

Neurent Medical Inc. &
Neurent Medical Ltd.,
v.
The Foundry, LLC

IPR2024-00279 (US10,610,675)

IPR2024-00280 (US10,894,011)

IPR2024-00669 (US11,679,077)

PATENT OWNER'S DEMONSTRATIVE EXHIBIT

The Patents and IPRs

- U.S. 10,610,675 – IPR2024-00279
 - '675 patent
- U.S. 10,894,011 – IPR2024-00280
 - '011 patent
- U.S. 11,679,077 – IPR2024-00669
 - '077 patent
- Collectively “The Patents” or “The IPRs” for the purposes of oral argument

Petitioner's Grounds: '675 Patent

Ground	35 U.S.C. §	Claims	Reference(s)
I	102	1-3, 7, 9-10, 17-25	Saadat
II	103	24-25	Saadat
III	102	1-3, 7, 9-10, 17-25	Deem
IV	103	1-3, 7, 9-10, 17-25	Makower and Fang

Petitioner's Grounds: '011 Patent

Ground	35 U.S.C. §	Claims	Reference(s)
I	102	1-2, 5, 8-10, 12, 14	Saadat
II	103	12, 14	Saadat
III	102	1-2, 5, 8-10, 12, 14	Deem
IV	103	1-2, 5, 8-10, 12, 14	Makower, Fang, and Edwards-535

Petitioner's Grounds: '077 Patent

Ground	35 U.S.C. §	Claims	Reference(s)
I	102	1-8, 11	Saadat
II	103	3, 11	Saadat
III	103	4	Saadat and Stern
IV	102	1-8, 11	Deem
V	103	1-3, 5-8 11	Makower, Fang, and Edwards-535
VI	103	4	Makower, Fang, Edwards-535, and Stern

Pertinent Disputes

- Whether the claims are entitled to a July 21, 2006 priority date
 - Written Description Support
 - Priority Chain / Incorporation by Reference
- Whether Petitioner established the claims are obvious based on Makower and Fang
- Whether Petitioner established Makower's device concentrates/delivers "energy laterally"
- Whether Petitioner established Stern discloses multiple pairs of bipolar electrodes ('077 patent only)

The '675 Patent Independent Claims

What is claimed is:

1. A method of treating a nasal condition of a patient comprising:

positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient; and

administering therapy to the target tissue with the treatment device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage;

wherein administering therapy comprises at least one of delivering energy to the target tissue and changing the temperature of the target tissue.

17. A method of treating a nasal condition of a patient comprising:

positioning a distal portion of a treatment device proximate to target tissue in a nasopharyngeal passage of a patient; and

administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced; wherein administering therapy comprises delivering energy to the target tissue.

The '011 and '077 Patent Independent Claims

What is claimed is:

1. Apparatus for treatment of a nasal condition by altering function of a nasopharyngeal passage of a patient, the apparatus comprising:

a hand-held elongate body having proximal and distal portions, the distal portion being configured for positioning in a nasopharyngeal passage of a patient with the proximal portion positioned outside the nasopharyngeal passage;

an energy transmission element in the distal portion configured to deliver energy to target tissue in the nasopharyngeal passage; and

an energy source operatively coupled to the energy transmission element for supplying energy thereto according to one or more parameters selected so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced.

'011 Patent at 27:39-55.

What is claimed is:

1. An apparatus for treating rhinitis in a nasal cavity, the apparatus comprising:

an elongate body, comprising:

a proximal portion; and

a distal portion configured for positioning in the nasal cavity;

multiple radiofrequency electrodes coupled with the distal portion of the elongate body; and

a radiofrequency generator coupled with the proximal portion of the elongate body for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.

'077 Patent at 27:43-28:7.

Written Description

The Institution Decision

On the record before us, however, we do not discern how the Specification of the '675 patent provides written description support for the challenged claims. The challenged claims are purportedly directed to

21:43–53.⁴ In the '675 patent Specification, energy is applied only to achieve cell membrane permeabilization or poration and effectuate the delivery of neurotoxin into to target cells. *See, e.g., id.* at 4:49–51, 8:4–21.

Here, we note that the challenged claims do not recite administering neurotoxins, but instead only require the delivery of energy to the target tissue to administer therapy.

The Energy Delivery Limitations

'675 Patent – Claim 1: “*administering therapy to the target tissue* with the treatment device so as to disrupt the neural activity *such that mucus secretion is reduced*”

'675 Patent – Claim 17: “*administering therapy to the target tissue* with the treatment device so as to alter nasopharyngeal cells *such that congestion in the nasopharyngeal passage is reduced*”

'011 Patent – Claim 1: “an energy source coupled to the energy transmission element for *supplying energy* thereto according to one or more parameters selected *so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced*”

'077 Patent - Claim 1: “a radiofrequency generator coupled with the proximal portion of the elongate body for *supplying radiofrequency energy* to the multiple radiofrequency electrodes *to treat a target tissue in the nasal cavity and thus treat rhinitis*”

'675 Patent at claims 1 and 17;

'011 Patent at 1;

'077 Patent at 1.

Reversible and Irreversible Poration Energy Disclosed and Contemplated

According to the present invention, botulinum toxin, ricin, exotoxin A, diphtheria toxin, cholera toxin, tetanus toxin, other neurotoxins, and active fragments thereof are delivered to a patient's nasal membrane while applying energy to target cells within the membrane under conditions which cause a reversible (or in some instances non-reversible) poration of the cell membranes to enhance delivery of the toxin into the cells. The region where the toxin is introduced may comprise any portion of the nasal cavity, such as a single paranasal sinus or portion thereof, a main nasal passage, two or more paranasal sinuses, or in some cases may comprise substantially the entire nasal cavity of the patient. A particular target region for the toxin may comprise the nasopharynx which is at the back of the nasal passage. The nasopharynx comprises a cluster of goblet cells which are responsible for mucus secretion and which are susceptible to the disabling mechanism of the botulinum toxin and other neurotoxins.

Irreversible Poration Discloses Ablation

Dr. Bu-Saba:

- “Irreversible poration occurs when the cell membrane does not reseal, and the cell breaks down.”
- “While reversible electroporation is designed to maintain the operation of cells and enhance their treatment by other therapeutic agents, ablation is designed to alter (or destroy) the cells and thereby directly treat the condition or symptom. E.g., Ex. 1059-Rubinsky...

POR at 27;
Ex-1002 at ¶¶ 37-38.

Rubinsky

[0113] Currently, tissue ablation by electroporation is produced through the use of cytotoxic drugs injected in tissue combined with reversible electroporation, a procedure known as electrochemotherapy. The present invention shows that irreversible electroporation by itself produces substantial tissue ablation for the destruction of undesirable tissues in the body. The concern was that higher voltages

* * *

Engineering, 2004). Irreversible electroporation, therefore, has the advantage of being a tissue ablation technique, which is as easy to apply as high temperature ablation, without the need for adjuvant chemicals as required in electrochemical ablation and electrochemotherapy. In addition, a unique aspect of irreversible electroporation is that the affected area can be controlled in real time with electrical impedance tomography.

POSR at 2-3;
Ex-1059 at [0113].

Dr. Levine Agrees Irreversible Poration Ablates

56. Moreover, based on the above disclosures, a POSITA with the proper knowledge of nasal anatomy and physiology would have recognized that the '675 patent specification discloses applying irreversible energy in regions of the nose that have cells responsible for mucus secretion and congestion (e.g., goblet cells and nasal membrane, respectively). A POSITA would appreciate based on at least these teachings of the '675 patent that applying irreversible energy to such tissues disrupts and/or alters target tissue such that mucus secretion or congestion is reduced in the nasopharyngeal passageway.

