

1 The opinion in support of the decision being entered today was *not* written
2 for publication and is *not* binding precedent of the Board

3
4 UNITED STATES PATENT AND TRADEMARK OFFICE

5
6
7 BEFORE THE BOARD OF PATENT APPEALS
8 AND INTERFERENCES

9
10
11 *Ex parte* JEFFREY M. LEIDEN, OMAR S. KHALIL, ERIC BRIAN
12 SHAIN, STANISLAW KANTOR, SHU-JEN YEH, JAMES J. KOZIARZ,
13 CHARLES F. HANNA, XIAOMAO WU, and RONALD R. HOHS

14
15
16 Appeal 2006-1971
17 Application 10/144,224
18 Technology Center 3700

19
20
21 Decided: March 27, 2007

22
23
24 *Before:* TERRY J. OWENS, STUART S. LEVY, and
25 ANTON W. FETTING, *Administrative Patent Judges.*
26
27 LEVY, *Administrative Patent Judge.*

28
29
30
31 DECISION ON APPEAL

32
33 STATEMENT OF CASE

34 Appellants appeal under 35 U.S.C. § 134 (2002) from a final rejection
35 of claims 1, 3-10, 12-17, 19, and 20. Claims 2, 11, and 18 have been
36 cancelled (Br. 3). We have jurisdiction under 35 U.S.C. § 6(b) (2002).

1 Appellants invented a method and apparatus for determining blood
2 parameters and vital signs in a patient (Specification 1).

3 Claim 1 is representative of the invention and reads as follows:

4 1. An apparatus for monitoring changes in
5 blood parameters and vital signs of a patient, said
6 apparatus comprising:

7
8 a) means for introducing light into a body part
9 of a patient at a light introduction site;

10
11 b) means for collecting optical signals over a
12 period of time from said body part at a light
13 collection site, said means for collecting optical
14 signals capable of sampling tissue layers to a depth
15 of no more than approximately two millimeters,
16 said light introduction site separated from said
17 light collection site by no more than approximately
18 two millimeters;

19
20 c) means for effecting pressure changes or
21 temperature changes or both of the foregoing types
22 of changes in said body part;

23
24 d) means for measuring pressure changes or
25 temperature changes or both types of the foregoing
26 changes experienced by said body part;

27
28 e) means for calculating at least one value of at
29 least one blood parameter of said patient from the
30 collected optical signals, said at least one blood
31 parameter selected from the group consisting of
32 oxygenated hemoglobin, deoxygenated
33 hemoglobin, total hemoglobin, and hematocrit;

1 f) means for determining at least one value of
2 at least one vital sign of the patient from said
3 collected optical signals, said at least one vital sign
4 selected from the group consisting of cardiac pulse
5 rate, temperature, oxygen saturation, blood
6 pressure, and respiratory rate;
7

8 g) means for reporting said at least one value of
9 said at least one blood parameter and said at least
10 one value of said at least one vital sign; and
11

12 h) means for providing an alarm when (1) said
13 at least one value of said at least one vital sign
14 crosses a specified cut-off value or (2) the rate of
15 change in said at least one value of said at least
16 one vital sign crosses a specified cut-off value or
17 (3) said at least one value of said at least one blood
18 parameter crosses a specified cut-off value or (4)
19 the rate of change in the at least one value of the at
20 least one blood parameter crosses a specified cut-
21 off value.
22

23 REFERENCES OF RECORD

24

25 The prior art relied upon by the Examiner in rejecting the claims on
26 appeal is:

27	Gravenstein	US 5,101,825	Apr. 07, 1992
28	Mendelson	US 5,137,023	Aug. 11, 1992
29	Simons	US 5,152,296	Oct. 06, 1992
30	Steuer	US 5,372,136	Dec. 13, 1994
31	Osemwota	US 5,833,602	Nov. 10, 1998
32	Arakaki	US 5,931,779	Aug. 03, 1999

1	Mills	US 5,978,691	Nov. 02, 1999
2	Soller	US 6,006,119	Dec. 21, 1999
3	Aranow	US 6,018,674	Jan. 25, 2000
4	Misner	US 6,222,189	Apr. 24, 2001

5

6

THE REJECTIONS

7

8 The Examiner rejected claims 1, 3-10, 12-17, 19, and 20 under
9 35 U.S.C. § 103(a) (2004).

10 Claims 1 and 3-6, and 19 stand rejected under 35 U.S.C. § 103(a) as
11 being unpatentable over Steuer in view of Soller, Arakaki, Aronow,
12 Mendelson, and Mills.

