

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

CALLAGHAN, Terry S.
Price Heneveld LLP,
695 Kenmoor, S.E.,
P.O. Box 2567
Grand Rapids, Michigan 49501-2567
United States of America

Date of mailing (<i>day/month/year</i>) 06 December 2018 (06.12.2018)		
Applicant's or agent's file reference PAR022326BWO		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US 2018/046260	International filing date (<i>day/month/year</i>) 10 August 2018 (10.08.2018)	Priority date (<i>day/month/year</i>) 10 August 2017 (10.08.2017)
International Patent Classification (IPC) or both national classification and IPC A61B 5/00 (2006.01) G08B 23/00 (2006.01) A61B 5/11 (2006.01) A61F 13/42 (2006.01)		
Applicant PARASOL MEDICAL, LLC		

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 43bis.1(a)(i) with regard to novelty, inventive step and 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 66.1bis(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.

Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Date of completion of this opinion 30 October 2018 (30.10.2018)	Authorized officer S. Lyaskovskiy Telephone No. (495)531-64-81
---	--	--

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 2018/046260

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 43bis.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. ☐ forming part of the international application as filed:
☐ in the form of an Annex C/ST.25 text file.
☐ on paper or in the form of an image file.
 - b. ☐ furnished together with the international application under PCT Rule 13ter.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.
 - c. ☐ furnished subsequent to the international filing date for the purposes of international search only:
☐ in the form of an Annex C/ST.25 text file (Rule 13ter.1(a)).
☐ on paper or in the form of an image file (Rule 13ter.1(b) and Administrative Instructions, Section 713).
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/US 2018/046260

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 6-11, 24, 31-33, 38, 52-54, 58, 64-75, 85-89, 110-113, 117-120, 124-127, 131
because:
- ☐ the said international application, or the said claims Nos. _____ relate to the following
subject matter which does not require an international search (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed (*specify*):

- ☒ no international search report has been established for said claims Nos. 6-11, 24, 31-33, 38, 52-54, 58, 64-75, 85-89, 110-113, 117-120, 124-127, 131

- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing in the form of an Annex C/ST.25 text file, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ furnish a sequence listing on paper or in the form of an image file complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in the form and manner acceptable to it; or the sequence listing furnished did not comply with the standard provided for in Annex C of the Administrative Instructions.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

- ☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US 2018/046260

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

1. Statement

Novelty (N)	Claims	3-5, 61, 62, 77-83, 93, 95-100, 102	YES
	Claims	1, 2, 12-23, 25-30, 34-37, 39-51, 55-57, 59, 60, 63, 76, 84, 90-92, 94, 101, 103-109, 114-116, 121-123, 128-130, 132-134	NO
Inventive step (IS)	Claims		YES
	Claims	1-5, 12-23, 25-30, 34-37, 39-51, 55-57, 59-63, 76-84, 90-109, 114-116, 121-123, 128-130, 132-134	NO
Industrial applicability (IA)	Claims	1-5, 12-23, 25-30, 34-37, 39-51, 55-57, 59-63, 76-84, 90-109, 114-116, 121-123, 128-130, 132-134	YES
	Claims		NO

2. Citations and explanations:

D1 US 2008/0278336 A1

D2 US 2015/0109442 A1

D1 discloses a patient movement notification system ([0001], [0065]), comprising: a first sensor pad comprising a pressure sensor for sensing pressure applied by a patient, and a transmitter circuit for transmitting first wireless signals ([0001], [0011], [0015], [0038], [0062], [0065]); a second sensor pad comprising a pressure sensor for sensing pressure applied by a patient, and a transmitter circuit for transmitting second wireless signals ([0001], [0011], [0015], [0038], [0062]); and a monitor ([0010], [0062]-[0063]) having a receiver for receiving the first and second wireless signals, the monitor generating a notification of patient movement in response to one of the first and second wireless signals if the pressure signal indicates that the patient is no longer applying pressure to the sensor pad ([0010], [0062]-[0063]), wherein the monitor comprises an input for allowing a user to cause the monitor to terminate responsiveness to all sensor pads from which it receives wireless signals ([0044], [0049], [0065], [0076]), wherein the monitor comprises a plurality of inputs and a controller coupled to the plurality of inputs, wherein the controller is configured to reset to a factory preset condition in response to simultaneous activation of at least one of the plurality of inputs by the patient caregiver ([0052], [0071]), wherein the monitor comprises a hold input for allowing a patient caregiver to prevent generation of a notification of patient movement in response to the pressure signal from the sensor pad for a first predetermined time period after the hold input has been activated by the patient caregiver to allow the patient caregiver to temporarily remove the patient from the sensor pad ([0065], [0076]); wherein the second sensor pad is a different type of sensor pad from said first sensor pad ([0037], [0058]-[0059], [0062]), wherein the first and second wireless signals include a type code that identifies the type of sensor pad from which the first and second wire-

