UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KAZ USA, INC.,
Petitioner

v.

EXERGEN CORPORATION,
Patent Owner

Patent No. 7,346,386
Issued: March 18, 2008
Filed: October 14, 2003
Inventors: Francesco Pompei

Title: TEMPORAL ARTERY TEMPERATURE DETECTOR

Inter Partes Review No. Unassigned

PETITION FOR *INTER PARTES* REVIEW

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Ex. 1004	*Exergen Corp. v. Microlife Corp. et al.*, No. 1:15-cv-13387-RGS, D.I. 15 (Waiver of the Service of Summons by Kaz USA, Inc.) (Feb. 29, 2016)
Ex. 1005	U.S. Patent No. 5,012,813 to F. Pompei *et al.* ("*Pompei '813*")
Ex. 1006	U.S. Patent No. 6,030,342 to K. Amano *et al.* ("*Amano*")
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Ex. 1010	Y. Houdas and E.F.J. Ring, "Human Body Temperature, Its Measurement and Regulation," Plenum Press, N.Y. (1982) ("*Houdas*")
Ex. 1011	T. Ikeda *et al.*, "Influence of Thermoregulatory Vasomotion and Ambient Temperature Variation on the Accuracy of Core-temperature Estimates by Cutaneous Liquid-crystal Thermometers," *Anasthesiology,* 603-612 (March 1997)
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Ex. 1014	U.S. Patent No. 5,662,104 to M. Fuse *et al.*
Ex. 1015	Gray's Anatomy: The Anatomical Basis of Medicine and Surgery, Churchill Livingstone (38th ed. 1995)

Ex. 1016	File History of U.S. Patent No. 7,346,386 (Application No. 10/684,818)
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I. INTRODUCTION

U.S. Patent No. 7,346,386 ("the '386 patent") (Ex. 1001) is generally directed to a device for detecting a core body temperature based on a model of heat balance relative to a sensed skin surface temperature. The skin surface temperature is calculated by scanning the device across a target area, such as the forehead, and determining a peak temperature based on at least three readings per second. In the specification, the inventor, Francesco Pompei, admits that each element recited in the claims was already known and used. For example, he inventor admits that an arterial heat balance approach was previously used in the ear canal and under the armpit to calculate a patient's core temperature based on measured skin temperature and ambient temperature. Ex. 1001 at 1:26-65, 9:14-24; *see also* Ex. 1012 at 18-19; Ex. 1013 at 18. Similarly, the inventor admits that prior thermometer designs provided a peak temperature based on ten readings per second during a scan of the device across a target surface area. Ex. 1001 at 9:9-24. The alleged novelty recited in claims 1-4, 22, and 24 (the "Challenged Claims") of the '386 patent—the "unique combination" of these known elements, *see id.* at 9:6-9—however, is anticipated and rendered obvious by multiple references.

First, one of Patent Owner's earlier patents, also identifying Pompei as an inventor, anticipates and renders obvious the '386 patent. Seven years before the '386 patent's alleged priority date, Patent Owner obtained a patent for a radiation

detector that provides an indication of core temperature based on sensed skin temperature and ambient temperature measurements. Specifically, U.S. Patent No. 5,012,813 ("*Pompei '813*") (Ex. 1005) describes a temperature detector that provides a core body temperature based on a heat balance compensation relative to the sensed skin temperature. Like the claimed invention, the skin temperature used in *Pompei '813* is the peak temperature from multiple readings per second made during a scan of the detector across a target area. While the target area of the preferred embodiment in *Pompei '813* is the tympanic membrane of the ear, the reference applies broadly to other target "surface tissue," including the forehead. Indeed, recognizing the broad disclosure and claim scope of *Pompei '813*, Patent Owner previously asserted that forehead thermometers infringed the patent. Ex. 1013 at 20-22.

In addition to Patent Owner's patent, other references disclose the claimed temperature detector. For example, a textbook (Ex. 1010) describes the same equations and heat balance model for calculating a person's core temperature that the patent describes. As another example, an international patent publication (Ex. 1008) describes a radiation thermometer that provides an indication of a patient's core temperature based on scanning of a target area with multiple readings per second. And several printed publications (Exs. 1006, 1009, 1011) provide motivations and teachings to use infrared thermometers at a patient's forehead.

Accordingly, Kaz USA, Inc. ("Kaz" or "Petitioner") requests *inter partes* review ("IPR") of the Challenged Claims, which public records indicate are assigned to Exergen Corp. ("Exergen" or "Patent Owner"). This Petition and the supporting declaration by H. Frederick Bowman, Ph.D. (Ex. 1002), demonstrate by a preponderance of the evidence that the Challenged Claims are unpatentable due to anticipation and obviousness based on the aforementioned references and those discussed below. Petitioner therefore requests cancellation of the Challenged Claims.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8 AND COMPLIANCE REQUIREMENTS

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

The real parties-in-interest are Helen of Troy Ltd. and Petitioner Kaz USA, Inc., a wholly owned subsidiary of Helen of Troy Ltd.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '386 patent is currently at issue in a pending civil action brought by Exergen against Kaz: *Exergen Corp. v. Microlife Corp. et al.*, No. 1:15-cv-13387 (D. Mass) ("the *Exergen II* Litigation"). The earliest date of service of the complaint on Kaz is February 4, 2016, the date on which Kaz sent a waiver of service. Ex. 1004.

Other related patents may be affected by a decision in this proceeding. Specifically, U.S. Patent No. 9,194,749 ("the '749 patent") is the subject of an IPR

petition, which Petitioner has concurrently filed herewith ("the '749 IPR"), and is asserted in the *Exergen II* Litigation. In addition, U.S. Patent No. 6,292,685 ("the '685 patent") was asserted by Exergen in four civil actions, Nos. 1-01-cv-11306 (D. Mass.), 1-02-cv-10436 (D. Mass.), 1-13-cv-10628 (D. Mass.) ("*Exergen I* Litigation"), and 1-13-cv-11243 (D. Mass.). And U.S. Patent No. 7,787,938 ("the '938 patent") was asserted by Exergen in four civil actions, Nos. 1-11-cv-11410 (D. Mass.), 1-12-cv-12243 (D. Mass.), 1-13-cv-10628 (D. Mass.), and 1-13-cv-11243 (D. Mass.).

C. Lead And Back-Up Counsel And Service Information Under 37 C.F.R. §§ 42.8(b)(3) & (4)

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Please address all correspondence to lead and back-up counsel. A Power of Attorney is filed herewith under 37 C.F.R. § 42.10(b). Petitioner consents to electronic service by email.

D. Fee for IPR Under 37 C.F.R. §42.15(a)

The required fees for requesting *inter partes* review, as specified in 37 C.F.R. § 42.15(a) were paid at the time of filing. Should any additional fees be required in association with this petition, the Board is hereby authorized to deduct such fees from Akin Gump's Deposit Account No. 50-2310.

E. Certification of Compliance with Word Count Under 37 C.F.R. § 42.24

Under the provisions of 37 C.F.R. § 42.24(d), Petitioner certifies that the word count for this Petition totals 13,494, which is less than the 14,000 allowed under 37 C.F.R. § 42.24(a)(i).

F. Certification of Petitioner's Standing to Request IPR Under 37 C.F.R. § 42.101

Petitioner certifies that: (1) the '386 patent is eligible for IPR; and (2) neither Petitioner nor the other real party-in-interest is barred or estopped from requesting IPR of any claims of the '386 patent on the grounds identified herein. Petitioner waived service of a complaint asserting infringement of the '386 patent on February 4, 2016 (*see* Ex. 1004), which is not more than one year before the filing of this Petition. Neither Petitioner nor the other real party-in-interest has filed a civil action challenging the validity of any claim of the '386 patent.

III. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR UNDER 37 C.F.R. §§ 42.22(a) & 104(b)

Petitioner requests IPR under 37 C.F.R. § 42.108 as to the Challenged Claims and cancelation of these claims as unpatentable based on one or more grounds under 35 U.S.C. § 103 in view of the following prior art patents and publications:

Ex.	Reference	Publication, Issue Date, and/or Priority Date	Basis
1005	U.S. Patent No. 5,012,813 to F. Pompei *et al.* ("*Pompei '813*")	Issued: May 7, 1991	102(b)
1006	U.S. Patent No. 6,030,342 to K. Amano *et al.* ("*Amano*")	Priority: February 9, 1998 Issued: February 29, 2000	102(e)
1007	U.S. Patent No. 4,636,091 to F. Pompei *et al.* ("*Pompei '091*")	Issued: January 13, 1987	102(b)
1008	International Publication No. WO/93/03666 to K. Banke ("*Banke*")	Published: March 4, 1993	102(b)
1009	U.S. Patent No. 3,531,642 to R. Barnes *et al.* ("*Barnes*")	Issued: September 29, 1970	102(b)
1010	Y. Houdas and E.F.J. Ring, "Human Body Temperature, Its Measurement and Regulation," Plenum Press, N.Y. (1982) ("*Houdas*")	Published: 1982	102(b)

The application for the '386 patent was filed on October 14, 2003 and claims a priority date of September 11, 1998. Petitioner requests cancellation of the Challenged Claims on the following specific grounds:

Ground	Challenged Claims	Art
1	1 and 2	Anticipated under 35 U.S.C. § 102 by *Pompei '813*
2	3, 4, 22, and 24	Obvious under 35 U.S.C. § 103 by *Pompei '813* in view of *Pompei '091*
3	1 and 2	Obvious under 35 U.S.C. § 103 by *Pompei '813* in view of *Amano*
4	3, 4, 22, and 24	Obvious under 35 U.S.C. § 103 by *Pompei '813* in view of *Amano* and *Pompei '091*
5	1 and 2	Obvious under 35 U.S.C. § 103 by *Banke* in view of *Houdas* and *Barnes*
6	3, 4, 22, and 24	Obvious under 35 U.S.C. § 103 by *Banke* in view of *Houdas*, *Barnes*, and *Pompei '091*

Petitioner's identification of where each element of the Challenged Claims is found in the prior art and a description of the evidence relied upon are addressed in Section VIII of this Petition.