13 Claims 7, 9, and 13 stand rejected under 35 U.S.C. § 103(a) as being
14 unpatentable over Steuer in view of Soller, Arakaki, and Aronow.

15 Claims 14-16 stand rejected under 35 U.S.C. § 103(a) as being
16 unpatentable over Steuer in view of Soller, Arakaki, Aronow, and
17 Gravenstein.

18 Claim 12 stands rejected under 35 U.S.C. § 103(a) as being
19 unpatentable over Steuer in view of Soller, Arakaki, Aronow, Gravenstein,
20 and Osemwota.

21 Claim 20 stands rejected under 35 U.S.C. § 103(a) as being
22 unpatentable over Steuer, Soller, Arakaki, Aronow, Mendelson, Mills, and
23 Misner.

24 Claim 17 stands rejected under 35 U.S.C. § 103(a) as being
25 unpatentable over Steuer in view of Soller, Arakaki, Aronow, and Simons.

1 Claims 8-10 stand rejected under 35 U.S.C. § 103(a) as being
2 unpatentable over Steuer in view of Soller, Arakaki, Aronow, Misner, and
3 Simons.

4 Appellants contend that the claimed subject matter would not have
5 been obvious. More specifically, Appellants contend with respect to claims
6 1 and 3-6, that claim 1 recites that the means for collecting optical signals
7 penetrates the tissue to a depth of no more than approximately 2mm, and
8 that the light induction site is separated from the light collection site by no
9 more than approximately 2mm. Appellants contend that the prior art does
10 not teach or suggest these features. Appellants additionally contend (Br. 12)
11 that because six references have been applied, that the success of the
12 invention resulting from the combination could not have been predicted in
13 the absence of Appellants' disclosure (Br. 13). It is further contended (*id.*)
14 that the Examiner has used Appellants' disclosure as a road map for selecting
15 and combining prior art disclosures. The same arguments have been
16 presented for the other rejections.

17 The Examiner's contentions can be found on pages 3-13 of the
18 Answer.

19

20 We AFFIRM.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

ISSUE

Have Appellants shown that the Examiner has failed to establish that one skilled in the art would have incorporated the teachings and suggestions of the applied prior art to arrive at the claimed invention. In particular, has the Examiner erred in holding that the applied prior art would have suggested the claimed combination including a sampling depth of no more than approximately 2mm, and that the separation between the light introduction site and the light collecting site is no more than approximately 2mm.

FINDINGS OF FACT

Based upon a preponderance of the evidence we make the following findings of fact.

1. Appellants invented a method an apparatus for determining blood parameters and vital signs of a patient. (Specification 1).
2. The invention provides a method of monitoring a patient that comprises a non-invasive measurement of the hematocrit value or the concentration of hemoglobin coupled with the monitoring of one or more vital signs. The vital signs include cardiac pulse rate, blood pressure, etc. (Specification 6).
3. Optical probe 116 will sample tissue layers to a depth of approximately 2mm, when the separation between the light introduction fiber 120 and one of the light collection fibers

