PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	01 JUL 2011
Applicant's or agent's file reference: ADCI-219WO	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2011/032542	14 April 2011	16 April 2010

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 5/00 (2011.01)
USPC - 600/365

Applicant ABBOTT DIABETES CARE INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	24 June 2011	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2011/032542

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

   ☐ on paper

   ☐ in electronic form

   b. (time)

   ☐ in the international application as filed

   ☐ together with the international application in electronic form

   ☐ subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2011/032542

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4-5, 12-14, 18-19, 26-28, 30-31, 33-42, 44, 46, 49	YES
	Claims	1-3, 6-11, 15-17, 20-25, 29, 32, 43, 45, 47-48, 51-52	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-55	NO
Industrial applicability (IA)	Claims	1-55	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 6-11, 15-17, 20-25, 29, 32, 43, 45, 47-48 and 51-52 lack novelty under PCT Article 33(2) as being anticipated by Brister et al., hereinafter referred to as Brister.

With regards to claim 1, Brister discloses a system (analyte sensor system 10; see fig. 1, for example) for inherently determining real time analyte concentration (by continuously measuring the analyte concentration in order to alert a patient to his or her current health conditions such as hyperglycemic conditions; see pg. 1, para. 0004 as well as pg. 26, para. 0311; pgs. 31-32, para. 0358 and 0361-0362), comprising:
an analyte sensor (32; see figs. 5A-5C as well as pg. 10, para. 0171-0172) inherently having a portion in fluid contact with an interstitial fluid under a skin layer (by inserting the sensor through the skin which inherently comes into fluid contact with interstitial fluid such as blood; see pg. 4, para. 0103; pg. 8, para. 0151; and pg. 14, para. 0199; wherein the sensor 32 is exposed to analyte beneath the skin; and wherein the analyte includes interstitial fluid as cited from the passages above);
an on-body electronics including a housing (mounting unit 14 with housing/base 24 with electrical contacts 28; see figs. 1 and 3) coupled to the analyte sensor and configured for positioning on the skin layer (see figs. 9A-9C, 10B, 11B and 12C as well as pgs. 8-9, para. 0150, 0157 and 0159), the on-body electronics housing including a plurality of electrical contacts (28; see fig. 1, for example) provided on the housing (via contact holder 34; see figs. 1 and 3); and
a data analysis unit (electronics unit 16 in combination with receiver 158; see figs. 1-3 and 15A, for example) having a data analysis unit housing (see figs. 1-3 and 12A-12C) and including a plurality of probes (contacts for connection with contacts 28 of mounting unit 14; see pg. 8, para. 0155) inherently provided on the data analysis unit housing (for mating engagement with mounting unit 14 and electrical connection via contacts 28 to sensor 32; see pg. 8, para. 0155-0156), each of the plurality of probes on the data analysis unit housing inherently configured to electrically couple to the respective one of the plurality of the electrical contacts on the on-body electronics housing when the data analysis unit is positioned in physical contact with the on-body electronics ();
wherein one or more signals (via contacts 28; see pg. 8, para. 0150, 0155; and pgs. 25-27, para. 0304, 0312-0317; wherein the one or more signals are interpreted to be current signals from the sensor that are indicative of the analyte concentration and is received an processed by processor module 138 of sensor electronics 132 that is interpreted to correspond to a portion of the data analysis unit that comprises electronics unit 16) on the plurality of probes on the data analysis unit housing corresponds to one or more of a substantially real time monitored analyte concentration level, monitored analyte concentration level over a predetermined time period, or a rate of change of the monitored analyte concentration level, or one or more combinations thereof (see pgs. 25-27, para. 0304, 0312-0317; and pgs. 31-32, para. 0353-0355 and 0362-0363; wherein signals correspond to real time/current/continuous analyte concentration measurements as well as monitored analyte concentration levels over a predetermined period of time in order to produce trend graphs).