IV. SUMMARY OF THE '386 PATENT'S DISCLOSURE AND ALLEGED INVENTIONS

The '386 patent, entitled "Temporal Artery Temperature Detector," relates generally to a thermal radiation temperature detector. Ex. 1001, Abstract. Body temperature measurements are obtained by scanning a radiation sensor across a target surface area, for example over the forehead's temporal artery.[1] *Id.* at

[1] Although the specification describes the invention as a forehead thermometer, challenged claims 1, 22, and 24 are not limited to obtaining temperature measurements at the forehead. *Compare* Ex. 1001, Abstract ("scanning

Abstract, Fig. 1. Multiple readings per second are made during the scan and a peak temperature reading is obtained. *Id.* at 3:3-8. Using an "arterial heat balance approach," the internal body temperature (or core temperature) is then computed as a function of the ambient temperature and the sensed skin temperature.[2] *Id.* at Abstract, 7:8-12. As the Federal Circuit has confirmed, computing a core temperature using Patent Owner's claimed arterial heat balance formula is not, itself, patentable. *See Exergen Corp., v. Sanomedics Int'l Holdings, Inc.*, No. 2016-1099, 2016 WL 3430594 (Fed. Cir. June 22, 2016). Moreover, the patentee admits that the same "arterial heat balance approach" had been used in ear and axillary thermometers to estimate core temperature. *Id.* at 1:26-28, 63-65.

… across the side of the forehead"), 2:20-24 ("detecting the temperature of the forehead directly over the superficial temporal artery"), *with id.* at 9:32-39 ("scan … across an artery"), 11:6-12:12 ("scan … across the target surface area").

[2] Although claim 1 requires calculating an indication of the core temperature as a function of "detected arterial temperature," *id.* at 9:34-39, the '386 patent does not teach obtaining an arterial temperature. Instead, the patent repeatedly teaches using the heat balance method to estimate the core temperature as a function of "sensed surface temperature" and skin temperature. *Id.* at Abstract, 3:18-26, 3:27-32, 7:4-12.

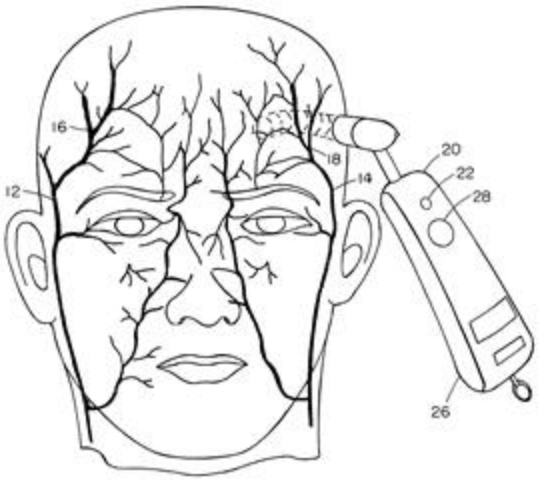


FIG. 1

In certain embodiments, the radiation sensor views a target surface through a reflective cup. *Id.* at 3:9-11. The cup has a large open diameter close to the target surface and a window at the base of the cup through which the radiation sensor views the target surface. *Id.* at Fig. 2A, 3:11-14. The cup is out of the sensor's field of view and spaced from the target surface by a smooth lip of low thermal conductivity material. *Id.* at Fig. 2A, 3:14-17. The cup is "preferably of low emissivity in order to provide emissivity compensation as disclosed in U.S. Pat. No. 4,636,091." *Id.* at 4:54-56.

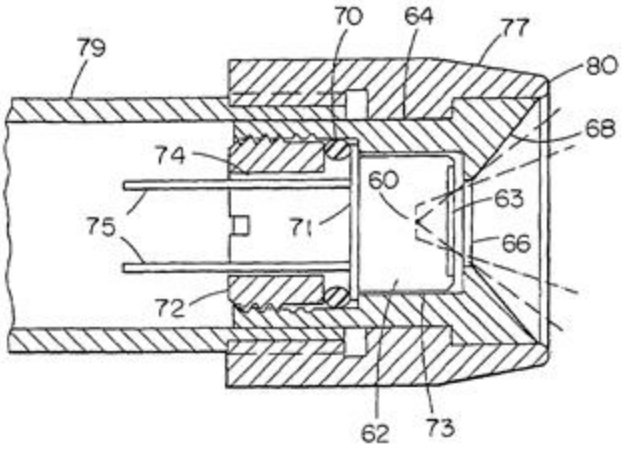


FIG. 2A

In the ’386 patent, the inventor admits that prior ear and axilla thermometers used the “arterial heat balance approach” to provide body temperature calculations. *Id.* at 1:23-65; *see also id.* at 9:14-24. The applicant also admits that a cup with low emissivity was disclosed in *Pompei ’091*. *Id.* at 4:54-56; *see also id.* at 9:9-17. Similarly, the applicant admits that its prior designs incorporated “individual aspects” of the claimed invention, including a heat balance computation, a peak temperature based on about ten readings per second, an emissivity compensating cup, and scanning across a target surface. *Id.* at 9:9-24.

V. CLAIM CONSTRUCTION

To the extent that it is sufficiently described,[3] the phrase “detected arterial temperature” as used in claim 1 should be construed under the broadest reasonable interpretation standard as “detected surface temperature of skin directly over an

[3] *See supra* n.2.

artery." The '386 patent describes the "present invention" as providing for convenient temperature readings "by detecting the temperature of the forehead *directly over* the superficial temporal artery." Ex. 1001 at 2:20-23 (emphasis added). The specification repeatedly discloses computing the core temperature "as a function of ambient temperature and the sensed surface temperature." *Id.* at Abstract, *see also id.* at 3:18-26 (computing core temperature as a function of "skin" or "surface" temperature); 3:27-32 (computing internal temperature as a function of "sensed surface temperature), 7:8-15 (using "determined skin temperature" in arterial heat balance approach), 7:53-64 (calculating core temperature as a function of "skin temperature").[4] There is no discussion in the patent of detecting an arterial temperature or using a heat balance method based thereon.

[4] The prosecution history of the '386 patent further supports the specification's description. In response to a non-final rejection, the applicant argued that "[i]n contrast, claim 1 recites that the displayed temperature is based on a model of heat balance relative to a detected arterial temperature. That is, it is arterial temperature that is detected, albeit through the skin, and an interior temperature is based on the detected arterial temperature." Ex. 1016 at 8. In other words, the "detected arterial temperature" is measured at the skin surface. *See* Ex. 1002, ¶ 47.

In addition, the specification describes the "temperature detector" as a "radiation sensor" that is scanned across the forehead. *Id.* at 4:23-27. An infrared radiation sensor measures the surface temperature of a target area; it cannot measure an interior temperature. Ex. 1002, ¶ 58 ("In other words, infrared radiation is a surface phenomenon and only provides the temperature of the surface; it cannot provide the temperature of an object below the surface."); *see also* Ex. 1001 at 7:4-8 ("It is well known that the output of the thermopile [or radiation sensor] is proportional to (Ts4- Td4) where Ts is the target skin temperature viewed by the radiation detector …."). Therefore, under the broadest reasonable interpretation, "detected arterial temperature" should be construed as "detected surface temperature of skin directly over an artery."

In contrast, "detected arterial temperature" should not be construed as the "measured temperature of an artery" or something similar. As described above, the invention is directed at an infrared thermometer that cannot measure the temperature of an object or an artery below the surface. Ex. 1002, ¶ 58. In addition, the heat balance approach disclosed in the '386 patent is based on "heat flow from the core arterial source." Ex. 1001 at 7:30-39. Thus, the sensed temperature must be a skin surface temperature, as opposed to an arterial temperature, because the '386 patent assumes the arterial temperature is the core temperature and thus utilizes the heat balance approach to compute the arterial temperature. *See id*. at

4:15-17, 7:43-64; Ex. 1002, ¶ 59 ("[I]f 'detected arterial temperature' were construed to be the 'measured temperature of an artery' or something similar, then the sensed temperature would be the same as the core temperature and there would be no adjustment to make via the 'heat balance' method.").

Petitioner does not believe any other terms require construction. However, any terms that are construed should be given their "broadest reasonable construction in light of the specification." 37 C.F.R. § 42.100(b). Petitioner submits that all claim terms of the Challenged Claims should be interpreted accordingly.

VI. LEVEL OF ORDINARY SKILL IN THE ART

A person having ordinary skill in the art would have had at least a bachelor's degree (or equivalent) in mechanical engineering, biomedical engineering, electrical engineering, or physics and at least 3-5 years of experience with medical devices. In particular, a person of ordinary skill in the art ("POSITA") at the time of the '386 patent would have been a person having an understanding of bio-heat transfer, biomedical instrumentation, blood flow, thermodynamics, software, and general physiology/anatomy. Ex. 1002, ¶ 54.

VII. SUMMARY OF THE PRIOR ART

A. U.S. Patent No. 5,012,813 ("*Pompei '813*")

Pompei '813 is directed to a radiation detector that obtains "[t]ympanic temperature measurements … from the output of a thermopile." Ex. 1005, Abstract. The sensed "tympanic temperature is adjusted to provide an indication of

core temperature." *Id.* Figure 1 shows an embodiment of the claimed radiation detector, where the end of the probe is rounded to avoid discomfort to the subject and the exterior of the probe is made of plastic material of low thermal conductivity. *Id.* at 3:40-43, 5:13-15. The embodiment provides a temperature display and electronics for determining an indication of a person's core temperature, *id.* at Abstract, which electronics read the thermopile data nine times a second. *Id.* at 13:16-40; Ex. 1002, ¶ 66.

