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.

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

PETITIONERS' REPLY

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I. INTRODUCTION

The Challenged Claims are unpatentable, and Patent Owner's ("PO") legally irrelevant and technically incorrect arguments do not show otherwise.

The Board correctly found no relevant priority application provides written description for the challenged energy-only treatment claims. Institution Decision ("ID"), 22-26. With the specification describing energy facilitating ***toxin*** therapy ***not*** energy-only therapy, PO merely argues the claimed treatment was ***obvious*** based on passing reference to non-reversible poration. Obviousness, however, is insufficient for written description. Absent earlier priority, Grounds I-III are ***uncontested*** and render all Challenged Claims unpatentable.

Regardless, Grounds V-VI render all Challenged Claims obvious. For claim 1, PO's suggestions that a POSITA would not even consider parts of indisputably analogous art are improper. So too is its mischaracterization of Makower as inoperable based on a scenario Dr. Levine testified ***was not an issue***. As Dr. Bu-Saba explains, a POSITA would have expected Makower's device would be safe and effective, as it teaches. And far from being inconclusive, Fang concludes, from statistically significant data, that radiofrequency ablation treated rhinitis symptoms. None of PO's arguments overcome the prior-art motivation to use Makower's radiofrequency electrode device to reasonably expect known benefits Fang (and

others) taught. PO's arguments regarding dependent claims 4—using unsupported implicit claim construction—and 7—which PO waived, but which are inconsistent with the '077 patent—fare no better.

Facing preponderant obviousness, PO resorts to disparaging Petitioners' eminently qualified experts despite raising ***no disputed issue*** they are unqualified for. Most issues are, in fact, undisputed, and where the declarants disagree, the evidence supports Petitioners.

II. GROUNDS I-IV: THE PRIORITY DATE IS NO EARLIER THAN OCTOBER 22, 2019

The only priority dispute is whether the '771 Provisional (incorporated in the '090 Application) provides priority before October 22, 2019. It does not, because it does not provide written description for the claims. Pet., 18-26; ID, 22-26. PO's argument that energy-only treatment would have been obvious is not enough to show otherwise, and its reliance on nested incorporation of a provisional is also legally improper. The Board should maintain that the claims are entitled to priority no

earlier than October 22, 2019. ID, 26. Should it do so, Grounds I, II, and III are uncontested.[1,2]

A. The Challenged Claims Do Not Have Written Description Support

The Challenged Claims do not have written description support in any earlier application. For priority, PO must show written description in an earlier application that "reasonably conveys to [POSITAs] the inventor had possession of the claimed subject matter." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Disclosure "that merely renders the invention obvious" is insufficient. *Id.*, 1352 (citation omitted).

The Challenged Claims recite energy-only treatment. Ex.1001-USP077, claim 1; POR, 24-25. RPI Aerin—the patent's exclusive licensee—correctly represented to the Office "the ***sole*** purpose of applying energy" the '771 Provisional

[1] PO raises no dispute regarding Stern in Ground III and any such argument is waived. *Honeywell International, Inc. v. 3G Licensing S.A.*, IPR2021-01141, Paper 52, 39 (P.T.A.B. Jan. 11, 2023). Regardless, PO is wrong regarding Stern. *See* Section III.C.

[2] If the Board finds written description but no legal priority claim, Ground IV is uncontested. Pet., 56-66.

describes is ***not*** treatment but "porat[ing] target cells to enhance uptake of a nerve toxin." Ex.1034-FH221-Aerin, 786; Pet., 24-25.[3] PO does not address this binding admission.[4] Instead, PO argues claims to energy-only treatment find written description in a ***single*** parenthetical reference to "non-reversible" poration and unconnected discussion of mucus cells and areas of administration. POR, 26-31. These arguments fail.[5]

First, PO wrongly suggests, POR, 22, that the specification describes energy-only treatment.[6] PO's claim that "[t]he '077 patent relates to an apparatus 'for altering autonomic nerve function by utilizing an electric field…." POR, 22 (quoting Ex.1001-USP077, 4:60-61), is incorrect. The (omitted) end of this specification sentence explains energy is used "to alter tissue…***via permeabilization***…to

[3] All emphasis and annotations added.

[4] PO also ignores Applicant separately pursued treating nasal conditions ***without*** neurotoxins. Pet., 24-25, n.13.

[5] Petitioners do not concede unchallenged claims 14-15 have written description. POR, 24.

[6] Without conceding earlier priority, Petitioners adopt the Board's shorthand of referencing the '077 patent. *See* ID, 22-26.

facilitate the translocation of **" *toxin***. Ex.1001-USP077, 4:59-65. The '077 patent discloses toxin, not energy alone, treats rhinitis. Pet., 24-26; Ex.1001-USP077, Title, Abstract, 1:38-47 ("present invention" delivering "therapeutically effective amount of…neurotoxin"), 3:31-62 ("improved methods…***for delivering toxins***"); 5:20-23; 8:45-67; 21:45-22:6. The Board correctly confirmed this at institution. ID, 22-26. Ex.1098-Reply-Decl., ¶¶50-55.

Second, PO cannot rely on a single reference to "non-reversible" poration, POR 26-27 (citing Ex.1001-USP077, 8:11-18), for written description of "treatment" because the specification does not describe non-reversible poration ***alone*** treats rhinitis symptoms. PO does not actually dispute this, but instead argues a POSITA "would recognize" or "would have appreciated" what is claimed. POR, 27, 30; Ex.1089-Levine-Tr., 186:3-7. This is insufficient; what a POSITA "would have" recognized or appreciated relates to ***obviousness***, which cannot substitute for written description. *Ariad*, 598 F.3d at 1351; *Impact Engine, Inc. v. Google LLC*, 2024 WL 3287126, at *10 (Fed. Cir. July 3, 2024) (testimony POSITA "would have understood" element insufficient); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164-65 (Fed. Cir. 2019) (written description of treatment limitation required description of why treatment effective); *Lockwood v. American Airlines, Inc.*, 107

F.3d 1565, 1572 (Fed. Cir. 1997) (no written description if POSITA must "speculate as to [undisclosed] modifications").

Regardless, PO is wrong about how a POSITA would have understood the '077 patent.[7] The specification sentence referencing non-reversible poration is directed to "enhanc[ing] delivery" of toxin. Ex.1001-USP077, 8:10-18. A POSITA would have understood the specification refers to non-reversible poration as a potential ***undesirable*** side effect of reversible poration (in some instances). *See* Ex.1091-Bikson-Tr., 57:10-19. This is different from disclosing destroying target cells in sufficient numbers to treat. Ex.1098-Reply-Decl., ¶¶56-61.

Nor does description of mucus-secreting cells, POR, 28, describe destroying such cells with non-reversible poration alone for treatment. The specification describes effects ***of toxin***, not irreversible poration, on such cells. *E.g.*, Ex.1001-USP077, 1:65-2:22, 3:31-55. PO's declarant, Dr. Levine, admitted the specification contains no non-reversible poration data and was aware of no prior art use of irreversible electroporation alone for therapy. Ex.1089-Levine-Tr, 186:3-7, 197:1-

[7] PO incorrectly equates non-reversible poration and ablation, POR, 27-28, treatment with which is not the same. Dr. Bu-Saba did not testify otherwise. POR 27-28; Pet. 11-13, 25. Ex.1098-Reply-Decl., ¶59.

