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
Patent No. 11,679,077

PATENT OWNER'S MOTION TO EXCLUDE

Pursuant to 37 C.F.R. § 42.64(c) and the Board's Scheduling Order (Paper 10), Patent Owner moves to exclude Exhibit 1113 and paragraphs 112-115 of the Reply Declaration of Dr. Nicholas Bu-Saba (Exhibit 1098). These exhibits contain new evidence improperly submitted with the Reply, and therefore, are highly prejudicial and should be excluded pursuant to Fed. R. Evid. 403.

I. Background

The Petition contends the Challenged Claims are invalid as obvious over, *inter alia*, the combination of Makower and Fang. (Petition at 66). In support, Petitioner relies on the Declaration of Dr. Bu-Saba (Exhibit 1002) submitted with the Petition. Petitioner's Makower-Fang combination relies on Fang for its purported teaching of using radiofrequency energy to treat rhinitis. (Petition at 80). Fang (Exhibit 1006) is an article titled "Nasal endoscopy combined with multiple radiofrequency for perennial allergic rhinitis." (Exhibit 1006). Fang cites to ten references in support thereof, which are listed at the end of the article under the heading "References." (Exhibit 1006 at 877). Petitioner did not submit any of these references with the Petition.

On October 25, 2024, Patent Owner filed its Patent Owner Response ("POR"). (Paper 22). As it relates to the Makower-Fang combination, Patent Owner explained that Petitioner failed to establish that a person of ordinary skill in the art ("POSITA") would have been motivated to combine Makower and Fang because the limited

information in Fang's short, two-page study renders Fang inconclusive. (POR at 46-49). For example, Patent Owner explained that Fang states "all the patients complied with the diagnostic criteria for perennial rhinitis [1]," but Fang does not describe the "diagnostic criteria." *Id.* Instead, Fang cites to Reference [1], an article from the Chinese Journal of Otolaryngology from 1998. (Exhibit 1006 at 876). Fang also cites to Reference [1] when identifying the efficacy criteria that Fang used in reaching the ultimate conclusion that Petitioner relies upon for its Makower-Fang combination: "The efficacy was evaluated according to the evaluation criteria for allergic rhinitis [1]." (Exhibit 1006 at 877). Importantly, ***Petitioner did not submit Reference [1] with the Petition, and Dr. Bu-Saba testified that he did not review Reference [1] as part of his analysis and was unable to determine how Fang determined efficacy or its basis for doing so.*** (POR at 48-49 (citing Exhibit 2002, Bu-Saba Tr. at 194:5-15, 207:2-208:21)).

Petitioner filed its Reply to the POR on January 17, 2025 (Paper 26), and submitted therewith Reference [1], which is Exhibit 1113, along with a 124-page Reply declaration from Dr. Bu-Saba. (Exhibit 1098). Despite testifying that he did not review Reference [1] in conjunction with his first declaration (Exhibit 1002) and did not understand how Fang determined efficacy or the basis thereof, in his Reply Declaration, Dr. Bu-Saba now opines on Fang's "diagnostic criteria" disclosed in

Reference [1] to say that it is the "diagnostic criteria…known in the art prior to 2006." (Exhibit 1098 at ¶¶112-115).

Patent Owner timely objected to this evidence on January 24, 2025. (Paper 27). Further, as noted in the Patent Owner Sur-Reply, despite having a copy of Exhibit 1113, this evidence was not presented to Patentee's expert during his cross-examination, and "[i]t is prejudicial (and is gamesmanship) to introduce new evidence without any opportunity for Patentee's expert to address it." (POSR at 21).

II. The Board should exclude Exhibit 1113 and Paragraphs 112-115 in Exhibit 1098 under Fed. R. Evid. 403 because they are Prohibited by the Board's Trial Practice Guide

The Consolidated Trial Practice Guide states that "Petitioner may not submit new evidence or argument in reply that it could have presented earlier, e.g., to make out a prima facie case of unpatentability." (PTAB Consolidated Trial Practice Guide, November 2019 at 73). But that is what Petitioner did here. Efficacy criteria for Fang's study (Exhibit 1113) and Dr. Bu-Saba's testimony regarding such criteria is evidence that Petitioner could have and should have presented with its Petition—it was not. Petitioner's belated submission of this new evidence with the Reply violates the Trial Practice Guide and is highly prejudicial to Patent Owner, as it provides no opportunity for Patent Owner to respond with any evidence or expert testimony refuting such evidence. Therefore, Exhibit 1113 and paragraphs 112-115 of Exhibit 1098 should be excluded under Fed. R. Evid. 403.

Specifically, as discussed above, Petitioner relies on Fang for its teaching that a POSITA would have known to use radiofrequency energy to treat patients with rhinitis. Thus, Fang's efficacy criteria are highly relevant to whether a POSITA would have even relied on Fang for such teaching. Despite having the ability to do so, Petitioner did not submit any evidence of Fang's efficacy criteria with the Petition. Indeed, Dr. Bu-Saba testified that he did not even consider such efficacy criteria in rendering his opinions in his first Declaration submitted with the Petition. (POR at 48-49 (citing Exhibit 2002, Bu-Saba Tr. at 194:5-15, 207:2-208:21)). After Patent Owner identified this fatal defect in Petitioner's Makower-Fang combination, Petitioner and Dr. Bu-Suba submitted and addressed Fang's Reference [1] for the first time in Reply. (Reply at 19). Petitioner's submission of this new evidence and testimony with its Reply is improper, as Petitioner undoubtedly could have submitted it with the Petition "to make out a prima facie case of unpatentability." As in *Dexcom, Inc. v. Waveform Technologies, Inc.*, No. IPR2016-01679 (P.T.A.B. Feb. 18, 2018), Petitioner's Reply relies on Exhibit 1113 and Dr. Bu-Saba's Reply Declaration Paragraphs 112-115 "to fill a gap in its prima facie case in view of Patent Owner's argument" that a POSITA would not have relied on Fang due to Fang's inconclusive disclosure. IPR2016-01679, Paper 53 at 50 (granting Patent Owner's motion to exclude new evidence submitted with the petitioner's reply). But, as the Board explained in *Dexcom*, "[u]nder our rules and trial practice guide, evidence

necessary to make out a prima facie case of unpatentability may not be introduced for the first time in the reply brief." *Id.* Thus, as in *Dexcom*, Petitioner's new evidence should be excluded.

Therefore, Patent Owner respectfully requests the Board grant this Motion and exclude Exhibit 1113 and paragraphs 112-115 of Dr. Bu-Saba's Reply Declaration (Exhibit 1098).

Dated: April 1, 2025

Respectfully submitted,

/s/ Heath J. Briggs

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CERTIFICATE OF SERVICE

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

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