

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KAZ USA, INC,
Petitioner,

v.

EXERGEN CORP.,
Patent Owner.

Case IPR2016-01437
Patent 7,346,386 B2

Before PHILLIP J. KAUFFMAN, MEREDITH C. PETRAVICK, and
WILLIAM V. SAINDON *Administrative Patent Judges*.

KAUFFMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Inter Partes Review
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. OVERVIEW

Kaz USA (“Petitioner”) filed a Petition (Paper 2¹, “Pet.”) requesting *inter partes* review of claims 1–4, 22, and 24 of U.S. Patent No. 7,346,386 B2 (Ex. 1001, “the ’386 patent”). Pet. 1. Exergen Corporation (“Patent Owner”) filed a Preliminary Response (Paper 5, “Prelim. Resp.”) to the Petition.

We instituted an *inter partes* review of claims 1–4, 22, and 24 of the ’386 patent. Paper 6 (“Dec.”). Subsequently, Patent Owner filed a Patent Owner Response (Paper 12, “PO Resp.”), and Petitioner filed a Reply (Paper 22, “Pet. Reply”). We held oral hearing on September 8, 2017, and a transcript is included in the record. Paper 42 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Petitioner has shown by a preponderance of the evidence that claims 1–4, 22, and 24 of the ’386 patent are unpatentable.

B. RELATED PROCEEDINGS

The parties indicate that the ’386 patent is at issue in *Exergen Corp. v. Microlife Corp. et al.*, No. 1:15-cv-13387 (D. Mass). Pet. 3; Paper 4, 2.

U.S. Patent No. 9,194,749 B2 (“the ’749 patent”) is a continuation of application No. 12/011,467, now Pat. No. 7,787,938, which is a continuation

¹ The first page of this paper is labeled as “Paper 1” (top right), but was filed as Paper 2.

of application No. 10/684,818, now the '386 patent. Ex. 1001 (63); *see also* IPR2016-01436, Ex. 1018 (63).

Petitioner also filed *inter partes* review 2016-01436 against the '749 patent. Pet. 3; Paper 4, 2. We denied institution of trial. IPR2016-01436, Paper 7; *see also* Paper 9 (denying the request for rehearing).

C. EVIDENCE AND GROUNDS OF UNPATENTABILITY

The critical date of the '386 patent is September 11, 1998. Ex. 1001 [63]; PO Resp. 13.

We instituted *inter partes* review with respect to the following grounds of unpatentability:

Claims	§	References
1, 2	102(b)	Pompei '813 ²
3, 4, 22, 24	103(a)	Pompei '813 and Pompei '091 ³
1, 2	103(a)	Banke, ⁴ Houdas, ⁵ and Barnes ⁶
3, 4, 22, 24	103(a)	Banke, Houdas, Barnes, and Pompei '091

² U.S. Patent No. 5,012,813, issued May 7, 1991 (Ex. 1005) ("Pompei '813").

³ U.S. Patent No. 4,636,091, issued January 13, 1987 (Ex. 1007) ("Pompei '091").

⁴ W.O. 93/03666, published March 4, 1993 (Ex. 1008) ("Banke").

⁵ *Human Body Temperature, Its Measurement and Regulation*, Y. Houdas and E.F.J. Ring, Plenum Press, N.Y. (1982) (Ex. 1010) ("Houdas"). This Exhibit only includes native page numbers.

⁶ U.S. Patent No. 3,531,642, issued September 29, 1970 (Ex. 1009) ("Barnes").

Petitioner relies upon the Declaration and the Reply Declaration of Mr. Frederick Bowman, Ph.D. Ex. 1002; Ex. 1025; *see also* Ex. 1003 (Dr. Bowman's Curriculum Vitae).

Patent Owner relies upon the Declaration testimony of Dr. John M. Collins. Ex. 2008; *see also* Ex. 2009 (Dr. Collin's Curriculum Vitae).

Patent Owner submits a variety of evidence regarding secondary considerations, including a Declaration from Dr. Francesco Pompei and a Declaration from Dr. Marybeth Pompei. Ex. 2010; Ex. 2011.

II. PRELIMINARY MATTERS

A. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibit 2031 and the portions of Exhibits 2010 and 2008 that rely upon Exhibit 2031. Paper 32. Patent Owner filed an opposition to the Motion (Paper 35) and Petitioner filed a Reply to the Opposition (Paper 38). Petitioner has the burden of establishing that the evidence at issue should be excluded. *See* 37 C.F.R. § 42.20(c), § 42.22. For the reasons that follow, Petitioner's Motion is *granted-in-part*.

Patent Owner served Exhibits 2008, 2010, and 2031 on Petitioner on March 22, 2017. PO Resp. 70. Petitioner filed objections to Exhibits 2008, 2010, and 2031 within five business days of service of those Exhibits. *See* Paper 13 (objections filed on March 29, 2017); 37 C.F.R. § 42.64(b)(1). Petitioner preserved those objections by filing a Motion to Exclude. *See* Paper 32; 37 C.F.R. § 42.64(c).

1. *Exhibit 2031*

Exhibit 2031, "Temporal Artery Thermometry Independent Clinical Studies and Reviews," is a six-page collection of quotations from clinical

studies and reviews. *See* Ex. 2031; Ex. 2010 ¶ 20, n.1; Ex. 1024 at 35:2-9 (Dr. F. Pompei characterizing Exhibit 2031).

Petitioner contends that because Patent Owner relies upon Exhibit 2031 to prove the truth of the matter asserted, it is inadmissible hearsay under Federal Rule of Evidence 801, and should be excluded under Federal Rule of Evidence 802. Paper 32, 2–4.

Patent Owner does not oppose the Motion with regard to Exhibit 2031. Paper 35, 1; *see also* Paper 38 (acknowledging the Patent Owner does not oppose).

Consequently, we grant Petitioner’s Motion to Exclude Exhibit 2031.

2. *Exhibit 2008*

Exhibit 2008 is the Declaration of Patent Owner’s expert, Dr. John M. Collins. PO Resp. 65. Petitioner seeks to exclude the third sentence of paragraph 182, which cites to, and repeats a portion of Exhibit 2031. Paper 32, 6; Ex. 2008 ¶ 182. Given that we exclude Exhibit 2031 and that this sentence at issue repeats a portion of Exhibit 2031, we do not consider this sentence in our patentability analysis.

Consequently, we deny Petitioner’s Motion to Exclude the third sentence of paragraph 182 of Exhibit 2008 as moot.

3. *Exhibit 2010*

Exhibit 2010 is the Declaration of Dr. Francesco Pompei. PO Resp. 65. In the Patent Owner Response, Patent Owner cites to paragraph 20 of Exhibit 2010 as evidence of praise of unexpectedly superior results. PO Resp. 60. Petitioner seeks to exclude: (1) the third sentence of paragraph 20, and (2) the associated footnote. Paper 38, 1 (identifying these portions of Ex. 2010). These portions follow.

In a segment on the Today Show in July 2001, Dr. Mark Widdome, of the American Academy of Pediatrics praised the Exergen Temporal Artery Thermometer as “rocket science.” See Ex. at 2031.

Ex. 2010 ¶ 20.

Ex. 2031 is a collection of quotations from clinical studies and reviews available on Exergen’s website. To the best of my knowledge they are true and correct quotes of the studies and reviews cited.

Ex. 2010 ¶ 20, n. 1.

a) Paragraph 20

Given that the third sentence of paragraph 20 of Exhibit 2010 repeats a portion of Exhibit 2031 and that we exclude Exhibit 2031, we will ignore the third sentence of paragraph 20 in our patentability analysis below. We deny Petitioner’s Motion to Exclude the third sentence of paragraph 20 of Exhibit 2010 as moot.

b) Footnote Associated with Paragraph 20

In the footnote, Dr. F. Pompei states his knowledge with regard to Exhibit 2031. Given that this statement only pertains to Exhibit 2031 and we exclude Exhibit 2031, we ignore this statement in our patentability analysis below. We deny Petitioner’s Motion to Exclude footnote 1 on page 11 of Exhibit 2010 as moot.

4. Summary

We grant Petitioner’s Motion to Exclude with respect to Exhibit 2031. We deny Petitioner’s Motion with respect to the third sentence of paragraph 182 of Exhibit 2008, paragraph 20 of Exhibit 2010, and the footnote to paragraph 20 of Exhibit 2010.

B. HOUDAS

This section addresses three interrelated issues: (1) Patent Owner’s Motion to Exclude (Paper 31) portions of Houdas (Ex. 1010); (2) Patent Owner’s contention that Petitioner’s Reply contains arguments regarding Houdas that are beyond the scope of a proper reply (Paper 28); and, (3) Patent Owner’s contention that Petitioner has not established that Houdas is a proper prior art reference (PO Resp. 61–63).

1. *Procedure and Context*

In the Petition, Petitioner asserts that Houdas “was published in 1982” and is prior art under 35 U.S.C. § 102(b) and § 103. *See* Pet. 20. After institution of trial, Patent Owner proffered the following objections regarding Houdas.

FRE 802, 901: Inadmissible hearsay, *e.g.*, the purported publication dates/copyright dates printed on the pages; not authenticated and not self-authenticating under FRE 902.

Paper 9, 3.

Patent Owner filed the objections within ten business days of institution of trial.⁷ *See* Paper 9 (objections filed on January 11, 2017); 37 C.F.R. § 42.64(b)(1). Petitioner did not file supplemental evidence in response to Patent Owner’s objections. Paper 1; *see also* Paper 36 (not contesting Patent Owner’s assertion).

In Patent Owner’s Response, Patent Owner argues that Houdas is not prior art because a copyright date does not establish public accessibility. PO Resp. 61–63.

⁷ We instituted trial on December 27, 2016.

In the Petitioner's Reply, Petitioner argues that a totality of the information on page 3 of Exhibit 1010 ("Houdas's copyright page") demonstrates that Houdas is prior art.⁸ Pet. Reply 26. As evidence that Houdas was sufficiently publically accessible in the Massachusetts Institute of Technology (MIT) Library, Petitioner relies on the Reply Declaration of Dr. Bowman (Ex. 1025), and the Declaration of Ms. Zimmerman, an MIT librarian (Ex. 1027). *Id.* at 26–27.

2. *Motion to Exclude*

Patent Owner moves to exclude portions of Houdas (Ex. 1010). Paper 31, 1–4. Although Petitioner interprets that Patent Owner seeks to exclude the entirety of page 3 (Paper 36, 1–2), our interpretation is that Patent Owner seeks to exclude: (1) the copyright date ("© 1982 Plenum Press, New York"), and (2) the "Library of Congress Cataloging in Publication Data," each found on page 3 of Exhibit 1010. Paper 31, 1; *see also id.* at 4 ("For the reasons stated above, the copyright date and the other alleged publication data on page 3 of Ex. 1010 are inadmissible hearsay."). Petitioner filed an opposition (Paper 36) to Patent Owner's Motion to Exclude and Patent Owner filed a Reply to the Opposition (Paper 37).