With regards to claim 15, Brister discloses an inherent associated method comprising:
positioning a portion of an analyte sensor (sensor 32; see figs. 5A-5C as well as pg. 10, para. 0171-0172) in fluid contact with an interstitial fluid under a skin layer (by inserting the sensor through the skin which inherently comes into fluid contact with interstitial fluid such as blood; see pg. 4, para. 0103; pg. 8, para. 0151; and pg. 14, para. 0199; wherein the sensor 32 is exposed to analyte beneath the skin; and wherein the analyte includes interstitial fluid as cited from the passages above);
positioning an on-body electronics housing (housing/base 24 of mounting unit 14; see figs. 1 and 3) coupled to the analyte sensor on the skin layer (see figs. 9A-9C, 10B, 11B and 12C as well as pgs. 8-9, para. 0150, 0157 and 0159), the on-body electronics housing including a plurality of electrical contacts (28; see fig. 1, for example) provided on the housing (via contact holder 34; see figs. 1 and 3); and
contacting a plurality of probes (contacts for connection with contacts 28 of mounting unit 14; see pg. 8, para. 0155) provided on a data analysis unit [electronics unit 16 in combination with receiver 158; see figs. 1-3 and 15A, for example] housing (the outer body of electronics unit 16; see figs. 1-3 and 12A-12C) to the respective one of the plurality of the electrical contacts on the on-body electronics housing (for mating engagement with mounting unit 14 and electrical connection via contacts 28 to sensor 32; see pg. 8, para. 0155-0156) to receive one or more analyte sensor related signals (see pg. 8, para. 0150, 0155; and pgs. 25-27, para. 0304, 0312-0317; wherein the one or more signals are interpreted to be current signals from the sensor that are indicative of the analyte concentration and is received an processed by processor module 138 of sensor electronics 132 that is interpreted to correspond to a portion of the data analysis unit that comprises electronics unit 16) corresponding to one or more of a substantially real time monitored analyte concentration level, monitored analyte concentration level over a predetermined time period, or a rate of change of the monitored analyte concentration level, or one or more combinations thereof (see pgs. 25-27, para. 0304, 0312-0317; and pgs. 31-32, para. 0353-0355 and 0362-0363; wherein signals correspond to real time/current/continuous analyte concentration measurements as well as monitored analyte concentration levels over a predetermined period of time in order to produce trend graphs).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2011/032542

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

With regards to claim 29, Brister discloses an analyte monitoring system (analyte sensor system 10; see fig. 1, for example), comprising: an on-body housing (mounting unit 14 with housing/base 24 with electrical contacts 28; see figs. 1 and 3) having a plurality of external electrical contacts (28; see fig. 1, for example);
a transcutaneous analyte sensor (32; see figs. 5A-5C as well as pg. 10, para. 0171-0172) electrically coupled to the plurality of external electrical contacts (see figs. 10B, 11B, and 12C) and extending from the on-body housing (see figs. 3, (9A-9Cm 10B, 11B and 12C);
an inherent hand-held analyte measurement instrument (releasable electronics unit 16 in combination with receiver 158; see figs. 1-3 and 15A as well as pg. 25, para. 0297, for example; wherein the electronics unit is inherently a hand held instrument when it is not connected to the mounting unit 14) having an instrument housing (see figs. 1-3, for example) and a plurality of probes (contacts for connection with contacts 28 of mounting unit 14; see pg. 8, para. 0155) inherently extending from the instrument housing (for mating engagement with mounting unit 14 and electrical connection via contacts 28 to sensor 32; see pg. 8, para. 0155-0156), each of the plurality of probes on the instrument housing configured to electrically couple to a respective one of the plurality of the electrical contacts on the on-body housing when the hand-held analyte measurement instrument is positioned in physical contact with the on-body housing (see figs. 11B and 12C as well as pg. 8, para. 0155-0156); and
a temperature sensor unit (temperature probe 140; see fig. 13) coupled to the on-body housing or the hand-held analyte measuring instrument (see fig. 13 as well as pg. 29, para.0335).