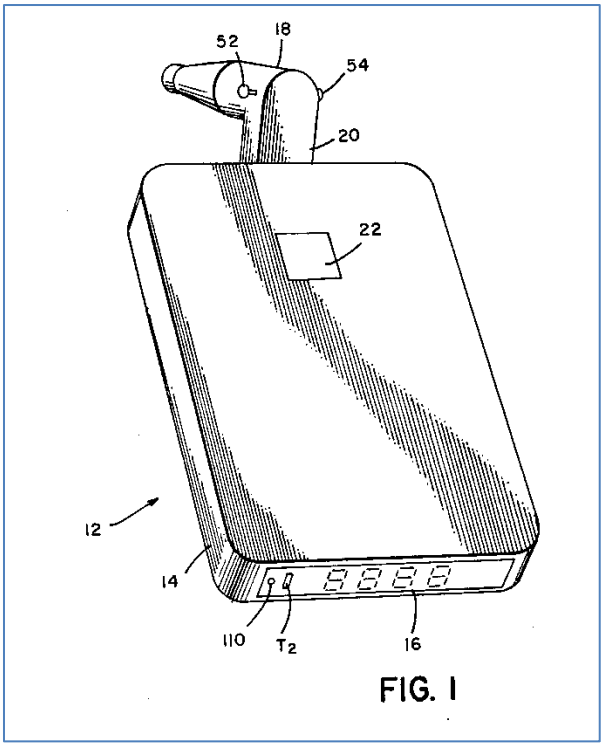


FIG. 1

Pompei '813 discloses that the detector "makes an accurate measurement when rotated to scan the ear canal." Ex. 1005 at 3:16-18. By "rotating the probe, the ear canal is scanned and … one can be assured that the maximum temperature is viewed." *Id.* at 3:44-47. The Patent Owner has previously admitted that *Pompei*

'813 discloses "a technique of scanning a radiation detector across a target to measure the maximum emitted radiation" and "swiping a radiation detector across a target." Ex. 1013 at 65. *Pompei '813* further discloses that the core temperature indication is computed as a function of sensed ear temperature and ambient temperature. Ex. 1005 at 10:63-11:10. In fact, *Pompei '813* discloses the same "heat balance equation" disclosed in the '386 patent. *Compare* Ex. 1005 at 11:8, *with* Ex. 1001 at 8:20; *see also* Ex. 1002, ¶ 65.

Although *Pompei '813* discloses an ear thermometer embodiment, it expressly teaches that the disclosed heat-balance approach "can be made in other applications," for example "in differential cutaneous temperature scanning." Ex. 1005 at 11:15-19. In other words, *Pompei '813*'s teachings can be used at any site sustained by the site's physiology. Ex. 1002, ¶ 67. Similarly, the claims broadly require targeting "biological surface tissue." Ex. 1005 at 14:50-66.

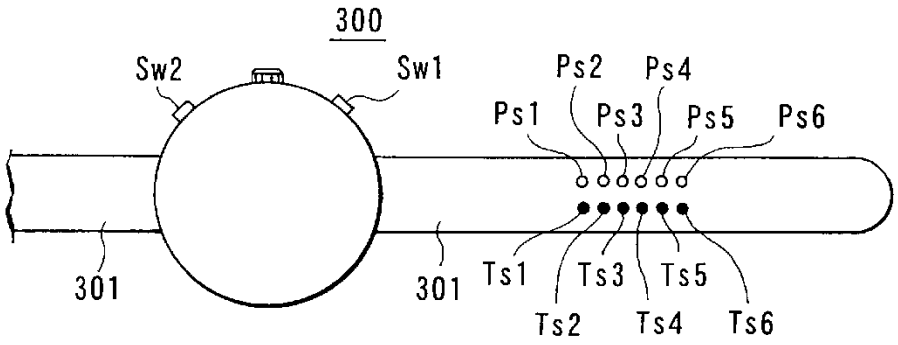
Pompei '813 issued on May 7, 1991, which is more than one year prior to the effective filing date of the '386 patent, and is, therefore, prior art under 35 U.S.C. § 102(b) and available under § 103.

B. U.S. Patent No. 6,030,342 ("*Amano*")

Amano discloses a device for measuring calorie expenditure and body temperature. Ex. 1006, 1:6-19. The device contains multiple temperature sensors and pressure sensors aligned in a row, for example longitudinally along a watch

band. *Id.* at 13:29-41, Fig. 3A. Because "the surface skin temperature directly above the artery is viewed to be sufficiently close to the deep body temperature," as compared to the temperature of the surrounding skin area, *id.* at 10:5-20, *Amano* teaches that any site with "skin close to an artery," specific "examples include the temporal artery," is an acceptable location to measure a person's body temperature. *Id.* at 31:11-22; *see also id.* at 10:27-33. *Amano* further discloses that the detected body temperature near an artery requires "some sort of correction" to account for the relationship between the "deep body temperature" (i.e., the detected temperature which is close thereto) and the "general body temperature" (i.e., temperature obtained orally or under the armpit, for example). *Id.* at 7:38-56.

FIG. 3A



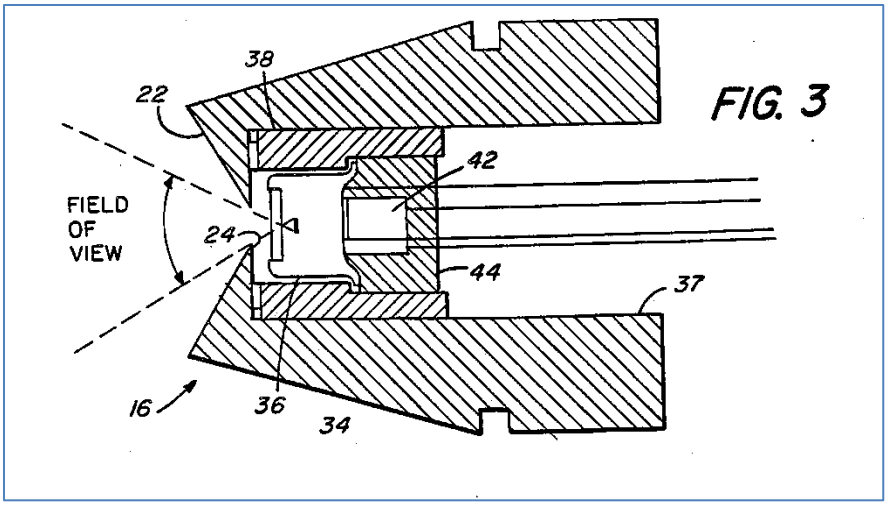
Amano discloses taking temperature measurements at 5 mm intervals along a line that intersects with the radial and/or ulnar artery. *Id.* at 9:61-10:2. *Amano* also teaches an embodiment in which the artery is located using pressure sensors and then temperature measurements are taken from the temperature sensor nearest the

detected artery. *Id.* at 23:29-65. The device "can continuously measure" a person's body temperature at skin locations above an artery, such as the radial artery and temporal artery. *Id.* at 1:15-17, 31:12-22.

Amano has a 35 U.S.C. § 371(c) date of February 9, 1998, which precedes the effective filing date of the '386 patent, and is, therefore, prior art under 35 U.S.C. § 102(e) and available under § 103.

C. U.S. Patent No. 4,636,091 ("*Pompei '091*")

Pompei '091 is directed to a hand-held radiation detector used for scanning a surface to provide temperature readings. Ex. 1007, Abstract, 1:6-8. The radiation detector has a nosepiece with a "high reflectivity" conical cup that can be placed directly against a surface. *Id.* at Abstract, 1:36-38. Radiation from the target surface is detected through a window and an aperture in the cup, *id.* at 1:38-39, 3:37-41, 4:63-68, Fig. 3, Ex. 1002, ¶¶ 76-78, and "[t]he field of view of the radiation sensor is less than the angle of the conical surface so that the radiation sensor only views the target surface." *Id.* at 1:59-61, Fig. 3.



Pompei '091 issued on January 13, 1987, which is more than one year prior to the effective filing date of the '386 patent, and is, therefore, prior art under 35 U.S.C. § 102(b) and available under § 103.

D. WO 93/03666 ("*Banke*")

Banke is directed to an infrared thermometer that can measure a person's body temperature in a fraction of a second. Ex. 1008 at 1:9-13. The thermometer uses an infrared sensor or thermopile that generates an electrical current signal that varies in accordance with target temperature. *Id.* at 1:20-23. The calculated temperature is displayed while the trigger is depressed, with the maximum calculated temperature displayed afterwards. *Id.* at 12:7-13. While the trigger is depressed, the temperature display is "updated approximately three times per second to show the present target temperature reading." *Id.* at 16:11-13. "This allows the operator to scan the eardrum, and more reliably obtain a temperature reading corresponding to the eardrum." *Id.* at 16:16-18. It further teaches that the

maximum temperature is displayed because "the temperature of almost all of the other objects within the ear will be lower than the eardrum temperature," which "is the more accurate indication of body temperature." *Id.* at 16:20-24. Although the invention was described with respect to an ear thermometer, *Banke* teaches that "the present invention has wide applicability with respect to thermometers of a wide variety of configurations." *Id.* at 17:11-16.

Banke was published as Internal Publication No. WO 93/03666 on March 4, 1993, which is more than one year prior to the effective filing date of the '386 patent, and is, therefore, prior art under 35 U.S.C. § 102(b) and available under § 103.

E. U.S. Patent No. 3,531,642 ("*Barnes*")

Barnes is directed to an infrared thermographic scanner and recorder that scans across a portion of a patient's body, for example the forehead. Ex. 1009 at 1:13-17. It also teaches a means for recording the scan in graph form. *Id.* at 1:16-22.

Barnes issued on September 29, 1970, which is more than one year prior to the effective filing date of the '386 patent, and is, therefore, prior art under 35 U.S.C. § 102(b) and available under § 103.