- 1 122, 124, and 126 is approximately 2mm. (Specification
2 19).
- 3 4. Steuer is directed to non-invasive monitoring of hematocrit
4 and other blood parameters of a patient (col. 1, ll. 14-17).
- 5 5. The sensor-emitter separation distances of Steuer are
6 important to provide a detection region in the subdermis 12.
7 The determination of optimum sensor 3 separation and
8 aperture 8 sizes is done empirically. Minimum sensor
9 separation and aperture diameters can be established. (col.
10 12, ll. 17-30).
- 11 6. Fig. 1B of Steuer illustrates a reflective mode system where
12 emitters 1 and photodiodes 3 are on the same side of the
13 patient's finger.
- 14 7. Soller is directed to a non-invasive optical and mathematical
15 method of measuring hematocrit. (col. 1, ll. 44-46).
- 16 8. Figs. 13 A and B of Soller describe a hematocrit measuring
17 device having a separation distance between the LEDs 804
18 and the detector 805 of 2-4mm. (col. 18, l. 66 to col. 19,
19 l. 3).
- 20 9. In addition, Soller describes that a separation of 1-5mm
21 between the illuminating fibers and receiving fibers
22 facilitates adequate depth penetration into the tissue. (col.
23 21, ll. 19-24).
- 24 10. Arakaki is directed to an optical method for non-invasive
25 measurement of muscle tissue oxygen saturation to calculate

1 myoglobin oxygen saturation of muscle tissue. (col. 3, ll.
2 36-38 and 41).

3 11. Arakaki uses a probe having separated illumination fibers in
4 useful reflectance measurements to assure that a discrete
5 minimal optical path length through tissue is obtained. The
6 reference refers to an article that suggests the source to
7 detector separation being roughly twice the average depth of
8 penetration of light into tissue, and that setting the spacing
9 between the two sets of fibers to about 1-3 mm is expected
10 to have an average penetration of about 0.5 mm to about 1.5
11 mm. (col. 8, lines 5-20).

12 12. Aranow is directed to using light, emitted through a patient's
13 finger tip, ear, etc. for use in analyzing a person's blood.
14 The detected light is amplified and used to determine a
15 patient's pulse and oxygen saturation level, and/or
16 oxyhemoglobin, etc. (col. 2, l. 60 to col. 3, l. 8).

17 13. Aranow discloses that in the event that a monitored
18 characteristic goes above/below predetermined threshold
19 values, an audio alarm may sound to alert attending medical
20 personnel. (col. 5, lines 48-57).

21 14. Mendelson indicates that his invention is directed to the
22 accurate measurement of blood analysis based on the
23 principle of transmission and reflection
24 photoplethysmography. Glucose is measured by analyzing
25 the difference or ratio of two different near infrared

- 1 radiations that are reflected from tissue surface before and
2 after blood volume change occurring in the systolic and
3 diastolic phases of the cardiac cycle. (col. 4, ll. 59-68).
- 4 15. The spectral location and magnitude of the near infrared
5 absorption peaks are temperature dependent, and that it is
6 important to perform the measurement under constant
7 temperature. (Mendelson, col. 6, lines 52-62).
- 8 16. In the preferred embodiment, the light sources are lasers.
9 The light is directed to a sample such as the earlobe of the
10 patient. The received light is picked up by detector 5 and
11 processed. (Mendelson, col. 6, l. 64 to col. 7, l.6).
- 12 17. Mills is directed to the non-invasive determination of blood
13 gases, hemoglobin level, etc. (col. 1, ll. 1-4).
- 14 18. Mills discloses using a light signal and photo detector, along
15 with heating/cooling element 16 for controlling the
16 temperature of the patient's finger. (col. 11, ll. 59-63).
- 17 19. Gravenstein is directed to non-invasively measuring
18 hemoglobin and hematocrit levels, etc. (col. 1, ll.1-5 and col.
19 2, ll. 15-17).
- 20 20. Gravenstein discloses, as correctly noted by the Examiner
21 (Answer 7) a method of determining hemoglobin
22 concentration from hematocrit. (col. 4, ll. 4-11).
- 23 21. Misner is directed to a method of enhancing optical signals
24 by mechanical manipulation in non-invasive testing. (col. 1,
25 l. 1-5).