Patent Owner has the burden of establishing that the Exhibits at issue should be excluded. *See* 37 C.F.R. § 42.20(c), § 42.22. For the reasons that follow, Patent Owner's Motion is *denied*.

Patent Owner contends that the information at issue is hearsay under Federal Rule of Evidence 801, and should be excluded under Federal Rule of Evidence 802, because Petitioner offered this evidence to prove the truth of

⁸ We count the cover page as page 1.

the matter asserted, namely, that Houdas was published in 1982.⁹ Paper 31, 2–4 (referring to Pet. Reply 26–27).

Petitioner argues that the information at issue falls under the exception of Federal Rule of Evidence 803(16). Paper 36, 2–3. Patent Owner counters that Federal Rule of Evidence 803(16) only applies to documents having established authenticity, and according to Patent Owner, Petitioner has not established the authenticity of Houdas under Federal Rule of Evidence 901(b)(8). Paper 37, 1–2. An unstated premise of Patent Owner’s argument is that the authenticity of Houdas may only be established under Federal Rule of Evidence 901(b)(8).

Federal Rule of Evidence 803(16) is not limited in the manner Patent Owner asserts. Federal Rule of Evidence 803(16) provides an exception to the rule against hearsay for statements in a document that are at least 20 years old and “whose authenticity is established.” Federal Rule of Evidence 803(16) does not refer to Federal Rule of Evidence 901(b)(8); rather, it more generally refers to authenticity. Further, Rule 901(b) expressly identifies the enumerated examples of authentication techniques, including Rule 901(b)(8), as “not a complete list.”

The title, authors, and publisher name found in Exhibit 1010 match the corresponding information acknowledged by Patent Owner as prior art to the ’386 patent. *Compare* Ex. 1010, 1–3 to Ex. 1002, 2 (Other Publications);

⁹ We note that Patent Owner objected to Houdas based on lack of proper authentication under Federal Rule of Evidence 901, but did not preserve that objection by addressing authentication in the Motion to Exclude. *See* Paper 9, 3; Paper 31. Additionally, Patent Owner did not preserve the objections to Exhibits 1025 and 1027 by addressing them in a Motion to Exclude. *See* Paper 24, 2–3; Paper 31.

see also Paper 36, 3 (pointing out these characteristics). This evidence is sufficient to support a finding that the information at issue is what Petitioner claims it to be. *See* Fed. R. Evid. 901(a); *see generally Lexington Ins. Co. v. Western Pennsylvania Hosp.*, 423 F.3d 318, 329 (3d Cir. 2005) (the burden of proof for authentication is “slight”).

We determine that Petitioner has established the authenticity of the information at issue. Given that the document appears to be at least 20 years old, Petitioner has demonstrated that the information qualifies for the hearsay exception of Federal Rule of Evidence 803(16), and therefore, should not be excluded.

Given our determination with regard to Federal Rule of Evidence 803(16), we need not address Petitioner’s assertion that the copyright date qualifies for the residual hearsay exception of Federal Rule of Evidence 807. Paper 36, 4–6.

We deny Patent Owner’s Motion to Exclude the portions of Houdas at issue.

3. *Scope of Reply*

Patent Owner contends that Petitioner makes two arguments that are beyond the scope of a proper reply under 37 C.F.R. § 42.23(b). Paper 28, 2–3. First, Patent Owner contends it has not had notice and opportunity to respond to Petitioner’s argument that the totality of the information demonstrates Houdas is prior art. *Id.* at 2 (referring to Petitioner’s argument at Pet. Reply 26–27). Second, and relatedly, Patent Owner contends that Petitioner’s argument that Houdas was publically accessible in the Massachusetts Institute of Technology (MIT) Library and the associated

evidence¹⁰ are beyond the scope of a proper reply. Paper 28, 2–3 (referring to Pet. Reply 27).

We agree with Petitioner that the argument in Petitioner’s Reply regarding the “totality of the information” directly responds to two of Patent Owner’s arguments. Those arguments are Patent Owner’s contention that the “evidence of record fails to demonstrate that Houdas was made publicly accessible before the critical date,” and that “Petitioner has failed to establish by [a] preponderance of the evidence that Houdas qualifies as a ‘printed publication’ under § 102(b).” See Paper 29, 1 (referring to Patent Owner’s arguments at PO Resp. 61–63); 37 C.F.R. § 42.23(b). Likewise, we agree with Petitioner that the Reply Declaration of Dr. Bowman (Ex. 1025) and the Declaration of Ms. Zimmerman (Ex. 1027) are also properly in response to the arguments raised by Patent Owner. Paper 29, 2; 37 C.F.R. § 42.23(b).

4. *Prior Art*

Patent Owner contends that in light of the contentions above, Petitioner has not established that Exhibit 1010 is a proper prior art reference. Paper 31, 1; PO Resp. 61–63; Paper 28, 1–3. This argument is, to a large extent, premised on Patent Owner’s contention that the copyright and publication dates on Houdas’s copyright page should be excluded as inadmissible hearsay and on Patent Owner’s contention that Petitioner has made arguments beyond the scope of a proper reply. However, as detailed above, we deny Patent Owner’s Motion to Exclude the portions of Houdas at

¹⁰ The reply Declaration of Dr. Bowman (Ex. 1025) and the Declaration of Ms. Zimmerman (Ex. 1027).

issue, and Petitioner's argument were not beyond the scope of a proper reply. Those determinations significantly undermine Patent Owner's argument here.

In an *inter partes* review, a ground of unpatentability cannot be based upon a public use or a sale; rather, the ground must be based upon prior art in the form of a patent or a printed publication. 35 U.S.C. § 311(b); 35 U.S.C. § 102. The determination of whether a particular reference qualifies as a prior art printed publication "involves a case-by-case inquiry into the facts and circumstances surrounding the reference's disclosure to members of the public." *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). To qualify as a printed publication, a document must be generally available. *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931 (Fed. Cir. 1990). The key inquiry is whether the reference was made "sufficiently accessible to the public interested in the art" before the critical date. *In re Cronyn*, 890 F.2d 1158, 1160 (Fed. Cir. 1989).

We acknowledge that a copyright notice alone is insufficient to demonstrate public accessibility. See PO Resp. 62; *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009). Here, Petitioner does not rely on the copyright notice alone; as we discussed above with respect to authenticity, the document itself has indicia of public accessibility and, Petitioner has other supporting evidence.

Ms. Zimmerman, a Scholarly Communications and Licensing Librarian at the Massachusetts Institute of Technology (MIT) familiar with the Library's business records and practices, testifies that the Library

received a copy of Houdas¹¹ on October 5, 1983, and it was entered into the MIT cataloging system on February 2, 1984. Ex. 1027 ¶¶ 1–6, 9–10, 20, Ex. A, Ex. B at 2, Ex. C at 3.¹² Ms. Zimmerman testifies that, in the normal course of business, Houdas would have been available to the public at the Library or through interlibrary loan no later than February 16, 1984. Ex. 1027 ¶¶ 11–12. Houdas became available through MIT Libraries’ Card Catalog between May 9, 1984 and February 9, 1985. *Id.* at ¶¶ 13–14. In 1987, MIT added an online catalog known as the Barton Catalog. Prior to that time, the Card Catalog was available on campus or via access to the Online Computer Library Center (OCLC) database. *Id.* at ¶ 15. From 1987 to 1995, the Barton catalog permitted keyword searching for words in the book title. *Id.* at 16.

Petitioner’s expert, Dr. Bowman, visited the MIT Library. Ex. 1025 ¶¶ 52–55. Dr. Bowman observed that the MIT Library’s copy of Houdas was cataloged in 1982, was received in 1983, and has been checked out numerous times. *Id.* at 53–54; Ex. 1026, 1–3.¹³ This information is consistent with, and corroborates, Ms. Zimmerman’s testimony.

Houdas was accessible on campus at MIT or through the Barton Catalog via a keyword search for words in the title no later than 1995.¹⁴ We

¹¹ The entry for Houdas in the MIT Library is shown at Exhibit C of Exhibit 1027, and this information matches that at Exhibit 1010.

¹² See tag field 910 (last line on the page) indicating the date as “840202.” The pages of Exhibit C of Exhibit 1027 are not numbered, we count the cover page (“Exhibit C) as page 1.

¹³ The pages of Exhibit 1026 are not numbered.

¹⁴ Notably, the title of Houdas, “Human Body Temperature – Its Measurement and Regulation,” relates to the content of the book.

agree with Petitioner that Houdas was sufficiently accessible to the public interested in the art using reasonable diligence more than a year prior to the critical date of the '386 patent. *See* Pet. Reply 26–27; *see also In re Hall*, 781 F.2d 897, 899-900 (Fed. Cir. 1986) (holding that uncontested evidence regarding a library's general practice for indexing, cataloging and shelving a reference established that reference was available as prior art).

III. THE CLAIMED SUBJECT MATTER

A. THE '386 PATENT

1. *Background*

As background, the '386 patent discloses that the arterial heat balance approach of calculating arterial core temperature based on sensed skin temperature and ambient temperature was known. Ex. 1001 at 1:39–44. For example, ear thermometers that measure the temperature of distal ear canal tissue and calculate arterial core temperature via heat balance were known. *Id.*, 1:15–28; 1:47–51 (citing several patents for infrared ear thermometers that use the arterial heat balance approach to calculate core temperature, to include Pompei '813).

2. *The Claimed Device*

The '386 patent is titled “Temporal Artery Temperature Detector,” and relates to computing internal body temperature from sensed ambient temperature and sensed surface temperature. Ex. 1001, (54), Abstract. Core temperature is deep body temperature and may be calculated from sensed skin and ambient temperature via a heat-balance approach. *Id.* at 1:29–30, 1:39–44. The heat-balance approach models heat flow through series thermal resistances from the arterial core temperature to the ear skin

temperature and from the ear skin temperature to ambient temperature. *Id.* Core temperature may also be computed from oral and rectal temperatures by adjusting the weighting factor. *Id.* at 1:44–47.