POR at 28;
Ex-2003 at ¶ 56.

No Dispute: Energy Delivery Regions Only Partially Overlap With Toxin Delivery Regions

When the energy applicator is incorporated with or within the catheter, the delivery pattern of the energy will usually be at least partially overlapping with the toxin delivery pattern of the catheter. For example, when a porous balloon is used for toxin delivery, the acoustic transducer, electroporation electrodes, or the like, will usually be disposed to deliver energy which at least partly overlaps with the dispersion pattern of the toxin. In some instances, the region of applied energy will be coextensive with the region of toxin dispersion. In other instances, the two regions will only partially overlap. In the latter case, the delivery of the toxin will be enabled or enhanced principally within the regions of overlap.

Energy Applied To Goblet Cells

The energy is preferably selectively applied to a targeted region containing a variety of cell types, including goblet cells, epithelial cells, ciliated and non-ciliated columnar cells, basal cells, and less or no energy applied to untargeted regions. It will be appreciated that the energy may be applied to regions of the nasal membrane which are the same or different from the regions to which the toxin has been introduced. By controlling the delivery area of both the toxin delivery and the energy delivery, the methods and apparatus of the present invention can more specifically target the epithelial or goblet and other recipient cells of interest while minimizing the amount of toxin which enters non-targeted cells. That is, only those cells in the nasal membrane which are exposed to both the toxin and the applied energy will preferentially be permeablized or porated to receive the toxin within the cytoplasm of the cell.

Undisputed: Ablating Goblet Cells Treats The Claimed Conditions

Dr. Levine:

- “[B]ased on the above disclosures, a POSITA...would have recognized that the ’675 patent specification discloses applying irreversible energy in regions of the nose that have cells responsible for mucus secretion and congestion (e.g., goblet cells and nasal membrane, respectively)[which] disrupts and/or alters target tissue such that mucus secretion or congestion is reduced in the nasopharyngeal passageway.”

Petitioner’s Reply does not dispute Dr. Levine’s goblet cell analysis/conclusions

Summary

1. Energy including irreversible poration energy (ablation) may be applied to the nasal cavity
2. Energy is applied to regions that only partially overlap with the area of toxin delivery
3. Energy is applied to goblet cells
4. Applying ablative energy to goblet cells reduces mucus secretion, reduces congestion and treats rhinitis

1+2+3+4 = Written Description Support for the Claims

Dr. Bu-Saba's Reply Testimony Confirms The Claims Are Supported

61. Additionally, a person of ordinary skill in the art would have understood that the '675 patent's single reference to "non-reversible" poration was an acknowledgement that when applying energy for reversible poration, a minority of cells may be incidentally destroyed. That is, the '675 patent's single reference to "non-reversible" poration simply acknowledges that some cells will be incidentally destroyed when reversible poration energy is applied. Indeed, Dr. Bikson agrees

Dr. Bu-Saba's Admits No Particular Degree of Efficacy Required

111. Additionally, the challenged claims at issue do not require any efficacy measure or particular degree of efficacy, and the '675 patent does not describe any such efficacy measures or requirements for treating rhinitis. *See generally* Ex.1001-

The Entire Nasal Cavity May Be Treated

According to the present invention, botulinum toxin, ricin, exotoxin A, diphtheria toxin, cholera toxin, tetanus toxin, other neurotoxins, and active fragments thereof are delivered to a patient's nasal membrane while applying energy to target cells within the membrane under conditions which cause a reversible (or in some instances non-reversible) poration of the cell membranes to enhance delivery of the toxin into the cells. The region where the toxin is introduced may comprise any portion of the nasal cavity, such as a single paranasal sinus or portion thereof, a main nasal passage, two or more paranasal sinuses, or in some cases may comprise substantially the entire nasal cavity of the patient. A particular target region for the toxin may comprise the nasopharynx which is at the back of the nasal passage. The nasopharynx comprises a cluster of goblet cells which are responsible for mucus secretion and which are susceptible to the disabling mechanism of the botulinum toxin and other neurotoxins.

Petitioner's Admissions Prove Support

1. Energy including irreversible poration energy (ablation) may be applied to the nasal cavity
 - *Dr. Bu-Saba admits irreversible energy applied with reversible energy, and irreversible energy destroys cells*
2. Energy is applied to regions that only partially overlap with the area of toxin delivery
 - *Energy may be applied to the entirety of the nasal cavity*
3. Energy is applied to goblet cells
4. Applying ablative energy to goblet cells reduces mucus secretion, reduces congestion and treats rhinitis
 - *Dr. Bu-Saba admits no claimed efficacy requirements*

Confirmation of Written Description Support for the Claims

Petitioner's Remaining Arguments Are Unpersuasive

1. “Written Description Obviousness”
 - *Patent Owner did not use obviousness to support W.D. arguments—express patent disclosures and supporting testimony used*
2. “Binding Admission”
 - *No case law for Petitioner and alleged admission was in different patent family by a different company*
3. “Present Invention,” “Single Instance” and “No data”
 - *Irrelevant under Ariad and other case law*

Priority Chain & Incorporation By Reference

Undisputed: There Is An Unbroken Priority Chain To The '090 Application

Related U.S. Application Data

- (60) Continuation of application No. 16/036,381, filed on Jul. 16, 2018, which is a continuation of application No. 15/358,187, filed on Nov. 22, 2016, now Pat. No. 10,022,529, which is a continuation of application No. 14/601,529, filed on Jan. 21, 2015, now Pat. No. 9,498,283, which is a continuation of application No. 13/660,629, filed on Oct. 25, 2012, now Pat. No. 8,961,391, which is a continuation of application No. 13/253,595, filed on Oct. 5, 2011, now Pat. No. 8,338,164, which is a continuation of application No. 12/559,278, filed on Sep. 14, 2009, now Pat. No. 8,133,497, which is a division of application No. 11/459,090, filed on Jul. 21, 2006, now Pat. No. 7,608,275.
- (60) Provisional application No. 60/702,077, filed on Jul. 22, 2005.

Undisputed: the '090 Application Incorporates the Entirety of the '771 Provisional

1

SYSTEMS AND METHODS FOR DELIVERY OF A THERAPEUTIC AGENT

CROSS-REFERENCES TO RELATED APPLICATIONS

This application claims the benefit of provisional application 60/702,077, filed Jul. 22, 2005, and of provisional application 60/747,771, filed on May 19, 2006, the full disclosures of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

Petitioner's First Argument: Improper Incorporation By Reference

- “Section 1.57(d) states no such limitation, but that ‘essential material,’ including for ‘written description of the claimed invention’ may not be incorporated by reference from a provisional. ... Here, [Patent Owner’s] priority claim using an incorporated provisional contravenes this Rule.”
- Incorrect: already considered and rejected by the Board

Case Law Confirms Proper Incorporation by Reference

“The limitations on the material which may be incorporated by reference in U.S. patent applications which are to issue as U.S. patents *do not apply to applications relied on only to establish an earlier effective filing date under 35 U.S.C. 119 or 35 U.S.C. 120.* ... Accordingly, an application is entitled to rely upon the filing date of an earlier application, even if the earlier application itself incorporates essential material by reference to another document. *See Ex parte Maziere*, 27 USPQ2d 1705, 1706-07 (Bd. Pat. App. & Inter. 1993).”

