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. IPR2024-00279

U.S. Patent No. 10,610,675

PETITIONERS' OPPOSITION TO PATENT OWNER'S MOTION TO EXCLUDE

TABLE OF CONTENTS

I. Legal Standard 1
A. Motions to Exclude 1
B. Reply Evidence 2
II. Background 2
III. Argument 5

TABLE OF AUTHORITIES

CASES

Page(s)

Apple Inc. v. Andrea Elecs. Corp., 949 F.3d 697 (Fed. Cir. 2020) 2, 6

Belden Inc. v. Berk-Tek LLC, 805 F.3d 1064 (Fed. Cir. 2015).....2

Dexcom, Inc. v. Waveform Techs., Inc.,
No. IPR2016-01679, Paper 10 (P.T.A.B. February 18, 2018).....7

Dexcom, Inc. v. Waveform Techs., Inc.,
No. IPR2016-01679, Paper 53 (P.T.A.B. February 18, 2018).....7

Intuitive Surgical, Inc. v. P Tech, LLC, IPR2020-00650, Paper 33 (P.T.A.B. September 8, 2021).....2

Provisur Techs., Inc. v. Weber, Inc., 50 F.4th 117 (Fed. Cir. 2022).....2, 7

Sony Interactive Entm't LLC v. Intellectual Pixels Ltd.,
IPR2021-00237, Paper 50 (P.T.A.B. June 5, 2024).....5

STATUTES AND REGULATIONS

37 C.F.R. § 42.20(c).....2

37 C.F.R. § 42.62(a)).....2

OTHER AUTHORITIES

Trial Practice Guide (2012).....7

Trial Practice Guide August 2018 Update 7

2019 Consolidated Trial Practice Guide 1-2, 5, 7

Patent Owner's ("PO") procedurally improper and substantively meritless Motion (Paper 36) should be denied. As the November 2019 Consolidated Trial Practice Guide ("TPG") makes clear, a motion to exclude should not "address arguments or evidence that a party believes exceed the proper scope of reply." TPG, 73. PO's Motion does exactly that, and it should be denied for that reason alone. Regardless, the single reply exhibit and corresponding testimony PO moves to exclude (which PO does not contest is admissible) was properly offered in support of Petitioners' response to a (meritless) argument PO raised for the first time in the Patent Owner's Response ("POR"). Petitioners' reply evidence was proper, and the Motion should be denied on that basis as well.

I. Legal Standard

A. Motions to Exclude

The November 2019 Consolidated Trial Practice Guide ("TPG") sets forth the type of relief that can be requested in a motion to exclude:

> A motion to exclude must explain why the evidence is not admissible (e.g., relevance or hearsay) but may not be used to challenge the sufficiency of the evidence to prove a particular fact. A motion to exclude is not a vehicle for addressing the weight to be given evidence—arguments regarding weight should appear only in the merits documents. Nor should a motion to exclude address arguments or evidence that a party believes exceeds the proper scope of reply or sur-reply.

TPG, 79. "Patent Owner, as the moving party, bears the burden of establishing that it is entitled to the requested relief." *Intuitive Surgical, Inc. v. P Tech, LLC*, IPR2020-00650, Paper 33, 40 (P.T.A.B. September 8, 2021) (citing 37 C.F.R. §§42.20(c), 42.62(a)).

B. Reply Evidence

While a Petition for *Inter Partes* Review must set forth a *prima facia* case of obviousness, a Petitioner may offer new evidence as rebuttal in a Reply. TPG, 73 ("A party also may submit rebuttal evidence in support of its reply." (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1077–78 (Fed. Cir. 2015)). Such reply evidence is appropriate unless it raises "a new theory of unpatentability." *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 706-707 (Fed. Cir. 2020); *see also, e.g.*, *Provisur Techs., Inc. v. Weber, Inc.*, 50 F.4th 117, 122 (Fed. Cir. 2022).

II. Background

The Challenged Claims are directed to treating a nasal condition to reduce mucus secretion in the nasopharyngeal passage with radiofrequency ("RF") electrodes. *See, e.g.*, Ex.1001-USP011, claim 1. The Petition explains that, among other Grounds for unpatentability, each of the Challenged Claims would have been obvious over the combination of Fang (Ex.1006). The Petition cites, more specifically, Fang's teaching of clinical results that application of radiofrequency

energy to the nose "block[s] the posterior parasympathetic fibers of the sphenopalatine nerve" and "parasympathetic pathway of the nasal mucosa" which "reduces glandular secretion" and reduces rhinitis symptoms. *See, e.g.*, Pet., 29, 64-77 (citing Ex.1006-Fang, 876-877). And Petitioners' expert Dr. Bu-Saba explains that Fang's teaching is consistent with multiple other prior art references. Ex.1002-Decl., ¶¶172, 174, 177 (citing, e.g., Ex.1044-Chen, Ex.1054-Aurora, Ex.1003-Saadat). There is no dispute that the Petition argues that a POSITA would have been motivated to use the nasal radiofrequency ablation device taught by Makower (Ex.1005) in view of the teaching of Fang, including its teaching regarding "known outcomes of applying RF therapy" to treat rhinitis with a reasonable expectation of success of reaching "the predictable result taught in Fang." Pet., 71-77.

