

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

NEURENT MEDICAL INC. & NEURENT MEDICAL LTD.
Petitioners,

v.

THE FOUNDRY, LLC,
Patent Owner.

IPR2024-00669
U.S. Patent No. 11,679,077

PATENT OWNER SUR-REPLY

TABLE OF EXHIBITS

Exhibit	Description
2001	Lewis, David, and Nicolas Y. Busaba. “Surgical Management.” Sinusitis. CRC Press, 2006. 233-268.
2002	October 17, 2024 deposition transcript of Dr. Nicolas Bu-Saba
2003	Declaration of Dr. Howard L. Levine (“Ex-2003-Levine”)
2004	CV of Dr. Howard L. Levine
2005	Declaration of Dr. Marom Bikson (“Ex-2005-Bikson”)
2006	CV of Dr. Marom Bikson
2007	Brook, Itzhak. “Sinusitis: From Microbiology To Management” 2006
2008	October 23, 2024 printout of https://europepmc.org/article/med/16027090
2009	Transcript of the September 24, 2024, Deposition of Dr. Gregory T. Martin
2010	Transcript of the September 25, 2024, Deposition of Dr. Gregory T. Martin
2011	February 21, 2025 deposition transcript of Dr. Nicolas Bu-Saba
2012	February 20, 2025 deposition transcript of Dr. Gregory T. Martin

TABLE OF CONTENTS

TABLE OF EXHIBITS	ii
I. The Effective Filing Date Is No Later Than July 21, 2006.....	1
A. The Claims Have Written Description Support	1
1. The Reply Does Not Challenge The Disclosures Cited By Patentee	1
2. Irreversible Poration Discloses Ablation	2
3. Petitioner’s Expert’s Supplemental Declaration Confirms The ’077 Patent’s Claims Are Supported	3
4. Patentee Did Not Apply Obviousness	5
5. Petitioner Misapplies The Law And Misrepresents Testimony.....	6
B. The Board Correctly Determined That The ’077 Patent Has An Unbroken Priority Claim to the ’090 Application, Which Properly Incorporated The ’771 Provisional By Reference.....	7
II. Petitioner’s New Imran Argument Should Be Rejected	9
III. Makower’s Unknown Device Would Not Reasonably Be Expected To Ablate Tissue	11
A. There Is No Dispute That Liquid In The Nose Would Render Makower’s Device Ineffective	11
B. Petitioner’s Art Shows Liquids Are Present	11
C. Makower’s Device Is Not Made Functional By Other Devices	15
D. Petitioner Conflates Inoperability With Reasonable Expectation Of Success	16
E. The Makower Device Is Unknown To Either Expert	17
IV. A POSITA Would Not Have Selected Makower Or Combined It With Fang	17
V. Claim 7 Is Not Disclosed by Imran Or Makower	22
VI. Claim 4: Stern does not disclose “multiple pairs of bipolar radiofrequency electrodes”	22
VII. Petitioner’s Approach On Reply Shows Its Case Is Unsupported And The Reply Declaration Should Be Given No Weight	25

VIII. Patentee’s POSITA Level Is Correct.....	26
IX. Conclusion	27
CERTIFICATE OF SERVICE	i
CERTIFICATE OF WORD COUNT	ii

This Patent Owner Sur-Reply (POSR) is in response to Petitioner's Reply (Reply). The Reply raises several new arguments while also misrepresenting the facts and misapplying the law. Petitioner's new arguments should be rejected, and the Petition's original arguments should be found unsupported and unpersuasive.

I. The Effective Filing Date Is No Later Than July 21, 2006

Petitioner argues that (1) the claims lack written description support, and (2) the priority chain was broken. (Reply, 2-9.) Both arguments fail, leaving only Grounds V-VI.

A. The Claims Have Written Description Support

1. The Reply Does Not Challenge The Disclosures Cited By Patentee

The Reply argues lack of written description support but does not disagree that the '077 patent discloses: (a) applying energy to target cells under conditions which cause reversible or non-reversible poration, (b) that energy is applied to the areas where goblet (and other) cells are located, and (c) the area of energy and toxin delivery may "only partially overlap." (Reply, 3-8; Ex-1001, 8:10-28, 9:65-10:10, 8:29-33.) Petitioner fails to rebut, and therefore concedes, that because the '077 patent describes energy delivery that may "only partially overlap" with toxin delivery, there was an intent by the inventors to energize tissue outside the area of toxin delivery. Energizing tissue outside of the area of toxin delivery must have a purpose, or otherwise, there would be no reason to have energy partially overlap.

