

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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Date of mailing  
(day/month/year)

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Applicant's or agent's file reference  
204293-WO

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US22/38775

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ADD. A61B 2090/401; A61B 2217/007; A61F 2002/30584; A61L 27/3616; A61L 27/3641; A61L 27/365; A61M 2209/06

Applicant KINAMED, 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 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/  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450, Alexandria, Virginia 22313-1450  
Facsimile No. 571-273-8300

Date of completion of this opinion

11 October 2022 (11.10.2022)

Authorized officer

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**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(b)).

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:

- a. ☐ forming part of the international application as filed.  
b. ☐ furnished subsequent to the international filing date for the purposes of international search (Rule 13*ter*.1(a)),  
☐ accompanied by a statement to the effect that the sequence listing does not go beyond the disclosure in the international application as filed.

4. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established to the extent that a meaningful opinion could be formed without a WIPO Standard ST.26 compliant sequence listing.

5. Additional comments:

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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. 4, 7-10, 16, 19-20

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. 4, 7-10, 16, 19-20 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 4, 7-10, 16, 19-20 are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

☐ 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. 4, 7-10, 16, 19-20

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

☐ furnish a sequence listing complying with WIPO Standard ST.26, and such listing was not available to the International Searching Authority in the form, language and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a).

☐ See Supplemental Box for further details.

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**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 | 1-3, 5-6, 11-15, 17-18 | YES |
|                               | Claims | NONE                   | NO  |
| Inventive step (IS)           | Claims | NONE                   | YES |
|                               | Claims | 1-3, 5-6, 11-15, 17-18 | NO  |
| Industrial applicability (IA) | Claims | 1-3, 5-6, 11-15, 17-18 | YES |
|                               | Claims | NONE                   | NO  |

**2. Citations and explanations:**

Claims 1 and 3/1 lack an inventive step under PCT Article 33(3) as being obvious over US 5,037,437 A to Matsen, F. (hereinafter "MATSEN") in view of US 6,322,785 B1 to Landesberg, R. et al. (hereinafter "LANDESBERG").

As per claim 1, MATSEN discloses a method of preparing a bone surface of a bone of a patient for an arthroplasty surgery of an implant (a method of bone preparation including on a bone surface of a bone of a patient for an arthroplasty surgery of an implant; column 4, lines 53-68), said method comprising the steps of: providing one or more materials prepared (providing one or more bone cement 22 (material) prepared; column 5, lines 1-8); resecting or shaping the bone surface of the bone for acceptance of a arthroplasty implant (sculpting (resecting or shaping) the bone surface of the bone for acceptance of an arthroplasty implant; column 4, lines 53-68); applying a dry gas to the bone surface (applying a dry gas to the bone surface; column 6, lines 5-18); and after applying the dry gas, applying the material to the bone surface and/or to the implant (after applying the dry gas, applying the bone cement (material) to the bone surface; column 6, lines 49-56). MATSEN fails to disclose cementless and one or more orthobiologic material prepared from the patient. LANDESBERG discloses cementless and one or more orthobiologic materials prepared from the patient (including platelet-rich plasma gel and matrix prepared as autologous thus from the patient; column 3, lines 28-46; column 6, lines 23-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of MATSEN to include cementless, as taught by LANDESBERG, in order to gain the advantages of reducing risks including compatibility problems, disease transmission dangers, clerical and storage errors (see LANDESBERG column 1, lines 30-36).

As per claim 3/1, MATSEN in view of LANDESBERG discloses the method according to claim 1. Modified MATSEN discloses wherein said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface (said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface; column 6, lines 5-24).

Claims 2, 3/2, 5-6 lack an inventive step under PCT Article 33(3) as being obvious over MATSEN in view of LANDESBERG in further view of US 4,294,251 A to Greenwald, A. et al. (hereinafter "GREENWALD").

