the Petition. *Corephotonics*, 84 F.4th at 1002.

(d) Claim 15.

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Stern renders Claim 15 obvious because Petitioners and Dr. Martin failed to assert or demonstrate it would have been obvious to incorporate Stern’s electrode arrangement of Figure 19 into Edwards-535’s device. (POR at 36-37.)

In response, Petitioners argue they *did* explain why it would have been obvious to incorporate Stern’s teaching of “two rows” into Edwards-535. (Reply at 29-30.)

Petitioners' argument is not credible. Petitioners relied on their limitation 1[d] and 1[e] analyses as purportedly showing that Stern's Figure 19 "electrode arrangement would have been obvious to incorporate in Edwards-'535." (Petition at 67.) Yet, Petitioners' limitation 1[d] and 1[e] analyses proposed combining Edwards-535 with Stern's Figure 15 schematic—not with Stern's Figure 19 electrode arrangement. (*Id.* at 32-45.) Indeed, Petitioners did not even discuss Stern's Figure 19 until their Claim 15 "analysis." (*Id.* at 66-67.)

Further, Petitioners' argument that "the presence of alternatives does not defeat obviousness" misses the point. (Reply at 29.) It is Petitioners' burden to prove obviousness, not Patent Owner's burden to "defeat obviousness." As noted above, Petitioners failed to meet their burden. In any case, Patent Owner provided uncontroverted evidence that it would *not* have been obvious to incorporate Stern's teaching of "two rows" into Edwards-535. (Ex-2001-Bikson, ¶102.)

(e) Claim 17.

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Stern teaches "the multiple pairs of bipolar radiofrequency electrodes are connected to one another." (POR at 38.)

In response, Petitioners argue Edwards-535 and Stern teach that "*any* two electrodes can be paired" and "Petitioners' analysis for claim 1 ... plainly showed

two different pairings of electrodes with reference to Stern's Figure 15." (Reply at 31 (emphasis is original).)

Like the Petition, Petitioners' Reply misconstrues Claim 17. According to the plain language of Claim 17, it is not enough that "two electrodes can be paired." (Ex-1001 at claim 17.) Rather, the claim expressly requires that "the *multiple pairs* of bipolar radiofrequency electrodes *are connected to one another*." (*Id.* (emphases added).) The Petition and the Reply make no attempt to show that Edwards-535 in view of Stern teaches multiple pairs of electrodes that are connected to one another, as claimed. (Petition at 69-71; Reply at 31; Ex-2001-Bikson, ¶104.)

B. Ground 2: Petitioners Failed To Show Edwards-535 In View Of Stern And Patel Renders Dependent Claim 6 Obvious.

As demonstrated in the POR, Petitioners failed to show Edwards-535 in view of Stern and Patel teaches "wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape." (POR at 38-41.) More specifically, Petitioners' proposed combination at most shows that Patel's electrodes disposed on the surface of Edwards-535's expandable member 132 comprise a shape-memory alloy material—not that the "multiple segments" of Edwards-535's expandable member 132 themselves comprise a shape-memory alloy material, as claimed. (*Id.*)

In response, Petitioners argue that Patent Owner “improperly narrows the claim” because “[n]othing in the claims requires the ‘segments’ to be different than ‘electrodes.’” (Reply at 20.)

Petitioners are wrong. “Electrodes” and “segments” are different claim terms, and “different claim terms are presumed to have different meanings.” *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008). Specifically, the Claims recite a device with a “treatment element ... configured to change from a first configuration to a second configuration” comprising “multiple segments that are expandable from the first configuration to the second configuration.” (Ex-1001 at claims 1 and 4.) “Bipolar radiofrequency electrodes,” which are separately claimed, are “disposed along the treatment surface of the treatment element” and are “coupled” with the “multiple segments.” (Ex-1001 at claims 1 and 5.) Thus, the Claims themselves are clear that electrodes are *different* than the claimed “multiple segments.” (Ex-1001 at claims 1 and 4-5; *id.* at 18:3-32; Ex-2001-Bikson, ¶110.) Notably, Petitioners fail to identify any portion of the ’318 patent that teaches that the claimed “segments” are the same thing as the claimed “electrodes,” or that the claimed “electrodes” may be made of a “shape-memory alloy material.” (Reply at 21.)

Even if Patel’s electrodes could be considered the claimed “multiple segments” (they cannot), Petitioners have still failed to show that Patel’s electrodes

are “configured to expand to a desired size and shape,” as recited in Claim 6. (Ex-1001 at claim 6; Ex-2001-Bikson, ¶112.) According to Dr. Martin, Patel’s balloon “necessarily expands from its folded to unfolded state during deployment.” (Ex-1083-Martin, ¶67.) But whether Patel’s *balloon* can fold, furl, or expand has no bearing on whether Patel’s *electrodes* are configured to expand to a desired size and shape. (Ex-2001-Bikson, ¶112.) Simply put, Petitioners have no evidence that Patel’s electrodes are “configured to expand to a desired size and shape,” as recited in the claim. (Petition at 72-74; Ex-1002-Martin, ¶¶236-237.)

C. Grounds 3-5.

Except for Claim 6, Petitioners do not dispute their Grounds 3-5 arguments rise and fall with their Ground 1 arguments. (Reply at 2-32.) Thus, for the same reasons discussed above in Ground 1, Petitioners have failed to show the Challenged Claims are obvious in Grounds 3-5. (POR at 41-48.)

