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Paper No. 7
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MASIMO CORPORATION,
Petitioner,

v.

MINDARY DS USA, INC.,
Patent Owner.

Case IPR2015-01240
Patent 5,987,343

Before MICHAEL W. KIM, MITCHELL G. WEATHERLY, and JEREMY M. PLENZLER, *Administrative Patent Judges*.

KIM, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Masimo Corporation ("Petitioner") filed a Petition ("Pet.") for *inter partes* review of claims 1–4 of U.S. Patent No. 5,987,343 ("the '343 Patent") (Ex. 1001) pursuant to 35 U.S.C. §§ 311–319. Paper 1. Mindray DS USA, Inc. ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 6; "Prelim. Resp." We have jurisdiction under 35 U.S.C. § 314, which

provides that an *inter partes* review may be instituted only if "the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Petitioner challenges the patentability of claims 1–4 of the '343 Patent under 35 U.S.C. § 103. We determine that the information presented in the Petition demonstrates that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1–4 are unpatentable. Pursuant to 35 U.S.C. § 314, we authorize an *inter partes* review to be instituted as to claims 1–4 of the '343 Patent.

A. The '343 Patent

The '343 Patent relates to a pulse oximeter probe or an intra-aortic balloon ("IAB") catheter which incorporates a memory unit to store parameters. Ex. 1001, 1:6–10. A pulse oximeter sensor (probe) is a device containing generally two light emitters of differing wavelengths and a photodetector, the emitters and photodetector being arranged so that the photodetector detects light from the emitters, which either diffuses through, or is scattered back by, the tissue of a patient's extremity, for example, a finger. Ex. 1001, 1:12–18. The signals detected by the photodetector correspond to the different wavelengths, are analyzed by a companion pulse oximeter instrument, which determines the oxygen saturation of the blood flowing through the tissue. Ex. 1001, 1:18–21. As is the case for any colorimetric analysis, the accuracy of the oxygen determination is dependent on the accuracy to which the emitter wavelengths are known. Ex. 1001, 1:21–24. Because the sensors are interchangeable, and often even disposable, accurate results require that the sensors be manufactured with

well controlled emitter wavelengths, or that the sensor include a means for encoding the emitter wavelength error, so that the oximeter may apply a calibration correction. Ex. 1001, 1:24–29. Conventionally, according to the ’343 Patent, a pulse oximeter codifies the wavelength error using resistors or resistance elements embedded in either the sensor or the sensor’s electrical connector. Ex. 1001, 1:41–44.

In one process, the emitters are tested and sorted prior to sensor assembly, which adds considerable material handling burden and cost to the manufacturing process. Ex. 1001, 2:3–6. According to the ’343 Patent, a more ideal process would feature a memory means which could be adjusted or programmed after the sensor is completely assembled. Ex. 1001, 2:6–8. The ’343 Patent also discloses that it would be desirable if the resistor coding method were able to encode more than a single parameter, in this case, wavelength error, such as emitter intensity, date of manufacture, sensor type, IAB dead volume, error detection code, expiration date, flow restriction, helium diffusion rate, membrane thickness, serial number, and configuration. Ex. 1001, 2:14–16, 42–47.

B. Related Matters

Petitioner and Patent Owner identify the following related district court proceeding between Petitioner and Patent Owner that involves the ’343 Patent: *Masimo Corporation v. Mindray DS USA Inc., Shenzhen Mindray Bio-Medical Electronics Co., LTD and Mindray Medical International LTD.*, No. 2:15-cv-00457-SDW-SCM (D.N.J.). Pet. 1; Paper 5, 2.

C. Illustrative Claim

Independent claim 1 is reproduced below:

> 1. A pulse oximeter comprising:
>
> a probe portion including two or more electromagnetic radiation emitters, each emitting a different wavelength, and a photodetector arranged to detect radiation emitted from the emitters after it has interacted with a subject, and further including a memory unit for storing data related to said emitters or said photodetector, and
>
> an oximeter portion including a control unit in communication with said emitters, said photodetector, and said memory unit, said control unit controlling the emitters and calculating the oxygen saturation from signals obtained from the photodetector, and including means for modifying the data in the memory unit.

