No. 24-1285

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION**,**

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors.

Appeal from the United States International Trade Commission,
Investigation No. 337-TA-1276

APPELLEE INTERNATIONAL TRADE COMMISSION'S NONCONFIDENTIAL RESPONSE IN OPPOSITION TO APPELLANT'S MOTION FOR A STAY PENDING APPEAL

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CONFIDENTIAL MATERIAL OMITTED

The body of the Commission's opposition to Apple's motion does not itself include confidential business information designated under the protective order in the Commission investigation. However, the attached addendum does. The material omitted from Exhibit 1 (ITC-Add-1–16), Exhibit 2 (ITC-Add-17–25), Exhibit 3 (ITC-Add-26–29), and Exhibit 7 (ITC-Add-96–98) relates to Intervenors' research and development of the asserted domestic industry products. The material omitted from Exhibit 8 (ITC-Add-99–101) relates to Apple's research and development of infringing products.

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Appellee International Trade Commission respectfully opposes Appellant Apple Inc.'s motion for a stay pending appeal. ECF 7–8 ("Stay-Mot.").[1] Apple presents a weak and unconvincing case to invoke the extraordinary remedy of a stay pending appeal under the *Standard Havens* factors. Its arguments amount to little more than an indisputably adjudicated infringer requesting permission to continue infringing the asserted patents.[2] Chiefly, Apple fails to demonstrate the two most important factors in granting a stay—likelihood of success on the merits and irreparable harm. *See Nken v. Holder*, 556 U.S. 418, 434 (2009).

For likelihood of success, there is no legal error in the Commission's final determination and Apple essentially and improperly asks the Court to reweigh the evidence supporting the Commission's factual findings, all of which are supported by substantial evidence. *See Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353, 1365 (Fed. Cir. 2019). Apple's lack of likelihood of success is underscored by the sheer number of issues on which it must prevail on appeal. For domestic industry, Apple needs to show a reasonable likelihood of success on each of three

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[1] "Stay-Add" refers to the Addendum to Apple's stay motion. "ITC-Add" refers to the Commission's Addendum to its opposition.

[2] Before the Commission, Masimo Corporation and Cercacor Laboratories, Inc. ("Intervenors") asserted infringement of, *inter alia*, U.S. Patent Nos. 10,912,502 and 10,945,648 ("'648 patent," collectively, "Asserted Patents") by Apple Watches having a light-based pulse oximetry feature, which measures blood oxygen levels. Apple's motion alleges no error in the Commission's infringement findings.

independent sets of factual findings; and, for obviousness, Apple needs to prevail on each of two independent sets of factual findings. Additionally, Apple's prosecution laches argument is waived.

Equally weak are Apple's irreparable harm arguments. Contrary to Apple's assertions (Stay-Mot. at 18–19), Apple's harm is not unquantifiable, but rather speculative, at least because Apple provided no affidavit to support its assertions of irreparable harm to its goodwill and reputation, instead relying on a declaration presented to the Commission that (inadequately) addressed its public interest argument. This stands in stark contrast to instances where this Court has granted a stay based on affidavits including specific assertions of "employee layoffs, immediate insolvency, and, possibly, extinction." *See, e.g.*, *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 515 (Fed. Cir. 1990). To the extent Apple relies on the soon-expected ruling from Customs and Border Protection ("CBP") as to whether certain redesigned Apple Watches infringe the Asserted Patents, those arguments are, at best, misplaced. A favorable ruling to Apple has no bearing on Apple's alleged likelihood of success on the merits as to any raised issue, and instead would undermine Apple's "irreparable harm" argument. *See, e.g.*, *Chamberlain Grp., LLC v. ITC*, No. 22-1664, Order at 3 (ECF 43) (Fed. Cir. June 6, 2022) (unpublished). The stay motion should therefore be denied.

I. BACKGROUND

The Commission issued a final determination on October 26, 2023, finding that Apple violated section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 ("section 337"), based on infringement of the Asserted Patents. *See* 88 Fed. Reg. 75032 (Nov. 1, 2023). Relevant here, the Commission affirmed with modification the final initial determination ("Final ID") of the ALJ with respect to non-obviousness and domestic industry. *See id.* The Commission did not review and therefore adopted the Final ID as to prosecution laches. The Commission issued a limited exclusion order and a cease and desist order ("remedial orders") against Apple's infringing products. *See id.*

Relying on essentially the same arguments presented here, Apple moved the Commission to stay its remedial orders pending appeal before this Court. The Commission denied that motion. Stay-Add-2–15.

II. ARGUMENT

This Court applies the *Standard Havens* factors in considering a motion for a stay pending appeal, namely:

> (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.

Standard Havens, 897 F.2d at 512. "The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion." *Nken*, 556 U.S. at 433–34. Apple cannot establish that the *Standard Havens* factors weigh in favor of granting a stay.

A. Apple Failed to Establish a Likelihood of Success on the Merits.

Apple asserts a likelihood of success on appeal as to technical prong, obviousness, and prosecution laches findings. None of Apple's arguments have merit.

1. Substantial Evidence Supports that Masimo Satisfied the Technical Prong of the Domestic Industry Requirement.

Section 337's domestic industry requirement has two prongs: (1) an "economic prong," which considers economic activities; and (2) a "technical prong," which requires that the industry relate to patent-protected articles. *Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1361 (Fed. Cir. 2019); 19 U.S.C. § 1337(a)(2)–(3). Similar to infringement, the technical prong considers whether the domestic industry products practice the asserted claims. *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1375 (Fed. Cir. 2003). The Commission's technical prong findings are reviewed for substantial evidence. *Broadcom Corp. v. ITC*, 28 F.4th 240, 249–50 (Fed. Cir. 2022).

In a careful and well-reasoned opinion, the Commission found, as a factual matter, that Masimo had shown the existence of at least one pre-complaint

domestic industry product that practiced the Asserted Patents. The Commission's conclusion is independently based on *three* separate products, the RevA, RevD, and RevE sensors, which were prototypes for a later commercial product. *E.g.*, Stay-Add-242–245; Stay-Add-221–223. Thus, Apple must prevail on each of three sets of factual findings to succeed, each of which is reviewed for and supported by substantial evidence. Apple will not do so.

Apple does not dispute that the Rev A, RevD, and RevE sensors produced in discovery practice the Asserted Patents, or even that the RevA sensor was completed prior to the complaint. Stay-Mot. at 8. Rather, Apple alleges only that the RevD and RevE sensors were not completed prior to the complaint. Stay-Mot. at 7–11. None of Apple's arguments have merit.

First, Apple's argument is based on the faulty assumptions that the complaint itself must include all the record evidence produced during discovery; that the produced sensors must exactly match the CAD drawings of the complaint; and that direct evidence is required to satisfy the technical prong. Stay-Mot. at 7–10. Apple cites no caselaw supporting any of these propositions, instead supporting only that an existing domestic industry must be satisfied by an "actual article," as of the complaint, which is not in dispute.[3] Companies, especially those

[3] Before the Commission, the parties disputed whether post-complaint articles could satisfy the technical prong. *E.g.*, Stay-Add-216–220. However, the

in the research phase, will continue developing and updating software, but the Commission's findings were based on evidence of the state of the sensors as of the complaint. Stay-Add-219. While Apple points out that Mr. Scruggs stated he was unaware "of any devices … in existence that are exactly the same as depicted" in the complaint's CAD drawings, Stay-Mot. at 8–9, that assertion is irrelevant, especially in view of the record evidence (discussed below).

Second, ample direct and circumstantial evidence shows at least one "actual" patent-practicing article existed before the filing of the complaint. As noted above, Apple does not dispute that the RevA sensor was complete before the complaint or that the RevA practices the '502 patent,[4] presenting only the irrelevant assertion that renderings of that sensor appear different compared to photographs. Stay-Mot. at 8–9.

Commission took no position on this dispute, basing its decision on articles completed as of the complaint. Stay-Add-97.

[4] Apple alleges no error in the Final ID's rejection of Apple's other RevA arguments—that, before the complaint, the RevA sensor did not have a strap (an argument also presented for the RevD sensor) and was not connected to a display. *E.g.*, Stay-Add-220–221; Stay-Add-242–43. Accordingly, Apple has abandoned those arguments. Nonetheless, substantial evidence supports the Commission's findings. *E.g.*, Stay-Add-220–221; Stay-Add-242–243; ITC-Add-2–7(265:15–269:25) (RevA testing, demonstrating that it was user-worn); ITC-Add-272:16–277:13 (testing); ITC-Add-97–98 (test results); ITC-Add-21–22(405:8–407:18) (RevA had a strap); ITC-Add-25(460:13–17) (RevD had a strap).

For the RevD and RevE sensors, Apple argues that the devices produced in discovery contained a post-complaint software version and thus cannot satisfy the technical prong. Stay-Mot. at 8–10. However, the Commission properly considered and rejected this argument, and, more importantly, its findings were based on evidence of the state of the sensors at the time of the complaint. *E.g.* Stay-Add-219; Stay-Add-221–222; Stay-Add-243–245. For example, as set out in the Final ID, for the RevD sensor, Masimo's Mr. Al-Ali described internal testing of blood oxygen saturation using a device consistent with that design in early 2021 (before the July 12, 2021 complaint), testing at a time consistent with RevD prototype iteration. Stay-Add-243–244; Stay-Add-221–222 (including n.26); ITC-Add-13–16(275:9–278:13) (describing oxygen saturation testing in the timeframe that the RevD sensor was completed); Stay-Add-219 (RevD sensor completed in April 2021). A device subject to blood oxygen feature testing must have had blood oxygen software when tested. Stay-Add-243–245.

For the RevE sensors (for which there were three separate devices), Masimo's Mr. Scruggs testified that at least one of these RevE devices had blood oxygen software loaded on July 9, 2021—prior to the complaint—and that each separate device was completed between May and September 2021. Stay-Add-244–

245; ITC-Add-24(457:9–21).[5] Mr. Al-Ali also testified that a RevE sensor was tested before the complaint was filed. Stay-Add-244–245 (discussing Mr. Ali's testimony and other evidence supporting the Commission's findings); ITC-Add-19–20(316:2–317:20) (RevE sensor tested prior to complaint).

Apple fails to even acknowledge that the above evidence exists, alleging a likelihood of succeeding on the merits because the evidence is allegedly circumstantial. Stay-Mot. at 10. However, the above evidence includes both direct and circumstantial evidence, and even if it was all circumstantial, "[c]ircumstantial evidence is not only sufficient, but may also be more certain, satisfying and persuasive than direct evidence." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009).

In sum, Apple fails to establish a reasonable likelihood of success on the merits.

2. Substantial Evidence Supports the Commission's Obviousness Findings.

The Commission's obviousness conclusion is independently supported on two grounds: (1) Apple failed to show that the prior art teaches or suggests the "oxygen saturation" limitations, and (2) Apple failed to show that the prior art teaches or suggests the "windows" limitations.

[5] "CPX-19C" is a RevE sensor. Stay-Add-215.

a. Substantial Evidence Supports the Commission's Finding that Apple Failed to Show that the Prior Art Teaches or Suggests the "Oxygen Saturation" Limitations.

Based on Apple's obviousness theory, it needed to show by clear and convincing evidence that a person of ordinary skill (1) "would have been motivated to combine or modify the teachings in the prior art," and (2) "would have had a reasonable expectation of success in doing so." *Regents of Univ. of Cal. v. Broad Inst., Inc.*, 903 F.3d 1286, 1291 (Fed. Cir. 2018). Both issues are questions of fact reviewed for substantial evidence. *Id.* Moreover, printed publications must be enabling to invalidate a patent claim. *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994). Prior art enablement is a mixed question of fact and law, *id.*, but only factual issues are present here.

With respect to the "oxygen saturation" limitations, Apple improperly faults the Commission for requiring a showing of a reasonable expectation of success as well as enablement of the prior art for measuring blood oxygen with a wristwatch, Stay-Mot. at 13, but that was the combination Apple itself alleged as invalidating the asserted claims. Apple's obviousness theory relied specifically on modifying Lumidigm's wristwatch embodiment, opting for that embodiment over Lumidigm's key fob, cell phone, and personal digital assistant embodiments. Stay-Add-652-3:35–38 (Lumidigm); ITC-Add-53 (identifying wristwatch embodiment); *see also* ITC-Add-50–86 (extensive discussion of the wristwatch embodiment).

For example, Apple cited to Dr. Warren's opinion that one of ordinary skill "would have been able to implement pulse oximetry functionality in Lumidigm's wristwatch," Stay-Add-273, and argued that that person "would have been motivated to use one of the thermistors[6] disclosed in Webster in Lumidigm's wristwatch embodiment," Stay-Add-285. Apple apparently chose that embodiment because it is the sole embodiment teaching or suggesting the "user-worn" claim limitation. Apple further relied on the wristwatch embodiment to support its motivation to modify the prior art to satisfy the "concave surface" limitation, a motivation based on user comfort and contact. Stay-Add-66–68. Because the claims also require measuring "oxygen saturation," Apple logically needed to show that it would have been obvious to modify, with a reasonable expectation of success, Lumidigm's wristwatch embodiment to measure blood oxygen, a showing Apple could not make.

The Commission's finding that the prior art did not teach or suggest the oxygen saturation limitations were based on extensive evidence that a person of ordinary skill would not have had a reasonable expectation of success in measuring blood oxygen saturation with a wristwatch, and evidence that Lumidigm did not enable a wristwatch that measures blood oxygen. Stay-Add-274–278. For

[6] The asserted claims require a "thermistor." Stay-Add-285.

example, Apple's own engineers described the significant difficulty of measuring blood oxygen at the wrist. Stay-Add-275–276 (the wrist is "just an incredibly different beast"); ITC-Add-28–29(1012:12–1013:6) (declaring that the signal at the wrist is "enormously weak"); ITC-Add-100–101(166:4–167:5 ("The wrist is one of the most difficult places on the body to do almost every physiological measurement"); Stay-Add-275–278 (discussing additional evidence). While, as Apple points out, prior art printed publications have a presumption of enablement (Stay-Mot. at 13–14), that presumption is overcome here because of evidence describing the difficulty in "configuring Lumidigm's wristwatch to measure blood oxygen at the time of the Poeze patents." Stay-Add-277. Given the ample evidence supporting the Commission's factual findings, Apple has not shown a likelihood of success on the merits.

Apple distorts the Commission's straightforward factual finding into a strawman argument that the Commission required the prior art to enable more than is required by the claims. Stay-Mot. at 11–14. Apple failed to timely raise (and therefore waived) this argument before the Commission. In addition, enablement of the claims, which is based on the Asserted Patents' disclosures, is irrelevant to whether Lumidigm is enabling prior art. *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005) ("The standard for what constitutes proper enablement of a prior art reference for purposes of anticipation under section 102,

however, differs from the enablement standard under section 112."). Furthermore, along with a misplaced reliance on *Epstein*, Apple presents an unsupported, attorney argument-based comparison of the Asserted Patents' and Lumidigm's disclosures. Stay-Mot. at 12–14. Contrary to Apple's assertions, *Epstein* includes no such broad, legal proclamations. Rather, like here, *Epstein* presents a straightforward factual question of whether the prior art was enabling for subject matter the patent challenger asserted against the claims. *Epstein*, 32 F.3d at 1568. The above-discussed substantial evidence supports the Commission's finding, even in view of Apple's unsupported comparison.

Apple also asserts that, when "claims encompass a range of embodiments (here, for example, the category of 'user-worn devices'), the prior art invalidates the claims so long as it discloses even a single embodiment." Stay-Mot. at 12. But, as discussed above, Apple relied on the wristwatch embodiment in Lumidigm, which is not enabled as to any oxygen measuring function and cannot be the basis for teaching or suggesting that limitation.

Apple further asserts that the Commission erred because Lumidigm discloses that its sensor can more broadly be placed into "*any* 'portable electronic device.'" Stay-Mot. at 13. First, Apple waived this argument by failing to present it to the ALJ. *See* ITC-Add-50–86 (arguing based on wristwatch embodiment); *Ajinomoto Co., Inc. v. ITC*, 597 F.3d 1267, 1277–78 (Fed. Cir. 2010). Second,

modifying the other Lumidigm embodiments (such as the key fob embodiment) to measure blood oxygen would *still not invalidate* because the modification would then not be "user-worn," as claimed. Third, Apple, who had the burden of proof, pointed to no wearable devices compatible with Lumidigm other than wristwatches. *See* ITC-Add-50–86; Stay-Add-273 ("Apple relies on Dr. Warren's opinion that one of ordinary skill in the art would have been able to implement pulse oximetry functionality in Lumidigm's wristwatch.").