With regards to claim 43, Brister discloses an inherent associated method comprising:
positioning an on-body housing (housing/base 24 of mounting unit 14; see figs. 1 and 3) on a skin surface (see figs. 9A-9C, 10B, 11B and 12C as well as pgs. 8-9, para. 0150, 0157 and 0159);
implanting a portion of a transcutaneous analyte sensor (sensor 32; see figs. 5A-5C as well as pg. 10, para. 0171-0172) under the skin surface below the on-body housing (see pg. 4, para. 0103; pg. 8, para. 0151; and pg. 14, para. 0199);
electrically coupling the analyte sensor to a plurality of electrical contacts (28; see fig. 1, for example) provided on the housing (via contact holder 34; see figs. 1 and 3) provided on the on-body housing (see figs. 1-3, 10B, 11B and 12C as well as pg. 8, para. 150, for example); and
inherently providing a temperature sensor (temperature probe 140; see fig. 13) on the on-body housing (see pg. 29, para. 0335);
providing a hand-held analyte measurement instrument (releasable electronics unit 16 in combination with receiver 158; see figs. 1-3 and 15A as well as pg. 25, para. 0297, for example; wherein the electronics unit is inherently a hand held instrument when it is not connected to the mounting unit 14) having an instrument housing (see figs. 1-3, for example) and a plurality of probes (contacts for connection with contacts 28 of mounting unit 14; see pg. 8, para. 0155) inherently extending from the instrument housing (for mating engagement with mounting unit 14 and electrical connection via contacts 28 to sensor 32; see pg. 8, para. 0155-0156), each of the plurality of probes configured to electrically couple to a respective one of the plurality of the electrical contacts on the on-body housing when the hand-held analyte measurement instrument is positioned in physical contact with the on-body housing (see figs. 10B, 11B and 12C as well as pg. 8, para. 0155-0156);
contacting the plurality of probes to the respective plurality of the electrical contacts on the on-body housing to receive one or more analyte sensor related signals (see pg. 8, para. 0150, 0155; and pgs. 25-27, para. 0304, 0312-0317; wherein the one or more signals are interpreted to be current signals from the sensor that are indicative of the analyte concentration and is received an processed by processor module 138 of sensor electronics 132 that is interpreted to correspond to a portion of the data analysis unit that comprises electronics unit 16); and
coupling an inherent temperature measurement circuit within the hand-held analyte measurement instrument with the temperature sensor on the on-body housing (as a part of the processor module 138 of electronics 132 of electronics unit 16; see fig. 13) to electrically couple with the temperature sensor when the hand-held analyte measurement instrument is positioned in physical contact with the on-body housing (in order to use the temperature measurement to add temperature compensation to the calculated glucose value; see pg. 29, para. 0335).

With regards to claims 2, 16, 34 and 47, Brister discloses the analyte sensor being a self powered sensor (see pgs. 27-28, para. 0320-0323).

With regards to claim 3, 17, 35 and 48, Brister discloses the analyte sensor being a glucose sensor (see pg. 25, para. 0296, for example.

With regards to claim 6 and 20, Brister discloses the data analysis unit inherently includes one of a reader or a blood glucose meter (see pgs. 25-27, para. 0296, 0304, 0312-0317; and pgs. 31-32, para. 0353-0355 and 0362-0363; wherein the inherent reader or blood glucose meter is interpreted to be the processor 138 of sensor electronics 132 of the electronics unit 16 in combination with processor module 176, output module 178 and user interface 160 of receiver 158; see figs. 13 and 15A).

With regards to claim 7, 21 and 39, Brister discloses the data analysis unit includes an output unit (output module 178 in combination with user interface 160; see fig. 15; wherein the data analysis unit is interpreted to be the electronics unit 16 with electronics 132 of sensor system 10 in connection with receiver 158; see figs. 13 and 15A) to output one or more indications related to the one or more of the substantially real time monitored analyte concentration level, the monitored analyte concentration level over a predetermined time period, the rate of change of the monitored analyte concentration level, or one or more combinations thereof (see fig. 15A as well as pgs. 31-32, para. 0358-0363).

With regards to claim 8 and 22, Brister discloses the output unit includes one or more of a visual output unit, an audible output unit, or a vibratory output unit (see fig. 15A as well as pgs. 31-32, para. 0357-0359).

With regards to claim 9 and 23, Brister discloses the predetermined time period includes about three hours (see pg. 32, para. 0362).

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2011/032542

Supplemental Box

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With regards to claim 10, 24, 38 and 51, Brister discloses the on-body electronics includes one or more data processing components (processor modules 138 and 176; see figs. 13 and 15A) to one or more filter, encode, store, analyze the one or more signals from the analyte sensor (see pgs. 26-27, para. 0312-0317; and pgs. 31-32, para. 0353-0355 and 0362-0363).

With regards to claim 11 and 25, Brister discloses the one or more data processing components inherentlydetermining a three hour trend information based on analyte concentration monitored by the analyte sensor (from the signals that are processed by processor modules 138 and 176; see pgs. 26-27, para. 0312-0317; and pgs. 31-32, para. 0353-0355 and 0362-0363, for a complete and detailed discussion)

With regards to claims 32 and 45, Brister discloses the temperature sensor inherently being thermally connected to the skin through a thermally conductive pathway (in order to sense the temperature in the vicinity of the glucose sensor 32; see pg. 29, para. 0335).

With regards to claim 52, Brister discloses the data processing component determines trend information based on analyte concentration monitored by the analyte sensor (see figs. 13 and 15A as well as pgs. 31-32, para. 0358-0363; wherein the data analysis unit is interpreted to be the electronics unit 16 with electronics 132 of sensor system 10 in connection with receiver 158).