Ex Parte Maziere still good law

- “In 2004, the Office codified in 37 CFR 1.57(b)–(g) existing practice with respect to explicit incorporations by reference with a few changes to reflect the eighteen-month publication of applications.” (MPEP 608.01(p))
- No cases overruling *Maziere* cited.

Petitioner's Second Argument: Broken Priority Chain

- “Applicant broke priority by dropping direct priority claims to and omitting content of the ’771 Provisional from two applications preceding the October 22, 2019 application.”
- **Incorrect:**
 - Petitioner’s case law inapposite and already considered

Related U.S. Application Data

- (60) Continuation of application No. 16/036,381, filed on Jul. 16, 2018, which is a continuation of application No. 15/358,187, filed on Nov. 22, 2016, now Pat. No. 10,022,529, which is a continuation of application No. 14/601,529, filed on Jan. 21, 2015, now Pat. No. 9,498,283, which is a continuation of application No. 13/660,629, filed on Oct. 25, 2012, now Pat. No. 8,961,391, which is a continuation of application No. 13/253,595, filed on Oct. 5, 2011, now Pat. No. 8,338,164, which is a continuation of application No. 12/559,278, filed on Sep. 14, 2009, now Pat. No. 8,133,497, which is a division of application No. 11/459,090, filed on Jul. 21, 2006, now Pat. No. 7,608,275.
- (60) Provisional application No. 60/702,077, filed on Jul. 22, 2005.

The July 21, 2006 Priority Date Means Only The Makower Grounds Remain

For at least the above reasons, the specification of the '675 patent reasonably conveys that the inventors had possession of the Energy Delivery Steps of the claims as of the filing date of the '090 application. There is also no dispute that the remaining limitations of the independent claims are disclosed by the '675 patent and its predecessors, and no priority date arguments were made by Petitioner as to the dependent Challenged Claims. (Petition at 24.) Thus, the Challenged Claims are entitled to a priority date at least as early as July 21, 2006, thereby removing Sadaat and Deem as prior art. Accordingly, Petitioners' Grounds 1-3 fail.

The Makower Grounds

Makower+Fang Applied Across All Remaining Grounds

- '675 Patent – Ground IV: Makower and Fang
- '011 Patent – Ground IV: Makower, Fang and Edwards-535
- '077 Patent – Ground V: Makower, Fang and Edwards-535
- '077 Patent – Ground VI: Makower, Fang, Edwards-535 and Stern

'675 Petition at 7;
'011 Petition at 7;
'077 Petition at 8.

Makower's Problem: Rigid and Straight Shafts

- [0036] One of the reasons why FESS and sinus surgery is so bloody and painful relates to the fact that straight instrumentation **with rigid shafts** are used. Due to the fact that the sinuses are so close to the brain and other important structures, physicians have developed techniques using **straight tools** and image guidance to reduce the likelihood of penetrating into unwanted areas. In an effort to target deep areas of the anatomy, this reliance on **straight instrumentation** has resulted in the need to resect and remove or otherwise manipulate any anatomical structures that may lie in the path of the instruments, regardless of whether those anatomical structures are part of the pathology. With the advances in catheter based technology and imaging developed for the cardiovascular system, **there exists a significant opportunity** to reduce the morbidity of sinus interventional through the use of flexible instrumentation and guidance.

Makower's Solution: Flexible Tooling

- [0037] *If flexible tools could be developed* such that sinus intervention may be able to be carried out with even less bleeding and post-operative pain, these procedures may be applicable to a larger group of patients. *Further, as described here, **flexible instrumentation** may allow the application of new diagnostic and therapeutic modalities that have never before been possible.*

Makower's Invention

- [0042] In general, the present invention provides methods, devices and systems for diagnosing and/or treating sinusitis or other conditions of the ear, nose or throat.
- [0043] *In accordance with the present invention, there are provided methods wherein one or more flexible catheters or other flexible elongate devices as described herein are inserted in to the nose,* nasopharynx, paranasal sinus, middle ear or associated anatomical passageways to perform an interventional or surgical procedure. Examples of procedures that may be performed using these flexible catheters or other flexible elongate devices include but are not limited to:.....

Makower's Disclosure

- 73 pages in length
- 242 paragraphs of text
- Over forty figures implementing Makower's flexibility teachings

Petitioner Failed To Show The Claims Are Obvious

Petitioner's Makower Selection

- No independent analysis
- Simply adopted Examiner's allegation that Makower is the "closest prior art"

During prosecution, the Examiner found Makower was the "closest prior art" because it taught most claim limitations, namely, "treating disorders of the ear, nose and throat via inserting an energy emitting device into the nasopharynx." Ex.1022-FH675, 122. The Examiner allowed the claims only after finding Makower did "not teach or suggest treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage, and wherein the target tissue has a change in temperature." *Id.* To the extent that is the case, Fang, which was not before the Office, teaches disrupting neural activity to treat rhinitis (e.g., reduce mucus secretion and congestion) by ablating tissue in the nasopharyngeal passage with RF energy to change its temperature. The Challenged Claims would therefore have been obvious.

Makower Is Not Close Prior Art

- Directed to flexible catheters – not RF ablation devices
- Over forty figures and numerous embodiments
- Only one figure (FIG. 5H) relates to RF energy and is discussed “in a total of nine sentences spanning two paragraphs ([0092], [0187])”
- The FIG. 5H device shrinks tissue, i.e. “has no bearing on treating nerves in the nasopharyngeal passage to reduce mucus secretion.”

Neither Expert Has Ever Seen A Device Like Makower's FIG. 5H

13 Q Prior to reading Makower, had you ever
14 seen a device like Figure 5H in practice?

15 MR. STERN: Objection to the form.

16 A Exactly like Figure 5H?

17 Q Yeah.

18 A Not that I recall.

Dr. Bu-Saba

Dr. Levine

combination. Initially, I understand that Dr. Bu-Saba testified that he has never seen a medical device having the structure of FIG. 5H in his practice. (Ex-2002-Bu-Saba-Tr. at 303:13-18.) I also am not aware of any such device. In other words, Makower's FIG. 5H device has a structure that is unproven to a POSITA and Fang does not provide any clarity as to whether a device with Makower's structure can be used to treat perennial allergic rhinitis.

POR at 61-62;
Ex-2002 at 303:13-18;
Ex-2003 at ¶ 89.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

41

Fang's Device Is Likewise Unknown

4 Q Okay. So it says "factory preset
5 settings," though. Does Level 3 connote to
6 you preset settings?

7 MR. STERN: Objection to form.

8 A As -- if I'm reading this -- as I told
9 you before, I'm not familiar with the device,
10 I've not used this device.

Dr. Bu-Saba

Dr. Levine

device. (Ex-1002-Bu-Saba, ¶81.) I disagree with Dr. Bu-Saba. Initially, prior to reading Fang, I had never heard of the SHP-I device—that is, I was not aware of it now or in the 2000s at the time of the '675 patent. At that time, and to this day, I referred to myself as an early adopter of technology for treating nasal conditions. I was consistently making myself aware of commercially available devices. If Fang's SHP-I device was "routinely used" as Dr. Bu-Saba alleges, I would have been familiar with the device.

POR at 42-43;
Ex-2002 at 182:4-10;
Ex-2003 at ¶ 69.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

42

Fang: Unknown Efficacy Criteria

Fang

“1.3 Evaluation criteria for efficacy The efficacy was evaluated according to the evaluation criteria for allergic rhinitis [1].