As per claim 2, MATSEN in view of LANDESBERG discloses the method according to claim 1. Modified MATSEN discloses applying the dry gas (applying the dry gas; column 6, lines 5-18). Modified MATSEN fails to disclose further comprising cleaning the bone surface prior to applying. GREENWALD discloses further comprising cleaning the bone surface prior to applying (cleaning the bone surface prior to insertion; column 2, line 36). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of MATSEN to include further comprising cleaning the bone surface prior to applying, as taught by GREENWALD, in order to gain the advantages of providing for better fixation of the prosthetic device (see GREENWALD column 2, lines 37-38).

As per claim 3/2, MATSEN in view of LANDESBERG in further view of GREENWALD discloses the method according to claim 2. Modified MATSEN discloses wherein said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface (said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface; column 6, lines 5-24).

As per claim 5, MATSEN in view of LANDESBERG discloses the method according to claim 1 or 2. Modified MATSEN fails to disclose further comprising applying suction to suction away fat, marrow and blood, and/or saline solution, from a region of the bone, the region including the bone surface. GREENWALD discloses further comprising applying suction to suction away fat, marrow and blood, and/or saline solution, from a region of the bone, the region including the bone surface (applying suction to suction away soft tissue which includes fat and hematopoietic and other fluid from a region of the bone, the region includes the bone surface; column 2, lines 33-54; claims 2-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of MATSEN to include further comprising applying suction to suction away fat, marrow and blood, and/or saline solution, from a region of the bone, the region including the bone surface, as taught by GREENWALD, in order to gain the advantages of providing for better fixation of the prosthetic device (see GREENWALD column 2, lines 37-38).

As per claim 6, MATSEN in view of LANDESBERG in further view of GREENWALD discloses the method according to claim 5. Modified MATSEN discloses wherein said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface (said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface; column 6, lines 5-24).

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Claims 11-15, and 17-18 lack an inventive step under PCT Article 33(3) as being obvious over US 5,514,135 A to Earle, M. (hereinafter "EARLE") in view of MATSEN in further view of LANDESBERG.

As per claim 11, EARLE discloses a system for a bone surface of a bone of a patient for an arthroplasty surgery of an implant (a bone cement delivery gun 10 (system) for facilitating (preparing) delivery to a bone surface of a bone of a patient for a hip replacement (arthroplasty surgery) for attachment of a prosthetic (implant); column 1, lines 11-12; column 1, lines 64-67; column 2, lines 33-37), said system comprising: a hand piece having a hand piece body having an inlet port (a second housing 14 (hand piece) having a first housing 12 (hand piece body) having a filling port 34 (inlet port); fig 1; column 2, lines 41-67), an outlet port (as shown in fig 1 an outlet port near the end wall 30 and a screw mount fitting 32; column 2, lines 44-57), and an internal passageway extending there through from said inlet port to said outlet port forming a flow path (a cylindrically shaped reservoir (internal passageway) extending there through from said filling port 34 to said outlet port thus forming a flow path; fig 1; column 2, lines 44-67), said hand piece having a valve for opening and closing said internal passageway (said second housing 14 having a disc shaped plunger 22 acting as a valve for opening and closing said cylindrically shaped reservoir; fig 1; column 3, lines 13-19), and said hand piece having a trigger configured to adjust said valve (said second housing 14 includes a trigger mechanism adjusting said disc shaped plunger 22; fig 1; column 4, lines 12-34); a nozzle coupled to said hand piece at said output port (an extension nozzle that is not shown coupled to said second housing 14 at said output port with screw mount fitting 32; column 2, lines 44-57); tubing coupled to said hand piece at said input port (an aperture 40 (tubing) coupled to said second housing 14 via first housing 12 at said filling port 34; fig 1; column 2, line 58-column 3, line 2), said tubing coupling to a supply to deliver to said internal passageway for flowing from said outlet port to apply onto the bone surface (said aperture 40 coupling to a supply to deliver to said cylindrically shaped reservoir for flowing from said outlet port applying onto the bone surface; column 2, line 58-column 3, line 2); and a supply of orthobiologic material (a supply of bone cement (orthobiologic material); fig 1; column 2, line 58-column 3, line 2). EARLE fails to disclose a bone preparation system for preparing a bone surface. MATSEN discloses a bone preparation system for preparing a bone surface (a bone preparation system and method for preparing a bone surface; column 4, lines 53-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the system of EARLE to include a bone preparation system for preparing a bone surface, as taught by MATSEN, in order to gain the advantages of providing an implant prosthesis fixation process involving sculpting the bone to a desired shape thus preparing the bone for the fixation. EARLE fails to disclose a cementless arthroplasty surgery. LANDESBERG discloses a cementless arthroplasty surgery (an arthroplasty surgery with a gel matrix of bone graft material thus cementless of an implantation of the gel matrix; column 6, lines 23-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the system of EARLE to include a cementless arthroplasty surgery, as taught by LANDESBERG, in order to gain the advantages of a progressive increase in both load-bearing and complete osteointegration in accordance with conventional analysis (see LANDESBERG column 6, lines 23-50). EARLE fails to disclose dry gas. MATSEN discloses dry gas (applying a dry gas to the bone surface; column 6, lines 5-18). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the system of EARLE to include dry gas, as taught by MATSEN, in order to gain the advantages of achieving a higher penetration into the bone than would otherwise be possible (see MATSEN column 6, lines 49-56).