Supplemental Box

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

less signals are sent ([0015], [0051], [0079]), and wherein the first and second wireless signals include an active code that identifies whether the sensor pad from which the first and second wireless signals are sent is active ([0012], [0015], [0080]). The present patient movement notification system also comprises: a removable key module associated with the monitor and including a module ID code ([0012], [0015], [0051], [0079]-[0080]), wherein the first and second sensor pads each include a connector for electrically coupling to the removable key, and wherein the first and second sensor pads receive the module ID code from the removable key and subsequently includes the module ID code in the first and second wireless signals ([0012], [0015], [0051], [0079]-[0080]); a motion sensor in communication the monitor for detecting movement of the patient ([0001], [0010]-[0011], [0015], [0038], [0062]-[0065]), wherein the monitor tracks a time period from the last detected movement and generates a notification of non-movement if the motion sensor does not detect movement of the patient for at least a threshold time period ([0001], [0010]-[0011], [0015], [0038], [0062]-[0065], [0069]); a light strip for selectively illuminating an area where the patient is located ([0065], [0067]), wherein the monitor is communicatively coupled to the light strip for controlling the light strip to illuminate the area in response to the pressure signal if the pressure signal indicates that the patient is no longer applying pressure to the sensor pad ([0065], [0067], [0073]-[0074]). Herewith, the notification of patient movement can be transmitted to a mobile communication device of a caregiver ([0010], [0062]-[0063], [0080]). Moreover, the monitor further includes: at least one user input, a speaker, and a controller coupled to the receiver, the user input, and the speaker, wherein the controller is responsive to inputs received from the user input and controls the speaker to play back confirmation tones or pre-recorded vocal confirmations of actuation of the user inputs ([0065], [0073], [0077], [0080]); a touchscreen display coupled to the controller, wherein the controller is responsive to inputs received from the touchscreen display and controls images displayed on the touchscreen display ([0010], [0062]-[0063]). Thus, the controller determines whether the pressure signal indicates that the patient is no longer applying pressure to the sensor pad and generates a notification of patient movement in response to the pressure signal if the pressure signal indicates that the patient is no longer applying pressure to the sensor pad ([0010], [0062]-[0063]). The system known from D1 can comprise the light for illuminating an area near the patient ([0065], [0068], [0078]), wherein the controller controls the at least one light to selectively illuminate the area near the patient ([0065], [0068], [0078]).

Therefore, the inventions of independent claims 1, 15, 19, 25, 39, 49, 55, 104, 107, 121, 128, 132 do not meet the criterion of novelty.

The system of independent claim 94 differs from this known from D1 in that it comprises: a nurse call relay device having a nurse call transceiver for providing two-way communication with the monitor transceiver, wherein the monitor transceiver transmits notification signals to the nurse call transceiver, and the nurse call transceiver transmits periodic status signals to the monitor transceiver.

Therefore, the invention of independent claim 94 meets the criterion of novelty.

However, said distinguishing features, providing two-way communication with a nurse in critical situations, are obvious for a person skilled in the art. Thus, the invention of independent claim 94 does not meet the criterion of inventive step.

D1 discloses a notification system for providing patient movement notification ([0001], [0065]) and incontinence notification ([0002], [0079]), wherein the notification system comprises: a pressure sensor pad comprising a pressure sensor for sensing pressure applied by a

Supplemental Box

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

patient and a transmitter for generating a pressure signal in response to the pressure sensor ([0001], [0011], [0015], [0038], [0062]); an incontinence sensor pad comprising an incontinence sensor for sensing moisture due to incontinence ([0001]-[0002], [0025], [0038]), a transmitter associated with the incontinence sensor pad for transmitting a moisture detection signal in response to the incontinence sensor ([0014]-[0015], [0040]); and a monitor ([0010], [0062]-[0063]) comprising a receiver for receiving the pressure signal and the moisture detection signal, wherein the monitor generates a notification of patient movement in response to the pressure signal, and generates a notification of incontinence in response to receipt of the moisture detection signal ([0062]-[0063], [0066]).