D. Prior Art References Applied by Petitioner and Alleged Ground of Unpatentability

Petitioner challenges the patentability of claims 1–4 as obvious under 35 U.S.C. § 103(a) based on the following item of prior art (Pet. 20–56):

US 4,942,877 ("Sakai") July 24, 1990 Ex. 1002

Petitioner also cites the Declaration of Mr. Joans Pologe (Ex. 1003; "the Pologe Declaration"), and the Declaration of Mr. Eric Kinast (Ex. 1006; "the Kinast Declaration").

II. ANALYSIS

We turn now to Petitioner's asserted grounds of unpatentability to determine whether Petitioner has met the threshold standard, under 35 U.S.C. § 314(a), for instituting review.

A. Claim Construction

As a step in our analysis for determining whether to institute a review, we determine the meaning of the claims for purposes of this Decision. In an

inter partes review, a claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278 (Fed. Cir. 2015) ("We conclude that Congress implicitly approved the broadest reasonable interpretation standard in enacting the AIA."). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). We must be careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

1. "control unit"

Independent claims 1 and 3 each recite "a control unit in communication with said emitters, said photodetector, and said memory unit, said control unit controlling the emitters and calculating the oxygen saturation from signals obtained from the photodetector, and including means for modifying the data in the memory unit." Patent Owner makes two assertions concerning the claim construction of the aforementioned claim limitation, each of which we will address in turn. Prelim. Resp. 2–8.

Patent Owner asserts that based on the prosecution history, "control unit" should be construed more narrowly than a generic processor, in that the "control unit" must perform multiple functions that cannot be performed by

a generic processor. *Id.* at 4. We agree. Even without considering the prosecution history, the aforementioned claim limitation recites a "control unit," not a processor, and the aforementioned claim limitation further recites that the "control unit" is required to "control[ ] the emitters and calculat[e] the oxygen saturation from signals obtained from the photodetector, and includ[e] means for modifying the data in the memory unit." We agree that these functions collectively would not be performed by a generic processor.

Patent Owner asserts further, however, that the intrinsic evidence and prosecution history makes clear that in construing "control unit" as narrower than a generic processor, "control unit" should be construed as including "a combination of front-end electronics, a programmed microprocessor and a power source that powers a remote memory chip in a pulse oximeter probe." *Id.* We agree in part. Specifically, we agree that "control unit" should be construed as including a microprocessor programmed to perform the recited functions. We disagree, however, that "control unit" should be construed as including "front-end electronics" and "a power source that powers a remote memory chip in a pulse oximeter probe."

As an initial matter, we note that the Specification does not refer to a "control unit." The first mention of "control unit" is in the Examiner's Amendment mailed July 1, 1999, where the amendments to independent claim 1 were as follows:

> 1. A pulse oximeter comprising:
>
> a probe portion <u>including two or more electromagnetic radiation emitters, each emitting a different wavelength, and a photodetector arranged to detect radiation emitted from the emitters after it has interacted with a subject, and further</u>

> including [having] a memory unit for storing data related to said emitters or said photodetector, and
>
> an oximeter portion [having] including a [processor connected to] control unit in communication with said emitters, said photodetector, and said memory unit, said [processor] control unit controlling the emitters and calculating the oxygen saturation from signals obtained from the photodetector, and including [having a] means for modifying the data in the memory unit.

Ex. 1007, 72–73. As Patent Owner has noted, "processor" has been replaced with a "control unit" performing specific functions. Thus, we agree with Patent Owner that "control unit" must be narrower than a generic processor, in that it must perform the recited functions, namely, "a control unit in communication with said emitters, said photodetector, and said memory unit, said control unit controlling the emitters and calculating the oxygen saturation from signals obtained from the photodetector, and including means for modifying the data in the memory unit." The '343 Patent discloses that microprocessor 28 sends output signals to light emitting diodes ("LEDs") 12, 14 via front-end electronics 30, accepts input signals from photodetector 16 via front-end electronics 30, communicates with EEPROM memory unit 36, calculates blood oxygenation levels based on inputted values, and writes to non-volatile memory circuit 56. Ex. 1001, 3:55–58, 4:3–20; 12:59–66. Accordingly, we determine that "control unit" is properly construed as a microprocessor programmed to perform the recited functions.