One straightforward reason, as explained by Dr. Levine, is to target that area with the “non-reversible poration” energy (ablation) disclosed by the ’077 patent, which addresses the goal the ’077 patent seeks: the treatment of rhinitis. (Ex-2003, ¶¶51-60; Ex-1001, 7:41-64 (explaining embodiments of the invention treat symptoms of rhinorrhea, such as rhinitis).) Dr. Bu-Saba admits that irreversible poration is species of energy (Ex-1098, ¶59, n.13 (“irreversible (i.e., non-reversible) electroporation is a form of energy”), and further admits that applying ablative energy to areas where goblet cells are located will reduce mucus secretion and treat rhinitis. (Ex-1002, ¶¶33, 36-37, 43, 46.) The Reply effectively has no rebuttal, arguing the ’077 patent is silent as to what happens in areas where only energy is applied. (Reply, 7.) But both experts testified that applying energy in the form of irreversible poration constitutes ablation and that ablating goblet cells would reduce mucus secretion and treat rhinitis. (POR, 27-31.) Accordingly, the claims are fully supported.

2. Irreversible Poration Discloses Ablation

The Reply and Dr. Bu-Saba argue irreversible poration is not ablation (Reply, 6, n.7; Ex-1098, ¶59), yet Dr. Bu-Saba cited Rubinsky (Ex-1059) numerous times in his original declaration to support his opinions on poration (Ex-1002, ¶¶37-38, 41, 68, 79), and Rubinsky shows that irreversible poration discloses ablation to a POSITA. (Ex-1059, 0003 (“This document discloses another minimally invasive

surgical technique *for tissue ablation, irreversible electroporation.*”); 0113 (“The present invention shows that *irreversible electroporation by itself produces substantial tissue ablation* for the destruction of undesirable tissues in the body....*Irreversible electroporation, therefore, has the advantage of being a tissue ablation technique*, which is as easy to apply as high temperature ablation....”), *see also id.*, 0023, 0067, 0072, 0079-80, 0082, 0091, 0104, 0108)¹ Accordingly, the ’077 patent’s reference to non-reversible poration discloses ablation to a POSITA. (Ex-2003, ¶¶54-57.)

3. Petitioner’s Expert’s Supplemental Declaration Confirms The ’077 Patent’s Claims Are Supported

Dr. Bu-Saba’s opening declaration ties irreversible poration to ablation, and he testified that it was well-known to ablate the cells responsible for causing rhinitis. (POR, 27-29, Ex-1002, ¶¶37-38, 41, 46.) Realizing his initial testimony essentially shows the ’077 patent expressly disclosed ablation of cells resulting in the treatment of rhinitis, Dr. Bu-Saba attempts to correct his testimony with 20 additional pages on written description. (Reply, 4-8, citing Ex-1098, ¶¶48-69.) But his attempted correction instead proves the claims are supported.

Specifically, Dr. Bu-Saba’s supplemental declaration states:

¹ Emphasis added herein unless otherwise noted.

“That is, the ’077 patent’s single reference to ‘non-reversible’ poration simply acknowledges that some cells will be incidentally destroyed when reversible poration energy is applied.” (Ex-1098, ¶61.)

This testimony confirms that the ’077 patent discloses destroying cells using non-reversible energy. The ’077 patent also discloses: (1) energy (reversible or otherwise) is applied to regions “containing a variety of cell types, including goblet cells” including “regions of the nasal membrane which are the same or different from the regions to which the toxin has been introduced,” (2) the toxin, and thus the energy, may be applied to “substantially the entire nasal cavity of the patient,” i.e., a significant volume of tissue would receive non-reversible energy, and (3) the “nasopharynx comprises a cluster of goblet cells which are responsible for mucus secretion.” (Ex-1001, 8:10-44.) Collectively, at least these portions of the ’077 patent disclose applying irreversible energy in regions and in an amount that will destroy mucus-secreting cells, such as goblet cells, and doing so will reduce mucus secretion and treat rhinitis, as Dr. Bu-Saba admits.² (Ex-1002, ¶38, 46.) Thus, Petitioner’s own testimony confirms the claims are supported.

² Petitioner’s “destroying target cells in sufficient numbers” argument (Reply, 6) misses the mark; Dr. Bu-Saba testified that the claims do not require any particular degree of efficacy/treatment. (Ex-1098, ¶111.)

4. Patentee Did Not Apply Obviousness

The Reply incorrectly asserts Patentee used obviousness to support written description. (Reply, 3, 5.) Compliance with the written description requirement is a question of fact, examining what the patent application’s disclosure “reasonably conveys to those skilled in the art.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010)(*en banc*)(“*Ariad*”). Patentee pointed to various facts, including the testimony of Drs. Bu-Saba and Levine, each using phrases like “would have understood,” in establishing alleged facts, as is common (e.g., Ex-1002, ¶¶62-63, 92, 123 (among others); Ex-2003, ¶¶43, 65, 67, 95-96 (among others)). *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362, 1371-72 (Fed. Cir. 2022); *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012)(affirming written description support based on an expert witness’ testimony about what POSITA “would have understood from the specification”).³ The word “obvious” and the like is neither used by the POR nor Dr. Levine’s declaration in their written description sections.

³ *Impact Engine, Inc. v. Google LLC*, 2024 WL 3287126 (Fed. Cir. July 3, 2024) does not state “would have understood” means obviousness; the word “obvious” is not even in the opinion.