In the POR, PO and its declarants did not dispute Fang discloses on its face statistically significant data that RF energy treated rhinitis symptoms. *See* Ex.1006-Fang, 876-877; *see also generally* POR; Ex.2003-Levine; Ex.2005-Bikson. Instead, PO and one of its declarants—Dr. Levine—argued that "Fang's Study is Inconclusive" because, among other reasons, "Fang does not specifically disclose the diagnostic criteria it used for perennial rhinitis, but refers the reader to citation [1]." POR, 45-48; Ex.2003-Levine, ¶¶63, 66-67, 74-75. Despite acknowledging that Fang citation [1] is a Chinese Journal of Otolaryngology document cited by

Fang for diagnostic criteria and making arguments about Fang's criteria, PO did not submit citation [1] with the POR or provide it to its declarant as material for review (Ex.2003, ¶22).

In Reply, Petitioners explained, among other things, that PO's position regarding Fang is contradicted by Fang's plain teaching and by the content of Fang citation [1], which PO abstractly referenced but did not submit. Reply, 18-19. With reference to the actual content of Fang citation [1] (Ex.1113), Petitioners directly rebutted PO's new allegations that Fang did not identify reliable diagnostic criteria or that a POSITA would have purportedly found it "inconclusive." *Id.* Petitioners demonstrated that PO's arguments were contrary to fact with Exhibit 1113 itself, testimony from PO's own declarant regarding diagnostic criteria a POSITA would have considered that are consistent with Exhibit 1113, and the confirmatory opinions of Petitioners' expert Dr. Bu-Saba. *See* Reply, 18-19 (citing Ex.1089-Levine-Tr, 101:17-103:15, Ex.1113); Ex.1098-Reply-Decl., ¶¶109-115. This evidence directly responds to PO's arguments. The Reply does not rely on Exhibit 1113 or Dr. Bu-Saba's cited declaration paragraphs to identify any new basis for invalidity.

PO subsequently deposed Dr. Bu-Saba but did not cross-examine him regarding his opinion that Exhibit 1113's diagnostic and efficacy criteria are reliable. *See generally* Ex.2011-Bu-Saba-Tr.-2d. Nor did PO address Exhibit 1113 or the

consistency between its own declarant's testimony regarding diagnostic criteria and Exhibit 1113 substantively in its Sur-Reply. *See* Sur-Reply, 21-22. In fact, PO has not disputed that Exhibit 1113 describes acceptable rhinitis diagnostic and efficacy criteria, which directly refutes its contrary suggestion in its POR.

III. Argument

The Motion should be denied for either or both of two independent reasons.

First, PO's Motion should be denied because it exceeds the scope of a proper motion to exclude. TPG, 79 ("A motion to exclude must explain ***why the evidence is not admissible (e.g., relevance or hearsay)*** but may not be used to challenge the sufficiency of the evidence to prove a particular fact. . . . ***Nor should a motion to exclude address*** arguments or evidence that a party believes exceeds ***the proper scope of reply or sur-reply***." (emphasis added)). PO does not dispute that Exhibit 1113 is relevant to its POR argument and does not argue it is inadmissible. *See* POR, 47-48 (raising and discussing purported relevance of Fang citation [1])). This requires denial. *See Sony Interactive Entm't LLC v. Intellectual Pixels Ltd.*, IPR2021-00237, Paper 50, 90 (P.T.A.B. June 5, 2024) (denying motion to exclude reply evidence because "it does not argue admissibility of the challenged evidence" but instead argues proper scope of reply).

Second, even if PO's Motion were an appropriate vehicle to seek to exclude evidence as improper reply evidence (it is not), Petitioners' reply evidence is proper. In its Reply, Petitioners did not change their theory of unpatentability, including any of its proposed combinations, claim mappings, or motivations to combine. Instead, Petitioners responded to ***PO's (incorrect) argument*** that Fang was somehow inconclusive or that its diagnostic criteria were somehow unclear with evidence that unequivocally refutes PO's faulty premise. Reply, 18-19. This was proper. *Apple Inc.*, 949 F.3d at 706-07.