6. And Dr. Bikson confirmed use of irreversible poration depends on multiple factors. Ex.1091-Bikson-Tr., 55:9--57:9, 59:1-60:2, 60:7-13, 65:10-67:8. PO's suggestion a POSITA "would have appreciated" the named inventors possessed the claims based on referencing non-reversible poration with unstated, unknown, and contingent effects should be rejected. Ex.1098-Reply-Decl., ¶62.

High-level statements that toxin and energy delivery may not overlap, POR, 28-30, do not bridge this gap. The specification is silent about effects of energy in non-overlapping areas and does not describe ***treatment*** absent toxin. Instead it describes pairing a toxin delivery catheter ***and*** "energy applicator" to "enhance delivery ***of the toxin***," Ex.1001-USP077, 9:48-60, and treatment "enabled or enhanced" where toxin and energy ***overlap***. *Id.*, 9:65-10:10; *see also id.*, 21:66-22:6. Ex.1098-Reply-Decl., ¶¶63-68.

Indeed, surrounding reference to "non-reversible poration," the specification refers not to energy-only treatment, but states "the present invention" is "deliver[ing]" toxin "while applying energy," and that energy "cause[s]…poration…***to enhance delivery of the toxin***…." Ex.1001-USP077, 8:11-18. In sentences immediately following the parenthetical (which PO omits), the specification describes "where ***the toxin*** is introduced," a "target region for ***the toxin***," and cells "responsible for mucus secretion…susceptible to the disabling

mechanism of the" ***toxin***. *Id.*, 8:18-28. These passages do not describe the inventors possessed energy-only treatment. *Id.* Ex.1098-Reply-Decl., ¶¶63-68.

The Challenged Claims thus do not have written description and uncontested Grounds I-III render the claims unpatentable. Ex.1098-Reply-Decl., ¶¶48-69.

B. PO Cannot Rely on Nested Incorporation of the '771 Provisional

PO waived any argument it could legally claim priority before October 22, 2019 by not addressing the rule and cases in the Petition. Pet., 20-24; POR, 22-31; *Honeywell*, IPR2021-01141, Paper 52, 39; Scheduling Order, Paper 9, 9.

Regardless, Petitioners respectfully disagree with the Board's institution finding that 35 C.F.R. §1.57(d) does not apply to establishing written description for priority, and that PO could rely on nested incorporation of the '771 Provisional. ID, 21-22, n.17 (citing *Samsung Elecs. v. Acquis LLC*, IPR2021-00608, Paper 10 (P.T.A.B. Dec. 8, 2021)).

First, the Board's decision in *Samsung* that 35 C.F.R. §1.57(d) does not apply for establishing priority is incorrect. 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. *See* 37 C.F.R. §1.57(d); *NRG Energy, Inc. v. Midwest Energy Emissions Corp.*, IPR2020-00832, Paper 17 (P.T.A.B. Oct. 26, 2020); *Focal Therapeutics, Inc. v. Senorx, Inc.*, IPR2014-00116,

Paper 8 (P.T.A.B. Apr. 22, 2014). Here, PO's priority claim using an incorporated provisional contravenes this Rule.[8]

Second, 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. Pet. 21-23; *Droplets, Inc. v. E*TRADE Bank*, 887 F.3d 1309, 1315-20 (Fed. Cir. 2018); *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012); *Encyclopedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1351 (Fed. Cir. 2010); MPEP §211.02. The Board correctly noted these applications claim priority to the '090 application (which incorporates the '771 Provisional), ID, 22, but this nested incorporation is insufficient due to Applicant's affirmative break. *Lockwood*, 107 F.3d at 1571 ("***each*** application" in chain "must comply with written description requirement"); Pet., 22-24.

[8] *Ex parte Maziere*, 27 U.S.P.Q.2d 1705 (B.P.A.I. 1993) and M.P.E.P. §608.01(p) are inapplicable. *Maziere* was decided pre-§1.57 and addressed non-essential material. M.P.E.P. §608.01(p) (citing *Maziere*) is not binding and inconsistent with the Rule. *Nat. Alternatives Int'l, Inc. v. Iancu*, 904 F.3d 1375, 1382 (Fed. Cir. 2018) (citations omitted) ("MPEP 'does not have the force of law[.]'").

III. GROUNDS V-VI: CLAIMS 1-8 AND 11 ARE OBVIOUS

If the Challenged Claims cannot claim earlier priority, Grounds I-III indisputably render the claims unpatentable. If Grounds I-III are not dispositive, Grounds V-VI render the Challenged Claims obvious at any priority date.

A. A POSITA Would Have Had a Reasonable Expectation Makower's Device (in view of Fang) Would Successfully Ablate Tissue

PO does not dispute Makower, Fang, and Edwards-535teach all claim elements. Instead, PO argues that although Makower teaches its device ablates tissue to treat nasal disorders, Pet., 78-80, a POSITA would not expect it to do so. POR, 33-34. PO, however, identifies no teaching away, skepticism, or actual failure, and its technical mischaracterizations do not overcome reasonable expectation of success.

First, Makower is not limited to flexible catheters. POR, 35, 49-54. Makower's "present invention" includes "working devices" ***separate from***

"catheters used to deliver them." Ex.1005-Makower, [0161]-[0162]. Makower also ***claims*** working devices separately. *Id.*, claim 1.[9] Ex.1098-Reply-Decl., ¶¶73-76.

Regardless, Makower's inclusion of flexible catheters, and discussion of Figure 5H in several sentences, POR, 35, 38, are inconsequential. Makower indisputably teaches Figure 5H, Ex.1005-Makower, [0187], FIG.5H, and "must be considered for everything that it teaches[.]" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1349 (Fed. Cir. 2017) (citation omitted); *Neurent Medical Inc. v. Aerin Medical Inc.*, IPR2024-00278, Paper 9, 28-29 (PTAB, July 22, 2024) (rejecting same argument).

Second, a prior-art device need not be commercialized as PO argues (POR, 35, 42, 44), to support expectation of success. *Trustees of Columbia Univ. in City of New York v. Illumina, Inc.*, 620 F. App'x 916 (Fed. Cir. 2015) ("no requirement…closest prior art be commercialized"); *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737 (Fed. Cir. 2013).

[9] The '077 patent confirms "flexible catheters" and radiofrequency devices are not mutually exclusive. Ex.1001-USP077, 16:25-31, 18:24-46; Ex.1089-Levine-Tr., 171:14-172:18.