As per claim 12, EARLE in view of MATSEN in further view of LANDESBERG discloses the bone preparation system according to claim 11. Modified EARLE discloses further a dispenser for applying the orthobiologic material to the bone surface and/or the implant (a fluted end (dispenser) of the extension nozzles for applying the bone cement (orthobiologic material) to the bone surface; column 2, lines 44-57).

As per claim 13, EARLE discloses a system for a bone surface of a bone of a patient for an arthroplasty surgery of an implant (a delivery gun 10 (system) for facilitating (preparing) delivery to a bone surface of a bone of a patient for a hip replacement (arthroplasty surgery) for attachment of a prosthetic (implant); column 1, lines 11-12; column 1, lines 64-67; column 2, lines 33-37), said system comprising: a hand piece having a hand piece body having an inlet port (a second housing 14 (hand piece) having a first housing 12 (hand piece body) having a filling port 34 (inlet port); fig 1; column 2, lines 41-67), an outlet port (as shown in fig 1 an outlet port near the end wall 30 and a screw mount fitting 32; column 2, lines 44-57), and an internal passageway extending there through from said inlet port to said outlet port forming a flow path (a cylindrically shaped reservoir (internal passageway) extending there through from said filling port 34 to said outlet port thus forming a flow path; fig 1; column 2, lines 44-67), said hand piece having a valve for opening and closing said internal passageway (said second housing 14 having a disc shaped plunger 22 acting as a valve for opening and closing said cylindrically shaped reservoir; fig 1; column 3, lines 13-19), and said hand piece having a trigger configured to adjust said valve (said second housing 14 includes a trigger mechanism adjusting said disc shaped plunger 22; fig 1; column 4, lines 12-34); a nozzle coupled to said hand piece at said output port (an extension nozzle that is not shown coupled to said second housing 14 at said output port with screw mount fitting 32; column 2, lines 44-57); a tubing coupled to said hand piece at said input port (an aperture 40 (tubing) coupled to said second housing 14 via first housing 12 at said filling port 34; fig 1; column 2, line 58-column 3, line 2), said tubing coupling to a supply to deliver to said internal passageway for flowing from said outlet port (said aperture 40 coupling to a supply to deliver to said cylindrically shaped reservoir for flowing from said outlet port applying onto the bone surface; column 2, line 58-column 3, line 2); and an orthobiologic dispenser for dispensing orthobiologic material onto or into the bone surface and/or the implant (a fluted end (dispenser) of the extension nozzles for applying the bone cement (orthobiologic material) to the bone surface; column 2, lines 44-57). EARLE fails to disclose a bone preparation system for preparing a bone surface. MATSEN discloses a bone preparation system for preparing a bone surface (a bone preparation system and method for preparing a bone surface; column 4, lines 53-68). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the system of EARLE to include a bone preparation system for preparing a bone surface, as taught by MATSEN, in order to gain the advantages of providing an implant prosthesis fixation process involving sculpting the bone to a desired shape thus preparing the bone for the fixation. EARLE fails to disclose a cementless arthroplasty surgery. LANDESBERG discloses a cementless arthroplasty surgery (an arthroplasty surgery with a gel matrix of bone graft material thus cementless of an implantation of the gel matrix; column 6, lines 23-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the system of EARLE to include a cementless arthroplasty surgery, as taught by LANDESBERG, in order to gain the advantages of a progressive increase in both load-bearing and complete osteointegration in accordance with conventional analysis (see LANDESBERG column 6, lines 23-50). EARLE fails to disclose dry gas. MATSEN discloses dry gas (applying a dry gas to the bone surface; column 6, lines 5-18). It would have