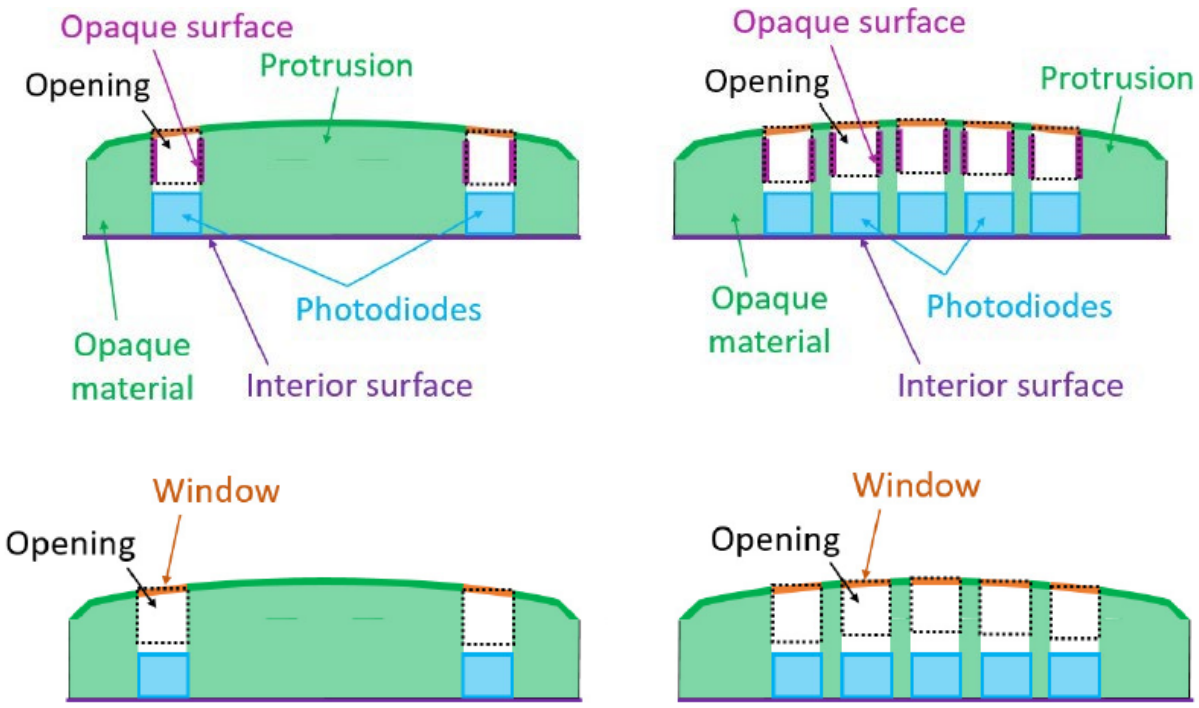
In sum, Apple cannot demonstrate a reasonable likelihood of success on the merits with respect to the "oxygen saturation" limitation.

b. Substantial Evidence Supports the Commission's Finding that Apple Failed to Show that the Prior Art Teaches or Suggests the "Separate Windows" Limitations.

Based on Apple's obviousness theory, it also needed to show by clear and convincing evidence that a person of ordinary skill "would have been motivated to combine or modify the teachings in the prior art" to arrive at the "separate windows limitations," which is a factual question reviewed for substantial evidence. *Regents*, 903 F.3d at 1291. Apple failed to do so.

Each asserted claim requires a specific orientation of separate LEDs, separate photodiodes, a protrusion having a convex surface, separate openings extending through that surface, opaque material, opaque surfaces, and separate "windows" or "optically transparent materials" "extending across" or "within"

each of the separate openings. *E.g.*, Stay-Add-59. The claimed positional relationships are illustrated below:



Stay-Add-68.

At issue before the Commission was whether the prior art provided a reason to use individual, separate windows over or within the separate openings (as illustrated above), as opposed to, for example, a single window over the plurality of openings (or no window at all). Stay-Add-65–68; ITC-Add-67–68. However, instead of providing a motivation to use separate windows, Apple presented only testimony that separate windows were well-known and that a person of ordinary skill *could* use them, which is insufficient. Stay-Add-65–69; ITC-Add-91–92; ITC-Add-32–33(1193:24–1194:14); ITC-Add-44(1221:16–1222:25); ITC-Add-

46–47(1235:24–1236:2); *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154, 1158 (Fed. Cir. 2022) ("The motivation-to-combine inquiry asks whether a skilled artisan not only could have made but would have been motivated to make the combinations." (quotations omitted)); *Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (same). Apple further failed to explain whether using separate windows was consistent with its motivation for modifying Lumidigm to include a convex surface, namely improved user comfort and contact. Stay-Add-66–67. Notably, Apple fails to allege any error in these findings. *See* Stay-Mot. at 14. Based on the record, substantial evidence supports the Commission's conclusion that Apple failed to show invalidity by clear and convincing evidence.[7]

Perhaps recognizing its lack of likelihood of success in challenging the above findings, Apple alleges, for the first time, that a person of ordinary skill would have been motivated to modify Lumidigm with separate windows based on an alleged dual choice between a single faceplate/window and separate faceplates/windows. Stay-Mot. at 14–15 (citing, *e.g.*, *KSR Int'l Co. v. Teleflex*

[7] The Commission's reasoning was consistent with the USPTO's rejection of Apple's invalidity argument over Lumidigm. Stay-Add-67–69; *see also Apple Inc. v. Masimo Corp.*, IPR2022-01274, 2023 WL 1092323, *7–8 (USPTO Jan. 24, 2023) (finding Apple's "convoluted combination of modifications" "grounded in hindsight rather than based on due consideration of the teachings of the pertinent prior art").

Inc., 550 U.S. 398, 401 (2007)). First, however, this argument is waived for not being presented to the ALJ or to the Commission in Apple's petition for review. *Finnigan Corp. v. ITC*, 180 F.3d 1354, 1362–63 (Fed. Cir. 1999); *Ajinomoto*, 597 F.3d at 1277–78. Second, it is unsupported by evidence and wrong because it overlooks that a single faceplate can cover, for example, only two of multiple openings, or that overlapping faceplates (each covering different subsets of openings) can be contemplated. Thus, Apple has failed to show "a finite number of identified, predictable solutions," as would be required under Apple's new *KSR* theory. *KSR*, 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of *identified, predictable solutions*." (emphasis added)). Third, Apple, who has the burden of proof, failed to explain whether using separate windows is consistent with its asserted motivation for modifying Lumidigm to include a convex surface (improved user comfort and contact). For example, a watch with multiple separate faceplates on the interior surface (in contact with the wrist) would likely have inferior contact with and be less comfortable for a user than a single faceplate.

In sum, Apple cannot establish a reasonable likelihood of success on the merits because the Commission's factual findings with respect to each of the "oxygen saturation" (discussed *supra*) and "windows" limitations (discussed here) are supported by substantial evidence.

3. Apple's Laches Argument Is Not Preserved for Appeal.

Apple cannot establish *any* likelihood of success on the merits based on its prosecution laches argument because it waived that argument by failing to present the argument to the Commission in its petition for review of the Final ID.

For petitions for review, 19 C.F.R. § 210.43(b)(2) requires:

> The petition for review must set forth a *concise statement of the facts material to the consideration of the stated issues*, and must present a *concise argument providing the reasons* that review by the Commission is necessary or appropriate to resolve an important issue of fact, law, or policy. … *Petitions for review may not incorporate statements, issues, or arguments by reference*. Any issue not raised in a petition for review *will be deemed to have been abandoned* by the petitioning party and may be disregarded by the Commission in reviewing the initial determination …, and any argument not relied on in a petition for review *will be deemed to have been abandoned* and may be disregarded by the Commission.

Id. (emphases added).

Despite these clear requirements, Apple presented its prosecution laches argument in its petition as follows (in its entirety):

> For the reasons discussed in Apple's initial post-hearing brief (RIB at 153–159) and consistent with Federal Circuit precedent regarding, as recently confirmed in *Personalized Media Communications* (No. 21-2275, Fed. Cir. Jan. 20, 2023), the ID erred in its finding that Apple had not shown the asserted Poeze patents unenforceable under the doctrine of prosecution laches and/or unclean hands. Complainants' twelve-year delay in filing the applications for the asserted Poeze patents was both unreasonable and prejudicial to Apple.

ITC-Add-94–95. Apple misleadingly states that it "identified the proper legal standard and noted why it was satisfied." Stay-Mot. at 17. Apple's petition did neither, providing a case citation, rather than a standard, and summarily stating that the alleged prosecution delay was "unreasonable and prejudicial." ITC-Add-94–95.[8]

Apple failed to include even a *concise* statement of the facts, for example, failing to mention any of the continuing prosecution during the alleged delay or any evidence showing whether the alleged delay was intentional. *See* Stay-Add-330–331. Apple additionally failed to provide any non-conclusory argument why the ALJ's decision was erroneous, for example, failing to point to any error in the Final ID's reasoning that Masimo prosecuted several applications during the alleged delay period and that Masimo's prosecution was distinguishable from cases where laches was found. *See* Stay-Add-332–334. Lastly, and most blatantly in violation of the Commission Rule, Apple incorporated by reference its argument from its post-hearing brief. Apple's "argument" was not sufficiently raised in its petition and was therefore rightfully disregarded under the Commission's rules and this Court's precedent. *Finnigan*, 180 F.3d at 1362–63; 19 C.F.R. § 210.43(b)(2);

[8] In implying that it presented additional pages of argument, Apple's stay motion cites to a similarly conclusory argument in its petition related to a *different patent*. Stay-Mot. at 17 (citing Stay-Add-571–572).

Certain Tobacco Heating Articles, Inv. No. 337-TA-1199, Comm'n Op., 2022 WL 279056 at *6 (Jan. 20, 2022).[9]

Apple's conclusory inclusion of this argument appears to have been an attempt to skirt the 100-page page limit for petitions, while attempting to preserve issues for appeal before this Court. *See, e.g.*, ITC-Add-89–95 (improper, conclusory of this and other unenforceability and invalidity arguments). Indeed, in contrast to the scant treatment of laches in its petition, Apple's motion includes several pages of argument. Stay-Mot. at 15–17. Accepting Apple's tactics would undermine the Commission's review process, effectively allowing the parties to present arguments to this Court for the first time without having sufficiently raised them before the Commission.

Thus, Apple cannot establish a likelihood of success on the merits based on prosecution laches.

B. Apple Fails to Show Irreparable Harm.

Apple asserts that it faces unquantifiable harm to its goodwill and reputation if barred from importing its "flagship" Apple Watch models during this appeal. The remedial orders, however, affect just a portion of Apple's watches, and Apple

[9] Apple's criticism of the Commission for failing to explicitly address certain facts, or address specific legal authority, Stay-Mot. at 17, ring hollow, particularly in light of its own failures to raise these facts or legal arguments in any detail (as required) in its petition for review.

Watches overall are just one product line of Apple's vast portfolio of product and services offerings. Moreover, Apple relies purely on attorney argument, failing to produce even an affidavit with its motion to support its alleged, vague "reputational" and "goodwill" harm. To the extent Apple relies on affidavits it provided to the Commission in support of its public interest arguments below, those affidavits address the alleged effects of the orders on consumers, *not on Apple*, which is an essential focus of the irreparable harm analysis. Thus, this case stands in stark contrast to instances where this Court provided a stay, where the movant demonstrated through affidavits that its entire existence was in jeopardy. *See Standard Havens*, 897 F.2d at 515.

Apple's reliance on *Celsis* and *Metalcraft* is misplaced. *See* Stay-Mot. at 18–19. In *Celsis,* this Court upheld a district court's entry of a preliminary injunction, under the abuse of discretion standard, affirming a finding of irreparable harm based on "unrebutted" testimony from the patentee's expert on the damage to the patentee's products' "price, reputation, and business opportunities," including "irreversible price erosion." *Celsis In Vitro v. CellzDirect, Inc.*, 664 F.3d 922, 930–31 (Fed. Cir. 2012). Similarly, in *Metalcraft*, the Court upheld a preliminary injunction against the accused infringer, under the abuse of discretion standard, based on the record in that case, including the accused infringer's own statements which supported the district court's finding that the

harm to the patentee was "difficult to quantify." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368–69 (Fed. Cir. 2017). Apple's unsupported and speculative assertions fall far short of this Court's precedent.

Further, as noted above, if CBP grants Apple a favorable ruling on its redesigned watches, Apple's (unsupported) rationale for its reputational and goodwill harm would largely dissolve. *See, e.g.*, Stay-Mot. at 18 ("Apple is losing goodwill and suffering reputational damage from being unable to provide U.S. consumers with its flagship Apple Watch products."); *Chamberlain,* No. 22-1664, Order at 3 (ECF 43) (denying stay of remedial orders pending appeal in view of CBP's ruling that redesigns are not subject to exclusion).

Thus, Apple cannot establish irreparable harm under the present facts.

C. The Balance of Hardships Does Not Support a Stay.

Apple's principal argument in support of the balance of hardships factor is that, as of the time it filed its motion, Masimo is allegedly not selling its W1 Watch in "any meaningful quantities" in the United States. Stay-Mot. at 20–21. However, "[w]here two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions." *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013). Thus, this factor also weighs against the issuance of a stay.

D. The Public Interest Weighs Against a Stay.

The Commission has twice determined that the public interest does not support a stay of remedial orders directed to Apple Watches, and the President has twice determined not to disapprove such orders for policy reasons. *E.g.*, Stay-Add-106–148; Stay-Add-127; *Certain Wearable Elec. Devices with ECG Functionality & Components Thereof*, Inv. No. 337-TA-1266, Comm'n Op., 2023 WL 372372, at *42–47 (Jan. 20, 2023) (involving all Apple Watches at issue here (as well as additional models) and very similar public interest arguments); 19 U.S.C. § 1337(d)(l), (f)(l), (j). In a detailed analysis spanning over forty pages, the Commission determined here that the issued remedy would not adversely affect the public interest factors.[10] More specifically, the Commission found that numerous alternatives to the infringing products are available on the market, including some of Apple's own watches. Stay-Add-119–123; Stay-Add-147–148; *see also Wearable Elec. Devices*, 2023 WL 372372, at *42–47. Moreover, Apple fails to point out that the Commission also provided an exemption in the remedial orders allowing Apple to service, repair, or replace infringing Apple Watches owned by consumers before the remedial orders became effective. Stay-Add-129–130.

[10] Those factors are "public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers." 19 U.S.C. § 1337(d)(l), (f)(l).

Apple also argues that the remedial orders would adversely affect medical studies using the Apple Watches' infringing blood oxygen feature and/or an ECG recording feature. Stay-Mot. at 21. The Commission, however, provided the above-noted exemption to ensure that any study participants could receive a replacement device to continue any study with a device having the same technology. Stay-Add-126–127; *Wearable Elec. Devices*, 2023 WL 373272, at *42–47. The Commission further found that research could be performed using the many alternatives, and that the United States already had a sufficiently large amount of potential study participants. Stay-Add-127–129; *Wearable Elec. Devices*, 2023 WL 373272, at *42–47. Apple further argues that remedial orders will adversely affect the economy, Stay-Mot. at 22–23, but Apple's arguments fail to tie the alleged harm specifically to Apple Watches, much less to the infringing Apple Watches (as opposed to the non-infringing Apple Watch SE). *See* Stay-Add-141–146. Last, importantly, "the public is best served by enforcing patents that are likely valid and infringed." *E.g.*, *Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006).

Thus, the public interest, as well as the other three *Standard Havens* factors, counsel against a stay.

III. CONCLUSION

For the foregoing reasons, the Commission respectfully requests that the Court deny Apple's motion.

Respectfully submitted,

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Date: January 10, 2024

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION, TYPEFACE, AND TYPE STYLE REQUIREMENTS

Pursuant to Federal Rule of Appellate Procedure 32(g)(1) and Federal Circuit Rule 32(b)(3), I hereby certify that the attached opposition complies with the type-volume limitation and typeface requirements of Federal Rules of Appellate Procedure 32(a)(7) and Federal Circuit Rules 32(b)(1) and 32(b)(2). This opposition has been prepared in a proportionally spaced typeface using Microsoft Word for Microsoft Office 365 in Times New Roman 14-point font, and contains 5120 words according to the word-count function of the word-processing system, which provided 5100 words, and a manual count of 20 words from the figures.

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CERTIFICATE OF COMPLIANCE WITH CONFIDENTIALITY REQUIREMENTS

Pursuant to Fed. Cir. R. 25.1(e)(2), I hereby certify that the attached opposition, which contains material marked as confidential under Fed. Cir. R. 25.1(d)(1), complies with the limitations and requirements related to confidential information set forth in Fed. Cir. R. 25.1(d) and 28(d). This brief contains 0 unique words marked as confidential, and only contains confidential information in the attached addendum.

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CERTIFICATE OF SERVICE

I, Ronald A. Traud, hereby certify on this 10th day of January 2024 that I filed the attached **Appellee International Trade Commission's Nonconfidential Response in Opposition to Appellant's Motion for a Stay Pending Appeal** using this Court's CM/ECF system, which accounts for service under the Rules of this Court.

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No. 24-1285

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

v.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors.

Appeal from the United States International Trade Commission,
Investigation No. 337-TA-1276

DECLARATION OF RONALD A. TRAUD IN SUPPORT OF APPELLEE INTERNATIONAL TRADE COMMISSION'S RESPONSE IN OPPOSITION TO APPELLANT'S MOTION FOR A STAY PENDING APPEAL

I, Ronald A. Traud, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am an attorney for the U.S. International Trade Commission, counsel to Appellee in the above-captioned appeal. I have personal knowledge of the facts set forth below.

