From: INTERNATIONAL SEARCHING AUTHORITY

To: SPRUSON & FERGUSON (ASIA) PTE LTD
P.O. Box 1531, Robinson Road Post Office
903031 Singapore
Singapore

CORRECTED VERSION

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)
20 December 2016

FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference
1105SG188

International application No.
PCT/SG2016/050408

International filing date (day/month/year)
24 August 2016

Priority date (day/month/year)
24 August 2015

International Patent Classification (IPC) or both national classification and IPC
A61B 5/00 (2006.01) G01N 33/00 (2006.01)

Applicant
TEMASEK POLYTECHNIC

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

<table>
<thead>
<tr>
<th>Box No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>X</td>
<td>Basis of the opinion</td>
</tr>
<tr>
<td></td>
<td>Priority</td>
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<tr>
<td></td>
<td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td>
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<td></td>
<td>Lack of unity of invention</td>
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<tr>
<td>X</td>
<td>Reasoned statement under Rule 43bis 1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement</td>
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<td></td>
<td>Certain documents cited</td>
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<td>Certain defects in the international application</td>
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<td>Certain observations on the international application</td>
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</tbody>
</table>

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
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606,
AUSTRALIA
Email address: pct@ipaustralia.gov.au

Date of completion of this opinion
21 April 2017

Authorised Officer
Ariane Le Guen
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. 0399359657
<table>
<thead>
<tr>
<th>Box No. 1</th>
<th>Basis of this opinion</th>
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<tbody>
<tr>
<td>1.</td>
<td>With regard to the <strong>language</strong>, this opinion has been established on the basis of:</td>
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<tr>
<td></td>
<td>X The international application in the language in which it was filed</td>
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<td>A translation of the international application into., which is the language of a translation furnished for the purposes of international search (under Rules 12.5(a) and 23.1(b)).</td>
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<td>2.</td>
<td>This opinion has been established taking into account the <strong>rectification of an obvious mistake</strong> authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))</td>
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<td>3.</td>
<td>With regard to any <strong>nucleotide and/or amino acid sequence</strong> disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:</td>
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<td>a. (means)</td>
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<td>b. (time)</td>
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<td>4.</td>
<td>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.</td>
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<tr>
<td>5.</td>
<td>Additional comments:</td>
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</table>
1. Statement

Novelty (N) Claims 2-3, 5-6, 13-14 YES
Claims 1, 4, 7-12, 15-17 NO
Inventive step (IS) Claims NONE YES
Claims 1-17 NO
Industrial applicability (IA) Claims 1-17 YES
Claims NONE NO

2. CITATIONS AND EXPLANATIONS:

CITATIONS

NOVELTY (N)

Document D1:

Claims 1, 4, 7 lack novelty and do not satisfy Article 33(2) of the PCT in view of Document D1.

D1 discloses a sensing system for detecting a substance in a dialysate (abstract), comprising: a hydrophobic barrier (240, Fig. 2a) capable of allowing the substance in the dialysate to equilibrate through the barrier to a gas (para 35 “Ammonia gas diffusing through the hydrophobic membrane 240 is collected via an ammonia channel 213 for further processing.”); a detector capable of detecting the gas (214); and an interface disposed between the hydrophobic barrier and the detector and configured to allow transport of the gas between the hydrophobic barrier and the detector following a concentration gradient of the gas along the interface (ammonia channel 213, the definition of a concentration gradient is the process of particles moving through a solution or gas from an area with a higher number of particles to an area with a lower number of particles. This occurs in D1 as the dialysate is moving through the hydrophobic membrane). Therefore D1 discloses all the features of claim 1.

Claim 4: Fig. 2a, para 35

Claim 7: abstract

Therefore D1 discloses all the features of claims 1, 4, 7.

Document D2:

Claims 1, 4, 7-9, 11-12, 15-17 lack novelty and do not satisfy Article 33(2) of the PCT in view of Document D2.

D2 discloses a sensing system for detecting a substance in a dialysate (abstract), comprising: a hydrophobic barrier (150, Fig. 2B) capable of allowing the substance in the dialysate to equilibrate through the barrier to a gas; a detector capable of detecting the gas (140, Fig. 2B); and an interface disposed between the hydrophobic barrier and the detector and configured to allow transport of the gas between the hydrophobic barrier and the detector following a concentration gradient of the gas along the interface (conduit between ammonia sensor 140 and hydrophobic membrane 150, the definition of a concentration gradient is the process of particles moving through a solution or gas from an area with a higher number of particles to an area with a lower number of particles. This occurs in D1 as the dialysate is moving through the hydrophobic membrane). Therefore D2 discloses all the features of claim 1.