F. Y. Houdas and E.F.J. Ring, "Human Body Temperature, Its Measurement and Regulation," Plenum Press, N.Y. (1982) ("*Houdas*")

Houdas provides a discussion of human body temperature, its regulation within the human body, and its measurements. Ex. 1010 at v. It discloses several systems used in clinical medicine to measure a person's temperature, including infrared radiometers and infrared thermography. *Id.* at 34-47. *Houdas* illustrates skin temperature distribution at different ambient temperatures, finding that the extremities show "considerable variation" in skin temperature while the forehead exhibits "less significant variations." *Id.* at 97. It also provides a detail of heat transfer within and from the body. *Id.* at 57. *Houdas* teaches that "[i]n conditions of thermal neutrality, the metabolic heat produced by the core is transferred to the skin" and that "[t]he environment removes heat at an equal rate from the skin." *Id.* at 110. It can be shown that *Houdas* discloses the same equations for calculating a person's core temperature as disclosed in the '386 patent. Ex. 1002, ¶ 93; *compare* Ex. 1010 at 110, *with* Ex. 1001 at 7:59, 8:20.

Houdas was published in 1982, which is more than one year prior to the effective filing date of the '386 patent, and is, therefore, prior art under 35 U.S.C. § 102(b) and available under § 103.

VIII. THE CHALLENGED CLAIMS OF THE '386 PATENT ARE UNPATENTABLE

Pursuant to 37 C.F.R. § 42.104(b)(4)-(5), the Challenged Claims of the '386 patent are unpatentable for the reasons set forth in detail below.

A. Ground 1: Claims 1 And 2 Are Anticipated By *Pompei '813.*

Each element of claims 1 and 2 is taught, and thus anticipated, by *Pompei '813*. *See* Ex. 1002, ¶ 94.

1. Patent Owner Agrees That *Pompei '813* Discloses A Forehead Thermometer.

Patent Owner's has expressly recognized, through its earlier assertions and arguments about *Pompei '813*, that the reference is not limited to ear thermometers. Patent Owner previously filed a patent infringement suit against several defendants, asserting that several forehead thermometers infringed *Pompei '813*. Ex. 1013 at 20-22. In that suit, Patent Owner acknowledged that the preferred embodiment, and its first embodying product of *Pompei '813*, was an ear thermometer. *Id.* at 15. However, Patent Owner argued that "the invention claimed in claim 7 of [*Pompei '813*], which the jury found valid and infringed here [against specific forehead thermometers], was broader and directed to a radiation detector that sensed a 'target of biological tissue.'" *Id.* Patent Owner's argument that forehead thermometers infringe *Pompei '813* necessarily suggests Patent Owner agrees that *Pompei '813* discloses forehead thermometry for invalidity purposes. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir.

2003) ("It is axiomatic that claims are construed the same way for both invalidity and infringement.").

2. Claim 1

(a) "A body temperature detector comprising:"

Pompei '813 discloses a thermopile or radiation detector that measures tympanic temperature and adjusts it "to provide an indication of core temperature." *E.g.*, Ex. 1005 at Abstract, 2:46-54, 10:63-11:10. It also discloses a detector that generically and broadly provides "an indication of an internal temperature within biological tissue … by adjusting a measured temperature of surface tissue for ambient temperature." *Id.* at 2:46-51. In fact, Patent Owner has stated that *Pompei '813* "sets forth a general mechanism to convert any appropriate bodily temperature measurement to a core body temperature." Ex. 1012 at 18:18-19:1; *see also* Ex. 1013 at 18 ("Because the rate of perfusion is constant, the arterial heat balance invention of [*Pompei '813*] has a solution at the temporal artery."). Thus, *Pompei '813* teaches a body temperature detector. Ex. 1002, ¶¶ 63-64.

(b) "a temperature detector;"

Pompei '813 discloses a radiation detector utilizing a thermopile to detect and obtain temperature measurements. *E.g.*, Ex. 1005 at Abstract ("Tympanic temperature measurements are obtained from the output of a thermopile …."), 1:45-46, 2:46-54, 3:20-21; 3:65-66; 10:64-11:3. *Pompei '813* therefore discloses this claim limitation. Ex. 1002, ¶¶ 63-64.

(c) "electronics which measure peak temperature from at least three readings per second during scan of the temperature detector across an artery and which process the detected peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature."

Pompei '813 discloses electronics that measure peak temperature from at least three readings per second during scan of the temperature detector and process the detected peak temperature. Ex. 1002, ¶¶ 63-67. In particular, *Pompei '813* discloses a microprocessor that processes software routines to obtain a digital reading of the radiation sensor (or thermopile) nine times a second. *Id.* at 7:4-8, 13:30-36; Ex. 1002, ¶ 66. An analog-to-digital ("A/D") conversion is performed every 100 milliseconds (i.e., ten times per second), Ex. 1005 at 13:16-22, and in nine out of ten A/D conversion cycles the analog output of the thermopile is digitally converted and stored in memory. *Id.* at 13:30-36; Ex. 1002, ¶ 66; *see also* Ex. 1001 at 9:20-24 (admitting that the Patent Owner's "prior ear temperature detectors have obtained a peak temperature from ten readings per second …"). In the "peak" mode of operation, the disclosed device processes radiation sensor measurements while the device is scanned over the target surface and displays the highest indication of the body's core temperature. Ex. 1005 at 12:56-57; *see also id.* at 2:13-27, 3:44-51. *Pompei '813* also discloses "scanning of cutaneous tissue" and scanning of the skin surface within the ear canal. *Id.* at 1:13-20, 3:44-51, 11:16-19.

Under the proposed construction of "detected arterial temperature," *Pompei '813* discloses scanning of the temperature detector across an artery and providing a temperature display based on a model of heat balance relative to a detected arterial temperature. Ex. 1002, ¶¶ 66-69. The disclosed embodiment provides a temperature readout on the housing's display in response to the signal from the thermopile. *Id.* at 2:13-27, 7:1-4. The output is calculated based on the heat balance approach and includes obtaining the raw radiation sensor data from memory, accessing the sensed ambient temperature, and calculating the temperature coefficient adjustment. *Id.* at 13:1-15, Fig. 4B. In other words, the core temperature indication is calculated relative to the sensed temperature measurement. *Id.* at 13:6-15; *see also id.* at 2:46-54, 10:63-11:14. In fact, *Pompei '813* discloses nearly identical heat balance equations as provided in the '386 patent. *Compare* Ex. 1001 at 8:20, *with* Ex. 1005 at 11:9; Ex. 1002, ¶ 65.

Pompei '813 discloses an ear thermometer embodiment that scans over the tympanic membrane and within the ear canal. Ex. 1005 at 3:44-51. The tympanic membrane includes arteries that arise from the deep auricular branch of the maxillary artery, which supplies the meatus cuticular lining and the exterior of the tympanic membrane. Ex. 1015 at 1373, 1519; Ex. 1002, ¶ 31. Thus, scanning of the ear canal, and specifically the scanning over the tympanic membrane, as disclosed in *Pompei '813*, necessarily includes scanning across arteries. Ex 1002,

¶¶ 67-68. *Pompei '813* also discloses that its heat balance "compensation" "can be made in other applications," including "in differential cutaneous temperature scanning." Ex. 1005 at 11:16-19. To this effect, Patent Owner has argued that *Pompei '813* discloses "a technique of swiping a radiation detector across a target" and claims forehead thermometers. Ex. 1013 at 65; *see also id.* at 18 ("Because the rate of perfusion is constant, the arterial heat balance invention of [*Pompei '813*] has a solution at the temporal artery."). Thus, *Pompei '813* discloses scanning across an artery, including: (1) the arteries located within the tympanic membrane, (2) the arteries located under the target area of a "differential cutaneous temperature scanning," and (3) the temporal artery of the forehead, as previously asserted by Patent Owner.

Accordingly, *Pompei '813* discloses electronics that satisfy this claim limitation.

3. Claim 2

Claim 2 depends from claim 1 and additionally recites "wherein the temperature detector comprises a radiation sensor which views a target surface area of the forehead." *Pompei '813* discloses a thermopile radiation sensor that is used on "surface tissue," which necessarily includes the forehead. Ex. 1005 at 2:49-51; 3:16-21, 3:44-51; *see also id.* at 14:50-66 (broadly claiming a radiation detector that views "a target of biological surface tissue"); Ex. 1002, ¶¶ 67, 94. In fact,

Patent Owner has stated that *Pompei '813* "sets forth a general mechanism to convert any appropriate bodily temperature measurement to a core body temperature." Ex. 1012 at 18:18-19:1; *see also* Ex. 1013 at 15 (stating claim 7 of '813 patent "was broader" than an ear thermometer and "directed to a radiation detector that sensed a 'target of biological tissue'"), 18 ("Because the rate of perfusion is constant, the arterial heat balance invention of [*Pompei '813*] has a solution at the temporal artery."). Thus, *Pompei '813* satisfies this limitation, just as Patent Owner previously recognized in its assertion of patent infringement against forehead thermometers. Ex. 1002, ¶ 68.

B. Ground 2: Claims 3, 4, 22, And 24 Are Rendered Obvious By The Combination Of *Pompei '813* And *Pompei '091*.

As illustrated above and below, each element of claims 3, 4, 22 and 24 are anticipated by *Pompei '813*, except for the claimed reflective cup configuration. *Pompei '091* teaches a reflective cup configured to be outside of the radiation sensor's field of view. Ex. 1007 at 1:36-39, 4:50-54, Fig. 3. The combination of *Pompei '813* with *Pompei '091* renders claims 3, 4, 22, and 24 obvious. *See* Ex. 1002, ¶ 101.

1. *Pompei '091* is Analogous Art.

Pompei '091 is analogous art to the '386 patent. Like the '386 patent, *Pompei '091* relates to radiation detectors used to provide temperature readings and is, therefore, in the same field of endeavor. *See* Ex. 1007 at 1:6-8; Ex. 1002, ¶¶

76-78. The mere fact that *Pompei '091* is focused on industrial applications as opposed to clinical applications does not render it non-analogous art. In fact, the teachings of *Pompei '091* had already been used in clinical applications prior to the invention. In the '386 specification, Dr. Pompei admits that the emissivity compensating cup of his "prior designs" was used in an axillary, or armpit, temperature detector. Ex. 1001 at 9:3-17. From the specification, it is clear that the prior design emissivity compensating cup used in a clinical setting to measure armpit temperature is the same cup disclosed in *Pompei '091*. *See* Ex. 1001 at 4:54-56. Patent Owner also admitted that in 1988, a decade before the alleged priority date of the '386 patent, it began to develop a thermometer to obtain "medically relevant body temperature" by "[a]dapting its infrared sensing technology developed for industrial products." Ex. 1013 at 14.

