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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE INC.,

Petitioner,

v.

MASIMO CORPORATION,

Patent Owner.

Case IPR2024-00241
U.S. Patent 10,687,743

MASIMO'S OPPOSITION TO APPLE'S MOTION TO EXCLUDE

Pursuant to the Board's Scheduling Order, Masimo hereby opposes Apple's Motion to Exclude ("Mot.").

I. INTRODUCTION

The Board's practice guide prohibits using a motion to exclude as a vehicle to introduce merits arguments. Yet Apple's motion improperly raises several pages merits arguments regarding whether the testimony of Apple's engineers and Apple's documents demonstrate a POSITA would not have had a reasonable expectation of success in determining oxygen saturation at the wrist as of 2015. Apple objects to such evidence as irrelevant under Federal Rules of Evidence 401 and 402, but Apple never applies the relevancy test. The bar is low, and Apple has not come close to showing the evidence is entirely irrelevant. Indeed, the ITC previously found the testimony of Apple's engineers and documents relevant and that it demonstrated a POSITA would not have had a reasonable expectation of success. The ITC also found it supported objective indicia of nonobviousness, including industry skepticism and failure of others. Apple's motion appears to be self-help to circumvent the word limit for its Reply.

Apple also argues that the testimony of its engineers and its documents are hearsay. But the Board already rejected that argument in IPR2022-01291 and -01465 because (1) they are opposing party statements which are excluded from hearsay and (2) qualified as trustworthy under the residual exception because they

were elicited under oath in the ITC Investigation to a large extent by ***Apple's*** attorneys. Apple's Motion never acknowledges that the Board already held that the same exhibits were admissible over the same hearsay objections. Those decisions collaterally estop Apple's hearsay arguments here.

Finally, Apple moves to exclude multiple paragraphs from Dr. Madisetti's declaration as allegedly conclusory, unsupported, or for relying on Apple's engineers' testimony and documents. At best, Apple's objections go to the weight, not the admissibility, of the evidence. But Apple's Motion offers no explanation for how the objected-to paragraphs are "conclusory" or unsupported when those paragraphs were replete with citations to evidence. Moreover, Dr. Madisetti attended the hearing in the ITC investigation and observed Apple's engineers testimony. In contrast, Apple's attorney in this IPR and its expert, Dr. Anthony, did not attend that hearing. Apple's Motion should be denied.

II. ARGUMENT

A. Apple's Engineers' Testimony and Documents Should Not Be Excluded Under FRE 401, 402, or 403

Apple argues that Exhibits 2076-2078, 2080-2086, and 2094 should be excluded under FRE 401, 402, and 403 as irrelevant and misleading. Mot., 2-8. Relevance is a low bar. FRE 401 ("Evidence is relevant if: (a) it has ***any tendency*** to make a fact more or less probable than it would be without the evidence; and (b)

the fact is of consequence in determining the action."); FRE 402 (relevant evidence is admissible unless another rule provides otherwise).

The evidence at issue includes (1) transcripts of sworn testimony by Apple's engineers during proceedings between the parties in the ITC and district court litigation and (2) Apple's internal engineering documents relating to the blood oxygen feature. This evidence is relevant to several issues, including whether a POSITA would have had a reasonable expectation of success in determining oxygen saturation at the wrist as of the July 2015 critical date. It is also relevant to objective evidence of nonobviousness, including industry skepticism, failure of others, and long-felt-but-unmet need.

As discussed in Masimo's POR, the evidence showed that in 2015, Apple's engineers were tasked with researching oxygen saturation measurements at the wrist. For example, Dr. Mannheimer, an industry veteran in the field of pulse oximetry, rolled his eyes and thought "***good luck with that***," and even told his boss at Apple, "***I don't know if it can be done.***" EX2077, 1012:12-25; EX2080, 174:2-174:6.[1] The evidence further shows that Apple's engineers concluded that "***Conventional sensing methods do not result in waveforms that are consistent enough for SpO_2 measurements at the wrist***," and that "***Invention is required***" to do so. EX2085, 13.

[1] All emphases added unless noted otherwise.