2. Attached hereto as Exhibit 1 (filed under seal) is a true and correct copy of an excerpted version of the June 6, 2022 trial transcript in Investigation No. 337-TA-1276, *Certain Light-Based Physiological Measurement Devices and Components*

Thereof (hereinafter, the "1276 Investigation"). This exhibit contains confidential information. No public version of this document is currently available.

3. Attached hereto as Exhibit 2 (filed under seal) is a true and correct copy of an excerpted version of the June 7, 2022 trial transcript in the 1276 Investigation. This exhibit contains confidential information. No public version of this document is currently available.

4. Attached hereto as Exhibit 3 (filed under seal) is a true and correct copy of an excerpted version of the June 9, 2022 trial transcript in the 1276 Investigation. This exhibit contains confidential information. No public version of this document is currently available.

5. Attached hereto as Exhibit 4 is a true and correct copy of an excerpted version of the June 10, 2022 trial transcript in the 1276 Investigation.

6. Attached hereto as Exhibit 5 is a true and correct copy of an excerpted public version of Respondent Apple Inc.'s Second Corrected Post-Hearing Brief, dated September 2, 2022, which was filed in the 1276 Investigation. This exhibit is fully public, but was prepared by redacting confidential business version from the confidential version.

7. Attached hereto as Exhibit 6 is a true and correct copy of an excerpted public version of Respondent Apple Inc.'s Petition for Review of the Initial Determination of Violation of Section 337, dated January 23, 2023, which was filed

the 1276 Investigation. This exhibit is fully public, but was prepared by redacting confidential business version from the confidential version.

8. Attached hereto as Exhibit 7 (filed under seal) is a true and correct copy of an excerpted version of Trial Exhibit No. CX-0378C (Masimo Presentation regarding the Masimo Watch). This exhibit contains confidential information. No public version of this document is currently available.

9. Attached hereto as Exhibit 8 (filed under seal) is a true and correct copy of an excerpted version of Trial Exhibit No. CX-0299C (Stephen Waydo Deposition Transcript). This exhibit contains confidential information. No public version of this document is currently available.

Executed on: January 10, 2024

/s/ Ronald A. Traud
Ronald A. Traud

LIST OF EXHIBITS

1	ITC Trial Transcript, Closed Sessions, June 6, 2022, Excerpted	ITC-Add-1–16
2	ITC Trial Transcript, Closed Sessions, June 7, 2022, Excerpted	ITC-Add-2–25
3	ITC Trial Transcript, Closed Sessions, June 9, 2022, Excerpted	ITC-Add-26–29
4	ITC Trial Transcript, Open Sessions, June 10, 2022, Excerpted	ITC-Add-30–47
5	Respondent Apple Inc.'s Second Corrected Post-Hearing Brief, September 2, 2022, Excerpted	ITC-Add-48–86
6	Respondent Apple Inc.'s Petition for Review of the Initial Determination of Violation of Section 337, January 23, 2023, Excerpted	ITC-Add-87–95
7	Trial Exhibit No. CX-0378C (Masimo Presentation regarding the Masimo Watch), Excerpted	ITC-Add-96–98
8	Trial Exhibit No. CX-0299C (Stephen Waydo Deposition Transcript), Excerpted	ITC-Add-99–101

EXHIBIT 1

UNITED STATES
INTERNATIONAL TRADE COMMISSION

----------x

In the Matter of Investigation No.

CERTAIN LIGHT-BASED PHYSIOLOGICAL 337-TA-1276

MEASUREMENT DEVICES AND COMPONENTS

THEREOF

----------x

REVISED AND CORRECTED TRANSCRIPT

CLOSED SESSIONS

Pages: 1 through 282 (with excerpts)

Place: Washington, D.C.

Date: June 6, 2022

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EXHIBIT 2

UNITED STATES
INTERNATIONAL TRADE COMMISSION

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In the Matter of Investigation No.

CERTAIN LIGHT-BASED PHYSIOLOGICAL 337-TA-1276

MEASUREMENT DEVICES AND COMPONENTS

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CLOSED SESSIONS

Pages: 283 through 596 (with excerpts)

Place: Washington, D.C.

Date: June 7, 2022

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EXHIBIT 3

UNITED STATES
INTERNATIONAL TRADE COMMISSION

----------x

In the Matter of Investigation No.

CERTAIN LIGHT-BASED PHYSIOLOGICAL 337-TA-1276

MEASUREMENT DEVICES AND COMPONENTS

THEREOF

----------x

CLOSED SESSIONS

Pages: 862 through 1167 (with excerpts)

Place: Washington, D.C.

Date: June 9, 2022

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EXHIBIT 4

UNITED STATES
INTERNATIONAL TRADE COMMISSION

----------x

In the Matter of Investigation No.

CERTAIN LIGHT-BASED PHYSIOLOGICAL 337-TA-1276

MEASUREMENT DEVICES AND COMPONENTS

THEREOF

----------x

REVISED AND CORRECTED TRANSCRIPT

OPEN SESSIONS

Pages: 1168 through 1459 (with excerpts)

Place: Washington, D.C.

Date: June 10, 2022

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of 2008, what was known about the use of openings with opaque surfaces over photodiodes?

A. Well, I would say in 2008 and many decades prior, openings are a way for light or to allow light to get to a detector. A detector can't detect light without some sort of opening above it.

Q. And if we were to turn to the next slide, can you provide some examples before 2008 -- July of 2008 -- of devices that combine these concepts that you've been talking about -- multiple LEDs, four or more photodiodes, and openings over those photodiodes?

A. Yes. None of these tools existed in isolation. A designer would have used a collection of a grouping or permutation of many of them in their work.

One I really like a lot is Smart, RX-473, because it incorporates the LEDs, the photodiodes, the opaque material, the interior surfaces, the opaque surfaces, and the openings all in one bundle, 50 years ago.

Q. What are the others that you've identified on this slide? And just by name and exhibit number.

A. Okay. Haar, RX-667, and then McCarthy, RX-489, Lumidigm, RX-411, and then finally Imai, RX-1220.

Q. If we can turn to the next slide.

In July of 2008, what was known about the use of transmissive coverings or windows over photodiodes?

A. I noted earlier that you need an opening to allow light to reach a detector. A window is another way to allow that to happen where a window is a physical piece of material, or we call it a transmissive covering, where the covering would allow light through, but it would also physically protect the detector from dust and debris and dirt, liquid, things of that nature.

Q. What are your favorite examples here?

A. I'll pick a few. I really like Cramer RX-670 in the upper left, because it's more than 40 years old. Nippon, or what I call Jaib, RX-665, next to it. Seiko, we'll hear about in a moment, RX-666, and then also Haar, RX-667. And I might point out we also did this with Kansas State, RX-648.

Q. If we could turn to the last slide in this series.

In July of 2008, what was known about the use of structures protruding into the tissue in optical sensors?

A. So a person of ordinary skill would have already known that you could take a structure, we'll call it a protrusion or a sensor head, and push that into tissue, and what that would enable is that would push residual blood out of the way and increase your AC-to-DC signal ratio, meaning that you would see the tissue perfusion in a better way.

And there were a number of designs that did this.

Again, I like Smart, because it's so old, RX-473, but Cramer, next to it, RX-670, also implemented this mechanism.

And Seiko in the bottom left, Seiko 131, which is RX-666, not only implemented it, but explained well why the technique was important and why it worked.

Q. If we could go to the next slide.

Professor Warren, we're going to come back to the Apple Watch later, but until then just a few preliminary questions.

How long have optical sensors included four or more sets of LEDs?

A. At least since 1990, so 30 years.

Q. How long have optical sensors included four or more photodiodes arranged in quadrants?

A. Cramer 1978 would be a good example, so 40 years.

Q. How long have optical sensors included openings with opaque surfaces over photodiodes?

A. That goes all the way back to Herczfeld and Smart in the late '60s.

Q. And how long have optical sensors included convex protrusions to conform to a measurement site?

A. I would offer Smart for that one, early '70s.

Q. We're going to turn now to RDX-8.88.

You mentioned earlier that you have built pulse oximeters with your students in laboratory classes. Do you

recognize -- let me just ask you to remind us the timing of these laboratory courses.

A. I took these pictures in fall 2002.

Q. Okay. What are we seeing on the top row?

A. So the top row is just some example pictures from a Tuesday evening session that we managed with the students where I attempted to archive the pulse oximetry procedure.

Q. Is that Mr. Schmitz again on the left taking a measurement on his wrist?

A. It is, yes.

Q. And what are we seeing in the bottom row?

A. So the bottom row is a collection of sensors that were built by students. On the left row we have some built by Ryan, excuse me, by Austin Wareing. And in the center there were some other built by students as well as the right.

Q. I'd like to ask you about one in particular. We're going to turn to RDX-889.

Do you recognize the student-made sensor in the photo on the left here, RX-515?

A. Yes. This is a sensor that Austin Wareing built.

Q. Okay. And who was Austin Wareing?

A. Oh, yes, Austin Wareing was an undergraduate student in my laboratory working on an Honors Research project.

Q. Okay. And at the time he created this sensor, would he have met the agreed definition of a person of ordinary skill in the art?

A. No, he did not yet have his undergraduate degree.

Q. When did he create this sensor?

A. This was a summer 2004 project.

Q. Can you describe at a high level the primary components he included in his sensor?

A. Yeah. The sensor incorporated six photodiode detectors. These are large area detectors. And they were embedded on an interior foam surface, and that was sandwiched then with another piece of foam on top.

And to provide openings, Austin cut holes in the foam with an X-Acto knife, and then he cut the border around the entire unit with a pair of scissors.

Q. Do you recognize the photo on the top left, RX-517?

A. Yes. On the top right, it's Austin's sensor along with a data acquisition board to which it interfaced.

Q. What components would that data acquisition board have had?

A. That was a board driven by a PIC microcontroller, and it also had the sample on hold circuitry and some other circuitry on it.

Q. Including processors?

A. Yes, the PIC microcontroller was a processor with memory.

Q. What are we seeing in the bottom right, RX-652?

A. The image in the bottom right is a depiction of one of the Bluetooth boards that we used with RX-0517. This was a Bluetooth board that we had just a small number of.

Q. And we're going to quickly put on the ELMO three physical exhibits, RPX-6, RPX-7, and RPX-33.

Do you recognize these?

A. Yes, I do.

Q. And how would you compare these to what we just saw in the photos?

A. They're the same units that were in the photos, although I believe the one on the right is upside down.

Q. Sorry about that.

We're going to turn, then, to RDX-890.

Did any of your students ever use more than two LEDs in RDX-890?

A. Yeah. We looked at a previous viewgraph with some students' sensors in it, and it incorporated four sets of two LEDs around a central photodiode detector. And there is an image on the screen at the moment that depicts another student's work that incorporates three LEDs.

Q. Did any of your students ever include windows over the photodiodes in their sensors?

A. Yeah. One of the nice products available at the time is what we would call a can photodiode, which means a photodiode in a can with a window over the top to provide a lens and a protective function.

Q. And are we looking at RX-510 and RX-648?

A. Yes.

Q. If we could turn to the next slide.

MR. CLAUSSEN: Your Honor, I'd like to raise an objection before we move on. My objection is that RPX -- want to make clear for the record that RPX-18 is not part of the grounds for this case. And so we object to any implication that RPX-16 and RPX-18 are part of the grounds for this case.

MS. VREELAND: Your Honor, we're only introducing the photos so we're not going --

MR. CLAASSEN: With that representation, we can move on.

Q. If we could turn, then, to the next slide.

What is RX-508?

A. This is a publication from 2005 that we presented at the American Society for an Engineering Education Conference.

Q. And do you recognize the acquisition board and the sensor in the bottom left excerpt from this article?

A. Yes. Those are the same two pieces of hardware

that we just saw on the ELMO unit.

Q. Okay. And if we could turn, then, to the next exhibit.

What is RX-504?

A. This is a poster that Austin used for a public presentation in our college Honors Colloquium, the atrium exercise, and it speaks to the design of his sensor head in addition to the other hardware and software that was used.

Q. And what did he highlight about his design?

A. The highlighted element is -- speaks to the foam. So the optical foam that we use or the black foam was intended to be pliable so that the sensor head could conform to tissue. And there was a clear reason for using the foam itself, and that was to essentially block light or prevent light piping via the use of opaque material.

Q. Let's turn, then, to the Poeze patents. We're going to go to RDX-814.

Do you recognize the three patents on the screen, JX-1, JX-2, and JX-3?

A. I do.

Q. Can we call these the Poeze patents?

A. Yes.

Q. What types of pulse oximeters do the Poeze patents show in their figures and embodiments?

A. These would address what we would call clothespin

style transmissive finger clips.

Q. If we could go to the next figure.

So in the examples in the Poeze figures, are the LEDs and the photodiodes on the same side of the sensor?

A. The LEDs and photodiodes are on different sides of tissue, if that was the question you intended.

Q. And do the Poeze patents say anything about reflective pulse oximeters?

A. That mode is mentioned briefly in the spec but not in the pictures themselves.

Q. And in the examples in the Poeze figures, what part of the body is being used as the measurement site?

A. These are all fingertip sensors.

Q. Okay. Have you read each of the -- the patent specifications from front to back?

A. I've read them front to back twice, but I've studied a number of the other areas, many hours, countless hours it seems at this point.

Q. And have you seen anything anywhere in those Poeze specifications about taking a measurement on a wrist?

A. No.

Q. Nothing?

A. No. There is only a mention to finger, toe, hand, foot, ear, and forehead, as I recall, no wrist.

Q. If we could turn to the next slide, RDX-816.

Masimo has focused in particular on the fact that the Poeze patents disclose pulse oximeters with a protrusion.

What do the patents say about the shape of the protrusion that you can use with the -- in the purported invention?

A. The specification states that it can be convex, but then it also says it can be sized and shaped to conform the tissue to a flat or relatively flat surface. It also states that it can be cylindrical or partially cylindrical.

And then it says here at the bottom of the highlighted portion it could be sized and shaped differently for different measurement sites. So a variety of descriptions of shapes and sizes.

Q. Do the patents ever at any point suggest using a convex protrusion for taking a measurement at a wrist?

A. No.

Q. We're going to turn to the next slide.

Masimo has focused in its testimony on the reduction of light piping. What do the Poeze patents say about how to reduce light piping, if at all?

A. The only thing the spec says about reducing light piping, at least with regard to opaque material, is with regard to the protrusion in the upper example, black or other colored plastic. And then with regard to the noise

shield in the bottom exhibit, opaque color such as black or dark blue.

Q. So are there any teachings in these specifications, then, beyond using opaque materials?

A. Not for light piping.

Q. And how long have people in the industry been using openings with opaque materials to reduce light piping?

A. The Herczfeld reference shows it explicitly in 1969 so 50 years, decades.

Q. Professor Warren, have you studied the asserted claims of the Poeze patents?

A. Yes.

Q. And do you have an opinion on whether or not the Poeze claims describe anything new or novel?

A. My opinion is that they do not. In fact, the ideas or teachings are quite old.

Q. We're going to turn next, then, to RDX-818, the next slide, RDX-819.

Professor Warren, have you studied the Lumidigm patent, RX-411?

A. Yes.

Q. How did you first become aware of the company Lumidigm?

A. I learned of Lumidigm as a spinoff from Rio Grande Medical Technology, and I knew about them when I

worked at Sandia in Albuquerque in the mid-'90s.

Q. How did you first become aware of the Lumidigm '212 patent?

A. I found this patent when I was doing a recessed detector search online.

Q. Can we call it Lumidigm for short?

A. Yes, that's fine.

Q. How would you characterize Lumidigm's disclosures?

A. The spec -- I think the real novelty is in the idea of a personal identification system that uses liveness as an additional indicator.

But one of the other benefits of the specification is that it includes a collation of what was known about the time of optical sensor heads that were used in reflectance mode for spectroscopy purposes in terms of their various LED and photodiode detector layouts.

Q. We're going to pull on to the screen RX-411, Figures 3 through 7B.

What does Lumidigm describe in connection with these figures?

A. These figures are various examples or exemplary ideas of ways to lay out a variety of sources and detectors in reflectance mode on a sensor such as this, including in radial and rectilinear and Cartesian layout.

Figures 3 and -- let's see, 5, 7A and 7B -- where Lumidigm states that each of the locations for the LEDs, which, again, are the red dots on these figures, each of those locations can be comprised of LEDs with the same or different wavelengths, but also the light sources themselves can include sets of LEDs --

Q. Why don't we go --

A. -- at each location.

Q. Let's go, then, to the next limitation.

How does Lumidigm teach element 19B?

A. So this is the well-known idea of four photodiodes arranged on the user-worn device. Lumidigm addresses this specifically in Fig. 7A and 7B, where 7A incorporates five photodiodes in a linear arrangement, and Fig. 7B incorporates an 8x8 grid of 64 photodiodes.

Q. Let's turn, then, to element 19C or 19D, excuse me.

How does Lumidigm teach this?