Dr. Bu-Saba

6 Q "The efficacy was evaluated according to
7 the evaluation criteria for allergic
8 rhinitis." Again, we have the same document
9 cited there.

10 Do you see that, Document 1?

11 A That was evaluated, yes.

12 Q And we don't have a copy of that
13 document, and you've not evaluated it,
14 correct?

15 A I have not. I don't have a copy of it.

POR at 47-48;
Ex-1006 at 876, § 1.3;
Ex-2002 at 207:6-15.

Fang: Unknown Efficacy Calculations

Dr. Bu-Saba

8 Q What is the difference between efficacy
9 rate and total efficacy rate?
10 A I cannot sit here and answer you what
11 Fang meant with this. I don't know which
12 outcome measure he used, whether that was a
13 validated measure. All I can say that based
14 on his specification, the specification that
15 he relied on, he categorized outcome as
16 excellent recovery, efficacy rate and total
17 efficacy.

Fang: Unknown Number of Patients Received Just RF Surgery

Dr. Bu-Saba

18 | Q And those 63 received RF treatments that
19 | we've talked about, but they could have also
20 | received a variety of other treatments on top
21 | of that, correct?

22 | MR. STERN: Objection to form.

1 | A That's correct.

Fang Is Inconclusive

208:21; Ex-2003-Levine at ¶¶74-75.) For at least the above reasons, a POSITA would have determined that Fang's results were inconclusive as it relates to the application of RF energy for the treatment of perennial allergic rhinitis. Simply put, too many variables were changed by Fang at once across an unknown number of patients, while the criteria for perennial allergic rhinitis and efficacy according to Fang remain unknown. Indeed, Dr. Levine testifies that if he would have been

Petitioner's Analysis

- “***First***, Makower and Fang are analogous art to the Challenged Claims.”
- “***Second***, a POSITA would have been motivated to and would have found it obvious to apply Fang’s method (disrupting neural activity using ablation) with Makower’s device and method (using electrosurgical device in nasopharynx) to treat rhinitis.”
- “***Third***, a POSITA would have had a reasonable expectation of successfully combining Makower and Fang. A POSITA would have reasonably expected Makower’s electrosurgical device to obtain Fang’s clinical result.”

No Reasonable Expectation of Success Based on Makower+Fang

The Challenged Claims' Requirements

- '675 Patent – Claim 1: “...administering therapy to the target tissue with the treatment device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage....”
- '675 Patent – Claim 17: “...administering therapy to the target tissue with the treatment device to alter nasopharyngeal cells such that congestion in the nasopharyngeal passage is reduced....”
- '011 Patent – Claim 1: “an energy source ... for supplying energy ... so as to alter nasopharyngeal cells in the target tissue such that nasal congestion is reduced.”
- '077 Patent – Claim 1: “... for supplying radiofrequency energy to the multiple radiofrequency electrodes to treat a target tissue in the nasal cavity and thus treat rhinitis.”

'675 Patent at 27:44-47, 28:27-29;
'011 Patent at 27:51-55;
'077 Patent at 28:4-7.

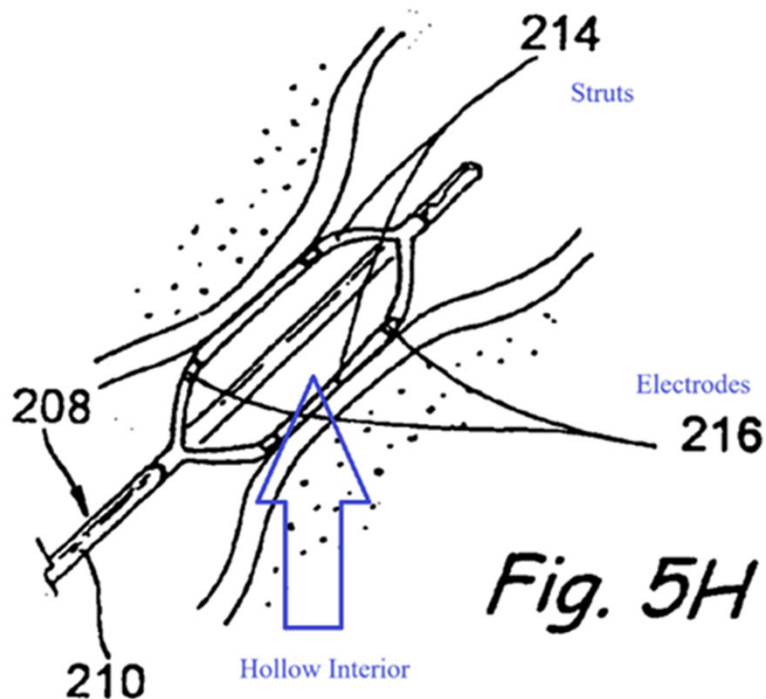
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

49

Petitioner's Argument

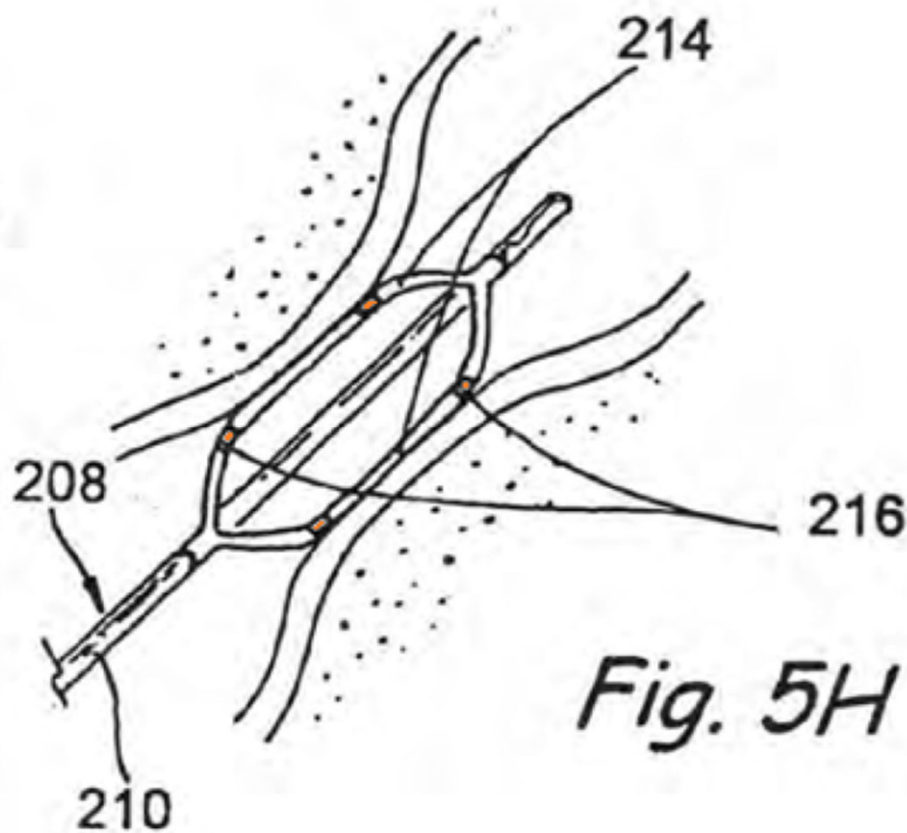
- “Because Makower and Fang are directed to the same problem (treating nasal conditions), types of energy-delivery devices, and solutions (applying energy to tissue), a POSITA would have had a reasonable expectation of success in using Makower’s known RF device according to a known method to reach the predictable result taught in Fang and Chen.”
- No actual analysis undertaken.