And Apple's lead engineer even testified under oath that, at the time, measuring oxygen saturation at the wrist was "unprecedented" and that there were no commercially available devices that did so. EX2076, 962:25-963:9, 964:2-6. Thus, the evidence has a tendency to make it more probable that no reasonable expectation of success existed. It also has a tendency to make Masimo's assertions of industry skepticism, failure of others, and a long-felt-but-unmet need more probable.

In fact, the ITC previously relied on the objected-to evidence to find no reasonable expectation of success to measure oxygen saturation at the wrist, industry skepticism, and failure of others. EX2093, 231 (Initial Determination finding no reasonable expectation of success based on Apple engineer testimony); EX2003, 51-52 (Commission Opinion finding objective evidence of skepticism and failure of others based on Apple engineer testimony). That another administrative tribunal found the evidence persuasive to the same issues here demonstrates its relevance.

Moreover, Apple has no basis for its objection that eleven entire exhibits should be excluded under FRE 403 because "portions of these exhibits are potentially misleading when taken out of context." Evidence may only be excluded under FRE 403 if Apple can demonstrate that its "probative value is substantially outweighed by a danger of … misleading the jury." FRE 403. Apple's Motion does not even identify a ***single*** statement out of those eleven exhibits that it contends is

misleading. Nor does Apple demonstrate that the probative value of such evidence is ***substantially outweighed*** by a danger of misleading the fact finder.

At best, Apple complains the evidence is "***potentially*** misleading when taken out of context." Mot., 2. But that is true of any evidence. Apple does not identify any evidence that was misleadingly taken out of context.[2] And Rule 403 plays little to no role here because the Board is capable of avoiding undue prejudice. *Collegium Pharm., Inc. v. Pharma*, 2021 WL 6340198, at *6 (P.T.A.B. Nov. 19, 2021) ("As the factfinders, we [the Board] are able to consider the evidence offered by Petitioner and Patent Owner, in light of the parties' arguments, and give it the appropriate weight, without risk of unfair prejudice.").

Rather than seriously challenge admissibility, Apple uses its Motion to introduce merits arguments about the weight that should be afforded to the engineers' testimony. Indeed, all of Section II.A. of Apple's Motion comprises merits arguments from either Apple's Reply or the Board's prior decision in IPR2022-01291. "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

[2] In contrast, Apple has repeatedly made misleading assertions about its engineers' testimony, such as arguing that the Apple Watch needed regulatory approval, when in fact, the Apple Watch has never received FDA approval or clearance for the blood oxygen feature. Reply, 23.

documents." Consolidated Trial Practice Guide (Nov. 2019) ("CTPG"), 79. All of Apple's arguments in Section II.A. should not be considered.

B. Exhibits 2076-2078, 2080-2086, 2089, and 2094 Are Not Hearsay[3]

1. Apple Is Collaterally Estopped from Arguing the Exhibits Are Hearsay

Apple previously lost when it asserted these exhibits were inadmissible hearsay. EX2035, 136-137. Apple failed to inform the Board that the same IPR2022-01291 final written decision it cited throughout its Motion for its merits arguments also decided that the same exhibits here are not hearsay. 37 C.F.R. § 42.11. In IPR2022-01291, the Board determined that the testimony of Apple's engineers and documents are opposing party statements that are (1) ***excluded*** from hearsay pursuant to Federal Rules of Evidence 801(d)(2)(A), (C), and (D), and (2) qualify under the residual exception of Rule 807. EX2035, 136-137. That decision concerned the same evidence (except for EX2094, which is new to this proceeding).[4]

Thus, Apple is collaterally estopped from re-litigating its hearsay objection at least with respect to Exhibits 2076-2078, 2080-2086, and 2089. Collateral estoppel applies when "(1) the issue is identical to one decided in the first action; (2) the issue

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[3] Apple's Section II.B. heading does not list EX2086, but Apple references it in its argument.