Claim 4: page 42 lines 27-31

Form PCT/ISA/237 (Box V) (July 2011)
Claim 7: ammonia sensor 140

Claim 8: page 42 line 30

Claim 9: page 45 line 15, Fig. 4a, 400

D2 discloses a sensing system for detecting a substance in a dialysate, comprising: a hydrophobic barrier (150, Fig. 2B) in contact with the dialysate and capable of allowing the substance in the dialysate to equilibrate through the barrier to a gas; a detector capable of detecting the gas (140, Fig. 2B); an interface disposed between the hydrophobic barrier and the detector and configured to allow fluid communication of the gas between the hydrophobic barrier and the detector (passed check valve); and a deformable diaphragm (71, Fig. 2B) in contact with the dialysate and configured to produce a back and forth gas movement within the interface in response to fluid pressure variations in the dialysate (page 41 line 31-page 42, line 10-23). Therefore D2 discloses all the features of claim 11.

Claim 12: page 40, line 26- page 41 line 11; page 42, line 10-23

Claim 15: page 24, line 14

Claim 16: page 24, line 18

Claim 17: claim 36

Therefore D2 discloses all the features of claims 1, 4, 7-9, 11-12, 15-17.

**Document D3:**

**Claims 1, 4, 7, 10 lack novelty and do not satisfy Article 33(2) of the PCT in view of Document D3.**

D3 discloses a sensing system for detecting a substance in a dialysate, comprising: a hydrophobic barrier capable of allowing the substance in the dialysate to equilibrate through the barrier to a gas (121, 122, Fig. 7); a detector capable of detecting the gas (137, Fig. 7); and an interface disposed between the hydrophobic barrier and the detector and configured to allow transport of the gas between the hydrophobic barrier and the detector following a concentration gradient of the gas along the interface (the conduits between the hydrophobic barrier and the sensor). Therefore D3 discloses all the features of claim 1.

Claim 4: para 87

Claim 7: para 88

Claim 10: para 92

Therefore D3 discloses all the features of claims 1, 4, 7, 10.

**Document D4:**

**Claims 1, 4, 7-8 lack novelty and do not satisfy Article 33(2) of the PCT in view of Document D4.**

D4 discloses a sensing system for detecting a substance in a dialysate, comprising: a hydrophobic barrier capable of allowing the substance in the dialysate to equilibrate through the barrier to a gas (page 20 lines 9-21, gas remover 94); a detector capable of detecting the gas (ammonia sensor 97); and an interface disposed between the hydrophobic barrier and the detector and configured to allow transport of the gas between the hydrophobic barrier and the detector following a concentration gradient of the gas along the interface (conduits that can be seen in Fig. 1b). Therefore D4 discloses all the features of claim 1.

Claim 4: page 20 line 19

Claim 7: page 20 line 5
Claim 8: page 20 line 10

Therefore D4 discloses all the features of claims 1, 4, 7-8.

Therefore the subject matter of claims 1, 4, 7-12, 15-17 is not new and does not meet the requirements of Article 33(2) of the PCT with regard to novelty.

Claims 2-3, 5-6, 13-14 meets the criteria set out on PCT Article 33(2) with regard to novelty. The prior art published before the priority date does not disclose wherein the interface is a certain length, wherein the hydrophobic barrier comprises a deformable diaphragm that is configured to deform in response to pressure changes in the dialysate, wherein the interface comprises an ammonia-gas-compatible water absorber within the interface, wherein the hydrophobic barrier comprises the deformable diaphragm.

INVENTIVE STEP (IS)
Claims 1, 4, 7-12, 15-17 lack novelty and therefore also lack an inventive step.

Claims 2 and 3 are considered to lack an inventive step in light of any one of D1-D4 because varying length of the interface are merely design variations that any person skilled in the art would be expected to make and therefore cannot contribute to a patentable invention.

Claims 5-6 are considered to lack an inventive step in light of any one of D1-D4 because having a deformable diaphragm comprising a hydrophobic barrier is considered merely a choice of one of several obvious known design arrangements would be available for use by the person skilled in the art.

Claim 13 is considered to lack an inventive step in light of D2 because having a deformable diaphragm comprising a hydrophobic barrier is considered merely a choice of one of several obvious known design arrangements would be available for use by the person skilled in the art.

Claim 14 is considered to lack an inventive step in light of D2 because a peristaltic pump is well known in the art and amounts to common general knowledge and therefore cannot contribute to a patentable invention.

Therefore, the subject matter of all claims 1-17 is obvious and does not meet the requirements of Article 33(3) of the PCT with regard to inventive step.

INDUSTRIAL APPLICABILITY (IA)
The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.