- 1 22. In one method of the invention of Misner, a mechanical
2 pressure is applied in an amount between diastolic and
3 systolic pressure, thereby enhancing the pulsability of the
4 arterial wall. The application of mechanical pressure
5 substantially enhances the pulse relative to the magnitude of
6 the normal cardiac pulse. (col. 5, ll. 58-67).
- 7 23. Controllable pressure device 10 exerts a pressure on a body
8 part located between the radiation source and the detectors
9 22. (Misner, col. 7, l. 66 to col. 8, l. 5).
- 10 24. Osemwota is directed to a process of non-invasive
11 hematology, but also discloses performing calibrations using
12 blood samples. (col. 1, ll. 5-6).
- 13 25. The Examiner held (Answer 8-9) that Osemwota shows it to
14 be well known in the art that optical measurements are
15 initially calibrated using invasive samples. We observe that
16 an invasive sample generally refers to drawing blood from
17 the patient to be tested.
- 18 26. Simons is directed to a dual-finger vital signs monitor that
19 uses a first radiation source and detector for blood pressure
20 measurement and a second radiation source and detector for
21 blood oxygenation measurement. (col. 2, ll. 1-14).

1 PRINCIPLES OF LAW
2

3 On appeal, Appellant bears the burden of showing that the Examiner
4 has not established a legally sufficient basis for combining the teachings of
5 the applied prior art. Appellant may sustain this burden by showing that,
6 where the Examiner relies on a combination of disclosures, the Examiner
7 failed to provide sufficient evidence to show that one having ordinary skill
8 in the art would have done what Appellant did. *United States v. Adams*, 383
9 U.S. 39 (1966); *In re Kahn*, 441 F.3d 977, 987-988, 78 USPQ2d 1329, 1336
10 (Fed. Cir. 2006); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H.*
11 *Patrick, Co.*, 464 F.3d 1356, 1360-1361, 80 USPQ2d 1641, 1645 (Fed. Cir.
12 2006). The mere fact that all the claimed elements or steps appear in the
13 prior art is not per se sufficient to establish that it would have been obvious
14 to combine those elements. *United States v. Adams, id*; *Smith Industries*
15 *Medical Systems, Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1356, 51 USPQ2d
16 1415, 1420 (Fed. Cir. 1999).

17 ANALYSIS
18

19 From our review of the entire record and the findings of fact, *supra*,
20 we hold, for the reasons which follow, that the teachings and suggestions of
21 the applied prior art would have suggested the invention of claims 1, 3-10,
22 22-17, 19, and 20.

23 We begin our analysis with claims 1, 3-6, and 19. From the
24 description of Steuer that the separation distances can be optimized; the
25 description in Soller that the reflectance LEDs and detector can have a

1 separation distance of 2-4 mm; the description of Arakaki that a separation
2 distance of 1-3 mm is expected to have a depth of penetration of 0.5mm –
3 1.5 mm we agree with the Examiner that the combined teachings and
4 suggestion of these references would have suggested the claimed penetration
5 depth of no more than approximately 2 mm and the light
6 introduction/collection separation distance of no more than approximately 2
7 mm. In addition, from the description of Mendelson and Mills of
8 having temperature control of the sample, and the description of Aranow of
9 providing an alarm to medical personnel in the event a monitored
10 characteristic went past a predetermined amount, we conclude that the
11 combined teachings of the applied prior art would have suggested the
12 invention of claims 1 and 3-6 as advanced by the Examiner.

13 We are not persuaded by Appellants' assertion (Br. 11) that in Steuer
14 the light travels completely through the finger because Fig. 1B of Steuer
15 discloses an embodiment having a reflective mode where the light does not
16 go completely through the finger. Nor are we persuaded by Appellants'
17 assertion (*id.*), that the light travels through the patient's finger and that
18 Aranow the penetration depth is greater than the 2 mm set forth in claim 1,
19 because Aranow was not cited for these features, but rather was cited to
20 suggest an alarm to notify medical personnel in the event that monitored
21 characteristic went outside of predetermined range.

22 Nor are we persuaded by Appellants' assertion (*id.*) that Mendelson
23 and Mills do not disclose sampling depth or separation distances because
24 these references were not cited to show sampling depth or separation
25 distances, but rather were cited to show temperature control. Thus, we find

1 that Appellants fail to argue the portions of the references relied upon by the
2 Examiner, but rather argue limitations that the references were not relied
3 upon for.