The '386 patent describes reading skin temperature by detecting the temperature of the forehead directly over the superficial temporal artery. *Id.* at 2:20–24; Fig. 1. Figure 1 follows:

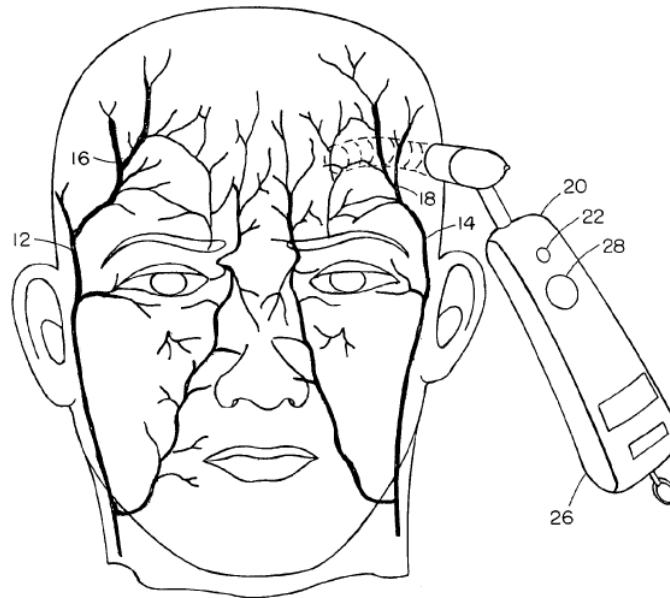


FIG. 1

Figure 1 illustrates an infrared thermometer scanning the temporal artery in the forehead. *Id.* at 3:59–61. Temporal arteries 12 and 14 extend upwardly toward the side of the human face and bifurcate at 16 and 18 in the forehead region. *Id.* at 4:10–12. A user scans temperature/radiation detector 20 across the side of the forehead over the temporal artery while electronics in the detector search for the peak reading which indicates the temporal artery. *Id.* at 4:23–27, 32–33. At least three readings per second, and preferably ten, should be made during the scan. *Id.* at 3:6–8; *see also* 6:45–48 (disclosing that taking at least three and preferable ten readings per second

avoids cooling of the forehead through the detector). This reading is then further processed in accordance with an algorithm specific to the temporal artery for providing a display temperature that may correspond to core temperature. *Id.* at 4:27–31.

B. ILLUSTRATIVE CLAIMS

Claims 1 and 22 are independent, and read as follows:

1. A body temperature detector comprising:

a temperature detector;

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.

22. A body temperature detector comprising:

a radiation sensor which views a target surface area;

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

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.

Claims 2–4 depend from claim 1 and claim 24 depends from claim 22.

C. CLAIM INTERPRETATION

1. *Applicable standard*

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation approach).

For the purposes of this decision, and on this record, we determine that only the following claim terms need express interpretation. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

2. *Apparatus not Method*

We emphasize that the challenged claims are apparatus claims. As apparatus claims, the claims cover what the device is, not what the device does. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990). Consequently, when comparing the claimed subject matter to the prior art, our inquiry is whether the prior art is capable of the claimed function. *See e.g., In re Schreiber*, 128 F.3d 1473, 1477-78 (Fed. Cir. 1997).

This contrast is illustrated by the related proceeding (IPR2016-01436). There, we denied institution of trial based on grounds of unpatentability and claims similar to those asserted here, except that the claims were directed to methods. *See* IPR2016-01436, Paper 7 (denial of institution), Paper 9 (decision on rehearing).

3. *detected arterial temperature (claim 1)*

The parties agree with our interpretation in the Institution Decision that, “detected arterial temperature,” as recited in claim 1, means, “detected surface temperature of skin directly over an artery.” See Dec. 10; Pet. 10–13; PO Resp. 13. In other words, the device detects the temperature of the skin above an artery rather than the temperature of an artery.

4. *Artery (claims 1–4)*

Claim 1 is directed to a body temperature detector that includes 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.” Ex. 1001, 9:32–39. Challenged claims 2–4 include this limitation by virtue of dependence from claim 1.

The parties agree that an artery as claimed is a tubular vessel that carries blood away from the heart. See PO Resp. 13; Ex. 1023, 81:3–11; Pet. Reply 2. The dispute is that Patent Owner contends that an “artery” as claimed is limited with regard to size and location. Specifically, Patent Owner contends that “artery” should be construed as a blood vessel that carries blood away from the heart and which is “near the skin and larger than the vessels in the skin.” PO Resp. 13–16. Petitioner contends that an artery as claimed is not limited with regard to the size and location. Pet. Reply 2–3.

Patent Owner’s argument does not fully account for the fact that, as mentioned above, claim 1 is not a method claim; rather, claim 1 is an apparatus claim. See PO Resp. 19 (acknowledging that the claims at issue

are apparatus claims, not method claims). The portions of the Specification cited by Patent Owner (PO Resp. 14–15) describe that arteries in general are a good choice for detecting core temperature, with the exception that arteries at the extremities of the body (e.g., wrist or ankle) have the drawback of being subject to vasoconstriction that can cause a large temperature change that is not representative of core temperature. Ex. 1001, 2:25–36. The cited portions go on to describe that the part of the external branch of the temporal artery that passes beneath the forehead has several characteristics that make it a particularly good choice for detecting core temperature. *Id.* at 2:27–3:8. For example, it: is a short distance from the heart, has high and relatively constant blood flow, is easily accessible on an individual, has two forks in the forehead area (doubling the chances of scanning across it), is not injured by touching, and it is less susceptible to vasoconstriction than many other areas of the body. *Id.* at 2:47–62. The method of scanning across the temporal artery at the forehead can be extended to other arteries near the skin such as in the axilla. *Id.* at 3:8–9.

These disclosures in the '386 patent are instructions for use of the claimed device. The '386 patent describes that the claimed device may scan to detect a peak temperature at many locations on the body, to include extremities (e.g., the wrist and ankle), the forehead over the temporal artery, and the axilla. A person of ordinary skill in the art would recognize that the '386 patent describes that scanning in some locations (e.g., the axilla and the forehead over the temporal artery) produces a more accurate result (more reflective of core temperature) than in other locations (e.g., the extremities). *See* Pet. Reply 2. The electronics of the temperature detector are the same regardless of where it is used.

Further, the measured peak temperature is not the temperature of an artery. Rather, as explained above, measured peak temperature means, “detected surface temperature of skin directly over an artery.” See Pet. 10–13 (Petitioner explaining that the ’386 patent describes the claimed invention as detecting skin temperature over an artery (e.g., the forehead over the temporal artery) rather than the temperature of an artery).

In light of this, claim 1 requires electronics capable of detecting a peak surface temperature of skin directly over an artery and processing that detected temperature to provide a temperature display based on a model of heat balance relative to that detected temperature.

As detailed in our patentability analysis below, Pompei ’813’s device includes electronics that are capable of measuring peak temperature during scan across an artery and processing the detected temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature. For that reason, even if an artery must be of a certain size or location, that does not matter because it is shown in the art to be an artery that provides a suitable input for an arterial model of heat balance.

5. *provide a temperature display (all challenged claims)*

Independent claims 1 and 22 each recite that the electronics process the detected peak temperature to “provide a temperature display.” Challenged claims 2–4 and 24 contain this limitation by virtue of dependence from claims 1 and 22.

Patent Owner contends that “provide a temperature display,” as recited in independent claims 1 and 22, should be construed as, “provide an accurate, clinically significant display of body temperature, such as core, oral or rectal temperature.” PO Resp. 16. According to Patent Owner, an

accurate, clinically significant body temperature must be within 0.5° C (about 1° F) of the true body temperature. *Id.* (citing Ex. 2008 ¶ 74).

The language of claims 1 and 22 does not support Patent Owner's assertion. Claims 1 and 22 are silent regarding accuracy.

Patent Owner does not assert that the '386 patent provides a lexicographical definition for "temperature display," nor does Patent Owner assert that interpretation of "temperature display" is impacted by the prosecution history. Further, Patent Owner does not identify any portion of the Specification as support for the proffered interpretation.

The Specification describes that an embodiment of the claimed device processes a peak temperature to provide a "display temperature, which may, for example, correspond to core, oral or rectal temperature." Ex. 1001, 4:23–31. The Specification also describes that the temperature determined by microprocessor 80 is displayed on liquid crystal display 100. *Id.* at 6:32–45. The Specification does not describe that the device provides an accurate, clinically significant body temperature within a certain variance of true body temperature (core temperature).

In support of Patent Owner's interpretation, Dr. Collins opines that displayed body temperature would need to be within 0.5° C (about 1° F) of the true body temperature to be clinically accurate or significant. Ex. 2008 ¶ 74 (citing Ex. 2021, 1 and Ex. 2022, Abstract). We analyze each of the Exhibits Dr. Collins relies upon.

Exhibit 2022 is an article regarding a study of the accuracy of measuring body temperature with a tympanic thermometer, and that study assessed temperature measurements of 60 children based on the criteria that a difference between measurements of $\geq 0.5^{\circ}$ C was clinically significant.

Ex. 2022, Abstract (Methods Section). This disclosure does not relate to the difference between temperature measurements taken and true body temperature; rather, it relates to the difference between detected temperatures. Consequently, this evidence does not support Dr. Collins's assertion that displayed body temperature as claimed means an accuracy of within 0.5° C (about 1° F) of the true body temperature.

Exhibit 2021 is an article regarding the accuracy of peripheral thermometers for estimating core body temperature in adults and children. Ex. 2021, Title; Abstract (Purpose Section). A premise of the analysis is that the predefined clinically acceptable range for the difference between estimated temperature and actual core body temperature is $\pm 0.5^{\circ}$ C. *Id.*, Abstract (Data Synthesis Section). This article is dated 2015 and does not state the predefined clinically acceptable range dates back to the critical date of the '386 patent (Sept. 11, 1998¹⁵). Consequently, this evidence does not support Dr. Collins's assertion that displayed body temperature as claimed means an accuracy of within 0.5° C (about 1° F) of true body temperature. Even if the accuracy described was the predefined clinically acceptable range as of the critical date of the '386 patent, at most it establishes a desired accuracy for thermometers. This does not serve to incorporate that accuracy into claims 1 and 22. As stated above, claims 1 and 22 are silent regarding accuracy, and in particular, do not recite that the body temperature detector is accurate within the clinically acceptable range.

Therefore, we do not interpret the phrase “provide a temperature display” (claims 1 and 22) as requiring that the temperature display is an

¹⁵ See Ex. 1001 [63]; PO Resp. 13.

accurate, clinically significant body temperature that is within 0.5° C (about 1° F) of the true body temperature.

6. *smooth lip (claims 4 and 24)*

Claim 4 depends from claim 3, which depends in turn from claim 1, and recites, “wherein the reflective cup is spaced from the target surface by a smooth lip of low thermal conductivity material.” Claim 24 depends from claim 22 and contains a similar limitation.

Patent Owner contends that “smooth lip” should be construed as a “lip having a smooth curve both to the inside and outside circumferential surfaces.” PO Resp. 17 (citing; Ex. 1001 6:1–7). In support, Dr. Collins opines that such interpretation is correct because when the embodiments shown in Figures 2A–C are scanned across the skin, the inside surface of the lagging edge of the reflective cup presses into the skin. Ex. 2008 ¶ 77. We disagree with Patent Owner’s interpretation for several reasons.

First, the language of the claims does not support that interpretation. Claims 4 and 24 recite that the reflective cup includes a “smooth lip,” but do not recite that the lip is smooth both on the inside and outside circumferential surfaces.

Second, Patent Owner does not identify, nor do we discern, that the ’386 patent includes a lexicographical definition of a smooth lip.