The Makower FIG. 5H Device



- [0092] FIG. 5H is a partial perspective view of a tissue shrinking electrode device being used in accordance with the present invention.
- [0187] FIG. 5H shows an electrosurgical device 208 comprising a flexible shaft 210 (e.g., a catheter or solid shaft) having arched strut members 214 attached thereto. Electrodes 216 are located on the strut members 214. In some cases, the strut members may be of fixed configuration and in other cases the strut members 214 may be collapsible and expandable. In operation, the device 208 is advanced into a passageway such as a nostril, nasal cavity, meatus, ostium, interior of a sinus, etc. Thereafter, current is applied to the electrodes 216 causing tissue adjacent to the struts 214 to be cauterized or heated. The electrodes 216 may be bipolar, monopolar or facilitated by any other suitable form of energy such as a gas or plasma arc. Additionally, sensing elements may also be attached to the catheter and/or strut members to monitor various parameters of the catheter and/or surrounding tissue (e.g., temperature, etc.).

FIG. 5H Has Ring Electrodes



“Makower’s device includes four electrodes (216) located on the struts adjacent tissue (shown in orange below).”

Petitioner: No Modifications to Makower Required

in temperature.” Ex.1022-FH675, 122. To the extent that is the case, a POSITA would have understood from Fang that Makower’s electrodes, like the similar RF device in Fang, would treat nasal disorders by disrupting neural activity in the same way, by heating parasympathetic nerves downstream of the SPG and Vidian nerve, thereby inhibiting their signaling of goblet cells that produce mucus. Makower’s device would not require modification to achieve this result. Indeed, Makower already teaches its device treats a nasal disorder, and Fang simply clarifies Makower operates in the same way as claimed. Ex.1002-Decl., ¶170.

Liquids Present During Use

Dr. Levine

“Specifically, a POSITA would expect that when Makower’s FIG. 5H device is placed into the nasopharyngeal passage, fluids in that passage, such as bodily fluids (e.g., blood or mucus) or saline (if the passage is irrigated and cleaned out before or during treatment) will enter the hollow space between the struts.”

Confirmed on Cross-Examination

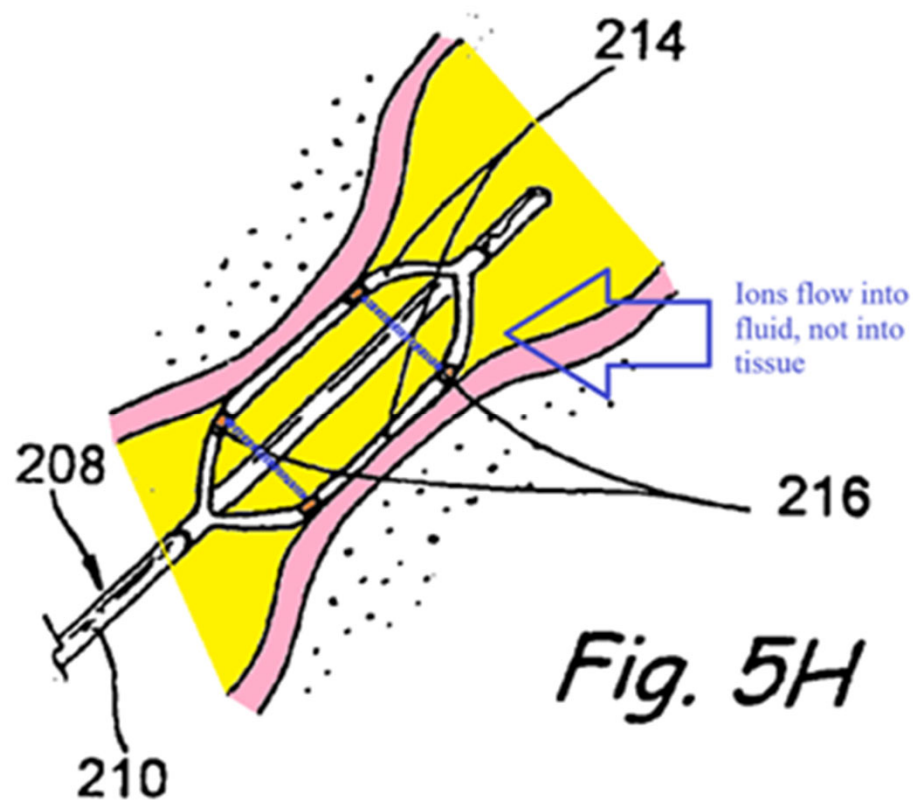
3 Q Okay. Would you do anything to clear
4 out the mucus?
5 A If it was obstructing my view. If it
6 was this thick, tenacious secretion, I might
7 have to mechanically remove it with forceps,
8 I might have to suction it, I might have to
9 irrigate the nose with a saline solution to
10 wash out the nose. And again, that's really
11 in the instance of this thick, sticky mucus
12 that forms a thing that we called biofilms,
13 which is whole nother thing that happens to
14 mucus in the nose.
15 But generally speaking, the mucus isn't
16 the issue.

Confirmed by Makower

[0132] The present invention provides a comprehensive system of devices...Specifically, examples of which are described below, the invention provides devices that wholly or partially effect a fluid-tight seal of the operative field (e.g., the nasopharynx and/or one or more of the sinus cavities or regional ducts). ...Further, this fluid-tight sealing of the operative field permits the retention and collection of any blood or flushing fluids released during the procedure.

[0135]... Such continuous turnover of fluid within a sealed operative field may be useful for clearing blood or debris from the operative field to facilitate unobstructed viewing of the anatomical structures using an endoscope or for various other reasons....One or more outlet openings 22, 24 are at location(s) in the tube such that a device (e.g., a catheter, fluid injector or other elongate device examples of which are shown in FIGS. 5A-5Y...) ... may be inserted [and] advanced through the working lumen 50 and out of a selected one of the outlet openings 22, 24 to a position within the nose, nasopharynx or paranasal sinus.

Undisputed: When Liquid Present, Ions Will Flow Into Liquid – Not Tissue



No Reasonable Expectation of Success

Given the foregoing, a POSITA would have recognized that Makower's hypothetical FIG. 5H device would not have reasonably been expected to ablatively treat target tissue.¹³ (Ex-2003-Levine at ¶¶89-98; Ex-2005-Bikson at ¶72.) Instead, energy applied to the electrodes would preferentially flow into the interior of Makower's device, i.e., the use of Makower's device would not have reasonably been expected to successfully achieve: **[what is claimed]**

Petitioner's Reply Positions: Unsupported and Unpersuasive

- Position 1: Use other electrodes with Makower
 - Improper new argument not included in the Petition
 - No evidence a POSITA was motivated to modify the Makower device
 - Petitioner argued no modifications to Makower are required
- Position 2: Liquids are not present during operation
 - False – Makower shows liquids are present and Petitioner failed to address the teachings of Makower on Reply

Petitioner's Reply Positions: Unsupported and Unpersuasive

- Position 3: Patent Owner Argued Inoperability
 - False – the reasonable expectation of success standard was employed
- Position 4: Other RF devices (e.g., Fang) ablate tissue
 - Irrelevant – those devices are either unknown or not hollow

No Motivation To Combine Makower+Fang

Petitioner's Combination Makes No Sense

- Unknown/Unproven Makower Device
- Unknown Fang Device
- Unknown Efficacy Criteria and Results
- Unknown Number of Patients Receiving Only RF Energy Treatment
 - It was just as likely that a rhinitis improvements resulted from other (non-RF) procedures
- Why would a POSITA apply/combine this art?