5. Petitioner Misapplies The Law And Misrepresents Testimony

The Reply incorrectly argues a “binding admission” prevents Patentee from showing written description support. (Reply, 3-4.) There was no “binding admission.” Statements made by another party in an unrelated patent family, as is the case here, are not binding.⁴ *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 667 (Fed. Cir. 1988). Even the Petition did not argue a binding admission was made. (Petition, 25-26.) Petitioner cites no law to support its position, and its argument should be rejected.

The Reply also incorrectly argues the use of “the present invention” limits the scope of the '077 patent’s written description. (Reply, 4-5, 7.) But simply using those words does not limit a patent’s scope. *Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 797-98 (Fed. Cir. 2019). Rather, the entire specification must be viewed for what it reasonably conveys. *Ariad* at 1351. For these same reasons, the Reply’s reliance on “single reference” is unpersuasive, as is the Reply’s lack of data argument. (Reply, 5-6); *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1310 (Fed. Cir. 2015)(efficacy data and working examples not required).

⁴ Ex-1034 relates to U.S. Patent No. 10,335,221, owned by Aerin Medical, Inc. (Ex-1034, 878.)

B. The Board Correctly Determined That The '077 Patent Has An Unbroken Priority Claim to the '090 Application, Which Properly Incorporated The '771 Provisional By Reference

In the Institution Decision (Paper 9; “Decision”), the Board rejected Petitioner’s priority claim arguments and correctly determined “the ’077 patent has an unbroken priority claim to the ’090 application, filed July 21, 2006.” (Decision, 21-22.) Petitioner does not contest, and therefore concedes, the accuracy of this determination. (Reply, 8-9.) Nonetheless, the Reply restates the Petition’s arguments on priority, which should again be rejected—neither the facts nor the law have changed.⁵

First, the Reply argues incorporation by reference was improper because the PTAB’s *Samsung* decision is incorrect. (Reply, 8-9, citing *Samsung Elecs. v. Acquis LLC*, IPR2021-00608, Paper 10 (P.T.A.B. Dec. 8, 2021)(“*Samsung*”).) Yet, Petitioner cites no Federal Circuit authority that contravenes *Samsung*. Further, the Reply’s arguments against *Ex parte Maziere* and MPEP §608.01(p) were already considered and rejected by *Samsung* (Reply, 9, n.8; *Samsung*, 5-10), and the *NRG Energy* and *Focal Therapeutics* cases were already considered by the Board here

⁵ The Reply incorrectly argues Patentee waived its ability to address this issue. (Reply, 8.) The POR need not have addressed the Board’s correct finding on this issue, but nonetheless Patentee did so. (POR, 15-16, 25-26.)

Patent No. 11,679,077

and found unpersuasive. (Decision, 18, 22.) The incorporation by reference of the entirety of the '771 provisional by the '090 application was proper under *Samsung*, *Maziere*, and MPEP §608.01.

Second, the Reply argues the priority chain was “broke[n]” because priority to the '771 application was dropped. (Reply, 9.) Again, these arguments have already been considered and found unpersuasive. (Decision, 18.) The *Encyclopedia Britannica* case was already considered here, and the *Droplets* and *Hollmer* cases were already considered by *Samsung* and found to be inapplicable. (*Id.*; *Samsung*, 11-17.) Further, unlike those cases, Patentee is not seeking to claim priority to the '771 provisional, and it is clear which prior applications are and were fully incorporated by reference. Indeed, *Droplets* confirms the incorporation by reference of the '771 provisional is correct:

“[A] recitation of priority is not part of the ‘written description of the invention’ described in § 112.... [and] 37 C.F.R. § 1.57 authorizes an applicant to incorporate by reference essential and nonessential material to satisfy § 112.” (*Droplets*, 1320.)

The *Lockwood* case is inapposite as incorporation by reference was not an issue, and it is undisputed that the '090 application is fully incorporated by each application in the priority chain. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997).

Accordingly, the '077 patent properly claims priority to the '090 application, providing a priority date of at least July 21, 2006, and removing Grounds I-IV.

II. Petitioner's New Imran Argument Should Be Rejected

Petitioner's Grounds V-VI are based on Makower, Fang, and Edwards-535 (Ground V) plus Stern for Ground VI. (Petition, 8.) For the first time, Petitioner argues the independent claim is obvious based on combinations involving Makower and Imran. (Reply, 12-14.) Entirely new obviousness theories on reply are impermissible. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1330-31 (Fed. Cir. 2019)(Petitioner replies cannot raise 'an entirely new rationale' for why a claim would have been obvious."), citing *Intelligent Bio-Systems v. Illumina Cambridge*, 821 F.3d 1359, 1370 (Fed. Cir. 2016); *Corephotonics, Ltd. v. Apple Inc.*, 84 F.4th 990, 1002 (Fed. Cir. 2023)(Board not permitted to entertain "[s]hifting arguments' but must, instead, reject any 'entirely new theory of prima facie obviousness absent from the petition'").