Third, the embodiments described are exemplary. The language of claims 4 and 24 is broader, reciting a smooth lip and not a lip that is smooth on both the inside and outside circumferential surfaces.

Fourth, we do not credit Dr. Collins’s claim interpretation because it is based on an incorrect characterization of the ’386 patent. Each embodiment (Figs. 2A–C) is depicted with an unidentified structure at the front of the cap

(caps 77, 138, 160) that appears to be a lens or protective cover. An annotated version of Figure 2A of the '386 patent follows.

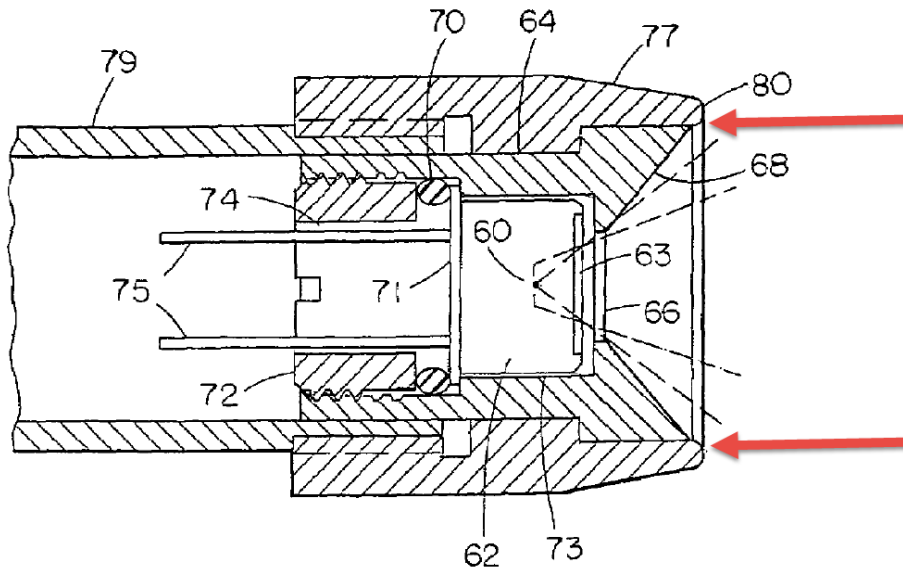


FIG. 2A

Annotated Figure 2A is a cross sectional view of an embodiment of the claimed radiation sensor assembly with arrows indicating where the lens/cover meets lip 80 of cap 77. Ex. 1001, 3:63–65. Indeed, each of the embodiments shown in Figures 2A–C includes a lens/cover that is flush with the distal end of the lip of the cap. *Id.*, Figs 2A–C. With this configuration, the lens/cover would prevent contact between the skin of the patient and the inner circumferential surface of the lip. Consequently, Dr. Collins’s reasoning that the inner side of the lip must be curved for comfortable contact with the patient’s skin is not persuasive because no such contact is possible. See Ex. 2008 ¶ 77

For these reasons, we agree with Petitioner that Patent Owner is improperly reading a limitation of a particular embodiment into the claims. Pet. Rely 5; Ex. 1025 ¶ 11.

Claims 4 and 24 do not require that a smooth lip as claimed is smooth on both the inner and outer circumferential surfaces.

IV. PATENTABILITY

A. ANTICIPATION BY POMPEI '813

Petitioner contends that claims 1 and 2 are unpatentable under 35 U.S.C. § 102(b) as anticipated by Pompei '813. Pet. 13–15, 21–26.

1. *Claim 1*

a) A body temperature detector comprising: a temperature detector

Pompei '813 is titled “Radiation Detector Having Improved Accuracy.” Ex. 1005, [54]. Pompei '813 discloses a body temperature detector in the form of a thermopile or radiation detector that measures tympanic temperature and adjusts it “to provide an indication of core temperature.” Ex. 1005, Abstract, 1:35–46, 2:46–54, 3:20–21, 10:63–11:10, Fig. 1; Pet. 22; *see also* Pet. 13–15 (providing an overview of the reference).

Patent Owner does not contest that Pompei '813 discloses “A body temperature detector comprising: a temperature detector.”

b) 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.

Petitioner contends that Pompei '813 discloses providing an internal body temperature approximation of a human body using a thermopile or radiation detector that measures tympanic temperature and adjusts it to provide an indication of core temperature. Pet. 22; *see also* Pet. 13–15. Petitioner contends that Pompei '813 discloses electronics that: obtain a

digital reading of the radiation sensor (or thermopile) nine times a second, process these measurements, and display the highest indication of the body's core temperature. *Id.* at 23. Petitioner contends that the displayed temperature is calculated based on a model of heat balance relative to a detected arterial temperature. *Id.* at 24–25.

According to Patent Owner, Pompei '813 processes the detected peak temperature to provide a temperature display based on a model of heat balance relative to a detected ear temperature, and this model cannot be relative to a detected arterial temperature because there are no arteries in the ear or under the tympanic membrane. *Id.* Patent Owner argues that even if the small vessels in the ear canal are arteries, Pompei '813's scanner cannot scan across those vessels and detect a peak surface temperature of skin directly over that vessel. PO Resp. 24–25.

Patent Owner concedes that the electronics of Pompei '813 process a detected peak temperature to provide a temperature display based on a model of heat balance relative to a detected ear cavity temperature taken as the tympanic membrane temperature. PO Resp. 19; Ex. 2008 ¶ 80; *see also* Ex. 1013, 65 (Patent Owner stating that Pompei '813 discloses a temperature detector (radiation detector) that may be scanned across a target area to detect peak temperature); Pet. 25 (citing that portion of Ex. 1013). Consequently, the contested aspect of this limitation is whether Pompei '813's electronics process the detected peak temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature. *See* PO Resp. 19–23, 26–30.

Patent Owner argues as if the model of heat balance claimed differs from location to location (i.e., from the ear to the forehead over the temporal

artery). We disagree. The '386 patent describes that it was known that internal core temperature can be computed using detected skin temperature and ambient temperature via the arterial heat balance approach. Ex. 1001, 7:7–12; see Pet. Reply 6. The '386 patent describes that prior ear thermometers computed internal core temperature from skin and ambient temperatures. Ex. 1001, 3:18–23. The '386 patent describes that heat loss of skin at the forehead, the external ear canal, and axilla all may be calculated with the same equation, and “[s]ince all body site temperatures of interest arise from the arterial temperature source, the arterial heat balance can be applied to any site.” *Id.* at 7:16–25; 8:63–65. This suggests that the arterial model of heat balance can apply to any location on the body.

Dependent claim 6 includes a weighting in the heat balance model specific to the forehead. This suggests that claim 1 is not limited to a specific site on the body.

In light of this, claim 1 broadly requires use of a model of heat balance relative to a detected arterial temperature for any site on the body, and the dependent claims further limit the heat balance model to more specific locations.

Patent Owner’s argument regarding Pompei ’813 is contradicted by the ’386 patent. As detailed above in Section III.A.1 (Background of the ’386 Patent), the ’386 patent expressly acknowledges that Pompei ’813’s device measures the temperature of distal ear canal tissue and calculates arterial core temperature via “arterial heat balance.”¹⁶ Ex. 1001, 1:15–51.

¹⁶ Because the patents are related as detailed in Section I.B. above, the term “arterial heat balance” has the same meaning in Pompei ’813 as in the patent at issue.

Similarly, Patent Owner admitted in the related litigation that the arterial heat balance model of Pompei '813 has a solution at the temporal artery. *See* Ex. 1013, 18, Pet. 22. Because Pompei '813 calculates core temperature by an arterial heat balance model, this implies that Pompei '813's device detects the temperature of the skin over an artery. It would make little sense for Pompei '813 to calculate core temperature based on a model of heat balance relative to a detected arterial temperature if that device did not detect the temperature of the skin over an artery. That is, Pompei '813 calculates core temperature by an arterial heat balance method and therefore must detect the surface temperature of skin directly over an artery. Consequently, we need not determine if an "artery" as claimed is limited to an artery of a particular size or distance from the skin.

We are persuaded by Dr. Bowman's testimony the ear canal includes arteries and that Pompei '813's device is structurally capable of scanning an artery of the forehead and provides a temperature display using a model of heat balance as claimed. *See* Ex. 1002 ¶ 65; Ex. 1025 ¶¶ 27–28; Pet. 15; Pet. Reply 11.

As detailed in our claim construction above, claim 1 does not include an accuracy requirement. Even if claim 1 requires an accurate, clinically significant body temperature, it is shown in Pompei '813. Specifically, Patent Owner has previously stated that Pompei '813's device obtains a "medically relevant temperature." Ex. 1013, 14.

We recognize that the model of heat balance used to calculate core temperature from a temperature detected in the ear canal could differ from the model used to calculate core temperature from a temperature detected at

another location (e.g., the forehead or the axilla). However, claim 1 broadly claims a model of heat balance applicable to any location on the body.

We conclude that Petitioner has demonstrated, by a preponderance of the evidence that claim 1 is anticipated by Pompei’813.

c) 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 scanning of “surface tissue,” and scanning of “biological surface tissue.” Pet. 25; Ex. 1005, 2:49–54; 3:16–21, 3:44–51, 11:15–19, 14:50–66. We are persuaded by Dr. Bowman’s explanation that Pompei ’813 is not limited to scanning the tympanic membrane; rather, it is capable of scanning “surface tissue” and target biological tissue such as the skin of the forehead. Ex. 1002 ¶ 67.

Patent Owner repeats the contentions made in support of claim 1. PO Resp. 33–34. Our analysis of claim 1 above is equally applicable here. We add that Patent Owner stated in prior litigation that claim 7 of Pompei ’813 covers scanning and obtaining a peak temperature from target biological tissue. See Ex. 1013, 15¹⁷ (referring to claim 7 of Pompei ’813 found at Ex. 1005, 14:50–66).

Petitioner has demonstrated by a preponderance of the evidence that claim 2 is unpatentable as anticipated by Pompei ’813.

¹⁷ We rely on the native page numbers of this Exhibit.

B. OBVIOUSNESS OVER POMPEI '813 AND POMPEI '091

Petitioner contends that claims 3, 4, 22, and 24 are unpatentable over Pompei '813 and Pompei '091. Pet. 13–15, 17–18, 26–34.

1. *Level of Skill in the Art*

The parties agree that a person of ordinary skill would have at least a bachelor's degree (or equivalent) in mechanical engineering, biomedical engineering, electrical engineering, or physics. Pet. 13; PO Resp. 13; Ex. 2008 ¶ 27. Petitioner adds, and Patent Owner does not contest, that the person of ordinary skill would have at least 3–5 years of experience with medical devices, and in particular, would have an understanding of bio-heat transfer, biomedical instrumentation, blood flow, thermodynamics, software, and general physiology/anatomy. Pet. 13 (citing Ex. 1002, ¶ 54); PO Resp. 13.