Third, PO is wrong a POSITA would conclude—contrary to Makower's teaching—that Figure 5H would not "properly deliver energy to target tissue to achieve the claimed therapeutic results." POR, 33-34.[10] PO argues Figure 5H is limited to ring electrodes and its hollow interior would purportedly fill with "electrolytic fluid" (mucus or blood), and not operate safely or effectively. POR, 35-42. Not so.[11]

Makower Figure 5H is not limited to ring electrodes. PO's contrary assumption based on how it "appear[s]," POR, 35-38, ignores Makower does not recite "ring electrodes" but "electrodes 216" that are "bipolar, monopolar," or use "other suitable" energy. Ex.1005-Makower, [0187]. Makower explains components of its device are well-known, and incorporates Imran, which teaches surface electrodes not facing the hallow interior.

[10] Notably, Dr. Levine respects Dr. Makower's engineering work "as high or beyond anyone that I know." Ex.1089-Levine-Tr., 45:4-47:10.

[11] PO does not contest Makower is presumed enabled for its teachings and bears the burden to show inoperability. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354-55 (Fed. Cir. 2003).

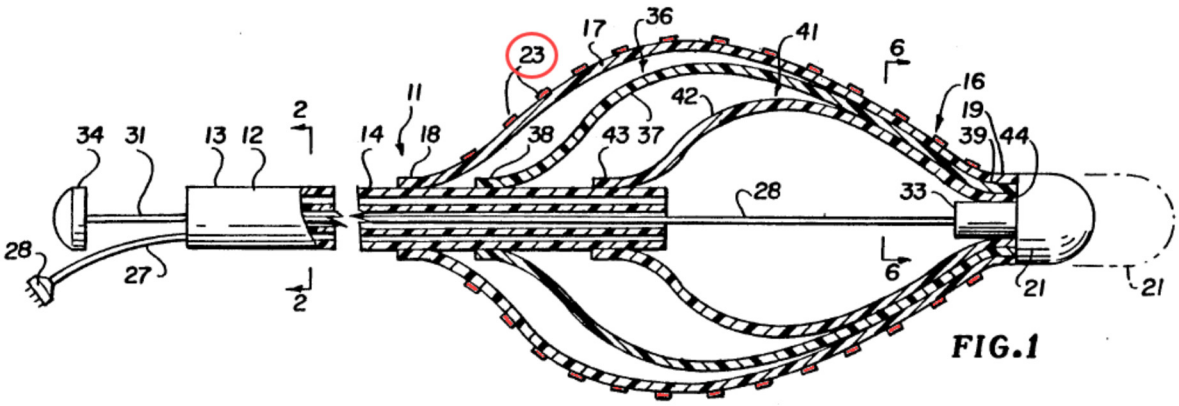


FIG.1

Ex.1068-Imran, FIG.1, 2:57-64, 3:2-7, claims 1, 62-66;[12] Ex.1005-Makower, [0164]. These teachings, not just Makower's "appearance," control. *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1300 (Fed. Cir. 2014). Contrary to PO's suggestion, a POSITA would have understood Makower teaches electrodes suitable for "causing tissue adjacent to the struts 214 to be…heated," Ex.1005-Makower, [0161]-[0161], [0187]; Ex.1089-Levine, 71:8-13, and not assume inoperable features. Ex.1098-Reply-Decl., ¶¶77-80.

Regardless, ring electrodes can ablate tissue, POR, 39-43, and such devices were well-known. Dr. Levine confirmed '077 patent Figure 5B uses a ring electrode, is covered by the claims, and is operable. Ex.1089, Levine-Tr, 195:4-196:6. A

[12] The Petition explains Figure 5H would be implemented using "well known" electrodes like Imran. Pet. 79; POR, 34 n.9. The two are connected, as Figure 5H is an electrode device. POR, 35. Ex.1098-Reply-Decl., ¶¶78-79.

POSITA implementing Makower Figure 5H using ring electrodes would have reasonably expected, as Makower teaches, they would successfully treat nasal tissue. Ex.1098-Reply-Decl., ¶¶89-91.

This treatment would not be impeded by electrolytic fluid, mucus, or blood, as PO suggests. POR 35-42. Dr. Levine confirmed mucus is present, but that during RF procedures "mucus isn't the issue," or alternatively, he would "suction it" or "irrigate the nose." Ex.1089-Levine-Tr., 82:8-83:18. During RF procedures, Dr. Levine confirmed patients are positioned so that fluids "fall to the bottom" (i.e., away from the site) by "gravity." *Id.*, 85:16-86:9. Dr. Bu-Saba agrees; in the nasal cavity/nasopharynx, Figure 5H would not fill with fluid, but with ***air***, which insulates against current transmission. Ex.1091-Bikson-Tr., 218:9-11, 221:18-222:7; Ex.1001-USP077, 18:11-14 (describing air as insulator).[13] A POSITA would have understood Makower's bipolar electrodes would deliver energy to treat

[13] Dr. Bikson's opinions, Ex.2005-Bikson, ¶¶67-76, are undermined by his apparent belief RF ablation cannot be performed if ***any*** mucus/fluid is present. Ex.1091-Bikson-Tr, 218:2-8. Nasal RF ablation was routinely performed. Ex.1089-Levine-Tr, 48:10-14, 48:20-49:13, 49:14-50:12, 54:3-10; Ex.1098-Reply-Decl., ¶89.

contacted tissue, as Makower describes, with surface ***or*** ring electrodes. Ex.1005-Makower, [0187]. Ex.1098-Reply-Decl., ¶¶81-88.

Fourth, contrary to PO's argument, POR, 42-44, the Petition sufficiently addresses reasonable expectation of success. The Petition discusses Makower's device and its effects, including its teaching that Figure 5H will therapeutically apply energy to nasal cavity/nasopharynx tissue. Pet. 67-85. PO tellingly cites no law or reason Petitioners had to preemptively rebut PO's (faulty) inoperability argument. *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 706 (Fed. Cir. 2020).[14]

Fifth, PO wrongly claims Fang's device was an "unknown quantity" and wrongly demands identity between Makower and Fang's devices to support obviousness. POR, 43-46. Fang teaches device details relevant for reasonable expectation of success: Fang's device used RF electrodes to ablate tissue, like Makower's Figure 5H. Pet., 78-84; Ex.1006-Fang, 876. More details were not necessary for a POSITA to reasonably expect—consistent with multiple references—that Makower's electrodes would function similarly. Pet., 14-15, 83-

[14] Dr. Bu-Saba considered Makower as a whole, *compare* POR, 42-43 *with* Ex.1002-Decl., ¶¶80, 151-224, and accurately explained certain (irrelevant) Figure 5H details are not specified/limited. Ex.1098-Reply-Decl., ¶¶92-94.

84; Ex.1002-Decl., ¶46 (citing references); Ex.1107-Levine-Article, 451; Section III.B.1. Ex.1098-Reply-Decl., ¶¶95-98.