PO suggests that Petitioners should have included evidence with the Petition to preemptively address PO's argument and that the Petition is somehow deficient without Fang Citation [1]. Motion, 3-4. This is wrong. The Petition relied on ***Fang's*** express teachings, including Fang's discussion of statistically significant clinical ***results*** demonstrating the well-known concept that RF ablation disrupts nerve function and treats rhinitis symptoms. That was enough to support Petitioners' *prima facie* case, as the Board found at Institution. DOI, 36. PO cites no authority that a Petition must cite and submit all underlying diagnostic criteria for a study before its published results are considered for purposes of obviousness. This would be inconsistent with the fact that the Challenged Claims do not require any particular diagnostic criteria, severity of symptoms, or degree of efficacy. *See* Ex.1089-

Levine-Tr, 184:21-185:20 (Dr. Levine acknowledging claims do not require particular degree of treatment). Indeed, the Challenged Patent itself cites no specific diagnostic criteria, let alone as a limitation on the Challenged Claims.

Dexcom, cited by PO, is inapposite. *Dexcom, Inc. v. Waveform Techs., Inc.*, No. IPR2016-01679, Paper 53 (P.T.A.B. February 18, 2018). As an initial matter, *Dexcom* was decided before the November 2018 TPG Update clarified the scope of motions to exclude and that responsive evidence can be submitted in reply. *Compare* TPG August 2018 Update, 16 *with* TPG August 2012, 48767; *see also* TPG, 79. Regardless, *Dexcom* is readily distinguishable. There, Petitioner cited evidence in its Petition but did not submit it as exhibits until Reply. Paper 10, 18 n. 11; Paper 53, 49. Here, Petitioners indisputably submitted Fang with the Petition as Exhibit 1006. Petitioners then submitted Exhibit 1113 in reply to ***rebut*** PO's unfounded arguments, and without changing their Grounds. *Provisur Techs.*, 50 F.4th at 122 (Fed. Cir. 2022) (finding appropriate admission of evidence that responded to arguments in the POR and where Petitioner's "invalidity theories did not change").

PO's conclusory complaint of prejudice, Motion 3, is meritless. PO was undoubtedly aware of Fang Citation [1] (now Ex.1113) because ***PO*** raised it in its POR. POR, 47-48. Petitioners then submitted it in reply and PO had a full opportunity to question Dr. Bu-Saba regarding it at his deposition and to address it

in Sur-Reply. PO chose not to do either. It also chose not to request a supplemental declaration or the submission of any additional evidence in sur-reply. There is nothing unfair or prejudicial with Petitioners submitting Exhibit 1113 to directly respond to PO's argument, particularly when PO had an opportunity to respond.

Instead, it would unduly prejudice Petitioners to exclude plainly relevant reply evidence. The POR suggests Fang's results were not based on known or reliable diagnostic criteria and that it therefore was inconclusive. POR, 47-48. There can be no dispute that such suggestion is wrong. As PO acknowledges, Fang cites Exhibit 1113 for its diagnostic criteria. POR, 47. Exhibit 1113 identifies diagnostic criteria that PO's own declarant, Dr. Levine, confirmed were consistent with criteria a POSITA would have considered at the relevant time. Reply, 18 (citing Ex.1089-Levine-Tr, 101:17-103:15, Ex.1113). Dr. Bu-Saba agrees. Ex.1098-Reply-Decl., ¶¶109-115. PO did not argue to the contrary in sur-reply. It would be unduly prejudicial to Petitioners to prevent it from offering reply evidence that directly and unambiguously contradicts PO's argument, particularly when the Petition did not require such argument and PO raised its argument for the first time in its POR.

Therefore, Petitioners respectfully request the Board deny PO's Motion.

Date: April 8, 2025

Respectfully submitted,

By: /David L. Cavanaugh/
David Cavanaugh
Registration No. 36,476

CERTIFICATE OF SERVICE

I hereby certify that, on April 8, 2025, I caused a true and correct copy of Petitioners' Opposition to Patent Owner's Motion to Exclude to be served on Patent Owner via electronic mail to:

Heath J. Briggs, BriggsH@gtlaw.com;

Trenton Ward, Trenton.Ward@gtlaw.com;

Benjamin P. Gilford, gilfordb@gtlaw.com;

Elana Araj, Elana.Araj@gtlaw.com;

Stephen M. Ullmer, UllmerS@gtlaw.com; and

AerinMed-IPRs@gtlaw.com.

/Alexander J. Nemtzow/
Alexander J. Nemtzow
Registration No. 82,130