2. *Claim 3 and 22*

Claim 3 follows.

3. A detector as claimed in claim 2 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.¹⁸

The reflective cup of independent claim 22 is similar.

¹⁸ Claim 2 depends in turn from independent claim 1. Petitioner incorporates the analysis regarding anticipation of claim 2 by Pompei '813. Pet. 26; Ex. 1002 ¶ 101.

a) *Petitioner's Contentions*

Pompei '813 is described above. In addition, Pompei '813's thermal probe is rounded to avoid patient discomfort and is formed of a plastic material of low thermal conductivity. Pet. 30–32; Ex. 1005, 3:40–43, 5:13–15, 6:5–8, 6:15–19; Ex. 1002 ¶ 99.

Pompei '091 is directed to a hand-held radiation detector. Ex. 1007, (54), Abstract, 1:6–8; Pet. 17. The radiation detector of Pompei '091's device includes a reflective cup in the form of a nosepiece with a “high reflectivity” conical cup that can be placed directly against a surface. Ex. 1007, Abstract, 1:36–38. Radiation from the target surface is detected through a window and an aperture in the cup 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 1:38–39, 1:59–61, 3:37–41, 4:63–68, Fig. 3; Ex. 1002, ¶¶ 76–78. Pompei '091's device negates the effects of surface emissivity with the reflective cup of the detector near or in contact with the target. *See* Ex. 1007, Abstract, 1:50–52, 3:16–18, 3:47–53; Pet. 26–30; Ex. 1002 ¶¶ 96–101.

Petitioner contends that Pompei '813 discloses the elements of claims 3 and 22 except a reflective cup, and concludes that it would have been obvious to add a reflective cup as taught by Pompei '091. Pet. 26 (citing Ex. 1007, 1:36–39, 4:50–54, Fig. 3; Ex. 1002 ¶ 101). Petitioner contends that for reasons of patient comfort and accurate measurements, a person of ordinary skill would have modified Pompei '091's cup to include a rounded lip of low thermal conductivity material. Pet. 30, 33–34. Petitioner contends that combining the identified elements of Pompei '813 and Pompei '091 would have been an application of a known technique to a known

device ready for improvement to yield predictable results. Pet. 28.

Petitioner reasons that a person of ordinary skill would recognize that the modification would provide more accurate and rapid surface temperature measurements by eliminating the effects of skin emissivity and background radiation during measurement of exposed skin. Pet. 28–30; Ex. 1002 98; Ex. 1007, Abstract, 1:33–47, 1:50–61, 3:47–66. Further, according to Petitioner, a person of ordinary skill in the art would recognize that measuring at sites other than the ear is more comfortable for the patient. Pet. 30 (citing Ex. 1002 ¶ 99 and Ex. 1005, 3:40–43 as evidence of a concern for patient comfort).

b) Patent Owner Arguments

Patent Owner contends that Pompei '813's ear thermometer would not benefit from Pompei '091's reflective cup because the modified device would be too big to use in the ear canal. PO Resp. 35–36; *see also* 36–39 (arguing that it would not be obvious to modify Pompei '813 for use as a skin thermometer.); 41–43 (arguing that the proposed modification would render Pompei '813's ear thermometer inoperable for its intended purpose in that it could no longer be used as an ear thermometer because the reflective cup would be too large for the ear canal). Patent Owner adds that considering the capabilities of Pompei '813's device is appropriate in an anticipation analysis, but not in obviousness analysis because it would be improper hindsight. *Id.* at 35–36.

Each of these arguments is premised on the inaccurate characterization that Pompei '813 only discloses use as an ear thermometer. As detailed in the analysis of anticipation by Pompei '813 above, Pompei '813 is not limited to scanning in the ear canal. Rather, Pompei '813 more

broadly discloses that the device is capable of scanning of “surface tissue,” and “biological surface tissue.” Pet. Reply 17; Pet. 25; Ex. 1005, 2:49–54; 3:16–21, 3:44–51, 11:15–19, 14:50–66; Ex. 1002 ¶ 67. Therefore, Pompei ’813 need not be modified for use as a skin thermometer.

Patent owner contends the combination would not have been obvious because at the time ASTM Standard E 1965-98 stated that skin temperature cannot be independently correlated with the internal body temperature. We agree with and adopt Petitioner’s explanation of why Patent Owner has misinterpreted the application of this ASTM Standard E 1965-98. See Pet. Reply 17–18.

Patent Owner makes a variety of contentions in support of the argument that Pompei ’091 teaches away from scanning against the skin. *Id.* at 39–40. According to Patent Owner, Pompei ’091 operates in two manners: (1) scanning a target surface from a distance, and (2) taking a temperature measurement with the reflective cup stationary and in contact with a target surface. PO Resp. 39–40. Patent Owner elaborates that stationary contact measurement would not permit the artery to be located, and recognition of that problem was only found in the ’386 patent. *Id.* Regarding scanning mode, Patent Owner elaborates that it is not appropriate for skin temperature because the friction at the leading edge would change the skin temperature. *Id.* at 40. Patent Owner adds that Pompei ’091’s device was intended to be used with a 0.1 inch gap from that target and such placement is not feasible when scanning skin surface.

Pompei ’091 discloses a detector that scans a surface to provide a temperature reading either with the detector a distance from the target surface, or with the detector directly against or near the target surface. See

Ex. 1007, Abstract, 3:16–18, 3:47–53. Pompei '091's detector provides more accurate measurements when positioned near or against the target surface. *Id.* at 3:47–53. Petitioner recognized this characteristic, and relied upon Pompei '091's disclosure to measure skin temperature with the reflective cup of the detector near or in contact with the target because operation in this mode negates the effects of surface emissivity. *See* Pet. 26–30; Ex. 1002 ¶¶ 96–101; Ex. 1007, 1:50–52, 3:47–53. Because Petitioner relied upon Pompei '091's teaching to measure with the cup in contact with the skin, Patent Owner's contentions regarding use of Pompei '091's device to scan from a distance are not relevant.

Patent Owner's contention that stationary contact measurement would not permit the artery to be located is not commensurate in scope with the claims. Claims 3 and 24 require that the device is capable of detecting a peak temperature of the skin over an artery, it does not require that the device is capable of locating an artery.

Patent Owner's contention that Pompei '091's device would cause friction that changes skin temperature is inapposite because Petitioner proposes to round Pompei '091's lip. *See* Pet. 30, 33–34.

For these reasons, Patent Owner's teaching away argument does not identify any disclosure in Pompei '091 that would have lead a person of ordinary skill in the art away from scanning against the skin. *See In re Haruna*, 249 F.3d 1327, 1335 (Fed. Cir. 2001) (“A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant.” (citation omitted)).

c) *Secondary Considerations*

We consider, as we must, Patent Owner’s argument and evidence regarding objective indicia. PO Resp. 54–61; *WBIP, LLC v. Kohler Co.* 829 F.3d 1317, 1328 (Fed. Cir. 2016) (when present, secondary indicia of non-obviousness must be considered).

“For objective evidence of secondary considerations to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.” *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (emphasis and internal quotation marks omitted) (cited with approval in *ClassCo, Inc. v. Appel, Inc.*, 838 F.3d 1214 (Fed. Cir. 2016)). There is a presumption of nexus for objective considerations when the Patent Owner demonstrates that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent. *WBIP*, 829 F.3d at 1329.

(1) Lack of Connection between the Products and Challenged Claims

Petitioner contends that Patent Owner’s Response does not establish a nexus between the secondary considerations and the claimed invention. Pet. Reply 22. We agree.

Patent Owner’s Response does not explain how the commercial thermometers referred to are the invention disclosed and claimed in the ’386 patent. See PO Resp. 54–61; 37 C.F.R. § 42.22(a)(2) (requiring motions to include a detailed explanation of the significance of evidence); 37 C.F.R. § 42.23 (applying the content requirements of motions to oppositions and replies); Pet. Reply 22 (asserting Patent Owner did not make an argument in the Response as required). Nor does Patent Owner’s Response cite to such

explanation in an exhibit. Information contained in exhibits or portions of exhibits, but not discussed in the Patent Owner's Response, is not incorporated in that Response merely by the exhibits' presence in the record. *See* 37 C.F.R. § 42.6(a)(3) ("Arguments must not be incorporated by reference from one document into another document."); *see generally Cisco Systems, Inc. v. C-Cation Technologies, LLC*, Case No. IPR2014-00454, slip op. at 7–10 (PTAB Aug. 29, 2014) (Paper 12) (informative) (explaining that Rule 42.6(a)(3) prohibits incorporating by reference arguments from supporting declarations). This prohibition is consistent with preventing circumvention of page and word count limits. *See* 37 C.F.R. § 42.24. Accordingly, we need not consider arguments not set forth in the Patent Owner's Response.

Patent Owner has not established a connection between the secondary considerations and the claimed invention. Consequently, this evidence does not weigh in favor or non-obviousness.

We note that our Scheduling Order cautions Patent Owner "that any arguments for patentability not raised in the [Patent Owner's Response] will be deemed waived." *See* Paper 7, 3; *see also See In re NuVasive, Inc.*, 842 F.3d 1376, 1380–81 (Fed. Cir. 2016). Consequently, Patent Owner has waived arguments that the secondary considerations are tied to the claimed invention.

Dr. F. Pompei's testimony addresses the connection between the commercial thermometers referred to and the claimed subject matter. *See* Ex. 2010 ¶¶ 4–5. Patent Owner does not cite or explain this evidence in the Response and, consequently we need not consider it. Further, even considering this evidence it is not persuasive.

Dr. F. Pompei states that claims 1–4, 22, and 24 of the '386 patent cover three of Patent Owner's temporal artery thermometer products (TAT 5000, TAT 2000 and TAT 2000C). Ex. 2010 ¶ 4. This assertion suffers from several shortcomings.

First, Dr. F. Pompei does not cite to or provide evidence (e.g., product manuals specification sheets, or diagrams) regarding the features of the commercial thermometers. See Pet. Reply 22. Second, Dr. F. Pompei is the inventor of the '386 patent and has a financial interest in Exergen. See Ex. 1024, 50:20–51:16. These biases decrease the value of his testimony as compared to evidence from unbiased sources.

Third, and most importantly, the commercial thermometers at issue (TAT 5000, TAT 2000 and TAT 2000C) are covered by numerous patents other than the '386 patent (to include Pompei '813 and Pompei '091). See Pet. Reply 23; Ex. 1024, 29:10–30:4; *see also* Ex. 2033 (email by Patent Owner stating that Patent Owner's temporal artery thermometry technology is covered by 15 patents); Ex. 1021 (showing that the TAT 2000C is covered by numerous patents to include Pompei '813 and Pompei '091); Ex. 1025 ¶¶ 39–41.