Last, contrary to PO's argument, POR 45-46, Makower's device could be used in the locations Fang teaches. PO presumes (without citation) Makower's "rigid" "struts limit the tissue that can actually be treated." *Id.* Not so. Struts 214 "may be collapsible and expandible," for insertion into, e.g., the "nasal cavity." Ex.1005-Makower, [0187]. Figure 5H does not specify a particular location, Ex.2002-BuSaba-Tr., 285:20-286:6, it teaches its device can be used in multiple locations, e.g., "nasal cavity, meatus, ostium, interior of a sinus, etc." Ex.1005-Makower, [0187]. Makower, like the '077 patent, identifies no challenges of applying energy throughout the nasal cavity. *Id.*; Ex.1001-USP077, 16:20-18:46; *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (lack of implementation detail in patent supports obviousness). Ex.1098-Reply-Decl., ¶¶99-101.[15,16]

[15] Makower teaches its device contacts tissue, Ex.1005-Makower, [0043], [0187], and in view of the specification, its drawing, POR, 46, does not convey otherwise. *Source*, 753 F.3d at 1300.

[16] Fang's results are not "inconclusive." POR, 45; Section III.B.1.

A POSITA would have reasonably expected Makower's device to successfully treat rhinitis as Fang teaches. Ex.1098-Reply-Decl., ¶102.

B. A POSITA Would Have Been Motivated to Combine Makower and Fang

PO's arguments against motivation to combine Makower and Fang are legally irrelevant and unsupported. Each fails. Ex.1098-Reply-Decl., ¶103.[17]

1. A POSITA Would Have Considered Fang

PO's suggestion a POSITA would ignore or dismiss Fang's positive results—despite not contesting it is analogous art—POR, 46-49, should be rejected.

PO's argument rests on fundamental misapplication of law: Dr. Levine's opinion a POSITA would not consider Fang absent "conclusive proof." POR, 46-49; Ex.2003-Levine, ¶71. This is not required. *Acorda Therapeutics, Inc. v. Roxane Lab'ys, Inc.*, 903 F.3d 1310, 1333 (Fed. Cir. 2018) (no "requirement of '[c]onclusive

[17] PO does not explain why the order of references is legally significant. POR, 46. It is not. *Schwendimann v. Neenah, Inc.*, 82 F.4th 1371, 1384 (Fed. Cir. 2023).

proof of efficacy'") (citations omitted); *In re Longi*, 759 F.2d 887, 896 (Fed. Cir. 1985) ("absolute predictability" unnecessary) (citations omitted).[18]

Fang's teaching that nasal cavity/nasopharynx parasympathetic nerve ablation improved rhinitis outcomes was sufficient for motivation. Ex.1006-Fang, 876-877. Fang reports statistically significant improvements between a control (no ablation) and study group (with ablation), and teaches "***radiofrequency technique*** completely blocks the parasympathetic pathway of the nasal mucosa," which "reduces glandular secretion, and thus achieves the therapeutic purposes." *Id.* That Fang's authors performed additional procedures, POR, 47-48, does not diminish Fang's attribution of rhinitis results to "radiofrequency," as Fang's other procedures treat other pathologies. Ex.1006-Fang, 876; Pet., 78-82. A POSITA would credit Fang's results, not ignore them. Ex.1098-Reply-Decl., ¶¶104-106, 116-120.

PO tellingly does ***not dispute*** Fang was right about radiofrequency ablation and identifies no teaching away, skepticism, or failure. Fang's findings are consistent with multiple undisputed prior-art references, Ex.1002-Decl., ¶46

[18] Dr. Levine was not instructed regarding reasonable expectation of success legal standards. Ex.2003-Levine-Decl., ¶¶19-20; Ex.1089-Levine-Tr., 160:5-18, 166:21-169:20.

(collecting references), ***and*** the '077 patent's admission blocking relevant cells with neurotoxin treated rhinitis symptoms was known. Ex.1001-USP077, 1:65-2:52, 3:31-55; Ex.1089-Levine-Tr, 199:12-15; *Incept LLC v. Palette Life Scis., Inc.*, 77 F.4th 1366, 1372 (Fed. Cir. 2023). Ex.1098-Reply-Decl., ¶¶107-108.

PO also wrongly faults Fang for not reciting sufficient study details and efficacy criteria. POR, 46-49. This is inconsistent with PO's priority argument that passing reference to non-reversible poration with ***no*** discussion of any study detail or outcome teaches treatment. *See* Section II; Ex.1089-Levine-Tr., 184:21-186:7, 172:9-173:17. But regardless, the claims require no particular level of efficacy, Ex.1001-USP077, claims; Ex.1089-Levine-Tr, 184:21-185:20, and clinical practice and studies have different standards. Ex.1089-Levine-Tr, 101:17-103:15. In any event, Fang cites efficacy criteria (Ex.1006-Fang, 877 n.1 (citing Ex.1113)), that are consistent with criteria Dr. Levine used pre-2006. Ex.1089-Levine-Tr, 96:8-100:14. Ex.1098-Reply-Decl., ¶¶109-115.

Nor did Fang need to be peer reviewed or cited a certain number of times for motivation. POR, 49. A reference "must be viewed in the context of what was generally known" and for all it teaches. *In re Taylor Made Golf Co., Inc.*, 589 F. App'x 967, 971 (Fed. Cir. 2014) (citation omitted); *CRFD*, 876 F.3d at 1349. Fang was cited at least seven times, Ex.1103 (not once, POR, 49), and Hytönen (which

PO referenced but did not submit, Ex.2008), cited Fang's results positively and as motivating further study. Ex.1112-Hytönen, 1261, 1264.[19] Ex.1098-Reply-Decl., ¶¶120-123.

2. A POSITA Would Have Considered Makower

As Section III.A discusses, Makower is not limited to flexible catheters, POR 49-54; it specifically teaches and claims "working devices." Ex.1098-Reply-Decl., ¶¶124-125.

3. A POSITA Would Have Been Motivated to Combine Makower and Fang

PO's arguments against motivation to use Makower's ablation device to achieve Fang's results, POR, 54-64, fail.

First, Petitioners did not use hindsight. POR 54-63. PO does not contest Makower is analogous art. *Id.*, 64. A POSITA considering nasal disorder treatments would look to Makower's devices, Ex.1005-Makower, [0001], [0132]; Pet., 78-80, which the Examiner independently confirmed during family prosecution. Ex.1022-

[19] PO also cited Fang during prosecution of U.S. Appl. No. 18/177,875. Makower has been cited over 700 times. Ex.1115.

FH675, 122 (Makower "closest prior art").[20] As Section III.A discusses, whether Figure 5H was "proven" or widely known, POR, 55, is irrelevant. *See Netflix, Inc. v. DivX, LLC*, 80 F.4th 1352, 1358 (Fed. Cir. 2023). Ex.1098-Reply-Decl., ¶¶126-130.

Second, Makower's device is not limited to removing obstructions. POR, 55-56, 58-61.[21] "Tissue shrinking" is, in Figure 5H, achieved through ablation. As Makower explains, "further aspects [and] details" of its devices were "understood" by POSITAs, Ex.1005-Makower, [0046], and one motivated to perform "therapeutic procedures" in the "nasal cavity" or "nasopharynx" would have looked to Fang to explain further effects of ablation. Pet., 78-82; Ex.1098-Reply-Decl., ¶¶131-135.