In addition, *Pompei '091* is reasonably pertinent to a problem addressed by the inventor of the '386 patent. The inventor identified a need to compensate for emissivity. Ex. 1001 at Abstract (identifying use of "an emissivity compensating cup"), 4:54-56 (identifying cup is of "low emissivity in order to provide emissivity compensation"). *Pompei '091* elaborates on this problem: "the radiation emitted is also a function of the emissivity of the surface and of background radiation. Because the emissivity of the surface is generally not accurately known assumptions must be made, and those assumptions lead to inaccuracies in the

temperature reading." Ex. 1007 at 1:27-32. And *Pompei '091* addresses this problem by using "a high reflectivity" cup that "reflect[s] all emissions from a target surface back onto that surface," which "causes the surface to behave as a black body, the emissivity of which is equal to one, regardless of the actual emissivity of the surface." *Id.* at 1:36-43. Accordingly the "present invention" of *Pompei '091* "relates to an improved radiation detector suitable for surface temperature measurements while negating the effects of surface emissivity." *Id.* at 1:50-52. Not only does *Pompei '091* address the same problem in the same fashion, the inventor of the '386 patent specifically identifies using a cup of "low emissivity in order to provide emissivity compensation as disclosed in [*Pompei '091*]." Ex. 1001 at 4:54-56.

2. Motivation or Reason to Combine

A POSITA would have been motivated to combine *Pompei '813* with *Pompei '091*. Ex. 1002, ¶¶ 96-100. Combining *Pompei '091* with *Pompei '813* would be the application of "a known technique to a known device (method, or product) ready for improvement to yield predictable results." *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007); *see also* MPEP § 2141.III. In particular, a POSITA would have recognized that *Pompei '813* would benefit by the high reflectivity conical cup teaching of *Pompei '091* to generate more accurate and rapid surface temperature measurements. Ex. 1002, ¶ 98. In other words, the

application of the technique of *Pompei '091* (using a high reflectivity conical cup near or on a target surface) to the device of *Pompei '813* (a temperature detector scanning a region of skin to detect a peak temperature over an artery) is nothing more than the simple and straightforward process of recognizing that the tympanic thermometer of *Pompei '813* would require adaptation to obtain temperature measurements from exposed skin to negate the effects of a subject's skin emissivity and background radiation. *See* Ex. 1007 at 3:47-66; Ex. 1002, ¶ 98. A POSITA would readily recognize that the use of the ear thermometer disclosed in *Pompei '813* would require a different head design for use at the desired measurement site. Ex. 1002, ¶ 98.

Based on the teachings of *Pompei '091*, a POSITA would recognize that a radiation detector having a conical cup with a "high reflectivity" surface out of the sensor's field of view, and placed near or directly against the target surface, would yield more accurate and rapid skin temperature measurements. Ex. 1007 at Abstract, 1:33-38 ("A more rapid and accurate temperature reading can be obtained with a radiation sensing device which further includes means for eliminating the effects of emissivity on the output."), 1:50-61; Ex. 1002, ¶ 98. To this effect, *Pompei '091* teaches that its conical cup teaching would yield a predictable result to any surface: "By reflecting all emissions from a target surface back onto that surface, the cup causes the surface to behave as a black body, the emissivity of

which is equal to one, regardless of the actual emissivity of the surface. With such an arrangement, the temperature can be rapidly detected by a thermopile … and assumptions with regard to emissivity are unnecessary." *Id.* at 1:39-47.

In addition, a POSITA would be motivated to use the cup design of *Pompei '091* when measuring temperature at sites other than the ear, because it would be more comfortable for the patient. *Pompei '813* teaches that it is desirable to select a head design that does not cause patient discomfort. In particular, for the ear thermometer embodiment, *Pompei '813* teaches that the end of the thermometer's probe is "rounded" to not cause discomfort to the patient. Ex. 1005 at 3:40-43. A POSITA would have been motivated to use the cup design, including a rounded lip, of *Pompei '091* when measuring the temperature of a flat surface, like the forehead, to promote patient comfort. Ex. 1002, ¶ 99.

3. Claim 3

Claim 3 depends from claim 2 and additionally recites "wherein the radiation sensor views a target through a reflective cup, the cup having a large open diameter close to the target surface and a proximal window at the base of the cup proximal to the radiation sensor through which the radiation sensor views the target and an open distal diameter larger than the window and closer than the window to the target surface, the cup being out of the field of view of the sensor."

Pompei '091 discloses a radiation detector with a "high reflectivity" conical cup through which the sensor views the target surface. Ex. 1007 at Abstract, 1:50-58, 3:37-39. The '386 patent admits that a reflective cup was well-known in the art. Ex. 1001 at 4:54-56 ("The cup is preferably of low emissivity in order to provide emissivity compensation as disclosed in [Pompei '091]."), 9:9-12 (identifying "the Exergen D501 Industrial Temperature Detector," which used an "emissivity compensating cup" as a "prior design"), 9:14-16 (admitting that the "emissivity compensating cup" of "applicant's prior designs" was "utilized in the axillary temperature detector").

The conical cup of *Pompei '091* also has a large base (or "open diameter") close to the target surface and a smaller diameter aperture (or "window") farther away from the target surface. *Id.* at 1:53-61, 4:45-54 (describing the cone having an aperture or window of 1/8 inch and a base of ½ inch), Fig. 3. It expressly discloses that "[t]he field of view of the radiation sensor is less than the angle of the conical surface so that the radiation sensor only views the target surface." *Id.* at 1:59-61. *Pompei '091* also discloses a window through which the sensor views the target. Specifically, *Pompei '091* uses a thermopile radiation sensor, *id.* at 2:37-42, which is mounted in a can with an opening covered by an infrared-transparent window through which the sensor views the target surface. *Id.* at 3:37-41, 4:63-68, Fig. 3; Ex. 1002, ¶¶ 75-78. Figure 3 of *Pompei '091* clearly shows a can enclosing

the thermopile radiation sensor and a proximal window mounted at the base of the cup and smaller than the open distal diameter of the cup. In fact, the can 36 housing the infrared sensor and window in *Pompei '091* are nearly identical to the can 62 housing the infrared sensor 60 and window 63 of the '386 patent. *Compare* Ex. 1007 at Fig. 3, *with* Ex. 1001 at Fig. 2A.

4. Claim 4

Claim 4 depends from claim 3 and additionally recites "wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal conductively material." The '386 patent describes the lip having a "smooth curve" for "comfort during scanning." Ex. 1001 at 6:6-7.

Pompei '813 similarly teaches that the end of the thermometer's probe is "rounded" to not cause discomfort to the patient. Ex. 1005 at 3:40-43. *Pompei '813* also discloses that the "outer sleeve 38 of the extension 18 and the intermediate extension 20 are of plastic material of low thermal conductivity." *Id.* at 5:13-15; *see also id.* at 6:5-8, 15-19. For the same reasons of patient comfort and accurate measurements, a POSITA would have been motivated to use the rounded lip and low thermal conductivity material of *Pompei '813* in the *Pompei '813/Pompei '091* combination. Ex. 1002, ¶ 99. Accordingly, *Pompei '813* satisfies this limitation. *Id.* at 80-81.

5. Claim 22

(a) "A body temperature detector comprising:"

As described above with respect to claim 1 in Part VIII.A.2(a) of this Petition, *Pompei '813* teaches a body temperature detector.

(b) "a radiation sensor which views a target surface area;"

As described above with respect to claims 1 and 2 in Parts VIII.A.2(b) and VIII.A.3 of this Petition, *Pompei '813* discloses a thermopile radiation sensor that views a target surface area.

(c) "a reflective cup through which the radiation sensor views the target surface area, the cup having a proximal window at the base of the cup through which the radiation sensor views the target and an open distal diameter larger than the window and closer than the window to the target surface, the cup proximal to the radiation sensor being out of the field of view of the sensor; and"

As described above with respect to claim 3 in Part VIII.B.3 of this Petition, *Pompei '813* in view of *Pompei '091* discloses a reflective cup with the claimed limitations.

(d) "electronics which measure peak temperature from at least three readings per second during scan of the temperature detector across the target surface area, the electronics processing the detected peak temperature to provide a temperature display based on a model of heat balance relative to the detected temperature."

This claim limitation is broader than the analogous limitation in claim 1 because there is no requirement to scan across an artery or to use a detected arterial temperature. Thus, as described above with respect to claim 1 in Part VIII.A.2(c) of

this Petition, *Pompei '813* discloses the electronics that satisfy this claim limitation.

6. Claim 24

Claim 24 depends from claim 22 and additionally recites "wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal conductively material." As described above with respect to claim 4 in Part VIII.B.4 of this Petition, *Pompei '813* discloses the claimed lip of low thermal conductively material.

C. Ground 3: Claims 1 And 2 Are Rendered Obvious By The Combination Of *Pompei '813* And *Amano*.

As illustrated above, each element of claims 1 and 2 is taught by *Pompei '813*. To the extent the Board concludes that *Pompei '813* does not teach the "scan … across an artery" and "forehead" limitations of claims 1 and 2, contrary to Patent Owner's own interpretation of the reference, *Amano* teaches a body temperature detector based on temperature readings taken across an artery, including the temporal artery. Ex. 1006 at 31:12-22. The combination of *Pompei '813* and *Amano* therefore renders claims 1 and 2 obvious. *See* Ex. 1002, ¶ 112.

1. Motivation or Reason to Combine

It would have been obvious to a POSITA to combine *Pompei '813* with *Amano*. Ex. 1002, ¶¶ 103-111. *Pompei '813* discloses a radiation detector that indicates body temperature from sensed surface temperature measurements.