Contrary to the Reply, Makower does not incorporate Imran by reference. (Reply, 12-13, 24, n.23.) Instead, Makower states "some of the working devices shown in FIGS. 5A-5Y[] and described herein incorporate assemblies...." (Ex-1005, 0164.) Two sentences later, Makower refers the reader to 19 patents, none of which are "incorporated by reference," and thus fails to incorporate Imran by reference. 37 C.F.R. §1.57(c)("an incorporation by reference...must [e]xpress a clear intent to incorporate by reference by using the root words 'incorporat(e)' and 'reference' (e.g., 'incorporate by reference')."); *Advanced Display Sys., Inc. v. Kent*

State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000)(must incorporate by reference with specificity).

Further, the “incorporate assemblies,” language is in the present tense (Ex-1005, 0164), meaning that Makower’s devices already incorporate assemblies from the 19 listed patents, and there is nothing in Makower to suggest new devices beyond those already disclosed by Makower are disclosed. Instead, Makower appears to refer the reader to these 19 listed patents merely to enable those skilled in the art to make and use the devices he describes.

Finally, Petitioner presents no analysis whatsoever as to why a POSITA would be motivated to combine the teachings of Imran with Makower. Simply because Makower includes Imran in a list of 19 other patents is insufficient to show obviousness. At best, such a listing aligns with a listing of potentially analogous art, which is merely a starting point for an obviousness analysis. *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017). Moreover, Imran is directed to an endocardial catheter having a new basket assembly for mapping or ablating a chamber of the heart (Ex-1068, 2:17-3:12), and its potential applicability to any of Makower’s devices, especially devices relating to the nose, remains unknown and unexplained.

III. Makower's Unknown Device Would Not Reasonably Be Expected To Ablate Tissue

A. There Is No Dispute That Liquid In The Nose Would Render Makower's Device Ineffective

As the POR explained, liquid in the nasal cavity or nasopharynx would cause ions produced by Makower's FIG. 5H electrodes to preferentially flow into the liquid and not the surrounding tissue. (POR, 39-42.) Petitioner does not dispute Patentee's ion flow testimony/findings. Rather, Petitioner disputes that liquid is present in the nasal cavity/nasopharynx. (Reply, 13-14.) As explained below, it is.

B. Petitioner's Art Shows Liquids Are Present

The Reply argues only air is present in the regions in which RF surgery would occur to treat turbinates or areas associated with rhinitis. (Reply, 14.) Not true. The Reply misrepresents Dr. Levine's testimony and fails to address the disclosures of Makower on this issue.

First, while it may be "fundamental human knowledge" (Ex-1098, ¶88) that "one can breathe through their nose," the inner workings of the nose, including the nasal turbinates and parasympathetic nerve, are not fundamental human knowledge. (Ex-2011, 92:6-93:6) Thus, Petitioner's expert's suggestion that even a lay person would understand how liquid affects the locations where Makower's device would allegedly be used is false.

Second, Petitioner fails to address Makower, which repeatedly addresses liquids in the nose. Indeed, one of the first things Makower discusses relative to his alleged inventive devices is liquid in the nose:

“The present invention provides a comprehensive system of devices...Specifically...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.**” (Ex-1005, 0132.)

Importantly, and consistent with Dr. Levine’s testimony, Makower teaches that the FIG. 5H device is used with devices that continuously turnover fluids in the nose:

“In some embodiments, it may be desirable for the device...to have separate lumens for infusion and aspiration, thereby allowing for concurrent infusion of an irrigation fluid or other fluid and suctioning of the irrigation fluid or other fluid from the operative field. 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...such that a device (e.g., a catheter, fluid injector or other elongate device examples of which are **shown in FIGS. 5A-5Y**” and described herebelow) or fluid(s) may be inserted into the device insertion opening 30, advanced through the working lumen 50 and out of a selected one of the outlet openings...to a position within the nose, nasopharynx or paranasal sinus.” (Id., 0135.)

Petitioner fails to address these teachings of Makower, which indicate fluids are present during operation of the FIG. 5H device. Indeed, fluid issues are so important to Makower that he repeatedly addresses them over at least 23 paragraphs of his disclosure. (Ex-1005, 0134-140, 0142-43, 0146-159.) If liquids were not an issue, Makower would have no reason to address them so extensively. Petitioner's failure to address Makower's liquid disclosures is fatal.

Dr. Bu-Saba's testimony on fluid in the nose is not persuasive. First, Dr. Bu-Saba fails to address Makower's express teachings on liquids in the nose. Instead, Dr. Bu-Saba relies on his experience and without support from other prior art sources. (Ex-1098, ¶¶81-86.) Expert testimony that fails to address the prior art and is uncorroborated is not persuasive and should be given no weight. *Elbit Systems of America, LLC v. Thales Visionix*, 881 F.3d 1354, 1359 (Fed. Cir. 2018); 37 C.F.R. §42.65.