[20] Petitioners' citation to this history was proper. POR, 61-63. *Google LLC v. Valtrus Innovations Ltd.*, IPR2022-01406, Paper 40, 69-70 (P.T.A.B. Apr. 3, 2024) ("prosecution history" supported obviousness)

[21] Obstruction and rhinitis treatment are also not mutually exclusive; rhinitis symptoms include obstruction (Ex.1089-Levine-Tr, 101:1-8, 101:17-102:10) and Dr. Levine's lasers treated both (Ex.1107-Levine-Article, 453). *See also* Ex.1107, 453 (mucus secretion reduction incident to turbinate reduction).

Third, as Section III.A discusses, PO has not shown Makower Figure 5H is inoperable. POR 56; Ex.1098-Reply-Decl., ¶135.

Fourth, Makower and Fang do not have "diametrically opposed objectives and treatment effects" or "fundamental differences." POR, 56-57. Both disclose treating nasal conditions by applying energy to tissue. Ex.1006-Fang, 876-877; Ex.1005-Makower, [0001], [0043], [0132], [0164], [0187]. Makower describes problems with ***undesired*** trauma from rigid instrumentation. *E.g.*, Ex.1005-Makower, [0161]. Fang's non-ablative resection techniques, however, are ***medically desirable*** for addressing conditions other than rhinitis. Ex.1006-Fang, 876-77; *see* Ex.1089-Levine-Tr, 89:12-91:8, 91:19-92:7. Far from opposing or teaching away from such procedures, Makower discusses performing them. *E.g.*, Ex.1005-Makower, [0043] (e.g., cutting, debulking, remodeling, scraping, and removing). As Dr. Levine admitted, it is "not unusual to combine several procedures." Ex.1089-Levine-Tr, 89:12-91:8. Ex.1098-Reply-Decl., ¶¶136-138.

Fifth, a POSITA would not have to use Figure 5H for undesirable ablation. POR, 58-60. A POSITA would adjust the device's position and/or radiofrequency parameters, e.g., by selectively activating electrodes contacting target nasal-wall tissue. Ex.1005-Makower, [0043], [0161], [0164], [0187]. And Dr. Levine has

ablated the septum, Ex.1089-Levine-Tr, 49:14-50:12, contradicting PO's suggestion that would be improper. Ex.1098-Reply-Decl., ¶¶139-143.

Last, obviousness of Makower Figure 5A, POR, 60-61, does not defeat obviousness of Figure 5H. *See Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) (unnecessary to show suitable combination best option).

Accordingly, a POSITA would have been motivated to apply Fang's method with Makower's device to treat rhinitis. Ex.1098-Reply-Decl., ¶144.

C. Claim 4: Stern Teaches Multiple Pairs of Bipolar Electrodes[22]

Claim 4 requires "***multiple pairs of bipolar electrodes***." Pet., 50-56. PO does not dispute Stern teaches bipolar electrodes or multiple pairs, motivation, or expectation of success. Under the claim's plain and ordinary meaning, Stern therefore teaches this claim.

PO's contention—based on implicit claim construction—that Stern does not disclose claim 4 because it allegedly only discloses activating its electrode pairs "sequentially," (i.e., one pair at a time), POR, 65-68, is unsupported and wrong.

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

[22] PO advances no separate argument for claims 2-3, 5-6, 8, or 11.

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.

PO's proposal is also inconsistent with the '077 patent specification and would exclude a preferred embodiment, which is "rarely, if ever, correct." *Broadcom Corp. v. Netflix, Inc.*, 2023 WL 4115909, at *1 (Fed. Cir. June 22, 2023). The '077 patent discloses activating "multiple pairs of electrodes" (as in claim 4) ***sequentially***. Ex.1001-USP'077, 18:42-46 ("***multiple pairs of electrodes***…may be activated…***in a sequential manner***…."). PO's position would improperly exclude this embodiment from the claims.[23] Absent PO's improper additional limitation, Stern indisputably teaches claim 4. Ex.1098-Reply-Decl., ¶159; Ex.1099-Martin-Decl., ¶¶15-22.

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

[23] "Multiple pairs of bipolar electrodes" was not addressed during prosecution. *See* Pet., 17.

is similar to the '077 patent's description. Ex.1001-USP077, 18:42-46. Ex.1098-Reply-Decl., ¶160; Ex.1099-Martin-Decl., ¶¶2325.

PO wrongly asserts "Petitioners' cited disclosure…only [shows] a single pair of electrodes" and that Stern is limited to closing two switches. POR, 67-68. Stern in fact includes multiple activation examples, including both one-at-a-time ***and*** activating all pairs in the array simultaneously. Pet., 51. Stern must be considered as a whole, including this example. *Sony Interactive Entertainment LLC v. Intellectual Pixals Ltd*., 2023 WL 6773879, *4 (Fed. Cir. Oct. 13, 2023) (focus on "more detailed example" over additional example erroneous). Ex.1098-Reply-Decl., ¶160; Ex.1099-Martin-Decl., ¶¶26-29.[24]

D. Claim 7: Makower Teaches Delivering Energy Laterally

PO did not present and thus waived response regarding Claim 7, Pet., 88-90, POR 65-69, and cannot rely on argument solely in supporting declarations. 37 C.F.R. §42.6(a)(3).

[24] PO faults Dr. Martin's analysis of claims 1-2, POR, 68-69, but raises no dispute for claim 4 regarding their limitations. Dr. Martin considered the device taught by Makower, Fang, and Edwards-535. Ex.1002-Decl., ¶¶215-224; Ex.1007-Decl., ¶¶46-49, 55-56, 78-108. Ex.1099-Martin-Decl., ¶¶46-48.

Regardless, PO's declarants' Claim 7 opinions are wrong. Makower Figure 5H concentrates energy laterally in tissue when current travels between bipolar electrodes, Pet., 89, just like '077 patent Figure 5A.[25] Ex.1098-Reply-Decl., ¶¶145-146.

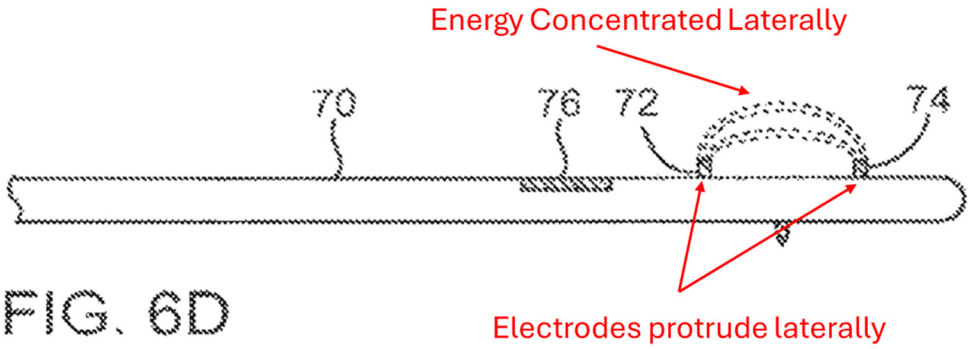
As Section III.A discusses, Makower is operable. Ex.2003-Levine, ¶¶102-111; Ex.2005-Bikson, ¶¶77-88. If Makower required ring electrodes (it does not), they would concentrate energy ***at least*** laterally into tissue. Ex.1089-Levine-Tr. 194:5-7 ('077 patent Fig. 5B ring electrode delivers energy uniformly ***and*** laterally), 195:4-196:6. If Figure 5H were implemented with Imran's surface bipolar electrodes, it would do the same. Ex.1005-Makower, [0164]; Ex.1068-Imran, FIG.1, claim 1, 62-66, 2:57-64, 3:2-7; Pet., 89-90. Ex.1098-Reply-Decl., ¶147.