In sum, Patent Owner has not shown that the commercial embodiments (TAT 5000, TAT 2000, and TAT 2000C) are the invention disclosed and claimed in the patent. Consequently, Patent Owner is not entitled to a presumption of nexus. See *WBIP*, 829 F.3d 1317.

Even if we presume a nexus, for the reasons that follow, Patent Owner's evidence provides little or no objective indicia of non-obviousness.

(2) Commercial Performance

Patent Owner contends they have sold over eight million temporal artery thermometers in the form of commercial and retail units. PO Resp. 56 (citing Ex. 2010 ¶ 6). According to Patent Owner, Patent Owner's thermometers are the "number one seller," the "number one preference of both pediatricians and nurses," and used by half the nurses in the country. *Id.* (citing Ex 2010 ¶ 7). Patent Owner asserts that studies show that consumer demand is attributable to the thermometer's ability to take temperature by passing across the forehead of the patient by taking three readings per second and displaying a temperature based on a model of heat balance relative to a detected arterial temperature. *Id.* (citing Ex. 2010 ¶¶ 9–10).

Patent Owner's argument and evidence do not provide the context necessary to assess the commercial performance of the products. First, and significantly, Patent Owner does not provide market share data. Absent market share data, gross sales figures have little value. *See e.g., In re Applied Materials, Inc.*, 692 F.3d 1289, 1300 (Fed. Cir. 2012) ("[T]he number of units sold without evidence of the market share is only weak evidence of commercial success."). Second, Dr. F. Pompei's assertions are not supported by underlying factual data. For example, Dr. F. Pompei refers to a study but does not identify or provide that study, and he states that the thermometers are used by half of all nurses, but does cite or provide any report or other data supporting that assertion. *See* Ex. 2010 ¶ 9. This omission is exaggerated by the fact that Dr. F. Pompei's testimony is less valuable than evidence from impartial sources. Third, Dr. F. Pompei

attributes the success to features that were known (Pompei '813).¹⁹ See Ex. 2010 ¶¶ 9–10; Ex. 1024, 46:4–48:21 (Dr. F. Pompei admitting that the heat balance equation of Pompei '813 applies to skin temperature of any location on the body as previously testified (Ex. 1022)), 50:9–19 (Dr. F. Pompei admitting that Pompei '813 is capable of use as a forehead thermometer but would not be “all that accurate”); Pet. Reply 24; Ex. 1025 ¶¶ 39–41.

(3) Long Felt Need

Patent Owner contends that there was a long felt need for an accurate, non-invasive thermometer. PO Resp. 56. According to Patent Owner, prior art thermometers were invasive, inaccurate, or both. *Id.*; Ex. 2010 ¶ 12; Ex. 2008 ¶¶ 160–172).

These contentions do not relate to claimed features because the claims do not include an accuracy requirement or a requirement that the device is not invasive. Further, as detailed above with regard to commercial success and in our anticipation analysis, Pompei '813's device was capable of use as a forehead thermometer prior to the critical date of the '386 patent.

Consequently, the need for an accurate, non-invasive thermometer was met prior to the critical date of the '386 patent and this evidence is not persuasive of non-obviousness. See *Newel Co. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

(4) Industry skepticism

Patent Owner contends that experts have long been skeptical about the possibility of achieving an accurate, non-invasive body temperature

¹⁹ Those features being: scanning the detector across the forehead, taking three readings per second during a scan, and displaying a temperature based on a model of heat balance relative to a detected arterial temperature.

measurement device for use at the forehead. PO Resp. 57–58. In support, Dr. M. Pompei and Dr. F. Pompei each testify that medical professionals were initially skeptical of the speed and accuracy of Exergen’s temporal thermometers and required persuasion through testing. Ex. 2011 ¶¶ 1–3. 2010 ¶¶ 15–16. Patent Owner also contends that an ASTM Standard E 1965-98 is an example of such skepticism. PO Resp. 58 (citing Ex. 2012, 10 and referring to PO Resp. 36–37).

Although the evidence shows that medical professionals were skeptical of the speed and accuracy of the thermometers, those are not claimed features. Further, Pompei ’813’s device was capable of use as a forehead thermometer prior to the critical date of the ’386 patent. *See ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016) (“A nexus may not exist where, for example, the merits of the claimed invention were ‘readily available in the prior art.’”); Ex. 1002 ¶ 65; Ex. 1025 ¶¶ 27–28; Pet. 15; Pet. Reply 11. Consequently, this evidence is not persuasive of non-obviousness.

Regarding the referenced ASTM standard, as explained in Section IV.B.b)(2) above, we agree with, and adopt, Petitioner’s explanation of why Patent Owner has misinterpreted the significance of this standard. *See* Pet. Reply 17–18. Consequently, this evidence also is not persuasive of non-obviousness.

(5)Praise of Unexpected Superior Result

Patent Owner contends that numerous experts and articles have praised Exergen’s temporal artery thermometers. PO Resp. 58–60; Ex. 2010 ¶¶ 18, 20; Ex. 2008 ¶¶ 180-184 (citing Ex. 2032, 1); Ex. 2013 at 56; Ex.

2014 at 3.²⁰ The evidence praises the accuracy and ease of use of Exergen's thermometers. As detailed above, the challenged claims do not include an accuracy requirement, and Pompei '813's device was capable of use as a forehead thermometer prior to the critical date of the '386 patent. Consequently, this evidence is not persuasive of non-obviousness.

(6) Licensing

Dr. F. Pompei testifies that he has received numerous "inquiries from companies and people seeking to license our temporal artery thermometer patents." See PO Resp. 60; Ex. 2010 at ¶ 21; Ex. 2033; Ex. 2034; Ex. 2035; Ex. 2036.

As an initial matter, none of these inquiries led to a licensing agreement and no licensing agreement is in the record for our review. Some of these inquiries (Exs. 2034, 2035) were requests for licenses intended to resolve potential litigation disputes, and as such, are not strong evidence of non-obviousness. See *In re Cree, Inc.*, 818 F.3d 694, 703 (Fed. Cir. 2016); *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004). The other inquiries are nonspecific (e.g., Ex. 2033 stating 15 patents cover the technology at issue, and Ex. 2036 referring generally to "infrared medical thermometry technology") and do not demonstrate that the request was driven by claimed features. Consequently, this evidence is not persuasive of non-obviousness.

²⁰ Page 3 of Exhibit 2014 is labeled as page "3 of 6" (lower left corner), but this page is actually the second page of the Exhibit. We do not consider the third sentence of paragraph 20 of Ex. 2010.

(7) Copying

Dr. F. Pompei testifies that Exergen has been forced to engage in litigation against numerous companies selling and/or manufacturing copycat forehead thermometers. Ex. 2010 at ¶ 22; PO Resp. 60.

Patent Owner does not provide sufficient evidence to demonstrate that a specific product was replicated. *See Iron Grip Barbell Co.*, 392 F.3d at 1325 (“[C]opying requires the replication of a specific product.”). Further, we agree with Petitioner that not every competing product that falls within the scope of a patent is evidence of copying. *See* Pet. Reply 26. Consequently, this evidence is not persuasive of non-obviousness.

(8) Secondary Indicia Summary

Patent Owner has not demonstrated that Exergen’s temporal artery thermometer products (TAT 5000, TAT 2000 and TAT 2000C) are the invention disclosed and claimed in the patent. This is true even if we consider Dr. F. Pompei’s testimony. Beyond this, even presuming a nexus, Patent Owner’s evidence is not persuasive of non-obviousness.

d) Conclusion

Pompei ’813 discloses a body temperature detector having electronics that measure a peak temperature from at least three readings per second during scan across an artery, and those electronics process the detected temperature to provide a temperature display based on a model of heat balance relative to a detected arterial temperature. Pompei ’813’s device is not limited to use within the ear canal; rather, and it is capable of scanning surface tissue. Pompei ’813 discloses the device should be designed with a patient in mind.

Pompei '091 discloses a hand-held radiation detector that includes a reflective cup as claimed. Pompei '091's device can take a temperature reading while the reflective cup is in contact with a target, and use in this manner provides more accurate and rapid surface temperature measurements by eliminating the effects of skin emissivity and background radiation during measurement of exposed skin.

Accordingly, the elements of claims 3 and 22 were known in the art.

As explained above, Pompei '813 discloses a device that is capable of scanning skin to detect a peak temperature and discloses that patient comfort is a design consideration. Although comfort to the patient is discussed with regard to rounding the probe for use within the ear canal (*see* Ex. 1005 3:40–43) a person of ordinary skill in the art would recognize that patient comfort is a concern for any use of the device. In light of this, Petitioner's reasoning that a person of ordinary skill would round the lip of Pompei '091's reflective cup for patient comfort has a rational underpinning.

Petitioner reasons that it would have been the application of a known technique to a known device ready for improvement to add Pompei '091's reflective cup to Pompei '813's device, and reasons that such modification provides more accurate and rapid surface temperature measurements. *See* Pet. 26–30. Given that Pompei '091's device eliminates the effects of skin emissivity and background radiation during measurement of exposed skin when taking a measurement in contact with the skin, this reasoning has a rational underpinning. Further, given that a person of ordinary skill would have 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, this modification was not beyond

the level of skill in the art.²¹ Patent Owner has not shown a nexus between the claimed subject matter and the evidence of secondary considerations. Even presuming a nexus, that evidence does little or nothing to demonstrate the non-obviousness of the claimed subject matter.

Consequently, on the record before us, Petitioner has demonstrated by a preponderance of the evidence that claims 3 and 22 are unpatentable over Pompei '813 and Pompei '091.

3. *Claim 4 and 24*

Claim 4 depends from claim 3 and adds that the reflective cup is spaced from the target surface by a smooth lip of low thermal conductivity material. Claim 24 depends from independent claim 22 and adds a similar limitation.

Pompei '813's thermal probe is rounded to avoid patient discomfort and is formed of a plastic material of low thermal conductivity. Pet. 32, 34; Ex. 1005, 3:40–43, 5:13–15, 6:5–8, 6:15–19; Ex. 1002 ¶ 99; Pet. 34 (relying on the analysis of claim 4). Petitioner reasons that for patient comfort and accurate measurements, a person of ordinary skill would have modified Pompei '091's cup to include a rounded lip of low thermal conductivity material. Pet. 32, 34.

Patent Owner argues that Pompei '813's lip is rounded on the outside circumferential surface, but not on the inside circumferential surface and from that reason the inner surface would dig into the skin as the detector is

²¹ We note that Patent Owner does not argue that the proposed combination was beyond the level of skill in the art or lacked a reasonable expectation of success, nor do we find sufficient evidence or technical reasoning that would support such a conclusion.

scanned in contact with the skin. PO Resp. 43–45. Based on this, Patent Owner contends both that it would not be obvious to combined Pompei '813 and Pompei '091, and that if combined, the device does not disclose a smooth lip as claimed.