A. The notion of an optically transparent material is, again, quite well-known where the material is in each of the openings. Lumidigm states in column 8 that an optical relay, which is not shown in the diagram, between the sensor and sensor surface and the skin, and helped to transfer light by directionally either from the light source from the skin or from the skin back to the detector.

And I've illustrated, for example, a well-known optical relay, which is a lens, in the opening of the photodiode that's depicted in Fig. 2, but Lumidigm also states that you can use fiber-optic faceplates for this purpose, where you could use a single faceplate for multiple openings or you could do an individual -- a person of skill would know that you could do an individual faceplate for each of the individual openings as a means to provide light but still optimize the process.

Q. And what about the example, the fiber bundle, what would a person of skill in the art understand about that?

A. Right. This is one that I mentioned in my report where you could use a fiber bundle to essentially direct the light from a portion of tissue straight to the detector as a means to optimize the detection process.

Q. And in July 2008, what materials would a person of skill in the art recognize a fiber-optic faceplate or a fiber bundle would be made of?

A. The individual fibers would have a glass core and then either a glass or a plastic cladding and then a protective layer. A fiber-optic faceplate, by the way, is like a bundle of spaghetti that you hold in your hand and you cut sideways so that you get all the little fibers lined up with one another.

If we could turn to the next slide.

How do Seiko and Cramer teach these limitations?

A. In Seiko, for example, these limitations are taught through the light transmittance plate that I already mentioned. It's a transparent material that allows light to reach the photodiode detector.

In Cramer, windows or transparent materials are taught two different ways. The first one, for example, is the lens that exists at the top of the can above the photodiode in this depiction, and the other is the windows that are between the raised boss regions as depicted in Fig. 6.

Q. If we could turn to the next slide.

What is the basis for your opinion that a person of skill in the art would have been motivated to combine Lumidigm's watch with Seiko's and Cramer's teachings on the use of optically transparent materials and windows over or within openings -- over or within the openings over photodiodes?

A. The basis for my opinion is, first, that Lumidigm expressly teaches this idea through the notion of an optical relay, which is a general way to say a transparent material for allowing light to pass.

And, in addition, independent of that idea, a person of ordinary skill would have known that windows could

be used and that Seiko 131 and Cramer would be suitable references to consult.

Q. Finally, then, let's turn to the limitation in the next slide -- limitation in claim 30 relating to a protrusion with chamfered edges.

How do Seiko and Cramer disclose this limitation?

A. Seiko discloses chamfered edges in several figures. I've noted Fig. 5 and Fig. 28 here where chamfered edges are illustrated in Fig. 5 at the edges of the protrusion, and in Fig. 28 on the opposite side of the sensor as a comfort mechanism.

And in Cramer, chamfered edges are incorporated in Fig. 3, as an example, where a chamfer allows the edge to transition from the main watch body to the raised boss area without a sharp, 90-degree orthogonal edge that would be uncomfortable for the user.

Q. And if we were to turn to the next slide, what is the basis for your opinion that a person of skill in the art would have been motivated to combine Lumidigm's watch with Seiko's and Cramer's teachings of protrusions with chamfered edges?

A. The basis for my opinion, again, is twofold. The first thought is that the compound curvature and the need for ergonomic features is expressly stated in Lumidigm. Additionally, a person of ordinary skill would understand

EXHIBIT 5

[redacted]

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Monica Bhattacharyya
Administrative Law Judge

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S SECOND CORRECTED POST-HEARING BRIEF

[redacted]

Id. 1198:17-1999:6; RDX-8.90 (summarizing Tr. [Warren] 1198:16-1200:15, RX-0510, RX-0648); *see also* incorporated exhibits.

b. Anticipation Under 35 U.S.C. § 102(a) / Single-Reference Obviousness Under 35 U.S.C. § 103(a) Based on Lumidigm

As discussed below and confirmed at trial by Professor Warren, Lumidigm anticipates all asserted claims of the Poeze Patents, and at a minimum, renders all asserted claims obvious. Tr. [Warren] 1207:1-12.[20]

(1) Lumidigm

U.S. Patent No. 7,620,212, titled "Electro-Optical Sensor" and originally assigned to Lumidigm, has an August 13, 2002 priority date and is prior art to the Poeze Patents under 35 U.S.C. § 102. RX-0411 ("Lumidigm"). The lead inventor, Dr. Robert Rowe, previously worked for Rio Grande Medical Technologies on light-based sensors that measured glucose and other blood analytes. Tr. [Rowe] 1142:10-17, 1143:12-1144:8, 1146:18-1147:9. Lumidigm formed as a spinoff to develop products that would use the same light-based sensors for biometrics. *Id.* at 1142:18-1143:1, 1144:15-1145:3.

Lumidigm's specification provides "a collation of what was known about [at] the time of optical sensor heads that were used for reflectance mode for spectrometry purposes." Tr. [Warren] 1204:8-17. Lumidigm's purported novelty focuses on detecting the liveness of tissue, but

[20] Complainants' expert Dr. Madisetti disagrees that the asserted Poeze Patent claims are invalid. *See* Tr. [Madisetti] at 1385:25-1387:25. Apple requests that the ALJ take judicial notice of the Final Written Decisions and corresponding declarations from Dr. Madisetti (attached hereto as Exs. 1-16). *See Certain Infotainment Sys., Components Thereof, & Automobiles Containing the Same,* Inv. No. 337-TA-1119, 2019 WL 4744857, at *1 (Sept. 23, 2019) ("Judicial notice is appropriate for USPTO decisions related to an asserted patent."); *Certain Movable Barrier Operator Sys. & Components Thereof*, Inv. No. 337-TA-1118, 2019 WL 1773475 at *1 (Apr. 16, 2019) (same).

[redacted]

Lumidigm repeatedly teaches that the same light-based sensors could be used to measure traditional parameters such as glucose, hemoglobin, and blood oxygenation. RX-0411 at 4:25-29, 10:11-21, 19:16-28; Tr. [Warren] 1204:8-17, 1205:1-11, 1215:18-1216:9; Tr. [Rowe] 1147:10-1148:4.

Lumidigm explains that its sensor can include any number and arrangement of ***light sources***, including LEDs, in any of a variety of wavelengths. RX-0411 at 6:38-53, 8:33-9:11, 9:26-34. Lumidigm further confirms that the sensor can include any number and any arrangement of ***detectors***, including "a single element, a plurality of discrete elements, or a one-or-two dimensional array of elements." *Id.* at 6:54-63, 9:39-45, 9:52-57. Lumidigm illustrates examples of such arrangements in Figures 3 through 7B, noting that "other numbers and arrangements" of sources and detectors "may alternatively be used" and that "[m]any variants exist:

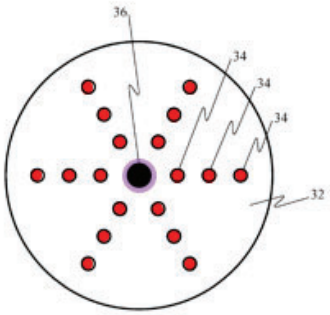


FIG. 3

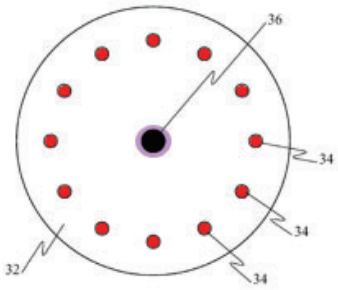


FIG. 4

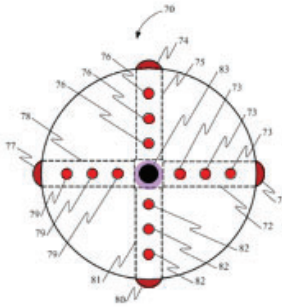


FIG. 5

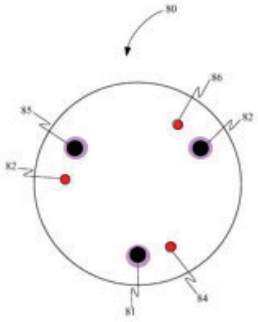


FIG. 6

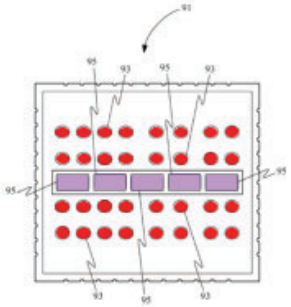


FIG. 7A

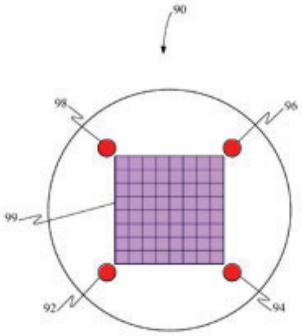


FIG. 7B

[redacted]

RX-0411 at Fig. 3-7B, 9:30-45; Tr. [Warren] 1204:18-12:05:11; Tr. [Rowe] 1148:5-19.[21]

Lumidigm explicitly confirms that the head of its sensor (i.e., the part in contact with the user's tissue) can have a "***compound curvature on the optical surface*** to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical coupling with the tissue being measured, or for other technical or stylistic reasons." RX-0411 at 7:58-63.

Lumidigm also discloses that the sensor can be incorporated into a "portable electronic device" and provides as exemplary devices: key fobs, cell phones, personal digital assistants, and user-worn watches.

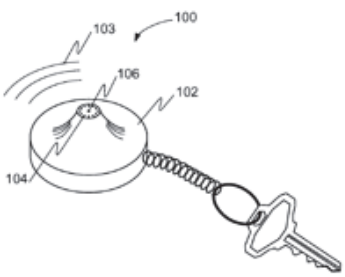


FIG. 8A

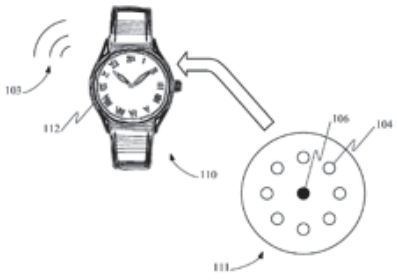


FIG. 8B

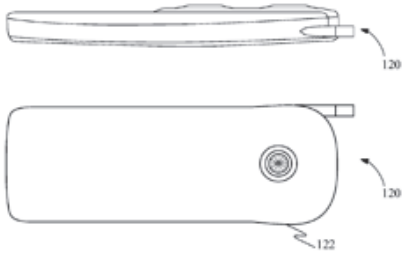


FIG. 8C

RX-0411 at Fig. 8A-C, 3:35-37. Lumidigm further explains that its wristwatch embodiment can include "***any*** of the sensor geometries previously disclosed or other equivalent configurations." *Id.* at 11:60-12:2; Tr. [Warren] 1205:12-1206:7; Tr. [Rowe] 1152:4-25.

Lumidigm's wristwatch and other portable devices also include a number of other standard components, including internal processors and memory for calculating and storing measurements (*e.g.*, RX-0411 at Fig. 9, 12:56-13:14) and interfaces for wireless communications (*e.g.*, *id.* at Figs. 8D-8E, 13:9-12).

[21] Apple has added color to Lumidigm's figures throughout this brief, to highlight the relevant components.

[redacted]

(2) '501 Patent, Claim 12

Lumidigm discloses all limitations of '501 claim 12 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1207:1-1215:10.

(a) '501 Patent, Claim 1

Limitation [1Preamble]: Lumidigm discloses "***[a] user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising***."

Lumidigm discloses that its sensor can be incorporated into a variety of devices including a user-worn wristwatch, as shown in Figure 8B:

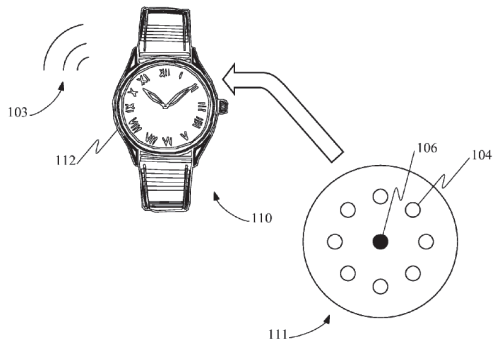


FIG. 8B

RX-0411 at 11:60-12:2, Fig. 8B; Tr. [Warren] 1207:23-1208:13; RDX-8.23 (summarizing RX-0411).

Lumidigm explains that, in this embodiment, the "biometric reader 11 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin on the area of the wrist." RX-0411 at 11:61-64. Lumidigm's sensor uses those signals to measure physiological parameters, based on the "concentration of a substance in the individual's tissue," including "oxygenation and/or hemoglobin levels in the blood." *Id*. at 19:16-28, *see also* 11:61-64; Tr. [Warren] 1208:1-13, 1214:12-1215:4.

Lumidigm introduces its wristwatch embodiment after discussing numerous illustrative arrangements for the sensor's light sources, detectors, and sensor head, and confirms that "any of

the sensor geometries previously disclosed or other equivalent configurations" can be used in the wristwatch embodiment. RX-0411 at 11:60-12:2. A POSITA[22] would have understood that this would include any of the disclosed arrangements of LEDs and photodiodes, any of the disclosed geometries for the sensor head including a "compound curvature," and any equivalent configurations. Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Limitation [1A]: Lumidigm discloses "***at least three light emitting diodes (LEDs)***."

The concept of using multiple LEDs in a sensor has been "known for many decades." Tr. [Warren] 1208:14-23, *see also* 1189:25-1191:22, 1195:6-12. Lumidigm teaches that its sensor can include any type of light sources, including LEDs, in any variety of wavelengths. RX-0411 at 6:38-53. For example, each light source in a sensor can comprise "sets of LEDs, laser diodes VCSELs, or other solid-state optoelectronic device," and the light sources can have the same wavelength characteristics, differing wavelength characteristics, or some sources with the same wavelengths and others with different wavelengths. *Id*. at 6:43-53; Tr. [Warren] 1208:14-23. Lumidigm also discloses that the sensor can include any number of light sources, in any arrangement.

Lumidigm includes a series of illustrative examples in Figures 2 through 7B, including examples with three or more LEDs, and confirms that "other arrangements" also can be used. RX-0411 at 9:26-34, Figs. 2-7B. For example, Figure 6 teaches that the sensor can have ***three LEDs*** positioned relative to three photodiodes:

[22] Professor Warren confirmed that he applied the parties' agreed definition of a person of ordinary skill in the art in evaluating anticipation and obviousness. Tr. [Warren] 1207:1-22. All references to a "POSITA" in this brief, for purposes of the Poeze Patents, are from the perspective of a POSITA with this skill level, as of the priority date of the Poeze Patents.

[redacted]

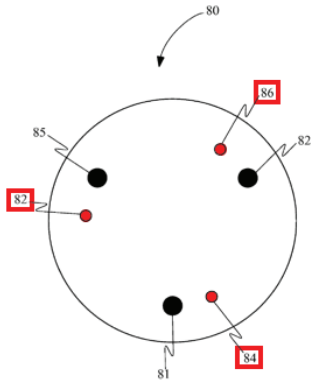


FIG. 6

RX-0411 at Fig. 6, 9:15-18, *see also* Figs. 3-5 and 7A-7B; Tr. [Warren] 1208:14-23; RDX-8.24 (summarizing RX-0411).

As referenced above, Lumidigm also discloses that any of the disclosed LED arrangements can be used in the wristwatch embodiment. RX-0411 at 11:60-12:2; Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Limitation [1B]: Lumidigm discloses "***at least three photodiodes***."

The concept of using three or more photodiodes in a sensor also was "quite well known," dating back more than 40 years. Tr. [Warren] 1208:25-1209:17, *see also* 1191:23-1192:22, 1195:13-15. Lumidigm discloses that its sensor's detectors "may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements," in essentially any arrangement. RX-0411 at 6:54-56. Lumidigm further explains that the detectors can be made of various materials, including "InGaAs," and that "a suitable detector material is silicon." *Id*. at 6:56-63; *see also* Tr. [Warren] 1208:25-1209:17. A POSITA would have understood that a detector made of InGaAs or silicon would be a photodiode. *Id.* at 1209:14-17 ("no doubt" a POSITA would understand these as photodiodes).

[redacted]

Lumidigm provides several illustrative examples, including examples with "at least three photodiodes" and again confirms that "other numbers and arrangements" may "alternatively be used." *Id.* at 9:30-34. For example, Figure 6 shows an example with ***three photodiodes***:

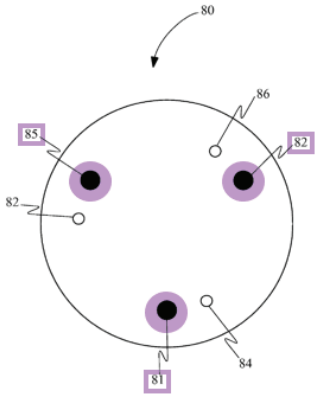


FIG. 6

RX-0411 at Fig. 6, *see also* Figs. 7A-7B; Tr. [Warren] 1208:25-1209:17; RDX-8.25 (summarizing RX-0411).

As referenced above, Lumidigm confirms that any of the disclosed photodiode arrangements can be used in its wristwatch embodiment. RX-0411 at 11:60-12:2; Tr. [Warren] 1204:18-1206:7, 1208:1-13, 1214:12-1215:4.