Petitioner's First Rationale

- The Examiner cited Makower as the “closest prior art”

During prosecution, the Examiner found Makower teaches an energy emitting device in the nasopharynx to treat nasal disorders, but does not teach “treating nasal conditions with a device so as to disrupt neural activity such that mucus secretion is reduced in the nasopharyngeal passage, and wherein the target tissue has a change in temperature.” Ex.1022-FH675, 122. To the extent that is the case, a POSITA

- *Irrelevant and Hindsight Driven* – No actual analysis completed by Petitioner as to whether Makower's Device is actually suited to ablate tissue

Petitioner's Second Rationale

- Fang provides more details on Makower's device

[0001], [00043], [0132], [0160]-[0164], [0187], claim 1. Fang provides additional details regarding the well-known design, construction, and operation of Makower's RF device. Ex.1002-Decl., ¶171.

- False: neither expert knows of the Fang device, what it looks like or how it operates

Petitioner's Third Rationale

- Fang teaches RF energy treats rhinitis
- False
 - Fang is inconclusive
 - Petitioner's Fang quotes are Fang quoting others

the Vidian nerve would treat rhinitis. *E.g.*, Ex.1003-Saadat, 2:39-47. Fang taught that disrupting the nerves with radiofrequency energy would also disrupt them and reduce rhinitis symptoms. Fang thus teaches RF energy in tissue surrounding the SPF “completely blocks the parasympathetic pathway of the nasal mucosa,” which “reduces glandular secretion, and thus achieves the therapeutic purposes” of relieving “perennial allergic rhinitis” while minimizing adverse effects. Ex.1006-Fang, 876-877. Ex.1002-Decl., ¶174.

Petitioner's Fourth Rationale

- Because Makower says “additional details” of its devices were “well known” one would be led to Fang

In view of Makower's statement that additional details regarding its devices were well known, a POSITA would have been motivated to combine Fang's teachings regarding the known outcome of application of RF therapy with Makower's device and method because the two teach similar energy-delivery devices in the same part of the body and for the same purpose (treating nasal

- *Illogical – neither the Fang article nor the device it describes are “well known”*

Petitioner's Fifth Rationale

- “Fang explains the mechanism and outcome of Makower’s method.”
- *False*: Fang used a different device that would not explain anything about “the mechanism and outcome of Makower’s method.”

Conclusion: Impermissible Hindsight Driven Analysis

Levine. (Ex-2003-Levine at ¶89.) It is apparent that Petitioners chose Makower's FIG. 5H device in view of the structural elements recited in the Challenged Claims, identified Fang as purportedly disclosing Makower's missing claim element, and then attempted to reverse engineer a motivation to combine these two prior art references. But "obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." *Cheese Sys., Inc. v. Tetra Park Cheese and Powder Sys., Inc.*, 725 Fed 1341, 1352 (Fed. Cir. 2013). This is quintessential hindsight that the well-settled law seeks to guard against. *In re Kahn*, 441 F.3d 977, 986-87 (Fed. Cir. 2006).

Makower Does Not Concentrate Energy Laterally

Lateral Energy Dependent Claims

'675 Patent - Claim 22: “wherein the energy delivery element is configured to **concentrate energy laterally** relative to the distal portion of the treatment device.”

'011 Patent - Claim 9: “wherein the energy transmission element is configured to **deliver energy laterally** relative to the distal portion of the body.”

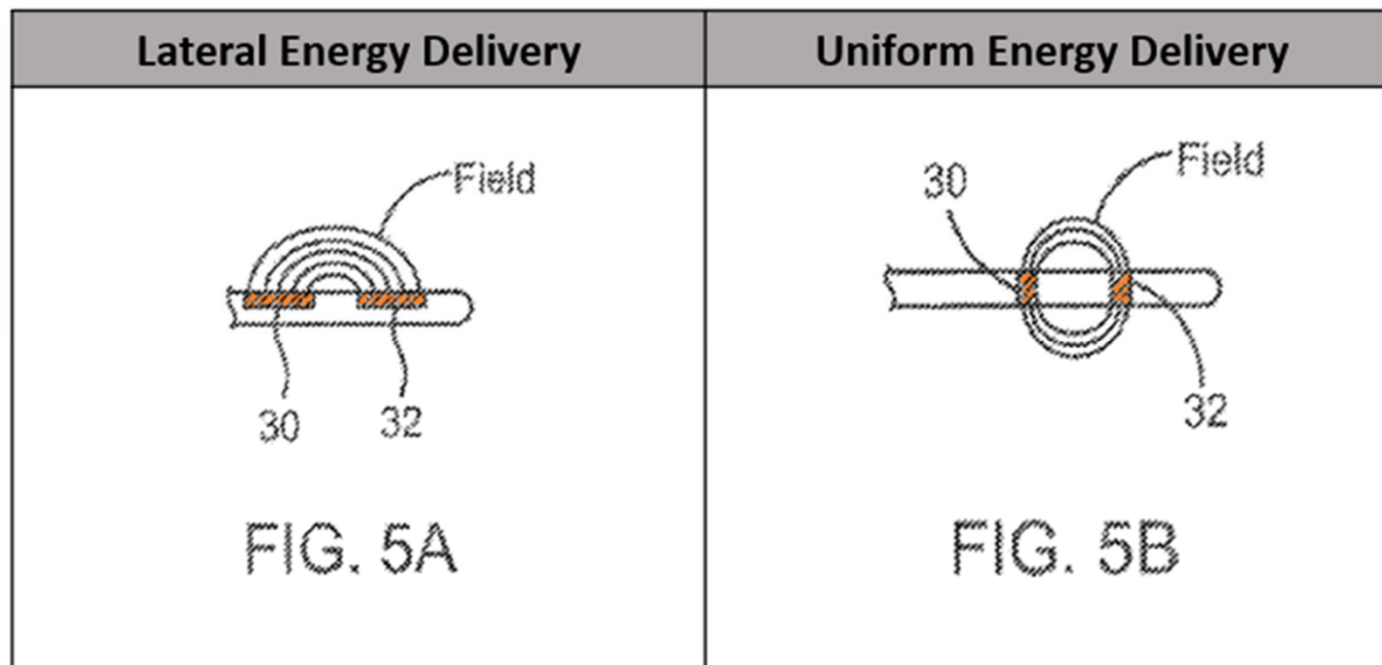
'077 Patent - Claim 7: “wherein the multiple radiofrequency electrodes are configured to **deliver energy laterally** relative to the distal portion of the elongate body.”