Patent Owner may be asserting that a microprocessor, even a programmed microprocessor, is not materially narrower than a generic processor, and, thus, must include other components. We are unpersuaded, as we determine that a microprocessor programmed to perform specific

functions is narrower than a generic microprocessor, and that no more components are necessary, especially where the programmed microprocessor, by itself, is capable of performing all of the recited functions.

For the front end electronics, Patent Owner cites to several portions of the ’343 Patent for support, asserting that those portions disclose that input signals from photodetector 16 are received by, and output signals are sent to LEDs 12, 14 from, microprocessor 28 via front-end electronics 30. Prelim. Resp. 4–7 (citing Ex. 1001, 4:3–26). While we find that Patent Owner states accurately what is cited in the aforementioned portion of the ’343 Patent, we are unpersuaded that this citation supports Patent Owner’s position that the recited “control unit” must include front-end electronics. In relevant part, independent claims 1 and 3 each require the recited “control unit” to be in communication with the recited emitters and photodetector, but does not require any particular manner in which such communications must occur. By implication, Patent Owner appears to be asserting that the recited “control unit” must be in “direct” communication with the emitters and photodetector, and that in this respect, a microprocessor alone is inadequate, because microprocessor 28 in the ’343 Patent is only in communication with LEDs 12, 14 and photodetector 16 via an intermediary component, such as front-end electronics 30. We determine, however, that such a “direct” communication requirement would be impermissibly importing a limitation from the Specification into the claim. *See CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005). The aforementioned portions of the ’343 Patent are consistent with a broad, but reasonable, construction that the recited “control unit” must be in

communication with the emitters and photodetector, and that such requirements are met by microprocessor 28 alone. Thus, we determine that the fact that there may or may not be an intermediary component, such as front-end electronics, between the emitters and photodetector and the microprocessor is superfluous to a proper construction of "control unit."

Our analysis is similar for "a power source that powers a remote memory chip in a pulse oximeter probe." Prelim. Resp. 4–7 (citing Ex. 1001, 4:3–26). Indeed, here, the connection is even more tenuous, as the cited portions of the '343 Patent disclose that microprocessor 28 is directly connected to EEPROM 36, and that EEPROM 36 is connected separately to power source 48. In relevant part, independent claims 1 and 3 each require the recited "control unit" to be in communication with the memory unit, and the connection between microprocessor 28 and EEPROM 26 disclosed in the '343 Patent corresponds properly to and is consistent with that claim language.

On this record, we construe "a control unit in communication with said emitters, said photodetector, and said memory unit, said control unit controlling the emitters and calculating the oxygen saturation from signals obtained from the photodetector, and including means for modifying the data in the memory unit" as "a microprocessor programmed to be in communication with said emitters, said photodetector, and said memory unit, said microprocessor programmed to control the emitters and calculate the oxygen saturation from signals obtained from the photodetector, and including programming for modifying the data in the memory unit."

2. other claim terms

We determine that it is unnecessary to expressly construe other claims terms at this time.

B. Claims 1–4 as Unpatentable over Sakai

Petitioner contends that claims 1–4 are unpatentable Sakai. Pet. 20–56 (citing Exs. 1002, 1003, 1006). Patent Owner disagrees. Prelim. Resp. 7–11 (citing 1001, 1002, 1007). Claims 1 and 3 are independent.