[4] Exhibits 2076-2078, 2080-2086, and 2089 are the same documents in all proceedings (IPR2022-01291, -01465, IPR2024-00241, -00243, -00244).

was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) [the party against whom collateral estoppel is being asserted] had a full and fair opportunity to litigate the issue in the first action." *Google LLC v. Hammond Dev. Int'l, Inc.*, 54 F.4th 1377,1 381 (Fed. Cir. 2022) (citation omitted). All elements are met. Apple contends the same exhibits are hearsay just like it did before. Apple's hearsay objection was actually litigated in IPR2022-01291. The Board resolved the issue and that resolution was essential to the Board's decision in IPR2022-01291. Indeed, the Board discussed that evidence and Masimo's arguments at length. And Apple had a full and fair opportunity to litigate the hearsay objection via its motion to exclude. Thus, collateral estoppel precludes a contrary finding here.

2. <u>Apple's Engineer Testimony and Documents Are Opposing Party Statements Excluded from Hearsay</u>

The exhibits Apple seeks to exclude include sworn testimony by ***Apple's witnesses*** in parallel proceedings (EX2076-2078, EX2080-2082, EX2094) and ***Apple's documents*** authored by ***Apple's engineers*** regarding the oxygen saturation feature in the Apple Watch (EX2083-2086, EX2089). These are opposing party statements offered against that party, and therefore not hearsay. FRE 801(d)(2).

Rule 801(d)(2) excludes from the definition of hearsay a statement that is "offered against an opposing party" and:

(A) was made by the party in an individual or representative capacity;

(B) is the one the party manifested that it adopted or believed to be true;

(C) was made by a person whom the party authorized to make a statement on the subject;

(D) was made by the party's agent or employee on a matter within the scope of that relationship and while it existed; or

(E) was made by the party's coconspirator during and in furtherance of the conspiracy.

FRE 801(d)(2)(A)-(E). All of the objected-to exhibits fall under one or more of these exclusions from hearsay.

Exhibits 2076-2078 are trial transcripts of sworn testimony from ***Apple's engineers*** in the ITC Investigation. Apple chose those specific engineers to testify on its behalf at the ITC. EX2029, 39:3-40:13 (Apple's opening statement introducing its witnesses); FRE 801(d)(2)(C). Moreover, Exhibits 2076-2078, 2080-2082, and 2094, which includes both trial and deposition transcripts, are Apple's engineers' testimony about their efforts in developing the oxygen saturation feature for the Apple Watch Series 6. All of those engineers were employed by Apple and testified on matters within the scope of their employment at Apple, namely their work on the Apple Watch. *See* EX2076, 952:15-18, 954:23-955:9 (Land employed by Apple to work on Apple Watch); EX2077, 993:17-20, 996:25-997:8 (Mannheimer employed by Apple to work on Apple Watch); EX2078, 918:22-919:8 (Waydo employed by Apple to work on Apple Watch); EX2082, 11:19-12:17 (Shui

employed by Apple to work on Apple Watch); EX2080 (Mannheimer deposition), EX2081 (Waydo deposition), EX2094 (Mannheimer deposition). Thus, they are statements "made by the party's … employee on a matter within the scope of that relationship and while it lasted." FRE 801(d)(2)(D).

Other evidence includes statements in Apple's internal documents (EX2083-2086 and 2089) made by Apple's engineers. Apple does not dispute that these exhibits are its own internal documents authored by its own engineers. Nor does Apple dispute that the statements in those documents are being used ***against*** Apple in this IPR. Thus, Exhibits 2083-2085 and 2089 constitute statements made by Apple's employees on matters within the scope of their employment relationship while it existed—the development of the oxygen saturation feature in the Apple Watch. FRE 801(d)(2)(D); *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 454 F. Supp. 2d 966, 973-74 (C.D. Cal. 2006) (company's internal emails and documents are not hearsay under FRE 801(d)(2)(D)). Accordingly, the objected-to exhibits are categorically ***not*** hearsay.

3. <u>The Exhibits Also Fall Under The Residual Exception (FRE 807)</u>

Even if the exhibits were somehow deemed hearsay, they fall under the residual exception (FRE 807), as the Board previously found. EX2035, 136-137. Rule 807 provides a statement is admissible even if it does not fall under another enumerated exception if:

> (1) the statement is supported by sufficient guarantees of trustworthiness—after considering the totality of circumstances under which it was made and evidence, if any, corroborating the statement; and
>
> (2) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts," and if the "proponent gives an adverse party reasonable notice of the intent to offer the statement … so that the party has a fair opportunity to meet it.