1. Petitioners Failed To Show Makower In View Of Stern Renders Claim 6 Obvious.

As demonstrated in the POR, Petitioners failed to show Makower in view of Stern teaches or suggests “wherein the multiple segments comprise a shape-memory alloy material configured to expand to a desired size and shape.” (POR at 43-46.) More specifically, Petitioners failed to show Makower teaches or suggests its strut members 214 (*i.e.*, the alleged “multiple segments”) are made of nitinol (*i.e.*, the alleged “shape-memory alloy material”). (*Id.*)

In response, Petitioners argue Makower's disclosure that the catheter 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." (Reply at 22-23 (Petitioners failing to cite to Makower).) Petitioners also argue their mapping of Makower to Claim 6 "is the exact same mapping that the Examiner applied when it found that Makower anticipated this claim." (*Id.* at 22.) Petitioners' arguments are without merit.

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.)

As to Petitioners' second argument, Petitioners are incorrect that their mapping of Makower to Claim 6 "is the exact same mapping that the Examiner applied." (Reply at 22.) The Examiner relied on ***Figure 5F*** for the claimed

“multiple segments”—not Figure 5H, as Petitioners do here. (Ex-1003 at 509.) At no point did the Examiner find that Makower teaches that strut members 214 may be made from a shape-memory material. (*Id.*) Indeed, as discussed above, the Examiner could not have made such a finding.

III. DR. MARTIN'S REPLY TESTIMONY IS NOT CREDIBLE

Dr. Martin's Reply testimony is not credible and should be given little or no weight. In multiple instances, Dr. Martin attempts to discredit his own prior sworn testimony. (Ex-1083-Martin, ¶¶8, 41-42, 45-46.) Dr. Martin also provides numerous, conflicting definitions of “radiofrequency output channel”—none of which are the definition he provided during his prior deposition. (*Id.*, ¶¶36, 39, 40, 42, 45.)

When pressed on his conflicting definitions, Dr. Martin testified a “radiofrequency output channel” is whatever he says it is. (Ex-2008 at 85:22-86:6, 151:16-22.) Yet, when asked how many radiofrequency output channels are supposedly in Stern, Dr. Martin testified he did not know—he just knew it was more than one. (*Id.* at 76:5-21.)

Further, Dr. Martin repeatedly mischaracterizes Dr. Bikson's testimony (Ex-1083-Martin, ¶¶17-18, 29-30) and raises several improper reply arguments that Petitioners and Dr. Martin did not raise in the Petition. (Reply at 17, 26, 28.)

Accordingly, Dr. Martin's Reply testimony is not credible and should be given little or no weight. *Elbit Systems of America, LLC v. Thales Visionix*, 881 F.3d 1354, 1359 (Fed. Cir. 2018) ("The PTAB [i]s entitled to weigh the credibility of the witnesses.").

IV. PATENT OWNER'S POSITA DEFINITION IS CORRECT

Petitioners argue "an M.D. or engineer with three years' medical device *use*, design, development, *and/or testing*" qualifies as a POSITA. (Reply at 34 (emphases in original).) In support, Petitioners state the Claims recite a "generic" device, and clinicians learn to use RF devices safely. (*Id.* at 33.)

Petitioners' assertion is wrong. The Claims recite a highly specific device comprising, among other things, "multiple pairs of bipolar radiofrequency electrodes" and "multiple radiofrequency output channels." (Ex-1001 at claim 1.) Further, clinicians who merely use RF devices still lack the necessary background on the technical issues associated with implementing the claimed device. (Ex-2001-Bikson, ¶39.)

Petitioners also state that Dr. Wolf, one of the named inventors, "is an MD with no apparent clinical experience ... who nonetheless began developing medical devices immediately after graduating medical school." (Reply at 34.) But Dr. Wolf's experience is primarily in the *development* of medical devices—not the

clinical use of medical devices—which supports Patent Owner's position that design and/or development experience is required.

V. CONCLUSION

Accordingly, the Board should confirm the patentability of the Challenged Claims.

Dated: March 4, 2025

Respectfully submitted,

By: /s/ Benjamin P. Gilford
Benjamin P. Gilford (Reg. No. 72,072)
GREENBERG TRAURIG, LLP
77 West Wacker Drive, Suite 3100
Chicago, IL 60601
Phone: (312) 456-8400
Fax: (720) 904-6118
GilfordB@gtlaw.com

Counsel for Patent Owner

CERTIFICATE OF COMPLIANCE

This paper complies with the requirements of 37 C.F.R. § 42.24 and contains 5,593 words (exclusive of the table of contents, the table of exhibits, the certificate of service, and this certification).

This paper complies with the typeface requirements of 37 C.F.R. § 42.6 and has been prepared in 14-point Times New Roman proportionally spaced typeface with normal spacing.

Respectfully submitted,

Dated: March 4, 2025

By: /s/ Benjamin P. Gilford
Benjamin P. Gilford (Reg. No. 72,072)
GREENBERG TRAURIG, LLP
77 West Wacker Drive, Suite 3100
Chicago, IL 60601
Phone: (312) 456-8400
Fax: (720) 904-6118
GilfordB@gtlaw.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

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

David Cavanaugh
Gregory Lantier
Alexis Cohen
Joshua Stern
Alexander Nemtzow
Sarah Murphy
WILMER CUTLER PICKERING HALE AND DORR LLP
David.Cavanaugh@wilmerhale.com
Gregory.Lantier@wilmerhale.com
Alexis.Cohen@wilmerhale.com
Joshua.Stern@wilmerhale.com
Alex.Nemtzw@wilmerhale.com
Sarah.J.Murphy@wilmerhale.com
WHNeurentIPRService@wilmerhale.com

Dated: March 4, 2025

By: /s/ Benjamin P. Gilford
Benjamin P. Gilford (Reg. No. 72,072)
GREENBERG TRAURIG, LLP
77 West Wacker Drive, Suite 3100
Chicago, IL 60601
Phone: (312) 456-8400
Fax: (720) 904-6118
GilfordB@gtlaw.com

Counsel for Patent Owner