Lumidigm also discloses that the three photodiodes are "***arranged on an interior surface of the user-worn device***." For example, Figure 2, a cross-section of Figure 1, shows a detector placed on an interior surface of the device:

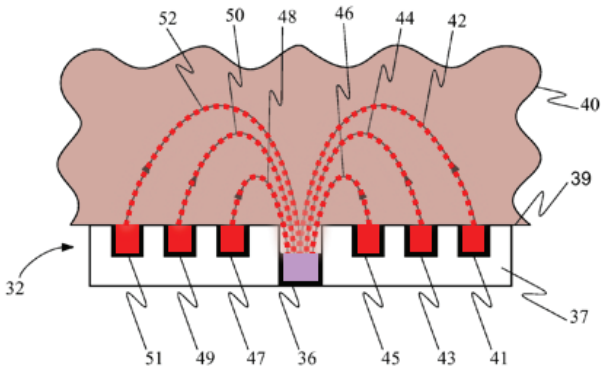


FIG. 2

RX-0411 at Fig. 2, 7:5-6, 8:1-4; Tr. [Warren] 1209:19-1210:11; RDX-8.26 (summarizing RX-0411). Although Figures 1 and 2 include only one detector, item 36, Lumidigm states that detector 36 is representative and "may comprise . . . a plurality of discrete elements." RX-0411 at 6:54-56, *see also* 3:9-11. A POSITA would have understood that, for the embodiments with multiple detectors, such as Figure 6, the additional detectors would be similarly arranged on the interior surface below the sensor head. Tr. [Warren] 1209:19-1210:11.

Lumidigm also discloses that the three photodiodes are "***configured to receive light attenuated by tissue of the user***." This was "another well-known principle," and is illustrated in Figure 2, showing the photodiodes receiving light that has been "reflect[ed] back" to the photodiodes after it has "propagated through the tissue." Tr. [Warren] 1209:19-1210:11. Lumidigm explains that the detectors are "disposed relative to the light sources to detect light that has propagated through tissue" and that the resulting signals "contain[ ] information about the tissue optical properties." RX-0411 at 3:25-28, 7:26-29, Fig. 2; Tr. [Warren] 1209:19-1210:11.

Limitation [1C]: Lumidigm discloses "a ***protrusion arranged over the interior surface, the protrusion comprising a convex surface.***"

The concept of using a protrusion with a convex surface was also a "well-known idea," dating back to the "early '70s." Tr. [Warren] 1210:13-1211:8, 1194:17-1195:5, 1195:20-22. As

referenced above, Figure 2 depicts a cross-sectional view of the sensor head, showing detectors recessed and placed on an interior surface below the sensor surface. RX-0411 at 7:5-6, 8:1-4. Although Figure 2 shows a flat sensor head, Lumidigm explains that "[t]he sensor head 32 may also have a ***compound curvature on the optical surface*** to match the profile of a device in which it is mounted, ***to incorporate ergonomic features that allow for good optical and mechanical coupling*** with the tissue being measured, or for other technical or stylistic reasons." *Id.* at 7:57-63, 8:27-28 ("Optionally, the surface of the light relay can be contoured to fit specific product applications and ergonomic requirements."); RDX-8.27 (summarizing same).

A POSITA would have understood that, when the sensor has a "compound curvature on the optical surface" (i.e., the surface directly in contact with the user's tissue), it has a protrusion, with a convex surface, arranged over the interior surface holding the detectors. Tr. [Warren] 1210:12-1211:8. Lumidigm expressly teaches the benefits of a "compound curvature," including for "good optical and mechanical coupling." RX-0411 at 7:57-63. A POSITA would have understood the benefits of including a convex protrusion, including to improve signal quality. Tr. [Warren] 1210:12-1211:8.

Limitation [1D]: Lumidigm discloses "a ***plurality of openings extending through the protrusion and positioned over the three photodiodes***."

The concept of including individual openings over each photodiode was another "quite well-known" idea, dating back to the "late 60s," to allow light to reach the detectors. Tr. [Warren] 1211:10-12:12-3, *see also* 1192:25-1193:6, 1195:16-19. Consistent with this concept, Lumidigm explains that its detectors are "recessed from the sensor surface 39 in optically opaque material" and shows an example of such an opening in Figure 2:

[redacted]

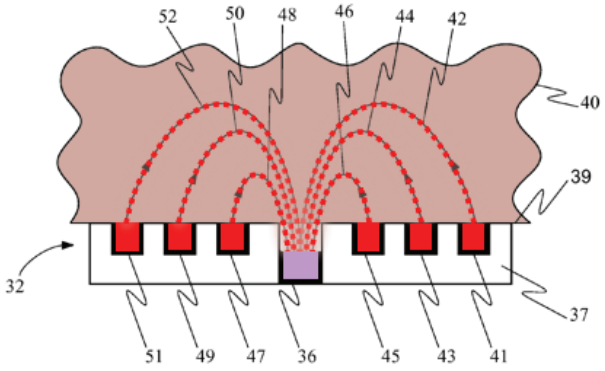


FIG. 2

Again, although Figures 1 and 2 include only one detector, item 36, Lumidigm expressly states that detector 36 is representative and "may comprise . . . a plurality of discrete elements." RX-0411 at 6:54-56, *see also* 3:9-11. A POSITA would have understood that the sensor can include a plurality of detectors, such as shown in Figure 6, and that for the embodiments with three or more photodiodes, the protrusion would include an opening positioned over each photodiode:

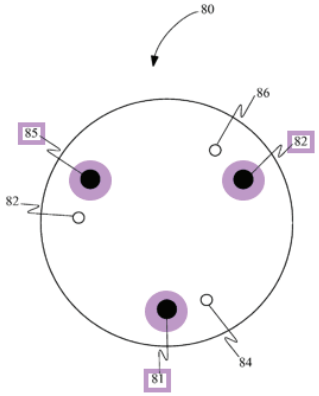


FIG. 6

RX-0411 at Fig. 6, 6:54-56, 3:9-11; Tr. [Warren] 1211:9-1212:10.; RDX-8.28 (summarizing RX-0411).

Limitation [1E]: Lumidigm discloses "***the openings each comprising an opaque lateral surface the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion***."

The concept of using opaque materials for openings over photodiodes was another "well-known idea," and also dated back to the "late '60s." Tr. [Warren] 1211:10-1212:3, *see also* 1192:25-1193:6, 1195:16-19. As Professor Warren explained, "if you recess the photodiodes or detectors from the sensor surface in optically opaque material, you can reduce the amount of light that's detected without going through the tissue." *Id.* at 1211:10-1212:3. Lumidigm expressly confirms that its detectors 36 are "recessed from the sensor surface 39 in optically opaque material 37" and that this ***opaque*** material performs "optical blocking" to avoid unwanted light (or light piping) through the protrusion:

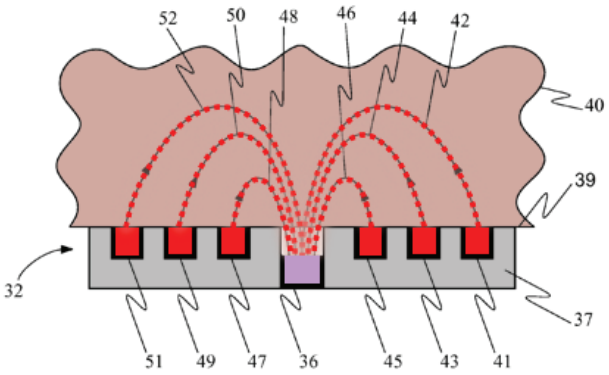


FIG. 2

RX-0411 at Fig. 2, 8:1-11; RDX-8.29 (summarizing RX-0411). A POSITA would have understood that openings made of opaque material over each detector avoid light piping through the protrusion (*i.e.*, light traveling from the LEDs to the photodiodes without first passing through the user's tissue). Tr. [Warren] 1212:11-1213:3, 1228:16-23. Lumidigm specifically discusses using this configuration to provide "optical blocking" for "shunted" light. RX-0411 at 7:64-8:11. Light shunting is another term for light piping. Tr. [Warren] 1212:22-1213:3.

Limitation [1F]: Lumidigm discloses "***one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user***."

[redacted]

The concept of including a processor to receive signals from photodiodes, calculate measurements, and "manage the overall set of events" is another "well-known idea." Tr. [Warren] 1213:4-1214:1. Lumidigm discloses that its portable devices, including the user-worn wristwatch, include a "processor [that] is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor." RX-0411 at 3:28-31. Lumidigm repeatedly refers to the processors in its devices, and confirms that "[o]nce the light passing through the tissue is detected, the signals can be digitized and recorded by standard techniques," and the "recorded data can then be processed" into spectral data "as is known to one of ordinary skill in the art." *Id.* at 9:58-62. This would include receiving and processing signals from the photodiodes and calculating physiological measurements. Tr. [Warren] 1213:4-1214:1; RX-0411 at 19:16-28 (confirming that system "quantif[ies] oxygenation levels").

Figure 9 provides an example of a "computational device" for "management of the functionality discussed herein" including "processor 332" and "processing acceleration unit 346":

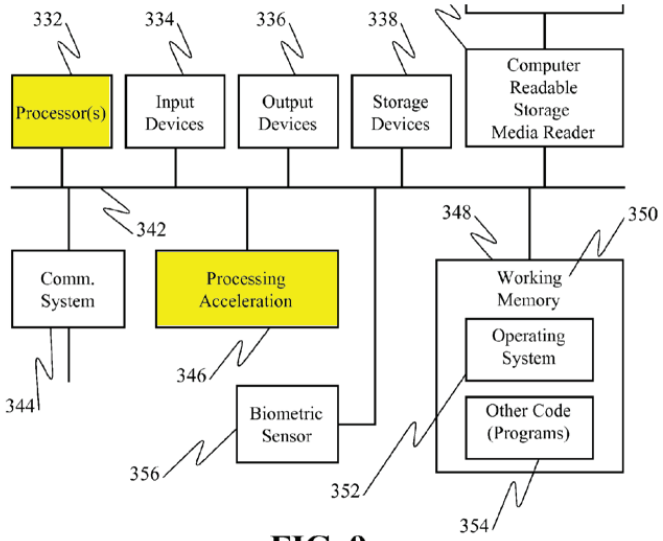


FIG. 9

RX-0411 at Fig. 9, 12:56-67; Tr. [Warren] 1213:4-1214:1; RDX-8.30 (summarizing RX-0411). Lumidigm further confirms that the components in Figure 9 can be implemented in a "separated

or more integrated manner." RX-0411 at 12:61-63. A POSITA would have understood that the processors could be implemented in a separate reader or integrated onto the same device as the sensor. Tr. [Warren] 1213:4-1214:1.

(b) '501 Patent, Claim 12

Lumidigm discloses "***[t]he user-worn device of claim 1***" for the reasons stated above for claim 1.

Lumidigm further discloses "***wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape***. Lumidigm discloses a "protrusion with a convex surface" for the reasons stated above for '501 limitation [1C]. A POSITA would have recognized that, if a sensor has a protrusion with a convex surface, and that protrusion is positioned next to tissue, "any pressure at all will conform the tissue into a concave shape." Tr. [Warren] 1214:2-11. Dr. Madisetti confirmed the same understanding. Tr. [Madisetti] 686:1-18.

(3) '502 Patent, Claim 22

Lumidigm discloses all limitations of '502 claim 22 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1215:11-1224:2.

(a) '502 Patent, Claim 19

Limitation [19Preamble]: Lumidigm discloses "[a] ***user-worn device configured to non-invasively measure***" a physiological parameter for the reasons discussed above for '501 claim 1, preamble.

Lumidigm further discloses that its user-worn device "***measure[s] an oxygen saturation of a user***." Lumidigm explains that its devices can be used to perform a variety of functions including measuring the "physiological state of an individual" using "a hemoglobin monitor." RX-

[redacted]

0411 at 19:16-19. Lumidigm further explains that this functionality detects "spectroscopic changes [that] are correlated with oxygenation and/or hemoglobin levels in the blood" and provides "the ability to quantify oxygenation levels." *Id*. at 19:22-28; RDX-8.35 (summarizing RX-0411).

A POSITA would have recognized from these disclosures that Lumidigm's devices are configured to quantify oxygenation levels. Tr. [Warren] 1215:18-1216:9. Moreover, a POSITA "would not have needed any additional information to make [pulse oximetry functionality] work" in Lumidigm's watch embodiment because this functionality was well understood at the time. *Id*. at 1216:10-25. In fact, Professor Warren and his students were able to build sensors and "work[] with them on their wrists" years earlier. *Id.* Although Apple had significant challenges to overcome in implementing pulse oximetry on Apple Watch, given the limited space and other competing features in Apple Watch, the simple light management problems addressed in the Poeze Patents had already been solved. DocID 773735 (substituting Warren Op. ¶ 244 for Tr. [Warren] 1217:11-21); Tr. [Warren] 1243:5-16.

Limitation [19A]: Lumidigm discloses "***a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs)***."

Lumidigm discloses that its sensor can include any number and arrangement of LEDs, including in its wristwatch embodiment, for the reasons discussed above for '501 claim 1, limitation [1A]. *E.g.*, RX-0411 at 6:38-53, 11:60-12:2, Fig. 6. Lumidigm further explains that the "light sources" can include "sets of LEDs." *Id*. at 6:48-53. A POSITA would have understood a "set of LEDs" as a "grouping" of LEDs, each including "for example, three LED dies." Tr. [Warren] 1190:25-1191:6, 1205:1-11.

[redacted]

The concept of including four or more emitters in an optical sensor, each comprising a set of LEDs, has been known for at least thirty years. Tr. [Warren] 1191:7-22, 1195:10-12. Lumidigm's illustrative examples including multiple examples with four or more sets of LEDs, including Figures 3, 5, 7A and 7B:

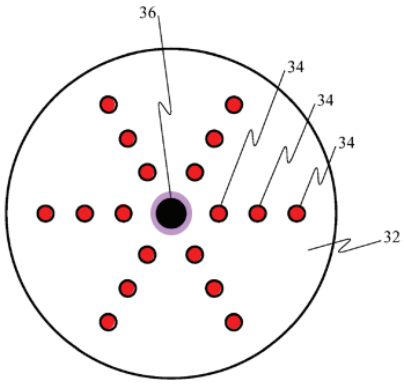


FIG. 3

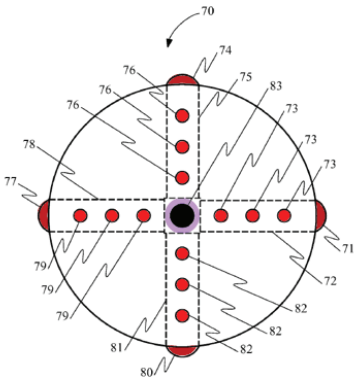


FIG. 5

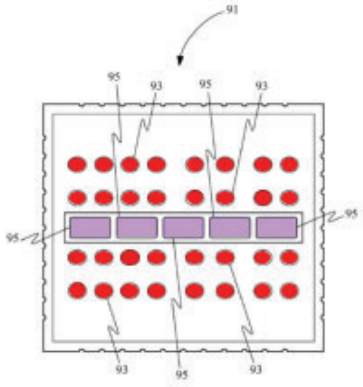


FIG. 7A

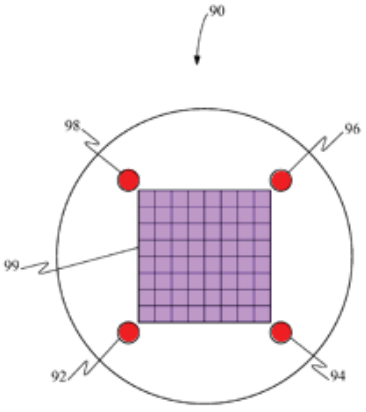


FIG. 7B

RX-0411 at Figs. 3, 5, and 7A-7B, 9:30-33; Tr. [Warren] 1220:12-1221:8.

A POSITA would have understood that the light sources disclosed in these examples would include at least four emitters, each with a set of three LEDs. Tr. [Warren] 1220:12-1221:8; RX-0411 at 6:38-53, Figs. 3, 5, and 7A-7B; RDX-8.36 (summarizing RX-0411). For example, Figure 3 would include 6 emitters, each with three radial LEDs (where the light sources are ***single*** LEDs) or 18 light sources, each with three LEDs in a set (where the light sources are ***sets*** of LEDs). *See*

Tr. [Warren] 1220:12-1221:8. Figures 5 and 7A similarly demonstrate four or more emitters, each with three or more LEDs, whether the circles that mark individual light sources are single LEDs or sets of LEDs. And Figure 7B demonstrates four emitters, each with a set of three LEDS, when the sources are sets of LEDs.

Limitation [19B]: Lumidigm discloses "***four photodiodes arranged within the user-worn device***."