Claims 4-5, 18-19, 37 and 50 lack an inventive step under PCT Article 33(3) as being obvious over Brister in view of Hoss et al., hereinafter referred to as Hoss, and Berner et al., hereinafter referred to as Berner.

With regards to claims 4-5, 18-19, 37, and 50, Brister does not specifically discuss [as per claims 4, 18, 37 and 50] the plurality of electrical contacts on the on-body electronics housing being concentrically positioned on the on-body electronics housing; wherein [as per claims 5 and 19] each of the plurality of electrical contacts on the on-body electronics housing are spaced apart by a predetermined distance relative to each other.
However, the incorporation of concentric conductive patterns within analyte sensor systems that are concentrically positioned on the on body electronic housings, wherein each of the plurality of electrically conductive patterns on the on-body electronics housing are spaced apart by a predetermined distance relative to each other, is well known and of common knowledge in the art as evidenced by Hoss (see figs. 3B and 4B-4C as well as pgs. 3 and 4, para. 0033 and 0036-0037 of Hoss; wherein the on body housing is interpreted to be transmitter portion 102 that is connected to analyte sensor 402; and the conductive patterns is interpreted to be a concentric contact pattern on the housing of the transmitter 102) and Berner (see fig. 1A as well as col. 15, lines 17-35 of Berner; wherein on body housing is interpreted to be collection reservoirs 4 and 6, respectively; and the conductive patterns are associated with concentric spaced conductive patterns 12, 14, 16, and 18 that are upon the reservoirs 4 and 6).
It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the plurality of electrical contacts on the on-body electronics housing of the system of Brister be concentrically positioned on the on-body electronics housing (as shown by Hoss and Berner), wherein each of the plurality of electrical contacts on the on-body electronics housing are spaced apart by a predetermined distance relative to each other, as shown by Berner, for the purpose of consolidating the amount of space that is occupied by the contacts in order to reduce the size of the associated components as well as minimize noise and potential arcing between adjacent contacts.

Claims 12-14, 26-28, 40-42 and 53-55 lack an inventive step under PCT Article 33(3) as being obvious over Brister in view of Cozzette et al., hereinafter referred to as Cozzette.

With regards to claim 12, 26, 40 and 53, Brister does not specifically discuss the on-body electronics comprising a first and second resistor-capacitor [RC] pair in series and electrically coupled to the analyte sensor such that a first voltage across the first RC pair represents a real-time current analyte concentration level, a second voltage across the second RC pair represents an average analyte concentration level over a period of time, and a difference between the first and second voltages represents a real-time trending of the analyte concentration level; and wherein the one or more signals on the plurality of probes on the data analysis unit housing comprises the first voltage and the second voltage.
However the incorporation of RC pairs within analyte sensor systems for the purpose of accurately determining the changes in the concentration of analytes, is well known and of common knowledge in the art as evidenced by Cozzette (see col. 8, line 27-col. 10, line 31 of Cozzette). In addition, Cozzette teaches that RC pairs can be analyzed and manipulated in order to quickly determine analyte concentrations (see col. 9, lines 11-17 of Cozzette). Moreover, the incorporation of multiple RC pairs in various connections such as being connected in series with different voltages across each RC pair for the purpose of optimizing sensor sensitivity and measurement accuracy, is notoriously well known and of common knowledge in the art of sensor/analysis systems; and . the incorporation of voltage signals within analyte sensor systems that represent current analyte concentration levels in combination with voltage signals that represent average analyte concentration levels over a period of time, for the purpose of calibrating sensor data in order to reduce noise and accurately determining trend information associated with changes in analyte concentration over time, is also notoriously well known and of common knowledge in the art
Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the on-body electronics of the system of Brister comprise well known first and second RC pairs and vary the connection of the pairs through routine experimentation and find that the first and second RC pairs should be connected in series and electrically coupled to the analyte sensor such that a first voltage across the first RC pair represents a real-time current analyte concentration level, a second voltage across the second RC pair represents an average analyte concentration level over a period of time, and a difference between the first and second voltages represents a real-time trending of the analyte concentration level; and wherein the one or more signals on the plurality of probes on the data analysis unit housing comprises the first voltage and the second voltage, for the purpose of calibrating sensor data and determine changes in analyte concentration, in order to reduce noise and accurately determining trend information associated with changes in analyte concentration over time.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2011/032542

Supplemental Box

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Continuation of:

With regards to claim 13, 27, 41 and 54, Brister does not specifically discuss the data analysis unit calculates the difference between the first voltage and the second voltage to determine the real-time trending of the analyte concentration level.
However, the incorporation of comparators within data analysis units of analyte sensor systems for calculating differences between two voltage signals in order to isolate analyte concentration information, is notoriously well known and of common knowledge in the art of sensor systems.
Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the data analysis unit of the sensor system of Brister in view of Cozzette calculate, through the use of a well known comparator, the difference between the first voltage and the second voltage to determine the real-time trending of the analyte concentration level, for the purpose of isolate analyte concentration data in order to track changes in concentration.