FRE 807. The Board has admitted trial and deposition testimony from a prior proceeding, particularly where the objecting party had the ability to defend or cross-examine the witness in the prior proceeding. *Nevro Corp. v. Boston Sci. Neuromodulation Corp.*, IPR2017-01812, Paper 79 at 32-34 (Feb. 1, 2019); *Captioncall, LLC v. Ultratec, Inc.*, IPR2013-00540, Paper 78 at 31-35 (Mar. 3, 2015); EX2035, 136-137.

The testimony of Apple's engineers and its documents are supported by sufficient guarantees of trustworthiness, at least when used against Apple. Apple's engineers' testimony was made under oath during the ITC hearing and/or during depositions before the ITC and the parallel district court litigation. Those deposition transcripts and internal documents (other than EX2094 which is new) were received as evidence in the ITC hearing and in IPR2022-01291 and -01465. Apple's attorneys had every opportunity to defend and to elicit direct testimony from those witnesses

and had the same motivations to do so—the ITC Investigation involved substantially the same invalidity theories for the related '745 Patent as presented in this IPR.

But Apple had more than just a mere opportunity to defend its witnesses. By and large, ***Apple's attorneys elicited the testimony*** on which Masimo now relies. For example, Apple's counsel elicited Mannheimer's testimony about rolling his eyes, "good luck with that," and that he did not know if oxygen saturation at the wrist could be done. EX2080, 173:14-174:1; *see also* EX2081, 165:12-16, 166:4-166:18 (Apple eliciting Waydo's testimony); EX2082, 108:13-21 (Apple eliciting Shui's testimony); EX2076, 963:19-964:11 (Apple eliciting Land's testimony). Thus, ***Apple*** told the ITC about how challenging it was to measure oxygen saturation at the wrist in 2015 and how even industry experts were skeptical it could be done. Apple should not be allowed to now exclude the evidence it elicited just because it decided that it now wishes to tell the Board an entirely contradictory story.

The objected-to exhibits are also more probative as to Apple's attempts and failures to determine oxygen saturation at the wrist than any other evidence that Masimo can obtain through reasonable efforts. FRE 807. Apple has also been on notice of this evidence long before this IPR. Masimo presented this evidence in the ITC Investigation and in IPR2022-01291 and -01465 before this IPR was filed. Masimo repeatedly informed Apple that it sought to use this evidence and negotiated

for ***months*** to obtain it. *See* EX2110. Apple has also had a fair opportunity to address the evidence in its Petition, Reply, and its expert declarations.

The interests of justice also weigh in favor of admitting and fully considering these exhibits. The exhibits relate to reasonable expectation of success and objective indicia of nonobviousness. Such objective evidence "must always when present be considered." *Stratoflex, Inc.v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

4. <u>The Exhibits Are Also Admissible Under FRE 803(3), 803(6), and 803(1)</u>

Other hearsay exceptions also apply. Apple's engineers' testimony concerning their skepticism for pulse oximetry at the wrist are statements of the declarants' then-existing state of mind. FRE 803(3). That state of mind is admissible. Apple's internal documents regarding their development of the oxygen saturation sensor also demonstrate its engineers' state of mind regarding oxygen saturation at the wrist. *E.g.*, EX2085, 13 (Apple's engineers' belief that "Invention is required.").

Apple's internal documents (EX2083-2086, EX2089) are also admissible as records of a regularly conducted activity. FRE 803(6). Those exhibits comprise Apple's internal emails, dated presentations created by Apple's engineers, and an organizational chart. Those documents were already authenticated and received as evidence in the ITC Investigation and Apple, who agreed to produce them here

(EX2110), does not dispute their authenticity. *See also* EX2080, 64:1-66:3, 68:14-69:2 (Mannheimer testifying about EX2083/CX-0007C); EX2076, 981:24-983:12 (Land testifying about EX2085/CX-177C); EX2076, 976:4-980:1 (Land testifying about EX2089/CX-1793C). Thus, they are records made at or near the time of the activity by Apple's employees and regularly kept in the course of Apple's business. *See Conoco Inc. v. Dept. of Energy*, 99 F.3d 387, 391 (Fed. Cir. 1996) ("Because of the general trustworthiness of regularly kept records and the need for such evidence in many cases, the business records exception has been construed generously in favor of admissibility.").