Ex. 1005, Abstract. Although the example embodiment is directed at a device used in the ear canal, *id.* at 1:23-27, it was well known in the art that radiation detectors could be used to measure skin temperature at other locations on the body. *Id.* at 1:18-20 ("Another application has been in the scanning of cutaneous tissue to locate injured subcutaneous regions.") 2:49-51 (measuring of "surface tissue"), 14:50-66 (broadly claiming "a target of biological surface tissue); Ex. 1002, ¶ 105. In fact, Patent Owner argued that *Pompei '813* applies to forehead thermometers. Ex. 1013 at 18, 65.

To the extent that *Pompei '813* does not teach each limitation of claims 1 and 2, *Amano* similarly discloses measuring the surface temperature of skin above an artery, including the temporal artery, because it provides a more accurate representation of core temperature. Ex. 1006 at 1:13-18, 9:61-10:8, 31:12-22. *Amano* further discloses locating an artery by taking temperatures along a line that passes over and across an artery. Ex. 1006 at 9:51-10:8. Both *Pompei '813* and *Amano* teach methods for indicating a subject's core temperature based upon measurements at surfaces known to be "closer" to the core temperature. Ex. 1005 at 4:40-42; Ex. 1006 at 10:15-33.

And a POSITA seeking to obtain a person's core temperature from less invasive and more convenient locations than the ear canal (as does the disclosed embodiment in *Pompei '813*) would have been motivated to consider the forehead

as a candidate location. Ex. 1006 at 10:65-11:13, 31:11-22 (describing invention's temperature measurement sites, including temporal artery, as being "carried out comparatively simply" in contrast to "conventional" temperature sites); *see also* Ex. 1005 at 3:40-43 (describing design of rounded probe end to "avoid discomfort to the patient"), Ex. 1002, ¶ 107. Only a few sites are generally not covered by clothing and less invasive and more convenient than the ear canal. Ex. 1002, ¶¶ 107 ("For one, people are generally clothed, ruling out locations covered by clothing. This leaves the head, the neck, and hands."). The forehead also provided an obvious location because of its historical use and its physiological characteristics. *Id.* ("The forehead would be an obvious location because it has long been used as a site to take temperature measurements (by placing one's hand on another's forehead)."); Ex. 1013 at 10 (Exergen stating that "[s]ince the time of ancient Egyptians, humans have been feeling the forehead as a way to determine whether there is sickness. This age-old practice of the hands and fingers contacting the forehead reflects the common understanding that body heat is related to fever or disease."). For example, it was well known that the forehead provides skin temperatures "relatively closely linked to core temperature" because it uniformly provides consistent tissue insulation and is devoid of thermoregulatory arteriovenous shunts. Ex. 1011 at 604; *see also* Ex. 1013 at 17 (Patent Owner admitting that "[a]s a matter of anatomy, it was known that the temporal artery had

no anastomoses, or valves, that cause the rate of blood flow to vary."). Thus, it would have been obvious to a POSITA to configure the radiation detector of *Pompei '813* to determine core temperature based on temperature measurements above an artery in the forehead, including the temporal artery, as described in *Amano*. Ex. 1002, ¶ 107.

Similarly, a POSITA would have recognized the value of incorporating the scanning functionality of *Pompei '813* with *Amano*'s teachings. Ex. 1002, ¶ 110. *Pompei '813* discloses that by scanning the ear canal "one can be assured that the maximum temperature is viewed" because the ear canal cavity leading to the tympanic membrane was the area of highest temperature. Ex. 1005 at 3:44-51. *Amano* discloses a similar phenomenon—the temperature above an artery is higher than that of the surrounding skin surface because "the radial artery and other arteries carry blood, which is a heat source." Ex. 1006 at 10:5-8, 15-20. Thus, it would have been obvious to a POSITA that the scanning feature of *Pompei '813* enables a radiation detector to locate an artery, such as the temporal artery, by observing the peak temperature from measurements above and near an artery. Ex. 1002, ¶ 110.

A POSITA would also have been motivated to combine the heat balance approach of *Pompei '813* with *Amano*'s temperature measurement above an artery. Ex. 1002, ¶ 108. *Pompei '813* teaches that the sensed ear temperature is not

actually the core temperature. Ex. 1005 at 10:64-66. Because of thermal resistance between the sensed temperature and core temperature and between the sensed temperature and ambient temperature, *Pompei '813* discloses calculating core temperature as a function of sensed and ambient temperatures. *Id.* at 10:63-11:10. Similarly, *Amano* recognizes that the sensed temperature above an artery was "close" to, but not actually, the core temperature. Ex. 1006 at 2:17-22; *see also id.* at 7:29-56 (recognizing that "some sort of correction must be carried out" to convert the sensed "deep body temperature" to a "general body temperature"). Just as *Pompei '813* discloses core temperature compensation "can be made in other applications," *id.* at 11:1-17, a POSITA would have been motivated to combine *Pompei '813* and *Amano* to apply the heat balance method to indicate core temperature relative to the sensed temperature above an artery close to the skin surface. Ex. 1002, ¶ 109 ("[A] person of ordinary skill would understand that the most accurate core temperature estimate from temperature measurements of the skin over an artery would occur at an artery that minimizes the difference between the core temperature and the skin temperature. It would also obviously follow that the best site would provide the highest available absolute temperature (i.e., that closest to body/core temperature)."). To adapt the model at other locations, a POSITA would merely need to empirically determine the k value at the new location. Ex. 1002, ¶ 108. In fact, Patent Owner similarly admitted that "[b]ecause

the rate of perfusion is constant, the arterial heat balance invention of [*Pompei '813*] has a solution at the temporal artery." Ex. 1013 at 18; *see also* Ex. 1012 at 18:18-19:1 (Patent Owner admitting that *Pompei '813* "sets forth a general mechanism to convert any appropriate bodily temperature measurement to a core body temperature").

2. Claim 1

(a) "A body temperature detector comprising:"

As described above with respect to claim 1 in Part VIII.A.2(a) of this Petition, *Pompei '813* discloses a body temperature detector. Likewise, *Amano* teaches a "body temperature measuring device" that "can continuously measure a body temperature that which is as close as possible to the subject's deep body temperature." Ex. 1006 at 1:13-18, 7:29-37; Ex. 1002, ¶¶ 70-71. Thus, both *Pompei '813* and *Amano* teach a body temperature detector.

(b) "a temperature detector;"

As described above with respect to claim 1 in Part VIII.A.2(b) of this Petition, *Pompei '813* discloses a temperature detector.

(c) "electronics which measure peak temperature from at least three readings per second during scan of the temperature detector across an artery and which process the detected peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature."

As described above with respect to claim 1 in Part VIII.A.2(c) of this Petition and under the proposed construction, *Pompei '813* discloses electronics that satisfy this claim limitation.

Additionally, *Amano* discloses a method for detecting a temperature close to a patient's core temperature by taking temperature measurements above an artery. Ex. 1006 at 9:61-10:8, 10:15-20, 31:11-22. Specifically, *Amano* teaches taking temperature measurements at 5 mm intervals along a line intersecting with or across the radial and ulnar artery. *Id.* at 9:61-67. It further teaches that it "is clear" from experimental results that the temperatures above the radial and ulnar arteries are higher than the surrounding skin surface because "the radial artery and other arteries carry blood, which is a heat source." *Id.* at 10:2-17. *Amano* also teaches that the surface skin temperature above the artery is close to the core temperature. *Id.* at 10:17-20. Thus, *Amano* teaches taking temperature measurements across an artery in order to identify the local peak temperature and using that measurement to approximate core temperature. Ex. 1002, ¶¶ 106-110.

As discussed above, it would have been obvious to combine *Pompei '813*'s scanning radiation detector with *Amano*'s disclosure of taking measurements across an artery. Like *Pompei '813*, *Amano* attempts to solve the problem of accurate core temperature indications based on convenience and comfort. Ex. 1006 at 10:65-11:13; *see also* Ex. 1005 at 1:35-39, 3:33-36, 3:40-42. Accordingly, a

POSITA would have been motivated to employ *Pompei '813*'s scanning radiation detector with heat balance approximations to *Amano*'s arterial scanning to develop a temperature detector able to "scan across an artery and … provide a temperature display based on a model of heat balance relative to a detected arterial temperature." Ex. 1002, ¶¶ 103-111. This claim limitation is thus met by *Pompei '813* in view of *Amano*.

3. Claim 2

Claim 2 depends from claim 1 and additionally recites "wherein the temperature detector comprises a radiation sensor which views a target surface area of the forehead." As described above with respect to claim 2 in Part VIII.A.3 of this Petition, *Pompei '813* discloses the claimed radiation sensor. In addition, *Amano* discloses a device for measuring the surface temperature of skin above and across an artery, including the forehead's temporal artery. Ex. 1006 at 31:12-22. As discussed with respect to claim 1, a POSITA would have been motivated to combine the scanning radiation detector of *Pompei '813* with *Amano*'s measurements across an artery. Ex. 1002, ¶¶ 103-111. Accordingly, even if the Board concludes that *Pompei '813* does not fully satisfy this limitation, the combined disclosures of *Pompei '813* and *Amano* disclose this limitation.

D. Ground 4: Claims 3, 4, 22, And 24 Are Rendered Obvious By The Combination Of *Pompei '813*, *Amano*, And *Pompei '091*.

As illustrated above and below, each element of claims 3, 4, 22 and 24 are anticipated by *Pompei '813* and rendered obvious by the combination of *Pompei '813* and *Amano*, except for the claimed reflective cup configuration. *Pompei '091* teaches a reflective cup configured to be outside of the radiation sensor's field of view. Ex. 1007 at 1:36-39, 4:50-54, Fig. 3. The combination of *Pompei '813/Amano* with *Pompei '091* renders claims 3, 4, 22, and 24 obvious. *See* Ex. 1002, ¶ 119.