'675 Patent at 28:42-44;
'011 Patent at 28:4-6;
'077 Patent at 28:21-23.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

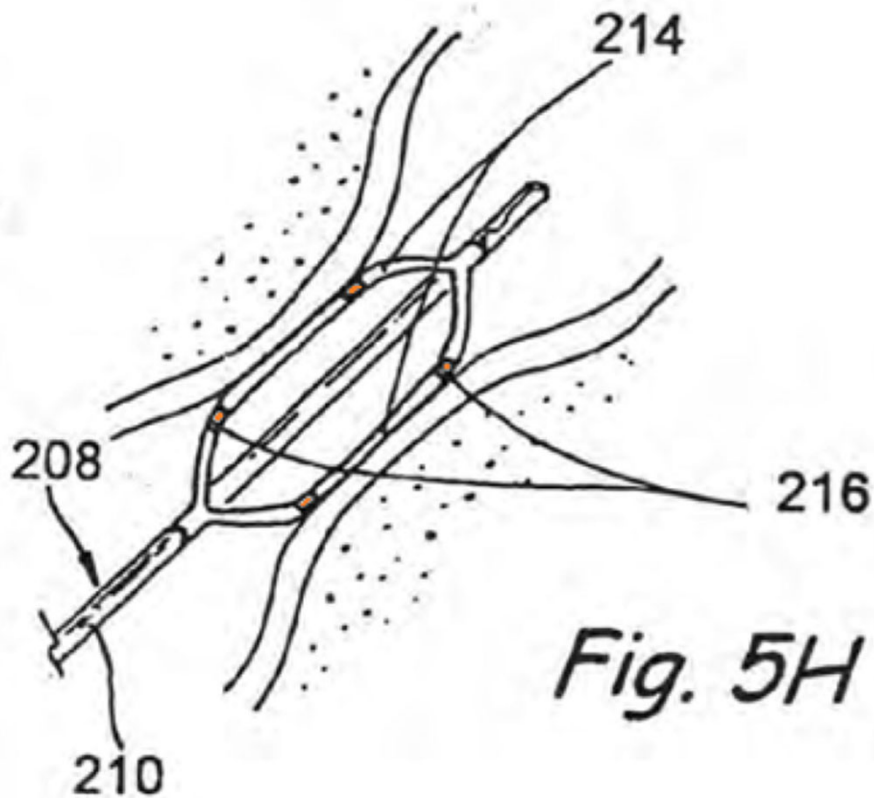
70

Lateral v. Uniform Energy Delivery



“FIG. 5A depicts an arrangement of electrodes **30** and **32** that produces an electric field concentrated in a lateral direction from the catheter body whereas, FIG. 5B shows a device constructed to create a more uniform electric field about the shaft of the catheter body.”

Makower's Ring Electrodes Deliver Energy *Uniformly*



“Makower’s ring electrodes are merely located on the surface of Makower’s struts and therefore fail to include any insulating surface that would cause the electrodes direct concentrate energy delivery in a lateral direction.”

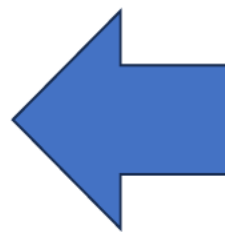
Petitioner's Imran Use

device (i.e., into the target tissue and away from the shaft). For example, Makower teaches that the RF electrodes in the Figure 5H electrosurgical device can be implemented as electrodes disposed on the lateral side of the strut as set forth in Imran. Ex.1005-Makower, [0164] (citing U.S. Patent No. 5,255,679 to Imran); *see* Ex.1068-Imran, 3:2-7 (electrodes 23 disposed on a lateral side of the distal portion of the treatment device that concentrate energy laterally into target tissue), claim 1.

Petitioner's Statements are False

[0164] Also, some of the working devices shown in FIGS. 5A-5Y"" and described herein incorporate assemblies, components or mechanisms (e.g., rotating cutters, radiofrequency electrodes, electrocautery devices, receptacles for capturing matter, cryosurgical apparatus, balloons, stents, radioactive or substance-eluting coatings, snares, electro-anatomical mapping and guidance, optical fibers, lenses and other endoscope apparatus, seals, hemostatic valves, etc. The designs and constructions of such components and assemblies are will known in the art. Non-limiting examples of some such designs and constructions are set forth in U.S. Pat. No. 5,722,984 (Fischell et al.), U.S. Pat. No. 5,775,327 (Randolph et al.), U.S. Pat. No. 5,685,838 (Peters, et al.), U.S. Pat. No. 6,013,019 (Fischell et al.), U.S. Pat. No. 5,356,418 (Shturman), U.S. Pat. No. 5,634,908 (Loomas), U.S. Pat. No. 5,255,679 (Imran), U.S. Pat. No. 6,048,299 (Hoffman), U.S. Pat. No. 6,585,794 (Wright et al.), U.S. Pat. No. 6,503,185 (Waksman), U.S. Pat. No. 6,669,689 (Lehmann et al.), U.S. Pat. No. 6,638,233 (Corvi et al.), U.S. Pat. No. 5,026,384 (Farr et al.), U.S. Pat. No. 4,669,469 (Gifford et al.), U.S. Pat. No. 6,685,648 (Flaherty et al.), U.S. Pat. No. 5,250,059 (Andreas et al.), U.S. Pat. No. 4,708,834 (Tsuno), U.S. Pat. No. 5,171,233 (Amplatz), U.S. Pat. No. 6,468,297 (Williams et al.) and U.S. Pat. No. 4,748,869 (Wardle).

- Actual language = “*incorporate assemblies*”
 - Not the required “Incorporate by Reference” language
 - In the present tense, i.e., the Makower’s assemblies already incorporate these assemblies

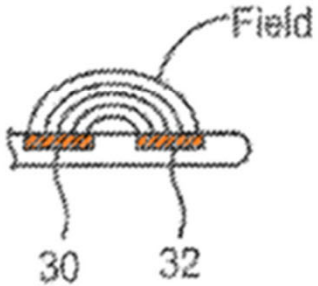
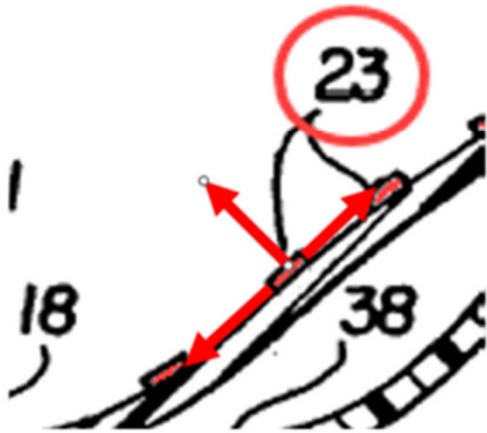


Imran NOT incorporated by reference into Makower

Imran Use Is Improper

- Imran NOT included in Petitioner's grounds
- NO explanation as to why A POSITA would combine Imran's "endocardial catheter having a new basket assembly for mapping or ablating a chamber of the heart" with Makower
- ***“Entirely new obviousness theories on reply are impermissible.”***
Henny Penny Corp. v. Frymaster LLC, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019).

Imran Fails To Disclose Lateral Energy Delivery

'675 Patent: Lateral Energy Delivery Through Top Electrode Surface	Imran: Energy Delivery Through Multiple Exposed Electrode Surface
 FIG. 5A	

'077 Patent: Multiple Electrode Pairs Are Not Disclosed

'077 Patent: Claim 4

“The apparatus of claim 2, wherein the at least two bipolar radiofrequency electrodes comprise multiple pairs of bipolar radiofrequency electrodes.”

Patent Owner's Expert: no pairs in Stern when all switches are open

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

95. Stern describes its electrodes as “an array of separate electrodes.” (Ex-1009-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.)

96. 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-1009-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-1009-Stern at FIG. 15, 12:37-13:2.)