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**Supplemental Box**

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been obvious to one of ordinary skill in the art at the time of the invention to have modified the system of EARLE to include dry gas, as taught by MATSEN, in order to gain the advantages of achieving a higher penetration into the bone than would otherwise be possible (see MATSEN column 6, lines 49-56).

As per claim 17, EARLE in view of MATSEN in further view of LANDESBURG discloses a method of using the bone preparation system of claim 11, 12, or 13. Modified EARLE further discloses applying to the bone surface with the hand piece through the nozzle (a fluted end (dispenser) of the extension nozzles for applying the bone cement (orthobiologic material) to the bone surface with the use of trigger mechanism 87 via second housing 14; fig 1; column 2, lines 44-57; column 4, lines 12-13). Modified EARLE fails to disclose dry gas. MATSEN discloses comprising applying a dry gas to the bone surface (applying a dry gas to the bone surface; column 6, lines 5-18). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of EARLE to include dry gas, as taught by MATSEN, in order to gain the advantages of achieving a higher penetration into the bone than would otherwise be possible (see MATSEN column 6, lines 49-56).

As per claim 18, EARLE in view of MATSEN in further view of LANDESBURG discloses the method according to claim 17. Modified EARLE fails to disclose wherein applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface. MATSEN discloses wherein applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface (said applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface; column 6, lines 5-24). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of EARLE to include wherein applying a dry gas includes applying a medical-grade carbon dioxide gas to the bone surface, as taught by MATSEN, in order to gain the advantages of presenting a significantly lower risk of embolism as compared to the use of nitrogen or oxygen (see column 6, lines 5-24).

Claims 14-15 lack an inventive step under PCT Article 33(3) as being obvious over EARLE in view of MATSEN in further view of LANDESBURG in even further view of GREENWALD.

As per claim 14, EARLE in view of MATSEN in further view of LANDESBURG discloses a method of using the bone preparation system of claim 11, 12, or 13. Modified EARLE fails to disclose comprising applying suction to suction away fat, marrow and blood, and/or saline, from a region of the bone, the region including the bone surface. GREENWALD discloses comprising applying suction to suction away fat, marrow and blood, and/or saline, from a region of the bone, the region including the bone surface (applying suction to suction away soft tissue including fat and hematopoietic and other fluid from a region of the bone, the region includes the bone surface; column 2, lines 33-54; claims 2-3). It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of EARLE to include comprising applying suction to suction away fat, marrow and blood, and/or saline, from a region of the bone, the region including the bone surface, as taught by GREENWALD, in order to gain the advantages of providing for better fixation of the prosthetic device (see GREENWALD column 2, lines 37-38).

As per claim 15, EARLE in view of MATSEN in further view of LANDESBURG in even further view of GREENWALD discloses the method according to claim 14. Modified EARLE discloses further comprising applying the orthobiologic material to the bone surface (a fluted end (dispenser) of the extension nozzles for applying the bone cement (orthobiologic material) to the bone surface; column 2, lines 44-57).

Claims 1-3, 5-6, 11-15, 17-18 have industrial applicability under PCT Article 33(4) because they can be made or used in industry.