Second, Dr. Bu-Saba mischaracterizes Dr. Levine's testimony:

“Dr. Levine's and Dr. Bikson's suggestion that the nasal cavity or nasopharynx would be **completely filled** with blood or mucus...”

(Ex-1098, ¶87). Dr. Levine never said the nose is “completely filled.” (Ex-2003, ¶¶95-96.) Rather, consistent with Makower, Dr. Levine stated “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.” (*Id.*, ¶95.)

Petitioner and Dr. Bu-Saba also mischaracterize Dr. Levine’s “mucus isn’t the issue” testimony. (Reply, 14; Ex-1098, ¶¶21, 86.) Here, Dr. Levine was discussing decongestants,⁶ mucus in general, and obstructed views during operation, and testified that “It’s there, and it is fine,” immediately after the statement referenced by Petitioner. (Ex-1089, 81:18-83:18.)

Petitioner and Dr. Bu-Saba also mischaracterize Dr. Levine’s testimony on liquids falling to the nasal floor. (Reply, 14; Ex-1098, ¶81.) Dr. Levine testified that, while some liquids may fall to the nasal floor in some surgical orientations, mucus and saline are still flowing in the nose. (Ex-1089, 87:8-88:20.)⁷ This testimony is consistent with Makower. (Ex-1005, 0226.)

Third, Dr. Bu-Saba did not testify that only air would be present in the nasal cavity during the procedure. Instead, Dr. Bu-Saba merely testified that “air would be present.” (Reply, 14; Ex-1098, ¶88.) Of course, “air would be present,” but so

⁶ Decongestants shrink tissue—they do not remove mucus from the nose. (Ex-1089, 81:18-82:7.)

⁷ Other mischaracterizations of Dr. Levine’s testimony by Dr. Bu-Saba are shown in §VII.

are liquids because the nose is never completely dry, and mucus, blood and/or saline are present during endoscopic surgery. (Ex-1005-Makower, ¶¶0036; Ex-2003, ¶¶47, 64, 78, 95; Ex-2001, 245 (“When sinus surgery is performed by experienced surgeons who have a detailed knowledge of sinus anatomy, complications are extremely rare....A small amount of bleeding is expected post-operatively. Nasal packing, and, at times, hemostasis in the operating room can control major bleeding.”).)⁸ Indeed, both experts agree normal mucus production is about 2-quarts per day, indicating mucus is typically present in the areas where RF ablation surgery occurs. (Ex-1089, 87:13-88:8; Ex-2011, 91:11-21).

C. Makower’s Device Is Not Made Functional By Other Devices

The Reply argues other devices evidence functionality of the Makower FIG. 5H device. Not so. First, the Reply points to FIG. 5B of the ’077 patent. (Reply, 13.) But the ’077 patent is not prior art and cannot be used to make Petitioner’s case. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983). Nonetheless, unlike Makower, the FIG. 5B device does not have a hollow interior, so it would not have the same issues as Makower. Petitioner also refers to the Imran

⁸ The Reply takes Dr. Bikson’s testimony out of context. (Reply, 14, n.13.) Dr. Bikson was testifying about the Makower FIG. 5H device, which is hollow, as opposed to the devices used by Drs. Levine and Bu-Saba. (Ex-1091, 216:6-218:10.)

Patent No. 11,679,077

device (Reply, 12-13), but as explained previously Petitioner's reliance on Imran is misplaced and improper. (§II, *supra*.)

D. Petitioner Conflates Inoperability With Reasonable Expectation Of Success

The Reply argues inoperability in the context of obviousness. (Reply, 1, 12-13, 15, 22.)⁹ This is, of course, incorrect because to prove obviousness there must be a motivation to combine, and the combination must reasonably be expected to achieve the claimed invention. *Intelligent Bio-Systems*, 821 F.3d at 1366-67. Indeed, even an operable device may not be expected to achieve what is claimed in any given patent. Further, contrary to the Reply, Petitioner bears the burden to show a reasonable expectation of success, not Patentee. (Reply, 12, n.11 (arguing inoperability burden on Patentee); *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1375 (Fed. Cir. 2016)(burden of persuasion always on petitioner); *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1382-85 (Fed. Cir. 2019)(reversing Board for lack of evidence on reasonable expectation of success).)

⁹ Petitioner mischaracterizes the POR as making an inoperability argument (Reply, 12-15). Neither the POR nor any of supporting testimony use the word “inoperable;” the POR followed the reasonable expectation of success standard.

E. The Makower Device Is Unknown To Either Expert

The POR pointed out “neither expert has ever seen or used a device like that of Makower in their over 80 combined years of clinical practice,” indicating Petitioner’s case relies on hindsight. (POR, 35.) Although it is true that a commercial embodiment is not required to show obviousness (Reply, 11), the fact that neither expert has ever seen a device like Makower’s FIG. 5H device is congruent with the device not reasonably being expected to ablate tissue and Petitioner’s use of hindsight reconstruction. (Ex-2002, 303:13-18; Ex-1098, ¶74, n.18, Ex-2003, ¶89.)