1. Sakai (Ex. 1002)

Sakai relates to an oximeter device for measuring the oxygen saturation degree in arterial blood. Ex. 1002, 1:7–9. Figure 1 of Sakai is illustrated as follows:

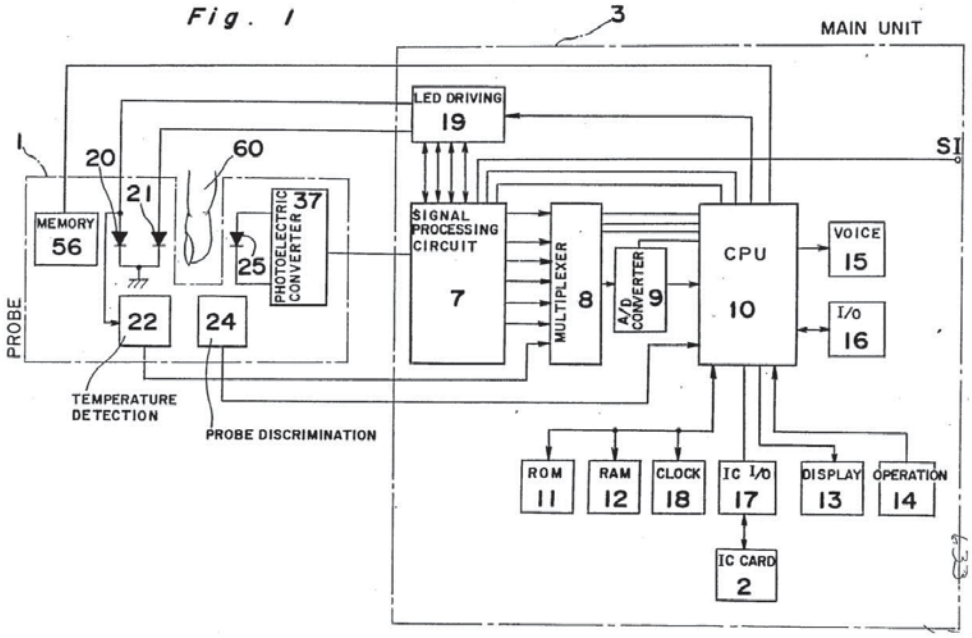

Figure 1 is a block diagram of an oximeter device.

Sakai discloses probe 1 detachably connected to main unit 3. Ex. 1002, 3:13–15. Probe 1 includes LEDs 20, 21 light receiving element 25, and non-volatile memory circuit 56, each of which are connected to CPU 10 in main unit 3. Ex. 1002, 3:15–19, 34–52. Output from light receiving element 25 is

processed by signal processing circuit 7 into a digital signal, which is then used by CPU 10 to calculate an oxygen saturation degree in arterial blood. Ex. 1002, 4:25–37. Main unit 3 includes LED driving unit 19, which supplies power to LEDs 20, 21 of probe 1. Ex. 1002, 4:48–51. LEDs 20, 21 are driven by LED driving unit 19, which is controlled by CPU 10. Ex. 1002, 5:57–60. Non-volatile memory circuit 56 is a rewritable memory, such as an EEPROM, and the data of the time for turning on LEDs 20, 21 may be rewritten by CPU 10. Ex. 1002, 12:59–66.

2. Analysis

Based on the information presented in the Petition and Preliminary Response, as well as all supporting evidence, we are persuaded that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1–4 are unpatentable over Sakai. Pet. 20–56; Prelim. Resp. 7–11. For example, independent claim 1 requires a probe portion including two emitters, a photodetector, and memory. Petitioner's cited portions of Sakai disclose probe 1 including LEDs 20, 21, light receiving element 25, and non-volatile memory circuit 56. Ex. 1002, 3:15–19, 34–52. Independent claim 1 further requires an oximeter portion including "a control unit in communication with said emitters, said photodetector, and said memory unit, said control unit controlling the emitters and calculating the oxygen saturation from signals obtained from the photodetector, and including means for modifying the data in the memory unit." Petitioner's cited portions of Sakai disclose that CPU 10 is in communication with LEDs 20, 21, light receiving element 25, and non-volatile memory circuit 56, controls LED driving unit 19, and writes to non-volatile memory circuit 56. Ex. 1002, 4:25–37, 4:48–51, 5:57–60, 12:59–66. Petitioner admits that

Sakai does not explicitly disclose certain aspects of CPU 10's programming, but provides citations to Sakai, Mr. Pologe's Declaration, and Mr. Kinast's Declaration to support the assertion that any such programming would have been within the abilities of one of ordinary skill at the time of the invention. Pet. 23–24 (citing Exs. 1002, 1003, 1006). Petitioner sets forth similar analyses for claims 2–4. Pet. 39–56 (citing Exs. 1002, 1003).