The concept of using four or more photodiodes was also well-known. Tr. [Warren] 1191:24-1192:22, 1221:9-15. Lumidigm discloses that its sensor can include any number and arrangement of photodiodes, including in its wristwatch embodiment, for the reasons discussed above for '501 claim 1, limitation [1B]. *E.g.*, RX-0411 at 11:60-12:2. Lumidigm further discloses multiple illustrative examples with "four photodiodes" or more, including in Figures 7A (five photodiodes in a linear array) and 7B (64 photodiodes arranged in rows and columns):

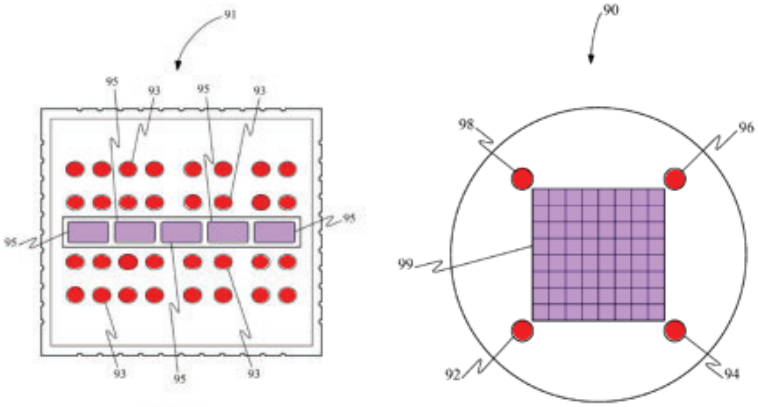


FIG. 7A FIG. 7B

RX-0411 at Figs. 7A-7B, 6:54-63; RDX-8.37 (summarizing RX-0411); Tr. [Warren] 1221:10-15.

Lumidigm also discloses that the four photodiodes are "***arranged within the user-worn device***" for the reasons discussed above for '501 claim 1, limitation [1B].

Lumidigm also discloses that these four photodiodes are "***configured to receive light after at least a portion of the light has been attenuated by the tissue of the user***" for the reasons

discussed above for '501 claim 1, limitation [1B]. For example, Lumidigm explains that the light detectors are "disposed relative to the light sources to detect light from the light sources that has propagated through the tissue." RX-0411 at 3:25-28; 7:26-29. A POSITA would have understood that the photodiodes would be configured to receive light attenuated by the tissue of the user. Tr. [Warren] 1209:19-1210:11.

Limitation [19C]: Lumidigm discloses "***a protrusion comprising a convex surface***" for the reasons discussed above for '501 claim 1, limitation [1C].

Lumidigm discloses "***separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one of the four photodiodes***" for the reasons discussed above for '501 claim 1, limitations [1D], [1E].

Lumidigm discloses "***the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue***" for the reasons discussed above for '501 claim 1, limitation [1E]. For example, Lumidigm expressly confirms that the openings over the photodiodes are made from "optically opaque material 37," that this configuration "minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue," and that "[o]ther equivalent means of optical blocking can be readily established by one of ordinary skill in the art":

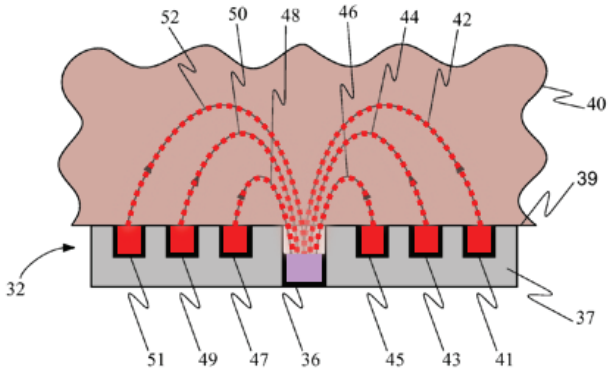


FIG. 2

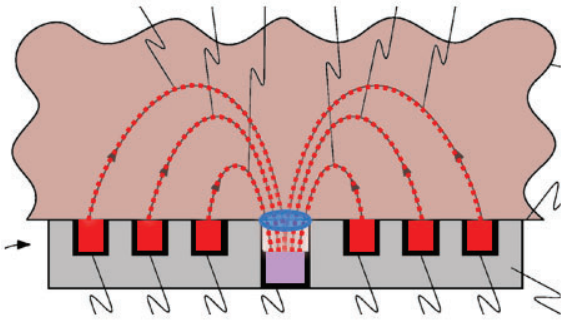
[redacted]

RX-0411 at Fig. 2, 8:1-11; Tr. [Warren] 1212:11-1213:3. RDX-8.29 (summarizing RX-0411). Lumidigm further explains that the sensor can have a "reflectance geometry" so that "when the tissue is illuminated by a particular light source 41, the resulting signal detected by the detector 36 contains information about the tissue optical properties along a path between the source 41 and detector 36." RX-0411 at 7:12-14, 7:26-29.

A POSITA would have also understood that Lumidigm's use of openings made from opaque material has the benefit of allowing light to pass through to the photodiodes while reducing light piping, or the amount of light reaching the photodiodes without being attenuated by the tissue. Tr. [Warren] 1212:11-1213:3.

Limitation [19D]: Lumidigm discloses "***optically transparent material within each of the openings***."

The use of windows or other optically transparent materials, within or across openings over photodiodes, was also "well-known." Tr. [Warren] 1221:16-12:22-9, 1193:24-1194:14. Consistent with this well-known idea, Lumidigm explains that its sensor can incorporate "an optical relay (not shown) between the sensor surface 39 and the skin 40" that "transfers the light . . . from the skin back to the detector(s)," and that this optical relay can include "fiber optic face plates," "individual optical fibers," and "fiber bundles." RX-0411 at 8:19-26. Professor Warren illustrates this optical relay in blue in Figure 2:



[redacted]

RX-0411 at Fig. 2; Tr. [Warren] 1221:16-1222:16; RDX-8.38 (summarizing RX-0411).

A POSITA would have understood that fiber optic face plates, individual optical fibers, and fiber bundles were well-known in the art, typically made of glass or plastic cladding, and could be placed within or arranged over the openings. Tr. [Warren] 1221:16-1222:25. A POSITA would have recognized, and Lumidigm confirms, that a well-known way to implement a fiber optic face plate would be to place it "between the sensor surface 39 and the skin" to cover individual openings. RX-0411 at 8:19-21; Tr. [Warren] 1221:16-1222:16. A POSITA would have further recognized that a fiber optic face plate could be implemented as a "single faceplate for multiple openings," or as "an individual faceplate for each of the individual openings." Tr. [Warren] 1221:16-1222:9. A POSITA would have recognized that a fiber optic face plate would be beneficial because it would "transfer light" from the tissue to the photodiodes and "protect the detector from dust and debris and dirt." *Id.* at 1193:24-1194:7, 1221:16-1222:16. A "fiber bundle" would similarly "direct light from a portion of tissue straight to the detector as a means to optimize the detection process." *Id.* at 1222:10-16.

A POSITA would have thus understood that non-invasive, optical sensing devices should have optically transparent material extending across the openings over the photodiodes and that the benefits would include providing a pathway for attenuated light to pass through to the photodiode while protecting the photodiode from damage or interference caused by contaminants from a user. *Id.* at 1193:24-1194:7, 1221:16-1222:25.

Limitation [19E]: Lumidigm discloses "***one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals***" for the reasons discussed above for 501 claim 1, limitation [1E]. For example, Lumidigm discloses both calculating and outputting measurements based on

signals from the photodiodes. RX-0411 at 3:28-31, 9:58-59, 12:56-13:14, Fig. 9; Tr. [Warren] 1213:4-1214:1. A POSITA would have understood that Lumidigm's "computational devices" include one or more processors configured to use signals to output measurements of physiological parameters and that the processors could be implemented in a separate reader or integrated onto the same device. Tr. [Warren] 1213:4-1214:1.

Lumidigm also discloses that its processors can output a measurement "***indicative of the oxygen saturation of the user***" for the reasons discussed above for '502 claim 19, preamble. A POSITA would have recognized that it is the processors in the device that output the measurements associated with Lumidigm's blood oxygen function. Tr. [Warren] 1215:18-1216:25; RX-0411 at 19:16-19, 19:22-28, Fig. 9; RDX-8.35 (summarizing RX-0411).

(b) '502 Patent, Claim 20

Lumidigm discloses "[t]he ***user-worn device*** of claim 19," for the reasons discussed above for '502 claim 19.

Lumidigm also discloses "***further comprising a thermistor***." This limitation relates to the "well-known notion" that "LEDs will change their behavior depending on temperature," and that if a processor "can receive a temperature signal, in this case from a thermistor, it can adjust the operation of the user worn device." Tr. [Warren] 1223:1-20. Consistent with this notion, Lumidigm discloses that its sensor may include "additional preprocessing steps" including "performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature" and other factors. RX-0411 at 14:21-28, Fig. 9; RDX-8.39 (summarizing RX-0411). Lumidigm also correctly comments that "[t]hese and other techniques are well-known in the art." *Id*. at 14:29.

A POSITA would have recognized that a thermistor was one of the "well-known" techniques in the art to perform "explicit corrections" for the "environmental influence[] of temperature," and it would have been obvious to include a thermistor in Lumidigm's device to take temperature readings so the processor could use that temperature signal to adjust operations. Tr. [Warren] 1223:1-20.

(c) '502 Patent Claim 21

Lumidigm discloses "[t]he ***user-worn device*** of claim 20," for the reasons discussed above for '502 claim 20.

Lumidigm discloses "***wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.***" As discussed above for '502 claim 20, Lumidigm discloses "performing explicit corrections" to account for "environmental influences of temperature" and confirms this is "well known in the art." RX-0411 at 14:21-29, Fig. 9; RDX-8.39 (summarizing RX-0411). Moreover, as discussed above in connection with '501 claim 1, limitation [1E], Lumidigm repeatedly refers to its sensor's processors throughout the specification. *E.g.*, RX-0411 at 12:61-67, Fig. 9. A POSITA would have understood that adjusting operations based on temperature requires, in addition to the thermistor, one or more processors to receive the temperature signal from the thermistor and to adjust operation of the sensor responsive to the temperature signal. Tr. [Warren] 1223:1-20.

(d) '502 Patent, Claim 22

Lumidigm discloses "[t]he ***user-worn device*** of claim 21," for the reasons discussed above for '502 claim 21.

[redacted]

Lumidigm also discloses "***wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs***," for the reasons discussed above for '502 limitation [19A]. The illustrative examples discussed in connection with '502 limitation [19A] include four emitters, each with a respective set of three LEDs. Tr. [Warren] 1220:13-1221:6.

(4) '502 Patent, Claim 28

Lumidigm discloses all limitations of '502 claim 28 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1224:3-1227:21.

Limitation [28Preamble]: Lumidigm discloses "***[a] user-worn device configured to noninvasively measure an oxygen saturation of a user, the user-worn device comprising***" for the reasons discussed above for '502 claim 19, preamble.

Limitation [28A]-[28B]: Lumidigm discloses "***a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength***" and "***a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength***."

As discussed above, the concept of including multiple emitters in an optical sensor, each comprising a set of LEDs, has been known for at least thirty years. Tr. [Warren] 1191:7-22, 1195:10-12. Each set of LEDs would include "for example, three LED dies," and "multiple wavelengths would be present, for example, in a multi-chip LED package." *Id.* at 1190:25-1191:6, 1205:1-11, 1224:23-1225:5.

[redacted]

Consistent with this "well-known idea," (Tr. [Warren] 1224:23-1225:5), Lumidigm discloses that its sensor can include any number and arrangement of LEDs, including sets of LEDs, and including in its wristwatch embodiment, for the reasons discussed above for '501 claim 1, limitation [1A], '502 claim 19, limitation [19A], and '502 claim 22. Lumidigm further explains that the light sources "can include some sources that have the same wavelengths as others and some sources that are different" and can include "sets of LEDs . . . with differing wavelength characteristics." RX-0411 at 6:38-53.

A POSITA reading Lumidigm would have understood that its sensor could include sets of LEDs; that those sets of LEDs could include LEDs of the same variety of differing wavelengths; and that a multi-chip LED package (a "source" in Lumidigm), commonly used at the time, could encapsulate a plurality of LED dies at multiple different wavelengths. Tr. [Warren] 1190:25-1191:6, 1224:9-1225:12.

Lumidigm provides multiple specific examples including the recited "first set" and "second set" of LEDs, which are "spaced apart" from each other, and which include LEDs configured to emit at a "first wavelength" and a "second wavelength," including the examples in Figures 3, 5, 6, 7A, and 7B:

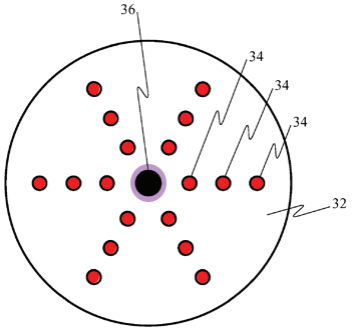


FIG. 3

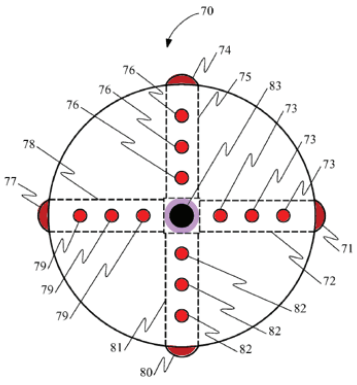


FIG. 5

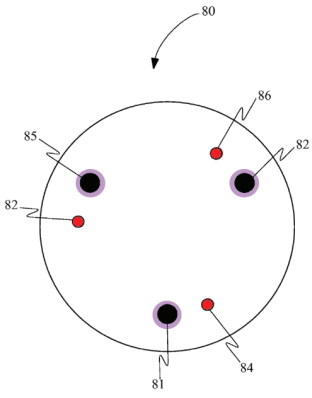


FIG. 6

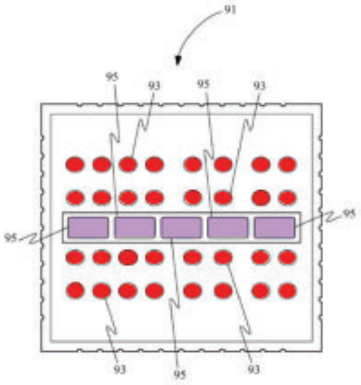


FIG. 7A

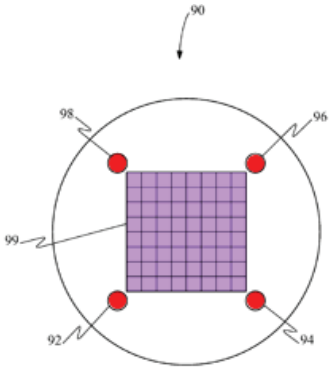


FIG. 7B

RX-0411 at Figs. 3, 5-6, and 7A-7B; Tr. [Warren] 1224:9-1225:12; RDX-8.42-RDX-8.43 (summarizing RX-0411). A POSITA would have understood, consistent with Lumidigm's disclosures, that each light source in these figures could comprise a set of LEDs, and that these sets of LEDs would be spaced apart from each other as shown in the figures. *Id*. at 6:38-53; Tr. [Warren] 1224:9-1225:12. A POSITA would have further understood that each set of LEDs would include LEDs configured to emit at a "first wavelength" and a "second wavelength," so that in each source location "multiple wavelengths would be present" (as in a multi-chip package). *Id.*

Lumidigm also incorporates by reference U.S. Patent Application Ser. No. 10/262,403 (RX-0411 at 1:40-44), which discloses in its Figure 6 multiple sets of LEDs, each with LEDs emitting at "first" and "second" wavelengths. RX-0460 ['403 Application] at Fig. 6, *see also* [0054]. A POSITA would recognize this as an example of the type of "sets of LEDs" that could readily be incorporated into Lumidigm's figures, particularly given that Lumidigm incorporates the application by reference and thus expressly suggests such a combination. Tr. [Warren] 1224:9-1225:12.

Limitation [28C]: Lumidigm discloses "***four photodiodes*** . . . ***configured to receive light after at least a portion of the light has been attenuated by the tissue of the user***" for the reasons discussed above for '502 claim 19, limitation [19B].

Lumidigm also discloses that the four photodiodes are "***arranged*** . . . ***on an interior surface of the user worn device***" for the reasons discussed above for '501 claim 1, limitation [1B]. Although this claim specifies four photodiodes rather than three, the same reasoning applies. Tr. [Warren] 1225:13-1226:1.