IV. A POSITA Would Not Have Selected Makower Or Combined It With Fang

As explained in the POR, Petitioner’s Makower-Fang combination is rooted in hindsight. (POR, 46, 54-65.) “Common sense and real world indicators indicate that to conclude otherwise would be to give in to hindsight.” *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1058 (Fed. Cir. 2016). Petitioner argues there is no hindsight because the art is analogous art. (Reply, 17, 20-21.) But that is merely the starting point for an obviousness analysis. The simple fact is that Petitioner adopted Makower because the Examiner cited it during prosecution, never considering Makower as a whole. Petitioner does not establish that a POSITA would have looked to Makower—a patent directed to flexible catheters—and then would have

been motivated to combine its obscure FIG. 5H embodiment with Fang's even more obscure, inconclusive study. (POR, 46, 54-65.)

Makower is directed to flexible catheters. (POR, 49-54.) The Reply argues Makower discloses "working devices" in addition to flexible catheters (Reply, 10-11), but Makower's working devices are tied to flexibility with avoidance of rigidity. (Ex-1005, 0160-61 (tying Makower's "working devices" to flexibility in all instances).) Petitioner's argument that Makower "claims working devices separately" is irrelevant as claim 1 relates to a port assembly for insertion of a working device, and it is clear that Makower's intent is for those working devices to be used per Makower's teachings.

Even so, a POSITA would not have been motivated to combine Makower with Fang due to Fang's inconclusive results. Petitioner's Reply does not dictate otherwise. Indeed, a POSITA would want to know that a medical procedure study is credible to be motivated to rely on its teachings. (POR, 46-49.)

Petitioner also mischaracterizes the POR as demanding "Makower and Fang's devices have been identical." (Reply, 15.) Not true. The fact remains neither expert has ever seen Fang's device, and there is no evidence showing its configuration, so it is not possible to tell whether Fang's device is sufficiently comparable to Makower's such that a POSITA would reasonably expect success from the use of Makower's device. Further, Fang's device is unlikely to be configured like

Makower's hollow device at least because Fang's device has a "firing head aligned with the sphenopalatine foramen on both sides" and, for some unknown reason, "[i]t was advisable to have a white ring around the radiofrequency head" of Fang's device. (Ex-1006, 876; Ex-2002, 203:9-22.) Fang's device also appears to have a "radiofrequency knife" (Ex-1006, 876), while Makower's device includes no such feature.

Petitioner incorrectly argues that Fang's use of multiple procedures at once is irrelevant to the conclusion of obviousness because "Fang's other procedures treat other pathologies." (Reply, 17-18.) The fact remains that Fang conducted multiple procedures/surgeries at once ("joint action of multiple links"), each of which was intended to address "the therapeutic effect of perennial allergic rhinitis," so it is not possible to tell whether the improvement in rhinitis is from RF ablation or from some other procedure:

*"Through the **joint action of multiple links**, the therapeutic effect of perennial allergic rhinitis is significantly improved.*

The case study of this experimental group has demonstrated the following advantages...(2) It is easy to identify and eliminate other nasal symptoms *that affect the therapeutic effect, such as hypertrophy of the uncinate process, hypertrophy of the middle turbinate, polypoid lesion, sinusitis, nasal polyps, etc.*"

(Ex-1006, 877; *see also* Ex-2003, ¶¶63, 73, 88.)¹⁰ Petitioner’s failure to address Fang as whole, including its “*joint action of multiple links*” and related disclosures is improper and an indication of hindsight. *In re Mercer*, 515 F.2d 1161, 1165-66 (CCPA 1975)(rejecting Board’s hindsight approach that relied on “isolated teachings of the prior art without considering the overall context” of those teachings); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986)(not permissible within §103 framework “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.”).

Citing Dr. Levine, Petitioner attempts to justify its reliance on Fang by arguing that multiple procedures could be conducted at the same time in the nasal cavity. (Reply, 21-22.) Petitioner’s argument is irrelevant and misrepresents Dr. Levine’s testimony. While multiple procedures can be conducted at once, doing so does not allow a POSITA to determine which one was responsible for a good/bad outcome. (Ex-2003, ¶73.) The Reply’s citation to Makower 0043 here is likewise illogical—

¹⁰ These quotes show Dr. Bu-Saba’s “different pathologies” testimony (Ex-1098, ¶¶116-118) is incorrect because Fang ties all of its procedures to “*the* therapeutic effect” of perennial allergic rhinitis.

simply because Makower discloses a litany of procedures does not mean a POSITA would be motivated to apply all of those procedures at once with Fang.

Petitioner mischaracterizes the POR by arguing Patentee did “not dispute Fang was right about” RF ablation. (Reply, 18.) Not true. The POR pointed out many reasons why there is no reason to believe Fang’s RF procedures alone are responsible for the improvement. (POR, 46-49.) The Reply also belatedly introduces Fang’s alleged efficacy criteria (Reply, 19, citing Ex-1113), but this evidence should have been submitted with the Petition and was not presented to Patentee’s expert during cross-examination. It is prejudicial (and is gamesmanship) to introduce new evidence without any opportunity for Patentee’s expert to address it. *Intelligent Bio-Sys.*, 821 F.3d at 1369. Further, without Ex-1113, both experts testified that they could not understand Fang’s results. (Ex-2003, ¶75; Ex-2002, 207:2-208:21.) Petitioner’s citation to Hytonen—an unauthenticated article—amounts to no more than impermissible hearsay. (Reply, 19-20.)