Therefore, the invention of independent claims 12 does not meet the criterion of novelty.

D1 discloses a sensor device for a patient activity notification system ([0001], [0061], [0065]), comprising: a sensor for sensing a patient activity ([0001], [0065]); a housing including a slot in which two electrical contacts are biased towards one another ([0037], [0039]); a kill tab ([0044], [0065]) removably disposed in the slot to connect to an electrical wire extending between the two electrical contacts, the electrical wire permitting current to flow between the two contacts, wherein, when the kill tab is removed from the slot, the electrical wire is pulled from at least one of the two electrical contacts so that current is prevented from flowing through the two electrical contacts ([0013], [0043]-[0044], [0065]); and a controller coupled to the sensor for determining whether to generate a patient activity signal in response to patient activity sensed by the sensor ([0047]-[0048]), wherein at least one of the two electrical contacts is coupled to the controller and the controller senses whether current is flowing through the two electrical contacts ([0047]-[0048]), and wherein, when the controller senses that current is not flowing through the two electrical contacts, the controller executes a shutdown routine and thereafter no longer executes any further steps or instructions so as to terminate the functionality of the sensor device ([0013], [0043]-[0044], [0047]-[0048], [0065]).

Therefore, the invention of independent claim 34 does not meet the criterion of novelty.

D1 discloses an incontinence warning system ([0001], [0065]), comprising: a sensor pad comprising a moisture sensor for sensing moisture due to incontinence ([0001], [0065]); a transmitter associated with the sensor pad for transmitting a moisture detection signal in response to the incontinence sensor ([0014]-[0015], [0040]); and a monitor ([0010], [0062]-[0063]) having a receiver for receiving the moisture detection signal, the monitor generates a notification of incontinence in response to receipt of the moisture detection signal ([0010], [0025], [0038]), wherein the monitor comprises a hold input for allowing a patient caregiver to prevent generation of a notification of incontinence in response to the moisture detection signal from the sensor pad for a first predetermined time period after the hold input has been activated by the patient caregiver to allow the patient caregiver an extended period to respond to an incontinence event ([0065], [0076]).

Therefore, the invention of independent claim 46 does not meet the criterion of novelty.

D1 discloses an incontinence sensing system ([0001], [0011], [0015], [0038], [0062], [0065]) comprising: an incontinence sensor pad comprising first and second electrically conductive tracings on a surface thereof that extend to a terminal portion of the surface ([0001], [0013], [0043]-[0044], [0065], fig. 2-3); and an incontinence electronic module releasably attached to the terminal portion of the surface of the incontinence sensor pad ([0013]-[0015], [0040], [0043]-[0044], [0065], fig. 2-3), wherein the incontinence electronic module comprises: electrical contacts for creating an electrical connection to the first and second electrically conductive tracings ([0013], [0043]-[0044], [0065]), and a circuit coupled to the electrical

Supplemental Box

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

contacts for sensing moisture across the first and second electrically conductive tracings and for generating an incontinence alarm signal when moisture is sensed ([0010], [0025], [0038], [0062]-[0065], [0076]).

Therefore, the invention of independent claim 59 does not meet the criterion of novelty.

The incontinence sensing system of independent claim 93 differs from this known from D1 in that it comprises: a temperature sensor for sensing the temperature of a patient lying on the incontinence sensor pad; and the circuit generates a bed sore advance warning signal when the temperature sensed by the sensing circuit reaches a threshold temperature.

Therefore, the invention of independent claim 93 meets the criterion of novelty.

However, D2 discloses an incontinence sensing system ([0164], [0307]), comprising: a temperature sensor for sensing the temperature of a patient lying on the incontinence sensor pad; and a circuit generating a bed sore advance warning signal when the temperature sensed by the sensing circuit reaches a threshold temperature ([0028], [0164], -0203], [0307]). Thus, the invention of independent claim 93 does not meet the criterion of inventive step.