Lumidigm also discloses that the four photodiodes are "***arranged in a quadrant configuration***." The concept of arranging photodiodes in a quadrant was also "quite well-known." Tr. [Warren] 1225:13-1226:1, 1191:24-1192:22, 1195:13-15. Lumidigm explains that its detectors can be implemented "as a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements." RX-0411 at 6:54-63. A POSITA would have understood that a two-dimensional array would include an arrangement of detectors in a quadrant configuration. Tr. [Warren] 1225:16-1226:1. Lumidigm specifically discloses many more than four photodiodes arranged in a quadrant in Figure 7B and states that "many variations on this configuration exist":

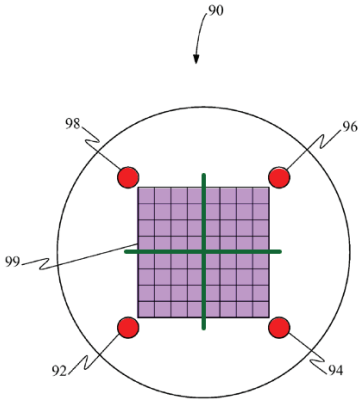


FIG. 7B

RX-0411 at Fig. 7B; RX-0411 at 9:42-45; Tr. [Warren] 1225:13-1226:1; RDX-8.44 (summarizing RX-0411). Figure 7B shows 64 detectors arranged in a quadrant, and a POSITA would recognize that any four of the photodiodes in this figure also could be arranged in a quadrant. Tr. [Warren] 1225:16-1226:1.

Limitation [28D]: Lumidigm discloses "***a thermistor configured to provide a temperature signal***" for the reasons discussed above for '502 claims 20 and 21.

Limitation [28E]: Lumidigm discloses "***a protrusion arranged above the interior surface, the protrusion comprising: a convex surface***" for the reasons discussed above for '501 claim 1, limitation [1C].

Limitation [28F]: Lumidigm discloses "***a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes***," for the reasons discussed above for '501 claim 1, limitation [1D] and '502 claim 19, limitation [19C]. A POSITA would have recognized that, for configurations with four or more photodiodes arranged in a quadrant, such as shown in Figure 7B, there would be an opening over each photodiode. Tr. [Warren] 1225:16-1226:1. This claim also specifies that the openings are in the convex surface of the protrusion, but the same reasoning applies as for the earlier limitations. *Id.* at 1224:3-8. Lumidigm teaches that the openings should be located within the convex surface to "incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured." RX-0411 at 7:57-63. Achieving good "optical coupling" would of course require locating the optical components (including the detectors and associated openings) so that they are aligned with the protrusion's convex surface. *Id.; see also* 8:27-28 ("Optionally, the surface of the light relay can be contoured to fit specific product applications and ergonomic requirements.").

Lumidigm also discloses "***each opening defined by an opaque surface configured to reduce light piping***," for the reasons discussed above for '501 claim 1, limitation [1E] and '502 claim 19, limitation [19C]. Although this claim references "reducing light piping" rather than "avoiding light piping," the same reasoning applies. Tr. [Warren] 1224:3-8.

[redacted]

Limitation [28G]: Lumidigm discloses "***a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings***" for the reasons discussed above for '502 claim 19, limitation [19D]. Although this claim specifies "transmissive windows extending across" the openings rather than "transparent materials within" the openings, the same reasoning applies. Tr. [Warren] 1224:3-8. A POSITA would have recognized that the fiber optic face plates and fiber optic bundles referenced in Lumidigm and discussed in connection with limitation [19D] are transmissive windows and that each would extend across a different one of the openings. Tr. [Warren] 1221:16-1222:25; RX-0411 at 8:19-26.

Limitation [28H]: Lumidigm discloses "***at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities***." As discussed above, Figure 2 shows a cross-section of Figure 1, illustrating the detectors "recessed from the sensor surface 39 in optically opaque material 37":

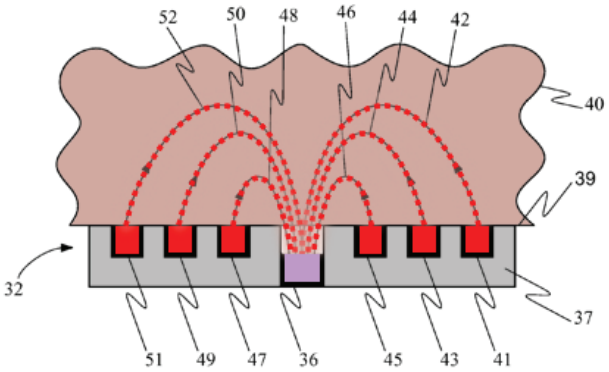


FIG. 2

RX-0411 at Fig. 2, 8:1-4; RDX-8.45 (summarizing RX-0411). Lumidigm expressly states, and a POSITA would have understood, that detector 36 in Figures 1 and 2 is representative and that it may comprise "a plurality of discrete elements." RX-0411 at 6:54-56, *see also* 3:9-11; Tr. [Warren] 1205:1-11. A POSITA would have further understood that there would be opaque walls

between the interior surface of the sensor and the protrusion, thereby forming cavities or recesses where the respective photodiodes are located. Tr. [Warren] 1226:2-8; RX-0411 at 8:1-11, Fig. 2.

Lumidigm further discloses that "***the photodiodes are arranged on the interior surface within the cavities***" for the reasons discussed above and for '501 claim 1, limitation [1B] and '502, claim 28, limitation [28C].

Limitation [28I]: Lumidigm discloses "***one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user***" for the reasons discussed above for '502 claim 19, limitation [19E].

Lumidigm also discloses "***the one or more processors further configured to receive the temperature signal***" for the reasons discussed above for '502 claim 21.

Limitation [28J]: Lumidigm discloses "***a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network***." By the time of the Poeze Patents, the use of wireless communications for sensors was also a "well-known idea." Tr. [Warren] 1226:9-21. Lumidigm repeatedly confirms that its sensors communicate measurements through wireless communication means. RX-0411 at 11:38-42, 13:9-12, Fig. 8B. Lumidigm also discloses that its devices have a "communication system 344" and that it "may comprise a wired, wireless, modem, and/or other type of interfacing connection and permits data to be exchanged with external devices." *Id*. at 13:9-12. Lumidigm shows its communications system 344 in Figure 9 and explains that these components can be incorporated into any of its exemplary embodiments including the wristwatch embodiment. *Id*. at Fig. 9, *see also* 12:58-61. Lumidigm also expressly illustrates its watch embodiment with wireless communications 103:

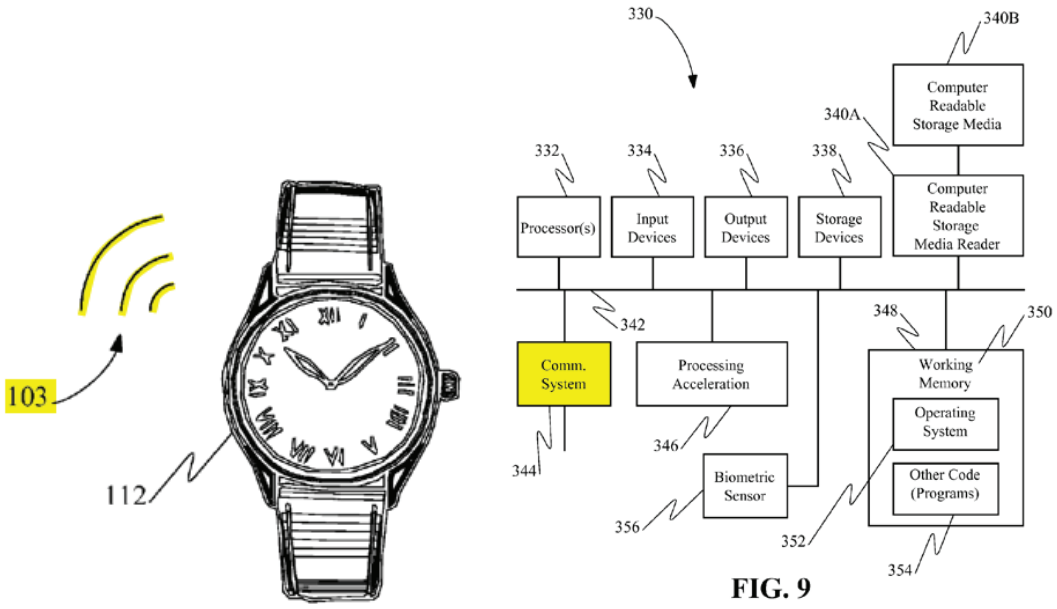


FIG. 9

RX-0411 at Figs. 8B and 9; RDX-8.46 (summarizing RX-0411). Lumidigm further explains the wristwatch embodiment's wireless communications capabilities in connection with the fob embodiment, which the patent describes as having identical operation to the wristwatch embodiment (including the wireless RF signals 103 shown in Figure 8B). RX-0411 at 11:38-42, 11:60-12:2.

A POSITA would have understood that a device with a "wireless . . . type of interfacing connection" (RX-0411 at 13:9-12) would have a network interface for wirelessly communicating the measurement of a physiological parameter, including oxygenation levels, to a mobile phone or computer network. *Id*. at 11:38-42, 19:22-28, Figs. 8B and 9; Tr. [Warren] 1226:9-21.

Further, Lumidigm also discloses that its processors can output a measurement indicative of "oxygen saturation" for the reasons discussed above for 502 claim 19, limitation [19E].

Limitation [28K]: Lumidigm discloses "a ***user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user***." The use of user interfaces with touch screens was also

[redacted]

"well known" by the time of the Poeze Patents. Tr. [Warren] 1226:23-1227:3. Lumidigm discloses embodiments of portable electronic devices that were well known to have touch-screens—a mobile phone and a PDA— and explains that those devices "display the retrieved information on the portable electronic device" in connection with Figures 8D and 8E. RX-0411 at 21:29-33; RDX-8.47 (summarizing RX-0411).

A POSITA would have understood from these disclosures that the recited user interface with a touch-screen display could be incorporated into any of the sensor embodiments, including the wristwatch embodiment. Tr. [Warren] 1226:23-1227:7.

Limitation [28L]: Lumidigm discloses "***a storage device configured to at least temporarily store at least the measurement***." Lumidigm repeatedly refers to processing, measurement, acquisition, and use of information, and a POSITA would recognize that such a device would require memory, another well-known idea, to carry out these operations. RX-0411 at Fig. 9; Tr. [Warren] 1227:9-14. Lumidigm specifically discloses hardware elements, software elements, and storage (including storage device 338, memory 348, and computer-readable storage medium 340*b*) that store measurements taken by the sensor in Figure 9 and the related discussion:

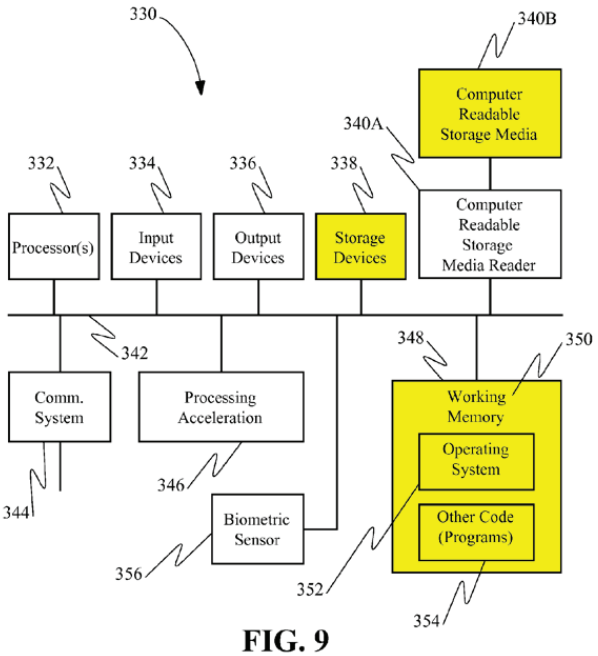


FIG. 9

RX-0411 at Fig. 9, 12:66-13:14; RDX-8.48 (summarizing RX-0411). Lumidigm further discloses that "[t]he storage devices typically hold information defining the stored spectra," which A POSITA would have understood to mean at least the temporary storage of the measurement (i.e., spectra). RX-0411 at 12:66-13:14; Tr. [Warren] 1227:9-14.

Limitation [28M]: Lumidigm discloses "a ***strap*** configured to position the user-worn device on the user." Specifically, Lumidigm discloses a strap for its wristwatch embodiment:

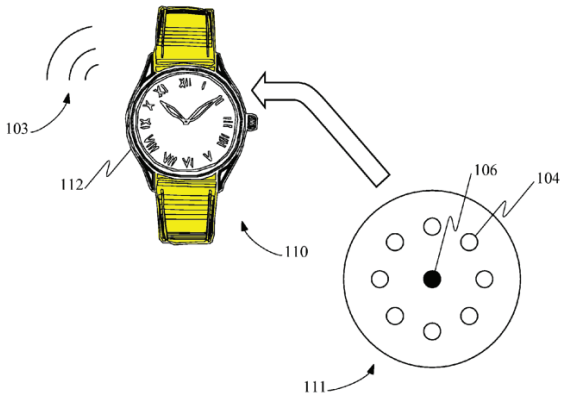


FIG. 8B

RX-0411 at Fig. 8B, 11:60-65; Tr. [Warren] 1227:16-17; RDX-8.49 (summarizing RX-0411).

[redacted]

(5) '648 Patent, Claim 12

Lumidigm discloses all limitation of '648 claim 12 and anticipates this claim or, at a minimum, renders it obvious. Tr. [Warren] 1227:22-1228:10.

(a) '648 Claim 8

Limitation [8Preamble]: Lumidigm discloses "a ***user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising***" for the reasons discussed above for '501 claim 1, preamble.

Limitation [8A]-[8B]: Lumidigm discloses "***a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength"*** and ***"a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength***," for the reasons discussed above for '502 claim 28, limitations [28A] and [28B].

Limitation [8C]: Lumidigm discloses "***four photodiodes***" for the reasons discussed above for '502 claim 19, limitation [19B] and '502 claim 28, limitation [28C].

Limitation [8D]: Lumidigm discloses "a ***protrusion comprising a convex surface***" for the reasons discussed above for '501 claim 1, limitation [1C].

Lumidigm also discloses in "***at least a portion of the protrusion comprising an opaque material***" for the reasons discussed above for '501 claim 1, limitation [1E], and '502 claims 19, limitation [19C], and claim 28, limitations [28F] and [28H]. Although this claim specifies that a portion of the protrusion comprises opaque material, rather than the surfaces of the openings or a wall, the same reasoning applies. Tr. [Warren] 1227:22-1228:2. Lumidigm explains that "the

body of the sensor head 32," which includes the protrusion, is made from "optically opaque material 37" to provide "optical blocking" and minimize unwanted light. RX-0411 at 8:1-11.

Limitation [8E]: Lumidigm discloses "***a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes***" for the reasons discussed above for '501 claim 1, limitation [1D], '502 claim 19, limitation [19C], and '502 claim 28, limitation [28F]. The same reasoning applies. Tr. [Warren] 1227:22-1228:2.

Limitation [8F]: Lumidigm discloses "***a separate optically transparent window extending across each of the openings***" for the reasons discussed above for '502 claim 19, limitation [19D] and '502 claim 28, limitation [28G]. Although this claim specifies a "separate optically transparent window" across each opening, rather than transparent material or a transmissive window, the same reasoning applies. Tr. [Warren] 1227:22-1228:2. A POSITA would have recognized that the fiber optic face plates and fiber bundles referenced in Lumidigm and discussed in connection with above limitations are optically transparent windows and that each would extend across a different one of the openings. Tr. [Warren] 1221:16-1222:25.

Limitation [8G]: Lumidigm discloses "***one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user***" for the reasons discussed above for '502 claim 19, Limitation [19E].

Limitation [8H]: Lumidigm discloses "***a housing***." For example, Lumidigm discloses that, for its wristwatch embodiment, "the biometric reader 111 is built into the case of a wristwatch 112 and operates based upon signals detected from the skin in the area of the wrist." RX-0411 at 11:60-64, Fig. 8B; Tr. [Warren] 1228:3-6; RDX-8.52 (summarizing RX-0411).

[redacted]

Limitation [8I]: Lumidigm discloses "***a strap configured to position the housing proximate tissue of the user when the device is worn***" for the reasons discussed above with respect to claim 28, limitation 28[M].

(b) '648 Claim 12

Lumidigm discloses "[***t]he user-worn device of claim 8***," for the reasons discussed above for '648 claim 8.

Lumidigm discloses "***wherein the physiological parameter comprises oxygen or oxygen saturation***" for the reasons provided above with respect to claim '502 claim 19, preamble.

(6) '648 Patent, Claims 24 and 30

Lumidigm discloses all limitations '648 claims 24 and 30 and anticipates these claims or, at a minimum, renders them obvious. Tr. [Warren] 1228:11-1229:14.

(a) '648 Claim 20

Limitation [20Preamble]: Lumidigm discloses "***[a] user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising***" for the reasons discussed above with respect to '501 claim 1, preamble.

Limitation [20A]: Lumidigm discloses "***a plurality of light emitting diodes (LEDs)***" including for the reasons discussed above for '501 claim 1, limitation [1A].

Limitation [20B]: Lumidigm discloses "***at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user***" for the reasons discussed above for '502 claim 19, limitation [19B] and '502 claim 28, limitation [28C]. Although this claim specifies that the four photodiodes are "arranged to capture light at different quadrants of tissue of a user," rather than being arranged "in a quadrant configuration," the same reasoning applies. Tr. [Warren] 1228:11-15.