Patent Owner's argument is unpersuasive for two reasons. First, as detailed in our claim construction above, claims 4 and 24 do not require the lip to be smooth on both the inner and outer circumferential surfaces. Therefore, Patent Owner's argument is unpersuasive because it is not commensurate in scope with the claims. Second, even if the claims required the lip to be smooth on both the inner and the outer circumferential surfaces, Patent Owner's argument is unresponsive in that Petitioner does not argue that Pompei '091's lip is smooth on both the inner and outer circumferential surfaces; rather, Petitioner's proposes to modify Pompei '091's lip to be smooth. *See* Pet. 32, 34.

Patent Owner has not shown a nexus between the claimed subject matter and the evidence of secondary considerations. Even presuming a nexus, that evidence does little or nothing to demonstrate the non-obviousness of the claimed subject matter.

Consequently, on the record before us, Petitioner has demonstrated by a preponderance of the evidence that claims 4 and 24 are unpatentable over Pompei '813 and Pompei '091.

C. OBVIOUSNESS OVER BANKE, HOUDAS, AND BARNES –
CLAIMS 1 AND 2

1. *Petitioner's Contentions*

Petitioner contends that claims 1 and 2 are unpatentable over Banke, Houdas, and Barnes. Pet. 13, 18–20, 46–52.

Petitioner contends that Banke discloses the limitations of claims 1 and 2 except for the forehead limitation (*i.e.*, scanning an artery in the target surface area of the forehead) and the “heat balance” limitation. Pet 46–49; Ex. 1002 ¶ 122. Petitioner relies on Barnes for the location on the body where the sensed skin temperature is obtained, and relies on Houdas for the “heat balance” limitation. Pet. 46–49. As observed in our Institution Decision, Petitioner does not propose modifying the combination of Banke and Houdas based on Barnes; rather, Petitioner only relies upon Barnes for a *use* of the device (scanning an artery in the forehead). *See* Dec. 20.

Banke discloses an infrared thermometer that determines a patient's body temperature using a thermopile to measure the surface temperature of a target surface such as the eardrum. Ex. 1008, Abstract, 2:1–10, 3:2–8, 6:23–7:15, 11:26–12:19; Ex. 1002 ¶¶ 122–125; Pet. 49–50. Banke discloses electronics that measure peak temperature from at least three readings per second and that process that detected peak temperature to provide a temperature display. Ex. 1002, ¶¶ 122–125; Ex. 1008, 16:11–15, 12:7–14; Pet. 50. Banke discloses that the “the present invention has wide applicability with respect to thermometers of a wide variety of configurations.” Ex. 1008, 17:6–18; Pet. 19.

Houdas discloses that the extremities show considerable variation in skin temperature while the forehead has less significant variations. Ex. 1010, 97; Pet. 20.

Patent Owner does not contest these aspects of the ground of unpatentability.

Petitioner contends that Houdas discloses how to compute a person's core temperature from a measured skin temperature and a known ambient temperature. Pet. 20, 47, 49 (citing Ex. 1010, 34, 40–41, 95–97, 108–111, 143–145). In support, Dr. Bowman opines that Houdas discloses that, in conditions of thermal neutrality, the environment removes heat at a rate equal to that produced by the core and therefore the metabolic heat ($\dot{H}_m$) from the core is equal to the heat loss to the environment ($\dot{H}_e$). Ex. 1002 ¶ 93. Dr. Bowman set metabolic heat ($\dot{H}_m$) equal to heat loss to the environment ($\dot{H}_e$) as expressed in Houdas, solved for core temperature, and determined that core temperature T_d can be expressed in the following equation.

$$T_d = h/h_b(T_s - T_a) + T_s$$

Where h_b represents pc as shown in equation (6) of the '386 patent. *Id.* According to Dr. Bowman, this equation in Houdas is equal to equation 6 of the '386 patent. *Id.*; see also Ex. 1001, 7:57–59 (equation (6)). Dr. Bowman also opines that with further manipulation Houdas's equation is equal to equation 11 of the '386 patent. *Id.*; see also Ex. 1001, 8:20 (equation (11)).

Petitioner concludes that a person of ordinary skill in the art would have modified Banke to determine a person's core temperature with heat-balance equations as taught by Houdas so that temperature may be measured at less invasive and more convenient body locations than the ear canal. Pet.

47. Petitioner adds that a person of ordinary skill would have recognized that the heat balance model disclosed in Houdas could be determined for any location on the body given the heat transfer coefficient for that location. *Id.*

2. *Patent Owner's Arguments*

Patent Owner provides four contentions in support of the argument that Dr. Bowman derived the heat balance equations from Houdas through improper hindsight. PO Resp. 46–53. This is Patent Owner's only argument and other arguments are waived.

First, Patent Owner contends that because Houdas's equations only apply while the body is in a state of thermal neutrality, those conditions are unsuitable for development of a practical thermometer. PO Resp. 48–49 (citing Ex. 2008 ¶¶ 146, 149; Ex. 1010, 108–109, 145–146; Ex. 1002 ¶ 93). We agree with Petitioner that Patent Owner's contention that the equations only work during thermal neutrality is an admission that Houdas's equations work in conditions of thermal neutrality. We are also persuaded by Petitioner's argument and evidence that those conditions do not preclude development of a practical thermometer. In particular, Houdas's equations serve as a starting point or reference point with other variables introduced for the impact of heat transfer. Pet. Reply 20; Ex. 1025 ¶¶ 37–38.

Second, Patent Owner contends that there is no equation 4 in Houdas, and Houdas does not disclose or suggest solving for core temperature as in Equation 4. PO Resp. 49–50 (citing Ex. 2008 ¶ 144). Patent Owner's argument is not responsive to the ground of unpatentability as articulated by Petitioner. Petitioner does not contend that Houdas explicitly discloses equation 4. Rather, as detailed above, Petitioner contends that a person of

ordinary skill in the art would understand Houdas discloses information equivalent to equation 4.

Third, Patent Owner contends that Houdas discloses heat balance with regard to the average body temperature and a variable heat transfer coefficient for the entire body, and does not disclose or suggest deriving an expression for body temperature based on skin temperature over an artery. *Id.* at 50–51. We are persuaded by Petitioner that a person of ordinary skill in the art would recognize that Houdas’s equations are applicable to a localized site. Pet. Reply 21; Ex. 1025 ¶ 35; *see also* Ex. 1023 (Patent Owner’s expert testifying that Figure 7.1 of Houdas provides a description of calculating core temperature from a localized skin temperature).

Fourth, Patent Owner contends that the complexity of thermal regulation recognized by Houdas would teach against the possibility of detecting body temperature from a simple skin temperature measurement. PO Resp. at 51– 53 (Ex. 2008 ¶ 151). Patent Owner does not identify, nor do we discern, any disclosure in Houdas that would have led a person of ordinary skill away from an attempt to calculate core temperature from skin temperature. To the contrary, as detailed above, Houdas provides information on the factors that influence skin temperature and the relationship to core temperature and thus teaches towards a solution rather than away from it.

Patent Owner contends that the claimed invention is the result of non-obvious insight. PO Resp. 53. In particular, according to Patent Owner, the ’386 patent made two key observations: (1) that blood flow is relatively constant at the skin surface over arteries, and (2) that an appropriate

coefficient for transfer of heat from an exposed surface can be defined. *Id.* (citing Ex. 1001, 2:25–46, 2:65–3:9; Ex. 2008 ¶ 152).

Patent Owner cites to the same portions of the Specification cited in support of their interpretation of “artery” as claimed. In our analysis of that argument (*see* Section III.C.5), we observed that the Specification describes that arteries in general, and the temporal artery in particular, are good locations for detecting a temperature reflective of core temperature. The Specification also describes that the claimed device is capable of scanning at other locations such as the extremities (ankle and wrist), but the temperatures taken there may not be as reflective of core temperature. *See, e.g.,* Ex. 1001, 2:25–3:9. In other words, the Specification describes techniques for using the apparatus that will produce more accurate results; however, even though scanning is done at different locations, the apparatus remains the same. Patent Owner cannot distinguish these apparatus claims over the prior art based upon a method of use of a device.

3. *Conclusion*

Banke discloses an infrared thermometer that determines a patient’s body temperature using a thermopile to measure the surface temperature of a target surface such as the eardrum, including electronics that measure peak temperature from at least three readings per second and that process the detected peak temperature to provide a temperature display. Banke’s device is capable of scanning an artery because the tympanum contains arteries. Houdas discloses that the forehead exhibits less temperature variation than the extremities.

Petitioner has demonstrated that Houdas discloses how to compute a person's core temperature from a measured skin temperature and a known ambient temperature.

In light of this, Petitioner's assertion that a person of ordinary skill in the art would have modified Banke to determine a person's core temperature with heat balance equations as taught by Houdas, so that temperature may be measured at less invasive and more convenient body locations than the ear canal, has a rational underpinning.

As detailed above, Patent Owner has not shown a nexus between the claimed subject matter and the evidence of secondary considerations, and even assuming a nexus, that evidence does little or nothing to demonstrate the non-obviousness of the claimed subject matter.

Consequently, on the record before us, Petitioner has demonstrated by a preponderance of the evidence that claims 1 and 2 are unpatentable over Banke, Houdas, and Barnes.

D. OBVIOUSNESS OVER BANKE, HOUDAS, BARNES, AND POMPEI '091 –
CLAIMS 3, 4, 22, 24

Petitioner contends that claims 3, 4, 22, and 24 are unpatentable over Banke, Houdas, Barnes, and Pompei '091. Pet. 52–57.

1. *Petitioner's Contentions*

Petitioner contends that it would have been obvious to modify the combination of Banke, Houdas, and Barnes to include a reflective cup as disclosed by Pompei '091. Pet. 52–57.

2. *Patent Owner's Arguments*

Patent Owner repeats the arguments used for claims 1 and 2 against the prior ground of unpatentability. PO Resp. 54. Patent Owner repeats the arguments again Pompei '091 from the ground of unpatentability based on Pompei '813 and Pompei '091. Each of these sets of arguments are not persuasive for the reasons given above.

Patent Owner contends that the large number of references alone suggests non-obviousness. PO Resp. 54. The number of references, without more, does not establish non-obviousness. *See generally In re Gorman*, 933 F.2d 982, 987 (Fed. Cir. 1991).

With regard to claims 4 and 24, Patent Owner contends “the Petition presents no prior art, relying only on a ‘design choice’ conclusion by Dr. Bowman.” PO Resp 54.

Dr. Bowman does not use the term “design choice” in the sense that the proposed modification was one of many routine ways a device could have been configured. Rather, Dr. Bowman provides a reasoned explanation that a person of ordinary skill would have recognized the need for a smooth lip to provide for patient comfort. *See* Ex. 1002 ¶ 131; Pet. 55, 57.

3. *Conclusion*

Our analysis above of Pompei '091 and the reason for modifying in view of Pompei '091 from the ground of unpatentability based on Pompei '813 and Pompei '091 is applicable here. Further, as detailed above, Patent Owner has not shown a nexus between the claimed subject matter and the evidence of secondary considerations, and even assuming a nexus, that evidence does little or nothing to demonstrate the non-obviousness of the claimed subject matter.