D1 discloses an incontinence sensing pad ([0001], [0011], [0015], [0038], [0062], [0065]) comprising: a substrate having a surface ([0001], [0065]); a first electrically conductive tracing on the surface of the substrate, which includes a first conductive bus connected to a first plurality of interdigitated conductive extensions, wherein the first conductive bus extends to a terminal portion of the surface ([0013], [0043]-[0044], [0065], fig. 2-3); and a second electrically conductive tracing on the surface of the substrate, which includes a second conductive bus connected to a second plurality of interdigitated conductive extensions, wherein the second conductive bus extends to the terminal portion of the surface ([0013], [0043]-[0044], [0065], fig. 2-3).

Therefore, the invention of independent claim 76 does not meet the criterion of novelty.

D1 discloses an incontinence chuck ([0001], [0011], [0015], [0038], [0043], [0062], [0065]) comprising: a substrate having a surface ([0001], [0065]); and an absorbent material disposed across at least a portion of the surface of the substrate ([0059]), wherein the absorbent material includes a color change material that changes color in response to moisture absorbed such that a caretaker can determine a relative volume of moisture that has been absorbed based upon a size of the absorbent material that has changed color ([0059]).

Therefore, the invention of independent claim 90 does not meet the criterion of novelty.

D1 discloses a patient movement notification system ([0001], [0065]), comprising: a toilet seat belt ([0058]) for securing a patient to a toilet, which comprises: a releasable clip connecting two portions of the seat belt to secure the patient; and a clip sensor for sensing whether the releasable clip is connecting the two portions of the seat belt; and a signal generator for generating an alarm signal when the clip sensor detects that the releasable clip no longer senses that the releasable clip is connecting the two portions of the seat belt ([0010], [0058],[0062]-[0063]).

Therefore, the invention of independent claim 101 does not meet the criterion of novelty.

D1 discloses an incontinence warning system ([0001], [0011], [0015], [0038], [0043], [0062], [0065]), comprising: a sensor pad comprising a moisture sensor for sensing moisture due to incontinence ([0001], [0013], [0043]-[0044], [0065], fig. 2-3); a transmitter associated with the sensor pad for transmitting a moisture detection signal in response to the incontinence sensor ([0010], [0062]-[0063]); and a monitor ([0010], [0062]-[0063]) having a receiver for receiving the moisture detection signal, wherein the monitor generates a notification of incontinence in response to receipt of the moisture detection signal ([0010], [0062]-[0063]), wherein the

Supplemental Box

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

notification of incontinence is transmitted to a mobile communication device of a caregiver ([0010], [0062]-[0063], [0080]).

Therefore, the invention of independent claim 114 does not meet the criterion of novelty.

With respect to dependent claims (considering the above), the following should be noted:

D1 discloses that the first and second wireless signals include an active code that identifies whether the sensor pad from which the first and second wireless signals are sent is active ([0015], [0051], [0079]); the monitor is configured to respond to wireless signals from only one sensor pad of a particular type ([0004], [0063]); the incontinence sensor pad is generally rectangular and the second terminal portion of the surface is proximate an opposite side of the incontinence sensor pad (fig. 1-2).

The features characterizing, for example, that: only one of the first and second sensor pads is active at any time; a monitor is configured to respond to wireless signals from only one sensor pad of certain type; the configuration of the chuck and the material from which it is made; the presence of a plug and a receptacle in the nurse call relay device; the presence of a toilet sensor pad comprising a pressure sensor for sensing pressure applied by a patient to a toilet seat on the toilet; etc., are obvious for the skilled person.

Thus, the inventions of dependent claims 2, 13, 14, 16-23, 26-30, 35-37, 40-45, 47, 48, 50, 51, 56, 57, 60, 63, 84, 91, 92, 103, 105, 106, 108, 109, 115, 116, 122, 123, 129, 130, 133, 134 do not meet the criterion of novelty; while the inventions of dependent claims 3-5, 61, 62, 77-83, 95-100, 102 do not meet the criterion of inventive step.

The inventions of claims 1-5, 12-23, 25-30, 34-37, 39-51, 55-57, 59-63, 76-84, 90-109, 114-116, 121-123, 128-130, 132-134 meet the criterion of industrial applicability.