[redacted]

Limitation [20C]: Lumidigm discloses "***a protrusion comprising a convex surface***" for the reasons discussed above for '501 claim 1, limitation [1C], '502 claim 19, limitation [19C], and '502 claim 28, limitations [28E].

Limitation [20D]: Lumidigm discloses "***a plurality of through holes . . . arranged over a different one of the at least four photodiodes***" for the reasons discussed above for '501 claim 1, limitation [1D], '502 claim 19, limitation [19C] and '502 claim 28, limitations [28F]. Although this claim refers to "through holes" rather than "openings," the same reasoning applies. Tr. [Warren] 1211:10-1212:10, 1224:3-8, 1227:22-1228:2.

Lumidigm also discloses "***each through hole including a window***" for the reasons discussed above for '502 claim 19, limitation [19D] and '502 claim 28, limitation [28G].

Limitation [20E]: Lumidigm discloses "***one or more processors configured to receive one or more signals from the at least one of the photodiodes and determine measurements of oxygen saturation of the user***" for the reasons discussed above for '502 claim 19, limitation [19E].

(b) '648 Patent, Claim 24

Lumidigm discloses '648 claim 24, which recites "***[t]he user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping***" for the reasons discussed above for '501 claim 1, limitation 1[E] and '502 claim 28, limitation [28F]. Although this claim references "substantially preventing light piping," rather than "reducing" or "avoiding light piping," the same reasoning applies. Tr. [Warren] 1228:16-23. Lumidigm explains that "the body of the sensor head," which includes the protrusion, is made from "optically opaque material" and that the detectors are recessed from the sensor surface in this optically opaque material to provide "optical blocking" and to "minimize" "shunted" light and other unwanted light from reaching the detectors. RX-0411 at 7:64-8:10. Lumidigm further

explains that "[o]ther equivalent means of optical blocking can be readily established by one of ordinary skill in the art." *Id*. at 8:10-11. A POSITA would have understood that the use of opaque material has the benefit of allowing light to pass through to the photodiodes while reducing light piping and other forms of optical noise. Tr. [Warren] 1212:11-1213:3, 1228:16-23; RDX-8.55 (summarizing RX-0411). Lumidigm specifically discusses using opaque material to provide "optical blocking" for "shunted" light, and light shunting is another term for light piping. Tr. [Warren] 1212:22-1213:3.

Significantly, the Poeze specification attributes its asserted reduction in light piping to the fact its protrusion is made from opaque material. *E.g.*, JX-001 ['501 patent] at 7:65-8:8, 37:51-52. If the Poeze Patents' use of opaque material is sufficient to support the claims, then Lumidigm's use of opaque material also meets the claim language. *See* Tr. [Warren] 1202:19-1203:9; RDX-8.17 (summarizing JX-001).

(c) '648 Patent, Claim 30

Lumidigm discloses '648 claim 30, which recites "***[t]he user-worn device of claim 20, wherein the protrusion comprises one or more chamfered edges***." The use of chamfered edges was also a "well-known mechanical principle." Tr. [Warren] 1228:24-1229:10. Lumidigm explains its sensor head can have essentially any shape, "including oval, square and rectangular shapes." RX-0411 at 7:57-63. Lumidigm also shows beveled edges on the top face of its watch in Figure 8B. A POSITA would have recognized that this type of edge also could be used for the sensor head. Tr. [Warren] 1228:24-1229:10. It would have been obvious to a POSITA that a protrusion for a user-worn device should have chamfered edges, as it was well-known in the art that a sensor that comes in contact with tissue should "incorporate ergonomic features" to increase comfort and optimally contact the user's tissue. Tr. [Warren] 1228:24-1229:10; RX-0411 at 7:57-

63 (referencing desirability of "incorporat[ing] ergonomic features" into sensor head); RDX-8.56 (summarizing RX-0411).

c. Obviousness Under 35 U.S.C. § 103(a)

Although Lumidigm alone discloses all limitations of the asserted claims, the following combinations also alternatively render the asserted claims obvious:

Combinations	Asserted Claims of Poeze Patents Rendered Obvious
Lumidigm + **Seiko 131 + Cramer**	All claims
Lumidigm + **Webster** Lumidigm + Seiko 131 + Cramer + **Webster**	'502 claim 22
Lumidigm + Webster + **Apple '047** Lumidigm + Seiko 131 + Cramer + Webster + **Apple '047**	'502 claim 28

See Tr. [Warren] 1229:11-1243:4. Seiko 131 and Cramer are wristwatch-based sensors, like Lumidigm, and teach most disputed limitations. Webster also teaches the "thermistor" limitations of '502 claims 22 and 28, and Apple '047 teaches the "user interface comprising a touch screen display" limitation of '502 claim 28. *Id*.

(1) Lumidigm in View of Seiko 131 and Cramer Render Obvious All Asserted Claims

U.S. Patent No. 5,766,131 ("Seiko 131"), titled "Pulse-Wave Measuring Apparatus," was filed July 30, 1996, issued June 16, 1998, and discloses a user-worn "wristwatch type" light-based sensor for physiological measurements. RX-0666 at Abstract; Tr. [Warren] 1230:18-1231:8; RDX-8.61-RDX-8.62 (summarizing RX-0666).

U.S. Patent No. 4,224,948 ("Cramer"), titled "Wrist Borne Pulse Meter/Chronometer," was filed November 24, 1978, issued September 30, 1980, and discloses a light-based physiological

EXHIBIT 6

[redacted]

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of **CERTAIN LIGHT-BASED PHYSIOLOGICAL MEASUREMENT DEVICES AND COMPONENTS THEREOF**	Inv. No. 337-TA-1276

RESPONDENT APPLE INC.'S PETITION FOR REVIEW OF THE INITIAL DETERMINATION OF VIOLATION OF SECTION 337

and intent elements of inducement. ID 198. Specifically, the ID found that the Complaint "contained allegations of infringement (including a claim chart for claim 27) similar to the evidence presented at the hearing." *Id.* But to support this finding, the ID cites only Complaint Exhibit 18, filed on June 30, 2021, and no other evidence. *Id.* This lone citation does not satisfy the "preponderance of evidence" standard, particularly where Complainants identified no testimony from any witness (including their own expert Dr. Madisetti) that Apple had the requisite knowledge to support a finding of inducted infringement. *See* RIB at 173; RRB at 88. Citation to *Certain Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 19-21 (Apr. 5, 2016), is also inapt because Complainants failed to show by a preponderance of evidence that the "infringement allegations set forth in [their Complaint] claim charts are substantially similar to [] ultimate infringement findings" (*id.*), nor can they because Dr. Madisetti heavily relies on his post-complaint testing results to attempt to prove infringement.

4. The Economic Prong Is Not Satisfied.

Because it relies on overlapping groups of devices, the ID's finding that the economic prong was satisfied for the '745 patent is clear error for the same reasons as the Poeze patents. *See* Section IV.E*, supra.*

5. The '745 Patent Is Unenforceable.

For the reasons discussed in Apple's initial post-hearing brief (RIB at 204-205) and consistent with Federal Circuit precedent, as recently confirmed in Personalized Media Communications v. Apple, Inc., Case No. 21-2275, Dkt. 49 (Fed. Cir. Jan. 20, 2023), the ID erred in its finding that Apple had not shown the asserted Poeze patents unenforceable under the doctrine of prosecution laches and/or unclean hands. Complainants' five-year delay and strategy of waiting until Apple further developed its technology and fostered the market for wearable technology was

[redacted]

both unreasonable and prejudicial to Apple who invested heavily in developing that technology and growing the market while Masimo inexcusably delayed its prosecution.

B. U.S. PATENT NO. 7,761,127

The ID rightly found no violation of U.S. Patent No. 7,76,127 ("'127 patent") based on its correct claim constructions and finding that the Accused Apple Watches do not infringe over those constructions. But if the Commission grants review of to this patent, it should correct errors in the ID's technical prong, invalidity and economic prong analyses.

1. The Early Rainbow Sensor Do No Satisfy The Technical Prong.

Complainants alleged that two product groups—(1) the "early rainbow® sensors" that [redacted] and (2) the "current rainbow® sensors [that] use a [redacted]—practice claim 9 of the '127 patent for purposes of the domestic industry, technical prong requirement. ID 273-275; CIB 36, 266-274. The ID correctly determined that Complainants failed to show that the Current Rainbow Sensors meet Element 7[A], which requires a "thermal mass" that stabilizes a bulk temperature, and Element 7[F], which requires that the temperature sensor be "capable of determining a bulk temperature for the thermal mass" that is a representative temperature for the thermal mass. ID 256, 259, 275-277, 279-281. However, the ID clearly erred in finding that the Early Rainbow Sensors meet the "thermal mass" and "bulk temperature for the thermal mass" limitations (ID 281, 279-281).

a. Early Rainbow Sensors Do Not Meet "Thermal Mass" Limitation.

The ID clearly erred in finding that the Early Rainbow Sensors satisfy the "thermal mass" limitation. ***First***, the ID erred in assuming that Mr. Diab's testimony regarding his simulations using [redacted] software on a prototype "model of [a] sensor" (Tr. [Diab] 200:14-16; 201:2-202:2) applied to actual Early Rainbow Sensors. ID 276. Mr. Diab never testified that his simulations

[redacted]

those errors however, it should review the following errors in the ID's invalidity analysis pertaining to the Poeze patents.

1. The Asserted Claims Are Invalid.

The ID clearly erred in finding that Lumidigm does not disclose a "convex protrusion" (all asserted Poeze claims). ID 88, 97. Lumidigm discloses a "compound curvature on the optical surface" of its protrusion "to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured." *See* RX-0411 at 7:57-63, 8:1-4, 8:27-28. A POSITA would have understood that a sensor with "compound curvature on the optical surface" has a convex protrusion. Tr. [Warren] 1205:12-1206:7; 1210:12-1211:8. Indeed, Lumidigm explicitly discloses that the sensor surface "can be contoured to fit specific product applications and ergonomic requirements." RX-0411 at 8:27-28.

The ID clearly erred in finding "optically transparent material within each of the openings" was not disclosed by Lumidigm or rendered obvious by its teachings ('502 claim 22). ID 121-124. The ID correctly determined Lumidigm "clearly discloses 'optically transparent material' over openings." *See* ID 123. Indeed, Lumidigm teaches an optical relay to "transfer[] the light from the light sources to the skin and from the skin back to the detector(s) while minimizing light loss and spreading." RX-0411 at 8:19-26; Tr. [Warren] 1221:16-1222:25, 1235:14-1236:2. A POSITA would have understood an optical relay (such as "fiber optic face plates," "individual optical fibers," or "fiber bundles) could be added to Lumidigm's sensor. RX-0411 at 8:19-26, Fig. 2; Tr. [Warren] 1221:16-1222:25. A POSITA would have further understood the optical relay could be placed over or within the openings to "transfer light" from the tissue to the photodiodes and "protect the detector from dust and debris and dirt." RX-0411 at 1193:24-1194:7, Tr. [Warren] 1221:16-1222:16. The "fiber bundles," for example, would be placed within

[redacted]

the openings and used "to essentially direct light from a portion of the tissue straight to the detector as a means to optimize the detection process. Tr. [Warren] 1222:10-16

The ID clearly erred in finding Lumidigm in combination with Cramer does not render "optically transparent material within each of the openings" obvious. The use of optically transparent materials extending across or within opening associated with photodiodes was well known in the art prior to 2008 and taught by Lumidigm. Tr. [Warren] 1221:16-12:22-9, 1193:24-1194:14; RX-0411 at 8:19-26, Fig. 2. A POSITA would have naturally looked to other references in the field to improve on Lumidigm's teachings and would recognize the CLT 2160 taught by Cramer as a "can" detector and would understand that each can would include a lens at the top end of the can, that the detector would be positioned inside the can at the focal point of the lens, and that there would be a gap between the detector and the lens, creating an opening between the detector and the lens. RX-0670 at Fig 6; Tr. [Warren] 1231:23-1232:9, 1234:3-8, 1234:22-1235:12. A POSITA would have been motivated to combine Lumidigm with Cramer because Lumidigm expressly teaches the benefits of transparent material within openings over photodiodes and, more generally, because the benefits were well known. Tr. [Warren] 1235:14-1236:2.

The ID clearly erred in finding Apple's combinations including Apple '047 [37] do not render "touch-screen" obvious ('502 claim 28). ID 133-136. Once again, the ID focused on the wrong issue – namely, whether a touch screen could be physically incorporated into the face of the wristwatch. ID 136. The asserted Poeze claims neither recite nor require such a structure. Nor could they: The Poeze specification does not disclose or enable such a structure. Indeed, the specification references the potential for a touch screen only twice as a purely hypothetical

[37] Apple offered two combinations that render '502 claim 28 obvious: (1) Lumidigm + Webster + Apple '047 and/or (2) Lumidigm + Seiko 131 + Cramer + Webster + Apple '047.

alternative (JX-0001 at 15:60, 17:25) and ***all*** the embodiments depict the display attached to but ***separate from*** the user-worn portion of the device (*id.* at Fig. 2A-D). *See Etter*, 756 F.2d at 859; *Allied*, 825 F.3d at 1381; *Sneed*, 710 F.2d at 1550; *Mouttet*, 686 F.3d at 1333-34. The ID also incorrectly found that Professor Warren failed to identify a motivation. To the contrary, he confirmed a person would have been motivated to make the combination because this was a "well-known mechanism" for a display. Tr. [Warren] 1240:8-17.

The ID clearly erred in finding written description support for the claimed combinations (all claims). The Poeze specification fails to disclose a single embodiment containing all the claimed limitations. While the ID identified various limitations dispersed throughout the specification, it erroneously found that they belong to the same embodiment by citing to generic language providing that one embodiment can mix-and-match between different sensors. The ID's finding cannot be squared with its treatment of the prior art, and specifically Lumidigm, which expressly confirms that its wristwatch embodiment can include ***any*** of the disclosed sensor geometries. RX-0411 at 11:64-12:2. This contrast is particularly significant given that combining different elements of the prior art is ***permitted*** when determining whether the prior art teaches the claimed invention, but it is ***not*** permitted when analyzing whether the asserted patent provides an adequate written description. *Flash-Control, LLC v. Intel Corp.*, 2021 WL 2944592, at *3-4 (Fed. Cir. July 14, 2021) ("[T]he specification must present each claim as an 'integrated whole.' … A patent owner cannot show written description support by picking and choosing claim elements from different embodiments…").

The ID clearly erred in finding enablement of a touch screen ('502 claim 28). ID 166. The '502 specification provides no guidance on how to use a touchscreen that "displays indicia responsive" to any "measurement," nor provides any guidance on how to implement a touchscreen

[redacted]

in a user-worn device. RRB 75-76. The ID, again, erroneously imposed a higher scrutiny in its obviousness analysis compared to its analysis here. Here, the ID found the scant references to a touch screen in the Poeze specification sufficiently enables a touch screen on a user-worn device but failed to find the same when examining the prior-art—which is arguably more detailed with respect to touch screens. ID 133-36. The ID was also inconsistent in its treatment of the underlying testimony. While the ID credited Dr. Madisetti's enablement explanation—where he simply recited a list of specification citations and concluded they are enabling—the ID described Dr. Warren's testimony on the subject as "conclusory," despite providing more explanation than Dr. Madisetti. *See* Tr. [Warren] 1226:22-1227:7, 1240:4-1242:9, 1241:1-17; RDX-8.83-84; Tr. [Madisetti] 1352:5-24; 1381:7-1382:8 (testimony cited by the ID concerning touch screens).

The ID clearly erred in finding enablement for avoiding and reducing "light piping" ('501 claim 12, '502 claim 28, '648 claim 24) and sufficient written description support for substantially preventing light piping ('648 claim 24). ID 169. The Poeze specification provides no guidance on how to avoid, reduce, or manage the problem of "light piping" aside from general reference to opaque materials. Tr. [Warren] 1247:24-1248:4. The specification fails to explain when "light piping" has been "substantially" prevented, how a POSITA accomplishes or determine this, and how the sensors were constructed to accomplish this limitation.

2. The Poeze patents Are Unenforceable.

For the reasons discussed in Apple's initial post-hearing brief (RIB at 153-159) and consistent with Federal Circuit precedent regarding, as recently confirmed in *Personalized Media Communications* (No. 21-2275, Fed. Cir. Jan. 20, 2023), the ID erred in its finding that Apple had not shown the asserted Poeze patents unenforceable under the doctrine of prosecution laches and/or

[redacted]

unclean hands. Complainants' twelve-year delay in filing the applications for the asserted Poeze patents was both unreasonable and prejudicial to Apple.

VI. CONCLUSION

For the foregoing reasons, Apple respectfully requests the Commission review and reverse the ALJ's erroneous conclusions concerning validity, infringement, technical DI, and economic DI for '648 patent. Should the Commission take review of issues relating to the other patents—though it need not do so—Apple further requests that the Commission review the additional issues set forth in this Petition.

EXHIBIT 7

CONFIDENTIAL INFORMATION REDACTED

CONFIDENTIAL INFORMATION REDACTED

EXHIBIT 8

CONFIDENTIAL INFORMATION REDACTED

CONFIDENTIAL INFORMATION REDACTED