Patent Owner asserts that the Petition only describes CPU 10 of Sakai as being in communication with memory circuit 56, which is insufficient to correspond properly to the recited "control unit," which Patent Owner proposes construing as "a combination of front-end electronics, a programmed microprocessor and a power source that powers a remote memory chip in a pulse oximeter probe." Specifically, Patent Owner asserts that the Petition only identifies CPU 10 of Sakai as corresponding to the recited "control unit," but that CPU 10 does not include a power source for memory circuit 56. As set forth above, we are unpersuaded that a proper construction of "control unit" requires a power source for memory. Instead, we construe "control unit" as "a microprocessor programmed to be in communication with said emitters, said photodetector, and said memory unit, said microprocessor programmed to control the emitters and calculate the oxygen saturation from signals obtained from the photodetector, and including programming for modifying the data in the memory unit," and determine that, on this record, CPU 10 corresponds properly to the recited "control unit."

Patent Owner asserts further that the Petition is flawed because the Petition does not set forth any articulated reasoning as to why one of ordinary skill in the art would have modified Sakai to include a programmed

processor. Specifically, Patent Owner asserts that the Petition's articulations concerning the modification are conclusory, and to the extent the Petition cites Declarations for evidentiary support, they are improperly incorporated by reference. We disagree. The Petition asserts the following concerning the proposed modification:

> The Sakai Patent does not explicitly recite the processor's programming. Ex. 1003 at ¶ 56. It was well understood, however, by a person of skill in the art in the 1997 time frame, that a processor, such as a CPU or microprocessor, must be programmed to operate. *Id.* The Sakai Patent does explicitly recite the functions that are to be performed by the processor, similar to the disclosure of the '343 Patent. *Id.* The Sakai Patent explains that the CPU functions to write data to the memory element 56. Ex. 1002 at 12:59-67; *see* 9:4-12:67 (describing the CPU's operation in detail); Ex. 1003 at ¶ 56. Providing programming for a processor, including programming for writing to memory, was a well-known and well understood technique. Ex. 1003 at ¶ 56. A person of skill in the art would readily know and understand how to write software to perform the operation of modifying a memory device on a probe by a pulse oximeter without undue experimentation. *Id.* at ¶¶ 56-57; *see also Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1549, 41 U.S.P.Q.2d 1801, 1805 (Fed. Cir. 1997) (writing computer programming code for software to perform specific functions is normally within the skill of the art once those functions have been adequately disclosed).
>
> In other words, as explained by the inventor of the '343 Patent, the "hardware and software changes [that] would need to be made to the oximeter and sensor . . . would have naturally been understood by and were well within the knowledge of a typical engineer working in pulse oximetry." Ex. 1006 at ¶ 7.

Pet. 23–24. In particular, the purported modification is that CPU 10 in Sakai is programmed to write to memory, a modification which has support in Sakai itself at the above-cited locations. Thus, we disagree with Patent

Owner that the reasoning is conclusory, as it is supported by specifically-cited portions of Sakai. Furthermore, we also disagree with Patent Owner that the Petition improperly incorporates evidentiary support from the Declarations by reference. Among several reasons, Sakai is specifically cited, and, as Patent Owner notes, the cited portions of the Declarations are almost identical to the reasoning set forth in the Petition, rendering any alleged incorporation by reference relatively superfluous.

C. Conclusion

On this record, we are persuaded that there is a reasonable likelihood that Petitioner would prevail in showing that claims 1–4 of the '343 Patent are unpatentable. The Board has not made a final determination concerning patentability of any of the challenged claims.

III. ORDERS

After due consideration of the record before us, and for the foregoing reasons, it is:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted as to claims 1–4 of the '343 Patent under 35 U.S.C. § 103(a) as unpatentable over Sakai; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '343 Patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

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