The suggestion Makower required additional "insulation," Ex.2003-Levine, ¶109; Ex.2005-Bikson, ¶86, is also wrong. Claim 7 does not require insulation. Regardless, a POSITA would have expected Makower's surface, ring or other electrodes would deliver energy laterally because air would insulate any portion not

[25] The POR does not address PO's infringement allegations, which undermine PO's position. Pet., 90.

contacting tissue. Ex.1091-Bikson-Tr., 218:9-11, 221:18-222:7; Ex.1001-USP077, 18:11-14; 23:65-24:3.

Indeed, directly contradicting PO's declarants' arguments Imran's protruding electrodes would not deliver energy laterally (Ex.2003-Levine, ¶109; Ex.2005-Bikson, ¶86; Ex.1089-Levine-Tr., 187:7-188:5), '077 patent Figure 6D depicts electrodes that "extend laterally" ***and*** create a lateral "energy field" akin to Figure 5A, and claim 10 of the related '011 patent claims energy transmission elements that ***both*** extend ***and*** deliver energy laterally. Ex.1001-USP077, Fig. 6D, 17:32-40; Ex.1023-USP011, claim 1; *see* Ex.1089-Levine-Tr, 190:6-9 (patent's energy fields accurate).



Ex.1001-USP077, Fig. 6D. Ex.1098-Reply-Decl., ¶¶148-153.

IV. PO's POSITA Disputes Are Irrelevant But Wrong

PO's POSITA-definition dispute (POR, 18-19) does not affect a specific contested issue but is solely a tactic to wrongly disparage Petitioners' experts. The Board should reject this gambit.[26]

A POSITA indisputably had an M.D. or engineering degree and three years' experience. Pet., 17-18; POR, 18-19. PO argues design or development (not clinical use or testing) experience is required; and nasal (not general) medical device experience is required. POR, 18-19.[27] Each is irrelevant and wrong. Ex.1098-Reply-Decl., ¶¶12-17.

A. Dr. Bu-Saba is a POSITA For All Contested Issues

Dr. Bu-Saba's testimony is supported by his extensive clinical expertise. PO only raises a specific skill level issue regarding operation of Makower Figure 5H.

[26] PO waived any argument the POSITA definition affects written description/priority.

[27] Dr. Levine's different definition, Ex.2003-Levine, ¶38, is incorrect for the same reasons.

POR, 19, n.4, 35-46.[28] PO's (incorrect) argument, however, turns on anatomy and clinical implementation (presence of mucus/blood), not device design or development.[29] Dr. Bu-Saba—a Board-certified otolaryngologist with extensive RF device experience—had the skill to explain PO inaccurately describes where mucus is.[30] Dr. Levine agrees Dr. Bu-Saba is a nasal cavity/nasopharynx anatomy expert, Ex.1089-Levine-Tr., 170:21-171:2, and Dr. Levine also advises Aerin on adverse event responses as a ***clinician***. *Id.*, 18:14-22, 19:15-20:3. Dr. Bu-Saba's experience supports his opinions and PO's manufactured dispute is irrelevant. *Incyte Corp. v.*

[28] PO vaguely references Dr. Bu-Saba's experience for claim 4, POR, 68-69, but identifies no specific issue. Regardless, Dr. Bu-Saba's clinical experience with bipolar electrodes was sufficient. Ex.1098-Reply-Decl., ¶21.

[29] Tellingly, though Dr. Levine has ***no*** electrode design/development experience (and consulted Dr. Bikson), PO offers his testimony regarding bipolar electrode operability. Ex.1089-Levine-Tr., 157:12-159:5, 192:2-13.

[30] Disparagement aside, PO and Dr. Levine extensively cite Dr. Bu-Saba.

Concert Pharms., Inc., PGR2021-00006, Paper 68, 8-9 (P.T.A.B. May 11, 2022) (crediting expert opinions within areas of expertise). Ex.1098-Reply-Decl., ¶21.[31]

Regardless, PO's POSITA definition is wrong[32]:

- The Challenged Claims' purported solution relates to "supplying radiofrequency energy" with generic (not specialized) components. POR, 18 (citing Ex.1001-USP077, 27:43-28:47); Ex.1001-USP077, claim 1.
- Clinicians used RF devices safely and effectively in the nose, including using "factory settings." Ex.1001-USP077, 16:42-49, 18:5-10, 18:24-36, 19:25-32.;

[31] The Board can, however, consider Dr. Levine's bias. Dr. Levine is ***currently*** consulting for (and received over $45,000 from) RPI Aerin and has significant relationships with Aerin principals. Ex.1089-Levine-Tr., 18:1-35:21, 36:11-44:22, 151:10-156:21; Ex.1090. Though PO critiques Dr. Bu-Saba for not previously testifying in patent cases, POR, 19, n.4, the Board rejected Dr. Levine's positions in his two cases. Ex.1105, Ex.1106.

[32] POSITA factors (which PO did not apply) include prior-art problems and solutions, rapidity of innovation, technology sophistication, and educational level in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 1201 (Fed. Cir.1986).

Ex.1006-Fang, 876-77. Dr. Levine performed nasal RF ablation in the 1990s without electrode design or development experience. Ex.1089-Levine-Tr., 54:3-10, 157:12-159:5.

- Clinicians learned safe, effective RF device operation through use, testing, instructions, education, and data. Ex.1089-Levine-Tr., 62:7-63:11, 74:9-75:11.
- Devices were unsophisticated: artisans chose between device types, selected settings and dosage, provided feedback, and used devices off-label "based on…experience as a clinician." Ex.1089-Levine-Tr., 13:10-16, 72:16-75:11, 122:19-124:3.
- Physicians "***must*** be familiar" with devices', e.g., "safety, energy dosage…and instrumentation." Ex.1107-Levine-Article, 451; Ex.1091-Bikson-Tr, 89:2-94:8. "Clincian[s]" need not have developed devices to "see another place [they] could be used." Ex.1089-Levine-Tr, 124:19-125:13.

Thus, ordinary skill included an M.D. or engineer with three years' use and/or testing experience. Excluding clinical use/testing from claims involving treatment is illogical. Ex.1098-Reply-Decl., ¶¶18-34.