Consequently, on the record before us, Petitioner has demonstrated by a preponderance of the evidence that claims 3, 4, 22, and 24 are unpatentable over Banke, Houdas, Barnes, and Pompei '091.

V. CONCLUSION

Petitioner has demonstrated by a preponderance of the evidence that the following claims are unpatentable in view of the following grounds:

- a) claims 1 and 2 as anticipated by Pompei '813;
- b) claims 3, 4, 22, 24 as obvious over Pompei '813 and Pompei '091;
- c) claims 1 and 2 as obvious over Banke, Houdas, and Barnes; and,
- d) claims 3, 4, 22, 24 as obvious over Banke, Houdas, Barnes, and Pompei '091.

VI. ORDER

For the reasons given, it is:

ORDERED that Petitioner's Motion to Exclude is *granted* with respect to Exhibit 2031 and *denied* with respect to the third sentence of paragraph 20 of Exhibit 2010, paragraph 182 of Exhibit 2008, and the associated footnote to paragraph 20 of Exhibit 2010;

FURTHER ORDERED that Patent Owner's Motion to Exclude a portion of Houdas (Ex. 1010) is denied;

FURTHER ORDERED that claims 1–4, 22, and 24 are held unpatentable; and

FURTHER ORDERED that that this is a Final Written Decision; therefore, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KAZ USA, INC,
Petitioner,

V.

EXERGEN CORP.,
Patent Owner.

Case IPR2016-01437
Patent 7,346,386 B2

Before PHILLIP J. KAUFFMAN, MEREDITH C. PETRAVICK, and
WILLIAM V. SAINDON *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge, dissenting-in-part*.

I respectfully dissent-in-part from my colleague's decision. In particular, I would propose a different claim construction for "artery." I would also determine, contrary to my colleagues, that: (1) Petitioner has not established by a preponderance of the evidence that claims 1 and 2 were anticipated by Pompei '813; (2) Petitioner has not established by a preponderance of the evidence that claims 3 and 4 would have been obvious in view of Pompei '813 and Pompei '091; (3) Petitioner has not established by a preponderance of the evidence that claims 1 and 2 were unpatentable over Banke, Houdas, and Barnes; and (4) Petitioner has not established by a

preponderance of the evidence that claims 3 and 4 were unpatentable over Banke, Houdas, Barnes, and Pompei '091.

To explain my reasoning, I first turn to the claim construction of “artery.” Artery, in the context of the '386 patent specification, means an artery near the surface of the skin that is accessible by the claimed device. It does not mean every blood vessel in the body that carries blood from the heart, which effectively renders the term a nullity because virtually every spot on the body contains an artery under the that definition. Without drawing a prescriptive, bright-line definition, which is unnecessary to resolve the issues in this proceeding, the specification distinguishes between the arteries it is interested in and those it is not, and arteries and ear canals. For example, the specification states that arteries in the extremities or those highly subject to vasoconstriction are not useful. Ex. 1001, 2:25–35. These arteries would provide inconsistent readings. Arteries not near the surface of the skin also are not useful. *Id.* at 2:49–52; 9:6–9. These arteries are not accessible. The specification also explains that those arteries closer to the heart and having a relatively stable blood flow are desirable. *Id.* at 3:24–25, 3:38–41, 4:15–22. Specific examples include the “two-prong fork[s]” of the temporal artery. *Id.* at 2:59–60. Specific prior art examples (i.e., in contradistinction to the present invention) include in the ear and the axilla (armpit). *Id.* at 1:52–2:2. These passages apprise a person of ordinary skill in the art what the invention is.

I also note that the '386 patent specification discussed different weighting coefficients for applying the arterial heat balance equation in the prior art to adult ears (0.09), neonates (0.05), and adult axilla (0.13), versus the '386 patent specification's discussion of the weighting coefficient

formula for use at the forehead. *Id.* at 8:35–61. This again indicates that measuring the ear canal is different from what is discussed in the '386 patent specification. Notably, the forehead experiences more exposure to the ambient environment than an ear canal or armpit, requiring a more complex coefficient that depends on the temperature of the skin. This also demonstrates that a person of ordinary skill would understand, based on this disclosure that the same model (arterial heat balance) is applicable to many sites, but the model must be “tuned,” so to speak, for a particular location in order for the model to work via the weighted coefficients. *Accord* Ex. 1010, 110 (formulas explaining that heat loss from the core of the body outward is based on the temperature differential and a weighting coefficient). In other words, although ear canals and foreheads may both use the same heat balance *model*, in practical application they must make the calculations using different heat balance *equations*.

It is my opinion, therefore, that although the arterial heat balance equation is applicable to anywhere in the body, the '386 patent specification makes a distinction between the model in the abstract and implementable instances of that model in the disclosed invention (e.g., forehead) and in the prior art (e.g., ear, armpit). A person of ordinary skill in the art reading claim 1's recitation of a model using as an input a reading from a detector *across an artery* would understand that what is being claimed is not the prior art ear application but rather some other surface containing an artery near the surface of the skin. The formula would be different because it would require different weights.

I recognize that dependent claim 2 specifically states “forehead” and that claim 1 is not so broad, and that claims 5–7, 11, 12, for example, recite

more particular characteristics of the particular model and its coefficients. I do not believe my proposed construction “reads in” those limitations. For example, in claim 1 other coefficients may work, the coefficient may be itself a linear or polynomial sub-model dependent on other environmental variables or other suitable locations may exist. Instead, I propose that a person of ordinary skill in the art, reading claim 1 in light of the specification, would understand that *scanning across an artery* was different from *scanning across an ear cavity*, and that a measurement from either activity would provide different data source types requiring different coefficients for the arterial heat balance model to work. Thus, a putative prior art device designed to use an arterial heat balance model using an ear cavity measurement would utilize a different structure (different stored program variables, at the least) than an arterial heat balance model using an artery measurement.

As such, I respectfully disagree with my colleagues’ assessment of Pompei ’813. The arterial heat balance model there uses a model tuned to be effective when the input is received from the ear canal. Claim 1 specifically recites that the model is tuned to be effective when the input is received from a scan across an artery. The program codes of these devices would not be identical because they would use different weighting coefficients. See *Typhoon Touch Technologies, Inc. v. Dell, Inc.*, 659 F.3d 1376, 1380 (Fed. Cir. 2011) (standing for the idea that a program that could be modified to satisfy a claim term does not satisfy the claim term). Petitioner has not shown that these coefficients would be the same; Petitioner has merely alleged that the ear canal has arteries. Although this may be true in some literal sense, as I have explained above a person of ordinary skill in the art

would understand when reading the specification that “across an artery” was intended to differentiate its application of the heat balance model from the application of the heat balance model configured to utilize inputs from an ear canal. I agree with my colleagues’ finding that the heat balance model, in the abstract sense, does not vary from place to place, just as Newton’s law of universal gravitation remains constant across the planets. However, just as we would weigh a different amount standing on each planet, the arterial heat balance model, *in application*, is different between input locations. Thus, I disagree that Petitioner has shown that Pompei ’813 anticipates claim 1.²² For that reason, I would also find Petitioner’s grounds based on Pompei ’813 defective for claims 2–4.

Petitioner’s ground for claim 22 is not deficient on this issue because the claim language does not attempt to distinguish itself from the prior art. It broadly claims application of a heat balance model to anything; there are no words to construe that could serve to distinguish over the prior art. Thus, not limited to input from “across an artery” and an instance of the arterial heat balance model calibrated to use such an input, Petitioner’s ground here does not suffer the deficiency I identified above. Accordingly, I join my

²² I also put no particular import on the term “arterial” in “arterial heat balance” model described in the prior art ear canal applications in the background of the specification. See Ex. 1001, 1:15-65 (discussing ways arterial heat balance is used to determine arterial core temperature). The term “arterial” here means that the model is modeling the temperature of an artery whose temperature is representative of core temperature, e.g., the pulmonary artery. This is not the ’386 patent specification admitting that ear temperature is measuring the temperature of an artery but rather explaining how ear temperature can be used as a proxy for arterial temperature, i.e., core temperature, using a balancing model.

colleagues as to the analysis of the first three *Graham* factors for claims 22 and 24, and, on the fourth, their analysis as to Patent Owner's failure to address properly and sufficiently the nexus requirement.

I now turn to the Banke, Houdas, and Barnes grounds. As I understand it, Banke teaches an infrared ear thermometer, Houdas teaches the heat balance model, and Barnes teaches the use of an infrared radiometer across a forehead. I credit Petitioner's position that Houdas' heat balance model is applicable anywhere on the body, and note it even suggests that the forehead exhibits less temperature variation based on environmental conditions. Ex. 1010, 97–98. Petitioner is missing, in my view; a reason a person of ordinary skill in the art would modify an ear thermometer for use on the forehead. Barnes does not provide that teaching, in my view. Barnes merely looks for temperature variations indicative, e.g., of a blood clot; the actual core temperature is irrelevant, only the variation in temperature across the forehead. See Ex. 1009, Fig. 8 (showing a left to right trace of temperatures across a portion of the body), 7:44–48 (diagnosis made by noting hot spots); Ex. 1010, Fig. 3.7 (depicting the same idea in an image format). Petitioner also cites to Ikeda, which discusses favorably measuring skin temperature using liquid crystal thermometers during surgical procedures. Pet. 48 (citing Ex. 1011, 604). I do not see, nor does Petitioner explain sufficiently, the link between this teaching and *infrared* measurements for a model designed to take inputs from across an *artery* in the forehead. Absent reason to modify, I conclude the combination could only be made, on this record, using improper hindsight.

I caution that I am not looking for a specific teaching, suggestion, or motivation to combine; *KSR* forecloses the exclusivity of that test. Instead, I

am looking for *Petitioner* to articulate a *credible explanation based in fact or technical reasoning* to modify the programming of the ear thermometer to be useable on the forehead,²³ and finding none. It is not Patent Owner's burden to say there is no reason; the absence of a credible reason in *Petitioner's* briefs is sufficient to find for Patent Owner. 35 U.S.C. § 316(e). That is what I would hold here. Thus, I would find that *Petitioner* has not established, by a preponderance of the evidence that claims 1–4 are unpatentable under the *Banke*, *Houdas*, and *Barnes* grounds. As to claims 22 and 24, the lacking rationale is harmless because no modification is necessary to make the device usable for the forehead; the claims are simply too broad and do not require modification of *Banke* in this manner. I join my colleagues as to their analysis of claims 22 and 24 on the first three *Graham* factors and, on the fourth, their analysis of Patent Owner's failure to address properly and sufficiently nexus.

²³ Which would require changing, at the least, the weighting coefficients of the *Banke* thermometer.

Case IPR2016-01437

Patent 7,346,386 B2

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