In sum, Petitioner’s Ground IV fails.

V. Claim 7 Is Not Disclosed by Imran Or Makower

The Reply argues Imran discloses claim 7. (Reply, 25-27.)¹¹ Petitioner’s use of Imran is improper—Imran is not incorporated by reference in Makower and there is no analysis by Petitioner relating to motivation to combine Makower with Imran. (§II, *supra*.) Further, neither Imran nor Makower disclose an arrangement that delivers energy laterally. (Ex-2003, ¶¶102-111; Ex-2005, ¶¶73-84.) Petitioner’s citation to FIG. 6D of the ’011 patent also misses the mark. (Reply, 25.) In contrast to Imran, which includes numerous electrodes that continuously engage “the wall of the heart” (Ex-1068, 2:44-45, 6:53-67), the FIG. 6D embodiment includes only two surface penetrating electrodes. (Ex-1001, 17:27-35.) Thus, Petitioner’s Makower-Fang combination fails to render claim 7 unpatentable.

VI. Claim 4: Stern does not disclose “multiple pairs of bipolar radiofrequency electrodes”

Petitioner’s Ground VI fails because Stern teaches a device configured to have at most a *single pair* of bipolar radiofrequency electrodes. (POR, 66-69.)

¹¹ Patentee did not waive its right to address claim 7. Nonetheless Petitioner opened the door by briefing this issue on Reply.

Petitioner's Reply mischaracterizes both Patentee's argument and Stern. (Reply, 23-25.)¹²

First, claim 4 does not require simultaneous activation; it requires a device having multiple pairs. (Ex-1001, claim 1 (“apparatus comprising...”)) Stern's Figure 15 does not disclose multiple pairs because a pair only occurs when certain switches are closed. (POR, 65-69; Ex-1091, 112:13-113:16; Ex-2012, 200:7-204:15.)¹³

Second, Stern's statement that “any combination of pairs of electrodes may be utilized together” (Reply, 24) does not disclose claim 4. When read in isolation, the above quote 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-1091, 110:14-116:20, *id.*, 131:13-21.) It is improper to read portions of the prior art in isolation (“[a] reference must be considered for everything it *teaches*.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985); *Bausch & Lomb, Inc.*,

¹² Patentee did not waive Ground III (Reply, 3, n.1); if Stern fails to disclose claim 4, neither Ground III nor VI are successful.

¹³ Patentee notes that related IPRs2024-00277, -00278, and -00282 also address Stern and its lack of “multiple pairs.”

796 F.2d 443. Here, when Stern is properly read in its entirety, any potential ambiguity is resolved in Patentee's favor.

Stern expressly teaches that its electrodes are “*independently and sequentially energized.*” (Ex-1009-Stern, 2:31-33, 2:49-53, 10:48-52, 17:54-55; Ex-2005-Bikson, ¶97; Ex-1007-Martin, ¶65.) Stern also 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-1009-Stern, 12:55-13:2; Ex-2005-Bikson, ¶97.) Stern does not teach closing three or more switches at the same time. (*Id.*)

Third, Stern's goal is to avoid uneven heating. (Ex-1009-Stern, 12:25-33; Ex-2012, 170:12-171:13.) However, utilizing multiple pairs at the same time in Stern's Figure 15 would *exacerbate* the problem of uneven heating—not help it. (Ex-2012, 50:2-15; *id.*, 28:7-19, 29:3-11, 33:9-19; Ex-1091, 253:6-254:4.)¹⁴ Further, utilizing

¹⁴ 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-2012, 24:12-20, 26:8-27:3, 29:12-30:7, 31:1-32:14, 39:3-9, 41:15-42:5; Ex-1091, 252:19-253:5, 255:10-19, 256:8-17.) Differences in impedance lead to different amounts of heating. (Ex-2012, 42:10-43:3, 43:18-22, 44:14-20, 46:10-47:11.) Differences in impedance

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-2012, 24:21-25:21; *id.*, 23:7-21; Ex-1091, 250:20-251:7 (“if you did that you would lose control.”).) Thus, a POSITA reading Stern would have known *not* to form multiple pairs in Figure 15. (*Id.*)

Accordingly, Petitioner’s Ground VI fails.