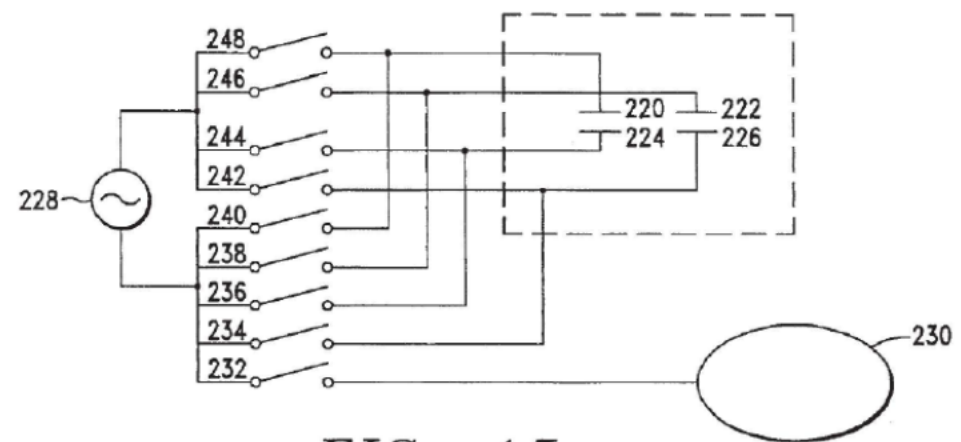


FIG. - 15

Ex-1009-Stern at FIG. 15

Petitioner's Expert: 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.

Ex-2009-Martin at 254:11-255:3

56. Stern's Figure 15, which I have reproduced below, shows the circuitry that controls the bipolar RF energy includes four electrodes 220, 222, 224 and 226 and switches 232-248 that determine which bipolar electrodes are active or return electrodes depending on which switch or switches are open and which are closed. See Ex.1009-Stern, 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. One such example would involve the scenario where "switch 248 is closed as well as switch 236" which would result in "bipolar operation" between "electrode 220 and electrode 224." *Id.*, 12:60-63.

Ex-1007-Martin, ¶ 56;
see also Ex-2005-Bikson, ¶ 96

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”**

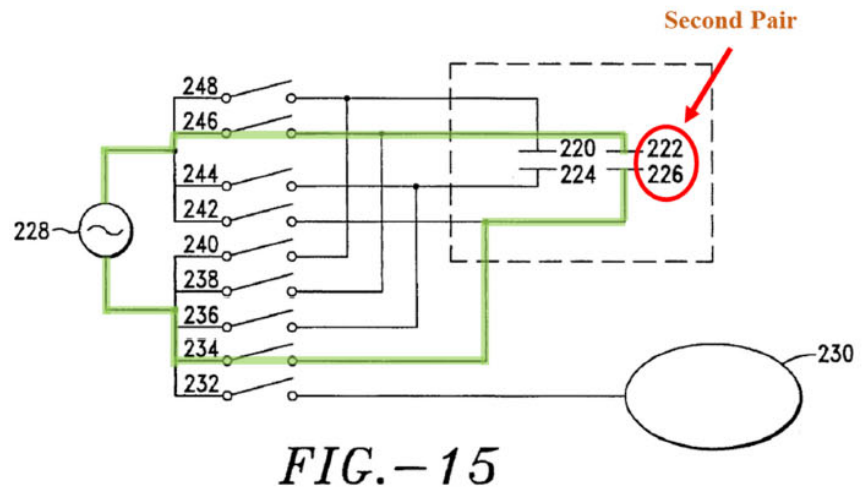
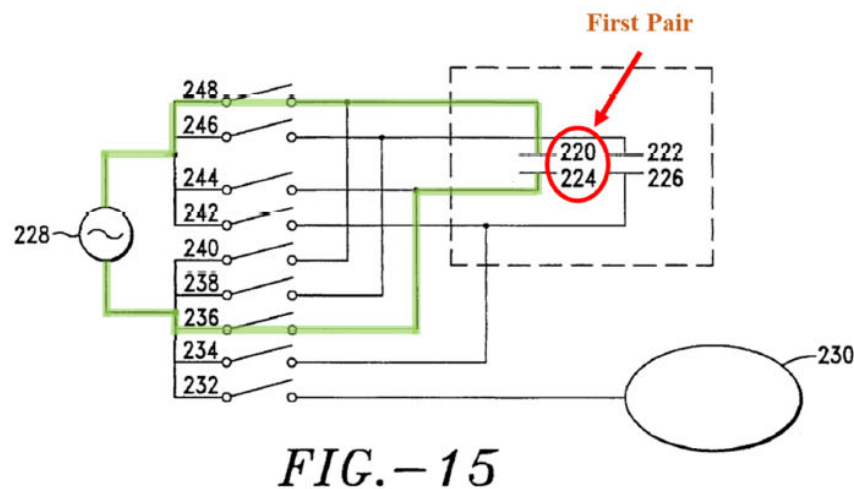
Patent Owner’s Expert

97. To form multiple pairs of bipolar 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-1009-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-2005-Bikson, ¶ 97

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Petition: two different configurations of one “pair”



077 Petition at 52-53

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-1009-Stern at 12:55-13:2

Patent Owner's Expert

97. To form multiple pairs of bipolar 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-1009-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-2005-Bikson, ¶ 97

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-1009-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-1009-Stern at 10:48-52

Patent Owner's Expert

97. To form multiple pairs of bipolar 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-1009-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-2005-Bikson, ¶ 97

Petitioner's Expert: 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-2012-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-2012-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-2012-Martin at 50:2-15

Both Experts: 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-2012-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-1091-Bikson at 250:20-251:7

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

First, PO's implicit claim construction is incorrect. The claims do not require multiple pairs of bipolar electrodes active "at the same time." The claims only require "multiple pairs of bipolar electrodes," i.e., more than one pair. PO tellingly identifies no claim language supporting otherwise. Ex.1098-Reply-Decl., ¶¶154-158.

077 Reply at 23-24

Petitioners mischaracterize Patent Owner's position

Patent Owner's Expert

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-1091-Bikson at 100:17-101:1

Patent Owner's Expert

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-1091-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-1009-Stern at 13:39-43

Second, even if PO's implicit construction were correct (it is not) Stern teaches activating multiple bipolar electrode pairs at the same time. Stern teaches "any combination of pairs of electrodes [in Figure 15] may be utilized together," i.e., electrodes activated at the same time. Ex.1009-Stern, 13:39-43; Pet., 51. This is similar to the '077 patent's description. Ex.1001-USP077, 18:42-46. Ex.1098-Reply-Decl., ¶160; Ex.1099-Martin-Decl., ¶¶2325.

077 Reply at 24-25

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

Patent Owner's Expert

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-1091-Bikson at 112:4-12

Patent Owner's Expert

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-1091-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.

007 Sur-Reply at 23

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

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-1009-Stern at 12:55-13:2

Patent Owner's Expert

97. To form multiple pairs of bipolar 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-1009-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-2005-Bikson, ¶ 97

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-1009-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-1009-Stern at 10:48-52

Patent Owner's Expert

97. To form multiple pairs of bipolar 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-1009-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-2005-Bikson, ¶ 97

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-1009-Stern at 12:25-32

Petitioner's
Expert

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-2012-Martin at 50:2-15

Neurent Medical Inc. &
Neurent Medical Ltd.,
v.
The Foundry, LLC

IPR2024-00279 (US10,610,675)

IPR2024-00280 (US10,894,011)

IPR2024-00669 (US11,679,077)

PATENT OWNER'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:

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WHNeurentIPRService@wilmerhale.com

Date: April 21, 2025

/s/ Heath J. Briggs

Heath J. Briggs