With regards to claim 14, 28, 42 and 55, Brister discloses the data analysis unit including an output unit (output module 178 in combination with user interface 160 of the data analysis unit that corresponds to receiver 158) that outputs a first indication of the real-time current analyte concentration level and a second indication of the real-time trending of the analyte concentration level (see fig. 15B as well as pg. 32, para. 0362; wherein the inherent real-time current analyte concentration is interpreted to be the single numerical value 186 and the second indication of real-time trending is interpreted to be trend graph 184).

Claims 30-31 and 44 lack an inventive step under PCT Article 33(3) as being obvious over Brister in view of Berner

With regards to claim 30, Brister does not specifically discuss the temperature sensor unit being a thermistor or thermocouple.
However, the incorporation of thermistors or thermocouples within analyte sensor systems for sensing temperature for enabling temperature correction of sensor data, is well known and of common knowledge in the art as evidenced by Berner (see col. 16, lines 43-47 of Berner).
Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the temperature sensor unit be a well known thermistor or thermocouple, as shown by Berner, for the purpose of sensing temperature in order to enable temperature correction of sensor data.

With regards to claim 31, Brister discloses the hand-held analyte measurement instrument further includes an inherent temperature measurement circuit (as a part of the processor module 138 of electronics 132 of electronics unit 16; see fig. 13) to electrically couple with the temperature sensor when the hand-held analyte measurement instrument is positioned in physical contact with the on-body housing (in order to use the temperature measurement to add temperature compensation to the calculated glucose value; see pg. 29, para. 0335).
Yet, Brister does not specifically discuss the temperature sensor being a thermistor.
However, the incorporation of thermistors within analyte sensor systems for sensing temperature for enabling temperature correction of sensor data, is well known and of common knowledge in the art as evidenced by Berner (see col. 16, lines 43-47 of Berner).
Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the temperature sensor unit be a well known thermistor, as shown by Berner, for the purpose of sensing temperature in order to enable temperature correction of sensor data.

With regards to claim 44, Brister does not specifically discuss the temperature sensor unit being a thermistor or thermocouple.
However, the incorporation of thermistors within analyte sensor systems for sensing temperature for enabling temperature correction of sensor data, is well known and of common knowledge in the art as evidenced by Berner (see col. 16, lines 43-47 of Berner).
Thus, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the temperature sensor unit be a well known thermistor, as shown by Berner, for the purpose of sensing temperature in order to enable temperature correction of sensor data.

Claims 33, 36, 46, and 49 lack an inventive step under PCT Article 33(3) as being obvious over Brister.

With regards to claims 33 and 46, Brister does not specifically discuss the hand-held analyte measurement instrument further includes an IR laser configured thermometer to shine on the thermally conductive pathway when the hand-held analyte measurement instrument is positioned in physical contact with the on-body housing.
However, the Brister discloses the incorporation of a temperature probe 140 that is inherently associated with a thermal conductive pathway when the hand held analyte measurement instrument/electronics unit 16 is positioned with the on-body housing in order to sense the temperature in the vicinity of the glucose sensor 32; and the use of IR laser configured thermometers within sensor systems for measuring temperature, is notoriously well known and of common knowledge in the art.
It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the hand-held analyte measurement instrument further includes an IR laser configured thermometer to shine on the thermally conductive pathway when the hand-held analyte measurement instrument is positioned in physical contact with the on-body housing, for the purpose measuring the temperature in the vicinity of the glucose sensor in order to add temperature compensation to the glucose value.

With regards to claims 36 and 49, Brister does not specifically discuss the analyte sensor being a ketone sensor.
However, Brister discloses the concept of the electronics unit 16 being able to detect analyte level concentrations of other types of analytes [outside of glucose]; and ketones are notoriously well known analytes.
It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have the analyte sensor of Brister alternatively be a ketone sensor for the purpose of sensing the levels of ketone within a patient in order to provide an additional way of determining the health status and well being of the patient.

Claims 1-55 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.