1. Motivation or Reason to Combine

A POSITA would have been motivated to combine *Pompei '813* and *Amano* with *Pompei '091*. Ex. 1002, ¶¶ 114-118. Combining *Pompei '091* with *Pompei '813/Amano* would be the application of "a known technique to a known device (method, or product) ready for improvement to yield predictable results." *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007); *see also* MPEP § 2141.III. In particular, a POSITA would have recognized that the combination of *Pompei '813/Amano* would benefit by the high reflectivity conical cup teaching of *Pompei '091* to generate more accurate and rapid surface temperature measurements. Ex. 1002, ¶ 116. In other words, the application of the technique of *Pompei '091* (using a high reflectivity conical cup near or on a target surface) to the device of *Pompei '813/Amano* (a temperature detector scanning a region of skin to detect a peak

temperature over an artery) is nothing more than the simple and straightforward process of recognizing that the tympanic thermometer of *Pompei '813* would require adaptation to obtain temperature measurements from exposed skin to negate the effects of a subject's skin emissivity and background radiation. *See* Ex. 1007 at 3:47-66; Ex. 1002, ¶ 116. A POSITA would readily recognize that the use of the ear thermometer embodiment disclosed in *Pompei '813* would require a different head design for use at the desired measurement site. Ex. 1002, ¶ 115.

Based on the teachings of *Pompei '091*, a POSITA would recognize that a radiation detector having a conical cup with a "high reflectivity" surface out of the sensor's field of view, and placed near or directly against the target surface, would yield more accurate and rapid skin temperature measurements. Ex. 1007 at Abstract, 1:33-38 ("A more rapid and accurate temperature reading can be obtained with a radiation sensing device which further includes means for eliminating the effects of emissivity on the output."), 1:50-61; Ex. 1002, ¶ 116. To this effect, *Pompei '091* teaches that its conical cup teaching would yield a predictable result to any surface: "By reflecting all emissions from a target surface back onto that surface, the cup causes the surface to behave as a black body, the emissivity of which is equal to one, regardless of the actual emissivity of the surface. With such an arrangement, the temperature can be rapidly detected by a thermopile … and assumptions with regard to emissivity are unnecessary." *Id.* at 1:39-47.

2. Claim 3

Claim 3 depends from claim 2 and additionally recites "wherein the radiation sensor views a target through a reflective cup, the cup having a large open diameter close to the target surface and a proximal window at the base of the cup proximal to the radiation sensor through which the radiation sensor views the target and an open distal diameter larger than the window and closer than the window to the target surface, the cup being out of the field of view of the sensor." As described above with respect to claim 3 in Part VIII.B.3 of this Petition, *Pompei '091* discloses a reflective cup with the claimed limitations.

3. Claim 4

Claim 4 depends from claim 3 and additionally recites "wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal conductively material." As described above with respect to claim 4 in Part VIII.B.4 of this Petition, *Pompei '813* discloses the claimed lip of low thermal conductively material.

4. Claim 22

(a) "A body temperature detector comprising:"

As described above with respect to claim 1 in Part VIII.C.2(a) of this Petition, both *Pompei '813* and *Amano* teach a body temperature detector.

(b) "a radiation sensor which views a target surface area;"

As described above with respect to claims 1 and 2 in Parts VIII.A.2(b) and VIII.A.3 of this Petition, *Pompei '813* discloses a thermopile radiation sensor that views a target surface area.

(c) "a reflective cup through which the radiation sensor views the target surface area, the cup having a proximal window at the base of the cup through which the radiation sensor views the target and an open distal diameter larger than the window and closer than the window to the target surface, the cup proximal to the radiation sensor being out of the field of view of the sensor; and"

As described above with respect to claim 3 in Part VIII.B.3 of this Petition, *Pompei '813* in view of *Pompei '091* discloses a reflective cup with the claimed limitations.

(d) "electronics which measure peak temperature from at least three readings per second during scan of the temperature detector across the target surface area, the electronics processing the detected peak temperature to provide a temperature display based on a model of heat balance relative to the detected temperature."

This claim limitation is broader than the analogous limitation in claim 1 because there is no requirement to scan across an artery or to use a detected arterial temperature. Thus, as described above with respect to claim 1 in Part VIII.A.2(c) of this Petition, *Pompei '813* discloses the electronics that satisfy this claim limitation.

5. Claim 24

Claim 24 depends from claim 22 and additionally recites "wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal

conductively material." As described above with respect to claim 4 in Part VIII.B.4 of this Petition, *Pompei '813* discloses the claimed lip of low thermal conductively material.

E. Ground 5: Claims 1 And 2 Are Rendered Obvious By The Combination Of *Banke*, *Houdas*, And *Barnes*.

The combination of *Banke*, *Houdas*, and *Barnes* renders claims 1 and 2 obvious. *See* Ex. 1002, ¶ 127.

1. Motivation or Reason to Combine

It would have been obvious to a POSITA to combine *Banke* with *Houdas* and *Barnes*. Ex. 1002, ¶¶ 121-126. *Banke* discloses a radiation detector that gives a "reliable indication" of the patient's body temperature. Ex. 1008 at 4:2-4, 7:2-6, 16:11-28. The disclosed radiation detector embodiment provides temperature readings approximately three times per second and displays the maximum temperature calculated during scan of the detector through a patient's ear. *Id.* at 16:11-28. Although the preferred embodiment is used to scan the eardrum, *Banke* teaches that "[t]here are, however, many configurations for thermometers not specifically described herein, but with which the present invention is applicable." *Id.* at 17:9-11. *Banke* instructs that its invention should not be narrowly construed and "limited to the particular embodiment described herein, but rather, it should be understood that the present invention has wide applicability with respect to thermometers of a wide variety of configurations." *Id.* at 17:11-16.

In order to apply the teachings of *Banke* to determine a person's core temperature from a less invasive and more convenient body location, a POSITA would have been motivated to combine *Banke*'s disclosed radiation detector with the heat balance equations and thermograms disclosed in *Houdas*. Ex. 1002, ¶ 123. *Houdas* discloses a thermal neutrality heat balance approach that allow a person's core temperature to be determined from skin temperature and ambient temperature measurements. Ex. 1010 at 108-11, 143-45; Ex. 1002, ¶ 93. In fact, it is readily shown that *Houdas* discloses the same equations disclosed in the '386 patent for calculating a person's core temperature as a function of sensed skin and ambient temperatures. Ex. 1002, ¶ 93. Under conditions of thermal neutrality, *Houdas* discloses that the metabolic heat produced by the core is transferred to the skin at an equal rate as the environment removes heat from the skin. Ex. 1010 at 110. Thus, the equations for these two modes of heat transfer can be set equal to each other ($h_b(T_d - T_s) = h(T_s - T_a)$) and solved for the core temperature (T_d): $T_d = \frac{h}{h_b}(T_s - T_a) + T_s$. This is the same as equation (6) in the '386 patent, where h_b here represents *pc* in the '386 patent. *Compare* Ex. 1001 at 7:59; *see also* Ex. 1002, ¶ 93. A POSITA would have readily recognized that the heat balance model disclosed in *Houdas* could be used at any skin surface location, given the local heat transfer coefficient for the chosen location was empirically determined. Ex. 1002, ¶ 123.

In addition and as described above, a POSITA seeking to obtain a less invasive and more convenient indication of a person's body temperature would have been motivated to consider the forehead as a candidate location. *See* Ex. 1008 at 1:9-15 (describing that infrared thermometers have "a number of desirable qualities," including patient convenience and ease of use); Ex. 1009 at 2:34-38 (describing benefits of the disclosed invention as including "convenient" functions); Ex. 1002, ¶ 124. Only a few body sites are generally not covered by clothing and less invasive than the ear canal. *Id.*, ¶ 124. The forehead also provided an obvious location because of its common use as an indicator of a person's temperature and its physiological characteristics. *Id.*, ¶ 124; Ex. 1013 at 10. For example, the forehead provides skin temperatures "relatively closely linked to core temperature" because it uniformly provides consistent tissue insulation and is devoid of thermoregulatory arteriovenous shunts. Ex. 1011 at 604. In light of the thermographs reproduced in *Houdas* and the fact that arteries carry blood, which is a heat source for nearby skin, a POSITA would recognize that the skin temperature above an artery is generally higher than that of surrounding skin surface. Ex. 1010 at inserts after 42; Ex. 1002, ¶ 124. Thus, it would have been obvious to a POSITA to configure *Banke*'s radiation detector to determine core temperature based on temperature measurements above an artery in the forehead, for example the temporal artery. Ex. 1002, ¶ 124.

Similarly, a POSITA would have recognized the value of integrating *Banke*'s scanning through the ear with *Barnes*' scanning of the forehead to capture the peak temperature above the temporal artery in the forehead. Ex. 1002, ¶ 125. As detailed above, *Banke* discloses that "saving the maximum temperature reading while the infrared sensor was scanned through the ear will save and display a temperature most likely to be that of the eardrum" because this temperature is greater than "almost all of the other objects within the ear." Ex. 1008 at 15:16-28. And Barnes teaches scanning across a person's forehead as a diagnostic aid. Ex. 1009 at 1:13-22, 4:61-5:1.

2. Claim 1

(a) "A body temperature detector comprising:"

Banke discloses an infrared thermometer that determines a patient's body temperature. Ex. 1008 at Abstract, 2:1-10, 3:2-8, 6:23-7:15, 11:26-12:19. Similarly, *Houdas* discloses various body temperature measurement devices used in clinical medicine, including infrared radiometers. Ex. 1010 at 34, 40-41. *Houdas* also teaches a POSITA how to compute a person's core temperature from a measured skin temperature and a known ambient temperature. *Id.* at 95-97, 108-11, 143-45.

(b) "a temperature detector;"

Banke discloses an infrared thermometer that is used in the disclosed embodiment to detect a patient's eardrum temperature, which is "generally an accurate indication of the patient's body temperature." Ex. 1008 at 2:1-10, 3:2-8;

4:2-4, 6:23-7:15, 7:2-6, 11:26-12:19, 16:11-28. Accordingly, *Banke* teaches a temperature detector. Ex. 1002, ¶¶ 122-125.