4 Nor are we persuaded by Appellants' assertion (Br. 12) that in
5 Arakaki, the upper limit of the range exceeds the upper limit of the claimed
6 separation distance. Appellants' argument fails to address the fact that the
7 disclosed range of 1-3 mm separation distance of Arakaki includes therein
8 the no more than approximately 2 mm separation distance.

9 Nor are we persuaded by Appellants' assertion (Br. 12-13) that
10 because of the number of applied references it is likely that the success of
11 the invention from the combination of references is not assured, because the
12 number of references applied is not evidence of non-obviousness. Rather,
13 the issue is whether the combined teachings and suggestions of the prior art
14 as a whole would have motivated an artisan to arrive at the claimed
15 invention. Nor are we persuaded by Appellants' assertion (Br. 13) that the
16 success of the combination could not have been predicted in the absence of
17 Appellants' disclosure, because the different reference have been applied to
18 address different features, each of which is old and well known in the prior
19 art, for the same purpose as Appellants.' In addition, we note that in
20 mechanical arts, there is a high degree of predictability. From the teachings
21 and suggestions of the prior art as outlined on our findings of fact, and the
22 evidence provided in the well reasoned Examiner's answer, we find ample
23 motivation for an artisan to have arrived at the claimed invention.
24 Motivation negates hindsight.

1 From all of the above, we are not convinced of any error on the part of
2 the Examiner in rejecting claims 1 and 3-6, and 19 under 35 U.S.C. § 103(a)
3 . The rejection of claim 1 is sustained. Claims 3-6 have not been argued
4 and Appellants present the same arguments for claims 1 and 19.
5 Accordingly, the rejection of claims 3-6 and 19 under 35 U.S.C.
6 § 103(a) is sustained.

7 We turn next to the rejection of claims 7, 9, and 13. Only claim 7 has
8 been argued by Appellants, so we consider claim 7 to be representative of
9 the group. Claim 7 does not recite the temperature control. As a result, the
10 Examiner did not rely upon Mendelson or Mills for the rejection of these
11 claims. Appellants present the same arguments that were presented for
12 claim 1. Accordingly, we sustain the rejection of claims 7, 9 and 13 for the
13 same reasons as we sustained the rejection of claim 1.

14 We turn next to claims 14-16 under 35 U.S.C. § 103(a) as being
15 unpatentable over Steuer, Soller, Arakaki, Aronow and Gravenstein. The
16 Examiner found (answer 8) that Steuer teaches that hemoglobin
17 concentration can be determined (col. 14, ll. 8-10). The Examiner relied
18 upon Gravenstein for a suggestion of how hemoglobin can be determined
19 and states that the combination determines hemoglobin concentrations using
20 660 nm and 805 nm. Claim 14 recites that the initial determination of total
21 hemoglobin is determined non-invasively using light having wavelengths in
22 the range of about 500 nm to 1100 nm. We observe that Steuer describes
23 that if hematocrit-independent oxygen saturation is desired, the emitter
24 wavelengths would be 660 nm, 805 nm, 950 nm, etc (col. 12, ll. 4-6). As
25 we found, *supra*, Gravenstein describes estimating hematocrit from total

1 hemoglobin (col. 4, ll. 11-22). Appellants do not dispute the Examiner's
2 holding, but rather argues the Gravenstein does not teach the depth
3 penetration or the claimed separation distance and repeats the same
4 arguments presented for claim 1. Thus, we find that Appellants fail to
5 address the portions of the reference relied upon by the Examiner.

6 Accordingly, we are not convinced of any error on the part of the
7 Examiner in rejecting claims 14-16. The rejection of claims 14-16 under
8 35 U.S.C. § 103(a) is sustained.