B. Dr. Martin is a POSITA For All Contested Issues

Dr. Martin's testimony about ***what*** electrodes Stern discloses was supported by extensive RF device engineering experience, and, as ***where*** they are used is not

disputed, his opinion did not require "nasal" device experience. POR, 19, n.4; Ex.1007-Decl., ¶¶55-56, 78-108.[33] Dr. Bikson has ***no*** nasal device experience, and testified his claim 4 opinions would not change under Petitioners' definition. *E.g.*, POR, 35-46; Ex.2005-Bikson, ¶¶38-44; Ex.1091-Bikson-Tr, 63:17-64:9, 80:4-81:1, 25:10-26:13. Nasal device experience is thus irrelevant.

PO's definition is also wrong:

- The '077 patent discusses "delivering neurotoxins" in "***any***…target region," and identifies no purportedly challenging nasal anatomy. Ex.1001-USP077, 2:23-67, 5:3-17, 4:67-5:1, 8:10-34, 17:12-17, 20:21-29, 21:14-36, claim 1.[34]
- Prior-art problems and solutions were addressed with "factory setting" generic RF devices (*e.g.*, Ex.1006-Fang, 876-77), and devices for multiple locations (*e.g.*, Ex.1005-Makower, [0043] (ear, nose, throat); Ex.1009-Stern, 1:15-23). Stern (uterine ablation) is indisputably analogous art. Dr. Levine admitted his prior-art

[33] Dr. Bu-Saba indisputably has nasal medical device experience.

[34] Dr. Bu-Saba did not testify POSITAs need nasopharynx experience, POR, 18-19, but that nasopharynx-specific questions would be directed to someone with knowledge. Ex-2002-Bu-Saba-Tr., 125:15-127:11.

laser device was informed by experience in other body areas. Ex.1089-Levine-Tr, 126:3-9; Ex.1107-Levine-Article, 451.

- PO represented non-nasal references were material during prosecution. Ex.1024-USP077FH, 101-114 (citing Ex.1110, Ex.1111).
- The named inventors are engineers, and PO offers no evidence either had prior nasal experience. *See* Ex.1108-Deem; Ex.1109-Gifford. The '077 patent cites ***others'*** nasal-anatomy work. Ex.1001-USP077, 3:31-55.
- Generic device elements claimed are not sophisticated, contingent, or site-dependent. The '077 patent recites few implementation and no performance details.
- Dr. Levine confirmed biomedical engineers "take in information from clinicians" to create devices. Ex.1089-Levine-Tr., 202:6-203:2. Engineers had extensive literature regarding nasal anatomy/pathology available. *See* Pet., 8-15.

These factors support Petitioners' definition. Nasal anatomy and physiology "complex[ity]" POR, 18, is inconsequential. The '077 patent does not turn on such complexities; it addresses ***any*** "target cells." Ex.1001-USP077, 4:31-55, 4:67-5:1. Under Petitioner's definition, a POSITA would have the skill—with relevant literature and/or clinician consultation—to apply general principles to a nasal device. *See Hologic, Inc. v. Minerva Surgical, Inc.*, 764 Fed. Appx. 873, 879 (Fed. Cir. 2019)

(non-precedential) (POSITA had general (not uterine-ablation-specific) electrosurgical device experience where patent applied to multiple cavities); *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360, 1373 (Fed. Cir. 2010) (allowing testimony from engineer with polymer experience without air-fryer-specific experience); *Medtronic, Inc. v. Teleflex Life Sciences Limited*, IPR2020-01343, Paper 85,17-18 (P.T.A.B. Feb. 23, 2022). Ex.1098-Reply-Decl., ¶¶35-46; Ex.1099-Martin-Decl., ¶¶30-45.[35]

The Board should adopt Petitioners' POSITA definition.

V. CONCLUSION

The Challenged Claims are unpatentable and should be canceled.

Respectfully submitted,

By: /David L. Cavanaugh/
David Cavanaugh
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[35] Aerin argues POSITAs had general (non-nasal-specific) device experience in similar IPRs. *Neurent Medical Inc. v. Aerin Medical Inc.*, IPR2024-00277, Paper 24, 8. Drs. Levine and Bikson elsewhere concluded clinician POSITAs need not have designed or developed devices and engineer POSITAs need not have particular anatomy experience. Ex.1104, ¶¶17-23, Ex.1116, ¶23.

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing, Petitioners' Reply, contains 5,598 words as measured by the word processing software used to prepare the document, in compliance with 37 C.F.R.§42.24(d), excluding the parts of the Petition exempted from the word count by 37 C.F.R. §42.24(a)(1).

/Gilbert Smolenski/
Gilbert Smolenski
Registration No. 78,549

CERTIFICATE OF SERVICE

I hereby certify that, on January 17, 2025, I caused a true and correct copy of the following materials:

- Petitioners' Reply
- Petitioners' Table of Exhibits
- Exhibits 1089-1116
- Certificate of Compliance Regarding Word Count

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Petitioners' Table of Exhibits

No.	Description
1001.	U.S. Patent No. 11,679,077
1002.	Declaration of Dr. Nicolas Bu-Saba from IPR2024-00281
1003.	U.S. Patent No 10,307,200 to Saadat
1004.	U.S. Patent Pub. No. 2008/0021369 to Deem
1005.	U.S. Patent Pub. No. 2005/0240147 to Makower
1006.	Fang (Translation)
1007.	Declaration of Dr. Gregory Martin from IPR2024-00281
1008.	U.S. Patent No. 6,517,535 to Edwards
1009.	U.S. Patent No. 5,562,720 to Stern
1010.	U.S. Provisional Appl. No. 60/702,077
1011.	U.S. Provisional Appl. No. 60/747,771
1012.	U.S. Patent No. 7,608,275
1013.	U.S. Patent No. 8,133,497
1014.	U.S. Patent No. 8,338,164
1015.	U.S. Patent No. 8,961,391
1016.	U.S. Patent No. 9,498,283
1017.	U.S. Patent No. 10,022,529
1018.	Prosecution history for U.S. Patent No. 10,022,529
1019.	U.S. Patent No. 10,729,897
1020.	Prosecution history for U.S. Patent No. 10,729,897
1021.	U.S. Patent No. 10,610,675
1022.	Prosecution History for U.S. Patent No. 10,610,675
1023.	U.S. Patent No. 10,894,011
1024.	Prosecution History for U.S. Patent No. 10,894,011
1025.	Prosecution History for U.S. Patent No. 11,679,077
1026.	U.S. Patent No. 7,655,243
1027.	Prosecution History for U.S. Patent No. 7,655,243
1028.	Prosecution History for U.S. Patent No. 8,636,684
1029.	U.S. Patent No. 8,105,817
1030.	U.S. Patent No. 8,636,684
1031.	U.S. Patent Pub. No. 2014/0114233
1032.	U.S. Patent No. 9,700,707
1033.	U.S. Patent No. 10,052,465
1034.	File History for U.S. Patent No. 10,335,221 assigned to Aerin