(c) "electronics which measure peak temperature from at least three readings per second during scan of the temperature detector across an artery and which process the detected peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature."

Banke discloses electronics that measure peak temperature from at least three readings per second and that process the detected peak temperature to provide a temperature display. Ex. 1002, ¶¶ 122-125. Specifically, *Banke* teaches that while the trigger on the disclosed embodiment is depressed, "the display 18 is updated approximately three times per second to show the present target temperature reading." Ex. 1008 at 16:11-13. It further teaches that the peak or "maximum calculated temperature" is displayed after the trigger is released. *Id.* at 12:7-14, 16:11-15.

Banke also discloses scanning of the temperature detector across an artery. In particular, it teaches that displaying the maximum temperature "allows the operator to scan the eardrum, and more reliably obtain a temperature reading corresponding to the eardrum." *Id.* at 16:16-18. "Therefore, saving the maximum temperature reading while the infrared sensor was scanned through the ear will save and display a temperature most likely to be that of the eardrum, giving a reliable indication of the likely body temperature." *Id.* at 16:24-28. Because the

eardrum (or tympanic membrane) contains arteries as discussed above, Ex. 1015 at 1373, 1519, *Banke*'s teaching of scanning "through the ear" necessarily involves scanning across an artery. Ex. 1002, ¶ 125. Similarly, *Barnes* discloses electronics that measure skin temperature during scan of the temperature detector across an artery. *Id.* at 125-127. For example, *Barnes* discloses a thermographic scanner and recorder that scans across a portion of a patient's body, in particular the forehead that includes the temporal artery. Ex. 1009 at 1:13-29, 2:28-46, 4:61-5:1, 5:28-32.

Houdas discloses a method for converting a skin surface temperature measurement into a core temperature via a heat exchange balance with a known ambient temperature. Ex. 1010 at 108-11, 143-45; Ex. 1002, ¶¶ 91-93, 123-124. In particular, *Houdas* teaches that in thermal neutrality there is equality between heat removed by the environment and heat production (from the core to the skin surface). Ex. 1010 at 108-11, 143-45. Assuming thermal neutrality and, thus, setting the equations for these two heat transfer modes equal to each other, the same equation for computing a core temperature at a given body site can be derived from *Houdas* as disclosed in the '386 patent. Ex. 1002, ¶ 93. Thus and for the reasons discussed above, a person of ordinary skill would have been motivated to combine the scanning thermometer of *Banke*, *Barnes*, or both with the heat exchange method of *Houdas* to calculate a person's core temperature based on a

known or measured ambient temperature and detected surface temperature. *See also* Ex. 1002, ¶¶ 123-124.

This claim limitation is thus met by *Banke* in view of *Houdas* and *Barnes.*

3. Claim 2

Claim 2 depends from claim 1 and additionally recites "wherein the temperature detector comprises a radiation sensor which views a target surface area of the forehead." *Barnes* teaches scanning across a person's forehead, which satisfies this claim's limitation of viewing "a target surface area of the forehead." Ex. 1009 at 1:13-29, 4:61-5:1, 5:28-32. In addition, although *Banke* discloses a thermometer embodiment that takes measurements in the ear canal, it teaches that its invention is not limited to the disclosed embodiment but has "wide applicability." Ex. 1008 at 17:6-18. Accordingly, this claim limitation is satisfied by *Banke* in view of *Barnes.* Ex. 1002, ¶¶123-126.

F. Ground 6: Claims 3, 4, 22, And 24 Are Rendered Obvious By The Combination Of *Banke*, *Houdas*, *Barnes*, And *Pompei '091*.

As illustrated above and below, each element of claims 3, 4, 22 and 24 are rendered obvious by the combination of *Banke*, *Houdas*, and *Barnes*, except for the claimed reflective cup configuration of claims 3 and 22 and the probe end of claims 4 and 24. *Pompei '091* teaches a reflective cup configured to be outside of the radiation sensor's field of view. Ex. 1007 at 1:36-39, 4:50-54, Fig. 3. The

combination of *Banke/Houdas*/*Barnes* with *Pompei '091* renders claims 3, 4, 22, and 24 obvious. *See* Ex. 1002, ¶ 133.

1. Motivation or Reason to Combine

A POSITA would have been motivated to combine *Banke*, *Houdas*, and *Barnes* with *Pompei '091*. Ex. 1002, ¶¶ 129-132. Combining *Pompei '091* with *Banke/Houdas*/*Barnes* would be the application of "a known technique to a known device (method, or product) ready for improvement to yield predictable results." *See KSR Int'l Co. v. Teleflex, Inc.*, 127 S.Ct. 1727, 1740 (2007); *see also* MPEP § 2141.III. In particular, a POSITA would have recognized that the combination of *Banke/Houdas*/*Barnes* would benefit by the high reflectivity conical cup teaching of *Pompei '091* to generate more accurate and rapid surface temperature measurements. Ex. 1002, ¶ 130. In other words, the application of the technique of *Pompei '091* to the device of *Banke/Houdas*/*Barnes* is nothing more than the simple and straightforward process of recognizing that the ear thermometer of *Banke* would require adaptation to obtain temperature measurements from exposed skin to negate the effects of a subject's skin emissivity and background radiation. *See* Ex. 1007 at 3:47-66; Ex. 1002, ¶ 130. A POSITA would readily recognize that the use of the ear thermometer disclosed in *Banke* would benefit from a different head design for use at the desired measurement site. Ex. 1002, ¶ 130.

Based on the teachings of *Pompei '091*, a POSITA would recognize that a radiation detector having a conical cup with a "high reflectivity" surface out of the sensor's field of view, and placed near or directly against the target surface, would yield more accurate and rapid skin temperature measurements. Ex. 1007 at Abstract, 1:33-38 ("A more rapid and accurate temperature reading can be obtained with a radiation sensing device which further includes means for eliminating the effects of emissivity on the output."), 1:50-61; Ex. 1002, ¶ 130. To this effect, *Pompei '091* teaches that its conical cup teaching would yield a predictable result to any surface: "By reflecting all emissions from a target surface back onto that surface, the cup causes the surface to behave as a black body, the emissivity of which is equal to one, regardless of the actual emissivity of the surface. With such an arrangement, the temperature can be rapidly detected by a thermopile … and assumptions with regard to emissivity are unnecessary." *Id.* at 1:39-47.

2. Claim 3

Claim 3 depends from claim 2 and additionally recites "wherein the radiation sensor views a target through a reflective cup, the cup having a large open diameter close to the target surface and a proximal window at the base of the cup proximal to the radiation sensor through which the radiation sensor views the target and an open distal diameter larger than the window and closer than the window to the target surface, the cup being out of the field of view of the sensor." As

described above with respect to claim 3 in Part VIII.B.3 of this Petition, *Pompei '091* discloses a reflective cup with the claimed limitations.

3. Claim 4

Claim 4 depends from claim 3 and additionally recites "wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal conductively material." The '386 patent describes the lip having a "smooth curve" for "comfort during scanning." Ex. 1001 at 6:6-7.

A POSITA would have recognized the need to provide a smooth probe end to the *Banke/Houdas*/*Barnes* device in order to avoid discomfort to a patient during scanning of the temperature detector across the forehead. Ex. 1002, ¶ 131. Similarly, a POSITA would have recognized the need to for the probe end to be made of low thermal conductivity material in order to minimize local cooling of the scanned temperature and, thus, inaccurate core temperature indications. *Id.* For the reasons of patient comfort and accurate temperature measurements, a POSITA would have been motivated to use the rounded lip of low thermal conductivity material in the *Banke/Houdas/Barnes/Pompei '091* combination. *Id.*

4. Claim 22

(a) "A body temperature detector comprising:"

As described above with respect to claim 1 in Part VIII.E.2(a) of this Petition, both *Banke* and *Houdas* teach a body temperature detector.

(b) "a radiation sensor which views a target surface area;"

As described above with respect to claims 1 and 2 in Parts VIII.E.2(b) and VIII.E.3 of this Petition, *Banke* discloses a radiation detector that views a target surface area.

(c) "a reflective cup through which the radiation sensor views the target surface area, the cup having a proximal window at the base of the cup through which the radiation sensor views the target and an open distal diameter larger than the window and closer than the window to the target surface, the cup proximal to the radiation sensor being out of the field of view of the sensor; and"

As described above with respect to claim 3 in Part VIII.F.2 of this Petition, *Banke* in view of *Pompei '091* discloses a reflective cup with the claimed limitations. In addition and as described above, a POSITA would have been motivated to combine *Pompei '091* with the *Banke/Houdas/Barnes* combination.

(d) "electronics which measure peak temperature from at least three readings per second during scan of the temperature detector across the target surface area, the electronics processing the detected peak temperature to provide a temperature display based on a model of heat balance relative to the detected temperature."

This claim limitation is broader than the analogous limitation in claim 1 because there is no requirement to scan across an artery or to use a detected arterial temperature. Thus, as described above with respect to claim 1 in Part VIII.E.2(c) of this Petition, *Banke* in view of *Houdas* and *Barnes* discloses the electronics that satisfy this claim limitation.

5. Claim 24

Claim 24 depends from claim 22 and additionally recites "wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal conductively material." As described above with respect to claim 4 in Part VIII.F.3 of this Petition, it would have been obvious to a POSITA to include the claimed smooth lip of low thermal conductively material to the *Banke/Houdas/Barnes/Pompei '091* combination.

IX. CONCLUSION

For the reasons set forth above, Petitioner submits that claims 1-4, 22, and 24 of the '386 patent are invalid based on 35 U.S.C. §§ 102 and 103. Accordingly, Petitioner requests institution of *inter partes* review of these claims for each ground presented herein and a determination that the Challenged Claims are unpatentable.

Date: July 14, 2016

Respectfully submitted,

By: /s/ *Kirt S. O'Neill*
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 7,346,386 and supporting materials (Exhibits 1001-1017 and Power of Attorney) have been served in their entirety this 14th day of July 2016, by FedEx Priority Overnight on:

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