9 We turn next to the rejection of claim 12 under 35 U.S.C. § 103(a) as
10 being unpatentable over Steuer, Soller, Arakaki, Aranow, Gravenstein and
11 Osemwota. The examiner additionally relies upon Osemwota for a
12 suggestion of using an invasive measurement to initially calibrate the
13 instruments. Appellants do not argue the portions of Osemwota relied upon
14 by the Examiner. Rather, Appellants assert (Br. 20-22) that Osemwota does
15 not teach or suggest the claimed penetration depth and separation distance,
16 and repeats the arguments made for claim 1. From our findings, *supra*, with
17 respect to the suggestions of Osemwota and the failure of Appellants to
18 argue the portions of the reference relied upon by the Examiner, we hold that
19 the prior art would have suggested the language of claim 12 and are not
20 persuaded of any error on the part of the Examiner. The rejection of claim 12
21 under 35 U.S.C. § 103(a) is sustained.

22 We turn next to the rejection of claim 20 under 35 U.S.C. § 103(a) as
23 being unpatentable over Steuer, Soller, Arakaki, Aronow, Mendelson, Mills,
24 and Misner. The Examiner additionally relies upon Misner for a suggestion
25

1 of effecting pressure changes and measuring pressure changes. Appellants
2 do not argue the portion of Misner relied upon by the Examiner but rather
3 argue (Br. 25-28) that Misner does not make up for the deficiencies of the
4 rest of the applied prior art because Misner does not disclose or suggest the
5 claimed depth penetration, and presents the arguments made for claim 1.
6 As we found, *supra*, Misner describes applying mechanical pressure to
7 substantially enhance the magnitude of the normal; cardiac pulse. From this
8 suggestion of Misner, and the failure of Appellants to address the portions
9 of Misner relied upon by the Examiner, we hold that the suggestions of the
10 applied prior art would have suggested the language of claim 20, and are not
11 convinced of any error on the part of the Examiner in rejecting claim 20.
12 The rejection of claim 20 under 35 U.S.C. § 103(a) is sustained.

13 We turn next to the rejection of claim 17 under 35 U.S.C. § 103(a) as
14 being unpatentable over Steuer in view of Soller, Arakaki, Aronow, and
15 Simons. The Examiner notes that Steuer describes measuring pulse and
16 hematocrit, and relies upon Simons for a suggestion of measuring the
17 patient's blood pressure in addition to hematocrit and cardiac pulse rate. As
18 we found, *supra*, Simon's discloses that heart rate and blood pressure, in
19 addition to Electrocardiogram results, suggest the health of a patient.
20 Appellants fail to address the portions of Simons relied upon by the
21 Examiner but rather argue that Simons does not disclose or suggest the
22 claimed depth penetration, and repeat the arguments presented for claim 1.
23 From the disclosure of Simons, and the failure of Appellants to address the
24 portions of Simons relied upon by the Examiner, we hold that the
25 suggestions of the applied prior art would have suggested the language of

1 claim 17, and are not convinced of any error on the part of the Examiner in
2 rejecting claim 17. The rejection of claim 17 under 35 U.S.C. § 103(a) is
3 sustained.

4 We turn next to the rejection of claims 8-10 under 35 U.S.C. § 103(a)
5 as being unpatentable over Steuer in view of Soller, Arakaki, Aronow,
6 Misner and Simons. The Examiner's position can be found on pages 12-13
7 of the Answer. Appellants argue that Misner and Simons do not disclose or
8 suggest the claimed penetration depth, and present the same arguments
9 presented, *supra*. From our review of the record, and our findings, *supra*,
10 with respect to the teachings and suggestions of the applied prior art, we
11 agree with the Examiner that the combined suggestions of the applied prior
12 art would have motivated an artisan to arrive at the claimed invention, and
13 are not persuaded of any errors on the part of the Examiner in rejecting
14 claims 8-10. The rejection of claims 8-10 under 35 U.S.C. § 103(a) is
15 sustained.

16
17 CONCLUSION OF LAW

18
19 On the record before us, we hold that Appellants have failed to show
20 error on the part of the Examiner in rejecting claims 1, 3-10, 12-17, 19
21 and 20.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22

DECISION

The Examiner's rejection of claims 1, 3-10, 12-17, 19, and 20 under
35 U.S.C. § 103(a) is affirmed.

AFFIRMED

vsh

ROBERT DEBERARDINE
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008