EX2085 is also a July 30, 2015 internal Apple presentation by Apple's engineers concerning their research and conclusions on measuring oxygen saturation at the wrist. *See* EX2085, 7-9, 13. Thus, EX2085 is admissible as a "statement describing or explaining an event … made while or immediately after the declarant perceived it." FRE 803(1); *see also FMC Techs., Inc. v. OneSubsea IP UK Ltd.*, IPR2019-00935, Paper 45 at 14-15 (Oct. 14, 2020) (meeting minutes admissible as present sense impressions).

C. <u>No Portion of Madisetti's Declaration Should Be Excluded</u>

Apple moves to exclude paragraphs 101-113 and 116-119 of Madisetti's declaration (EX2100) on three meritless theories. ***First***, Apple argues that the paragraphs should be excluded under FRE 702 and 703 as "conclusory, do not

disclose supporting facts or data, are based on unreliable facts, data, or methods, and/or include testimony outside the scope of Dr. Madisetti's specialized knowledge." Mot., 11-12. But Apple does not identify even a ***single*** statement in any of those paragraphs that it contends was unsupported or conclusory. *Id.* Nor can it—Madisetti meticulously cited numerous exhibits and thoroughly explained his reasoning. The Board should deny the motion for that reason alone. Indeed, the Board previously denied Apple's similar motion to exclude Masimo's expert's testimony in IPR2022-01291 because Apple "ma[de] no attempt to discuss in what way the opinions offered therein are unsupported by facts or data, despite that it is Apple's burden to establish entitlement to the requested relief." EX2035, 137-138.[5]

Second, Apple argues the same paragraphs should be excluded as based on the Apple engineer testimony and documents that Apple contends are hearsay (FRE 702, 703, 802). But, as explained above, none of those exhibits are hearsay when used against Apple. And, even if they were hearsay, an expert such as Dr. Madisetti—who also witnessed the testimony firsthand—can reasonably rely on such sworn testimony and admitted trial exhibits in forming his opinions. *See RTI Surgical, Inc. v. Lifenet Health*, IPR2019-00571, Paper 75 at 7-9 (Aug. 4, 2020)

[5] Apple also argues that those paragraphs "reveal apparent disregard or misunderstanding of the pertinent legal standards." *Id.* But those arguments go to the weight, not the admissibility, of Madisetti's testimony.

(admitting expert testimony relying on sworn trial testimony and admitted trial exhibits under FRE 703 because experts would reasonably rely on such information).

Third, Apple argues the paragraphs should be excluded as irrelevant (FRE 401/402) or misleading (FRE 403). Mot., 13. But Apple's Motion never explains why it believes those paragraphs are irrelevant. Instead, Madisetti's opinions regarding reasonable expectation of success are directly relevant to Masimo's arguments in this IPR. Indeed, paragraphs 116-119 even directly address the references that Apple relied upon for reasonable expectation of success. Apple does not provide any explanation why any of those paragraphs are somehow irrelevant.

Apple further argues that the probative value of Madisetti's testimony "is outweighed by their misleading nature." But Apple never identified even a single statement that it believes is somehow misleading. And even it had identified any such statement, Apple never demonstrated that the probative value of such statements would be "***substantially*** outweighed by a danger of … misleading the jury" in this proceeding without a jury. FRE 403.

III. CONCLUSION

For the foregoing reasons, the Board should deny Apple's Motion to Exclude.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: March 25, 2025

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CERTIFICATE OF SERVICE

I hereby certify that, pursuant to 37 C.F.R. § 42.6(e) and with the agreement of counsel for Petitioner, a true and correct copy of **MASIMO'S OPPOSITION TO APPLE'S MOTION TO EXCLUDE** is being served electronically on March 25, 2025 to the e-mail addresses shown below:

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