No.	Description
1035.	*Aerin Medical Inc. v. Neurent Medical Inc.*, 1:23-cv-00756-GBW, Amended Complaint for Patent Infringement, Dkt. 17 (October 16, 2023) ("Amended Complaint")
1036.	Reserved
1037.	Reserved
1038.	Exhibit Z to Amended Complaint – Foundry's Infringement Allegations for U.S. Patent No. 11,679,077
1039.	Docket Navigator District of Delaware Statistics as of January 18, 2024
1040.	U.S. Patent No. 8,939,970 to Stone
1041.	Stedman's Medical Dictionary (27th ed. 2001)
1042.	PDR Medical Dictionary (2nd ed. 2000)
1043.	Kong Yonggang, Low-temperature plasma ablation of inferior turbinate for the treatment of perennial allergic rhinitis, 19(5) J Clin. Otorhinolaryngol 214 (Mar. 2005) (Translation) ("Kong")
1044.	Chen Shi-qiang et al., Preliminary study on radiofrequency thermocoagulation of the posterior inferior nerve, anterior ethmoidal nerve, and inferior turbinate under nasal endoscopy for the treatment of perennial allergic rhinitis, 11(3) China Journal of Endoscopy 239 (Mar. 2005) (Translation) ("Chen")
1045.	Liang Jianping, *Radiofrequency treatment of ethmoidal nerve with allergic rhinitis under nasal endoscopy*, 13(8) J Clin. Otorhinolaryngol 341 (Aug. 1999) (Translation) ("Liang")
1046.	U.S. Patent No. 6,669,689 to Lehmann
1047.	U.S. Patent No. 6,685,648 to Flaherty
1048.	Stedman's Medical Dictionary (26th ed. 1995)
1049.	Webster's Third New International Dictionary (2002)
1050.	S. Waxman, *Correlative Neuroanatomy* (23rd ed. 1996)
1051.	Robert E. Windsor and Scott Jahnke, Sphenopalatine Ganglion Blockage: A Review and Proposed Modification of the Transnasal Technique, Pain Physician 7:283-286 (2004)
1052.	Ralph Fenton, Current Evaluation of Nasopharyngeal Defense Mechanisms (1955)
1053.	U.S. Patent No. 6,517,534 to McGovern

No.	Description
1054.	M.M. L. Arora, *Cryodestruction of Vidian Nerve Branches*, 32:3 Indian J. Otolaryngology 80 (Sept. 1980)
1055.	Reserved
1056.	Maureen McDaniel Sackenhein, *Radio Frequency Ablation*, JDMS 19:88-92 (March/April 2003)
1057.	U.S. Patent No. 5,766,605 to Sanders
1058.	U.S. Patent No. 874,178 to De Forest
1059.	U.S. Patent Pub. No. 2005/0171574 to Rubinsky
1060.	U.S. Patent No. 3,538,919 to Meyer
1061.	U.S. Patent No. 3,117,571 to Fry
1062.	International Pub. No. 2016/183337 to Townley
1063.	U.S. Patent No. 4,411,266 to Cosman
1064.	Andrew Lane, *Nasal anatomy and physiology*, Facial Plast. Surg. Clin. N. Am. 12:387-395 (2004)
1065.	Gray's Anatomy (2003)
1066.	U.S. Patent No. 6,273,886 to Edwards ("Edwards '886")
1067.	Joseph D. Bronzino, *Medical Devices and Systems*, The Biomedical Engineering Handbook (3rd ed. 2006)
1068.	U.S. Patent No. 5,255,679 to Imran
1069.	Dhanalakshmi Koyyalagunta and Danesh Mazloomdoost, *Radiofrequency and cryoablation for cancer pain*, Techniques in Regional Anesthesia and Pain Management 14:3-9 (2010)
1070.	Declaration of June Munford from IPR2024-00281
1071.	Translator Declarations for Chen
1072.	Translator Declarations for Liang
1073.	Translator Declarations for Fang
1074.	Translator Declarations for Kong
1075.	Munford Appendices for Chen
1076.	Munford Appendices for Liang
1077.	Munford Appendices for Fang
1078.	Munford Appendices for Kong
1079.	Munford Appendices for Shanghai
1080.	U.S. Patent No. 5,891,134 to Goble
1081.	U.S. Patent No. 5,575,788 to Baker
1082.	International Pub. No. 99/30655 to Hovda

No.	Description
1083.	April 1, 2024 Declaration of Dr. Nicolas Bu-Saba
1084.	April 2, 2024 Declaration of Dr. Gregory Martin
1085.	April 2, 2024 Declaration of June Munford
1086.	*Aerin Medical Inc. v. Neurent Medical Inc.*, 1:23-cv-00756-GBW, Scheduling Order, Dkt. 42 (March 26, 2024).
1087.	Declaration of Gregory H. Lantier
1088.	Declaration of Joshua L. Stern
1089.	Deposition Transcript of Dr. Howard Levine
1090.	Levine Deposition Exhibit 1
1091.	Deposition Transcript of Dr. Marom Bikson
1092.	Bikson Deposition Exhibit A
1093.	Bikson Deposition Exhibit B
1094.	Bikson Deposition Exhibit C
1095.	Bikson Deposition Exhibit D
1096.	Bikson Deposition Exhibit E
1097.	Bikson Deposition Exhibit F
1098.	Reply Declaration of Dr. Nicolas Bu-Saba
1099.	Reply Declaration of Dr. Gregory Martin
1100.	Errata from the October 17, 2024 Deposition of Dr. Nicolas Bu-Saba
1101.	Errata from the September 24, 2024 Deposition of Dr. Gregory Martin
1102.	Errata from the September 25, 2024 Deposition of Dr. Gregory Martin
1103.	Google Citations for Fang (Ex.1005)
1104.	Excerpts from the Declaration of Dr. Howard Levine filed in IPR2017-00498
1105.	Final Written Decision in IPR2017-00498
1106.	Institution Decision in IPR2018-00268
1107.	Howard L. Levine, Lasers in Endonasal Surgery, Ottolaryngologic Clinics of N. Am. 30:3, 451-455 (June 1997)
1108.	Pitchbook Profile of Mark Deem
1109.	Resume of Hanson Gifford
1110.	U.S. Patent No. 6,658,279
1111.	U.S. Patent No. 7,628,789

No.	Description
1112.	Hytönen et al., Radiofrequency Thermal Ablation for Patients with Nasal Symptoms: A Systematic Review of Effectiveness and Complications, 266 EUR. ARCH. OTORHINOLARYNGOL. (2009) ("Hytönen")
1113.	Haikou, Diagnostic Criteria and Efficacy Evaluation Criteria of Allergic Rhinitis, 33:3 Chin. J. Otorhinolaryngol 134 (June 1998)
1114.	Translation Declaration for Haikou
1115.	Derwent Innovation Record for Makower (Ex.1005)
1116.	Excerpts from the Declaration of Dr. Marom Bikson filed in IPR2022-00511