VII. Petitioner’s Approach On Reply Shows Its Case Is Unsupported And The Reply Declaration Should Be Given No Weight

As explained previously, Petitioner improperly uses Imran to backfill defects in its Petition, which is indicative of its entire approach on Reply including its lack of supporting testimony. Petitioner’s expert’s original Declaration is 158 pages. Incredibly, Petitioner’s expert’s supplemental Declaration is 131 pages, with 26 on POSITA, 20 on written description, and 57 on Ground V, obviousness, illustrating Petitioner’s lack of Petition-based evidence. Indeed, the Reply’s motivation to combine arguments spans 6 pages (Reply, 17-23) but cites 32 new pages of testimony by Dr. Bu-Saba on this issue (Ex-1098, ¶¶103-144) while only citing Dr. Bu-Saba’s original testimony once in this section (Reply, 18). The remainder of the

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-1091, 248:5-11, 253:6-254:4, 257:10-14; Ex-2012, 30:16-22.)

Reply cites Dr. Bu-Saba's original testimony *three times*. Petitioner's use of Dr. Bu-Saba's testimony should be seen for what it is: an attempt to circumvent the PTAB's word count requirements while also backfilling its defective Petition. *Cisco Systems, Inc. v. C-Cation Technologies, LLC*, IPR2014-00454 (Paper 12 at 8).

Dr. Bu-Saba's Reply testimony is not credible. In multiple instances, Dr. Bu-Saba attempts to correct his original testimony. (Ex-1098, ¶2, n.1, ¶¶36-37, 59, n.13, 92-93, n.27, 94, 100.) Dr. Bu-Saba also attempts to correct his defective analysis of Fang by belatedly offering documents cited by Fang, which documents were not available to Patentee's expert for analysis. (Ex-1098, ¶¶113-15.) Dr. Bu-Saba also refused to answer even simple questions about POSITA level on Reply cross-examination (Ex-2011, 20:20-38:16, 40:8-42:1, 43:1-46:22), and continuously mischaracterized Dr. Levine's testimony (e.g., Ex-1098, ¶¶87, 89, 95, 137; Ex-2011, 87:5-88:11, 96:9-98:4, 100:1-101:12). Dr. Bu-Saba's Reply testimony should be given little or no weight. *Elbit Systems of America*, 881 F.3d at 1358.

VIII. Patentee's POSITA Level Is Correct

The Reply argues nasal experience is not required for a POSITA. (Reply, 28-31.) Petitioner's definition makes no sense as it allows, for instance, an engineer without any RF or nose experience to assess and apply the prior art. Such a person is unqualified to evaluate, for instance, the Fang article directed to medical procedures in the nose. *Sundance, Inc. v. DeMonte Fabricating, Ltd.*, 550 F.3d 1356,

Patent No. 11,679,077

1363-64 (Fed. Cir. 2008). Further, that a POSITA “could learn about” the nose (Ex-1098, ¶44)) is incongruent with the correct standard—a POSITA must have the necessary background at the time of the invention. *Environment Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696-97 (Fed. Cir. 1983). The inventor’s background is irrelevant to the POSITA analysis. (Reply, 31; *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985).) Finally, design and development experience should be required to evaluate the art in this proceeding. (Reply, 28-31; POR, 18-20.)

IX. Conclusion

As shown herein and in the POR, Petitioner has not carried its burden to show the Challenged Claims are unpatentable.

Respectfully submitted,
GREENBERG TRAURIG, LLP

Date: March 4, 2025

By: /Heath J. Briggs/
Heath J. Briggs (Reg. No. 54,919)
Greenberg Traurig, LLP
1144 15th St. Suite 3300
Denver, CO 80202
Telephone: 303-685-7418
Facsimile: 720-904-6118
BriggsH@gtlaw.com

Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that on this 4th day of March 2025, a copy of this **PATENT OWNER SUR-REPLY** and Exhibits 2011-2012 were served by electronic mail on Petitioners' lead and backup counsel at the following email addresses:

- David.Cavanaugh@wilmerhale.com
- Gregory.Lantier@wilmerhale.com
- Alexis.Cohen@wilmerhale.com
- Joshua.Stern@wilmerhale.com
- Alex.Nemtsov@wilmerhale.com
- Gilbert.Smolenski@wilmerhale.com
- WHNeurentIPRService@wilmerhale.com

Date: March 4, 2025

By: /Heath J. Briggs/
Heath J. Briggs (Reg. No. 54,919)
GREENBERG TRAURIG, LLP
1144 15th St. Suite 3300
Denver, CO 80202
Telephone: 303-685-7418
Facsimile: 720-904-6118
BriggsH@gtlaw.com

Counsel for Patent Owner

CERTIFICATE OF WORD COUNT

Patent Owner certifies this Patent Owner Sur-Reply is 5,594 words, as counted by the word-processing program (Microsoft Word for Office 365) used to generate this document, and complies with the 5,600 word limit of 37 C.F.R. §42.24.

Respectfully submitted,
GREENBERG TRAURIG, LLP

Date: March 4, 2025

By: /Heath J. Briggs/
Heath J. Briggs (Reg. No. 54,919)
Greenberg Traurig, LLP
1144 15th St. Suite 3300
Denver, CO 80202
Telephone: 303-685-7418
Facsimile: 720-904-6118
BriggsH@gtlaw.com