PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 11813-708.600	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2013/030249	International filing date *(day/month/year)* 11 March 2013 (11.03.2013)	Priority date *(day/month/year)* 09 March 2012 (09.03.2012)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SI-BONE INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	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 Article 35(2) 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

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 09 September 2014 (09.09.2014)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Athina Nickitas-Etienne e-mail: pt04.pct@wipo.int

Form PCT/IB/373 (January 2004)

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)*	10 JUL 2013
Applicant's or agent's file reference 11813-708.600	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 13/30249	11 March 2013 (11.03.2013)	09 March 2012 (09.03.2012)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 1/32 (2013.01)
USPC - 600/205

Applicant SI-BONE 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.

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	28 June 2013 (28.06.2013)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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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(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

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the appicable time limit:

   ☐ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I: claims 1-9, 29, 30 directed to a soft tissue protector system

Group II: claims 10-14 directed to an expandable dilator

Group III: claims 15-20 directed to a delivery sleeve

Group IV: claims 21-25, 31-35 directed to a dilator system and corresponding method of use

Group V: claims 26-28 directed to a quick connect system

The groups of inventions above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Special Technical Features
The special technical feature of the Group I claims is the supply of a biologic aid through a fluid channel or port, which is not present in the claims of Groups II-V.
The special technical feature of the Group II claims is slidable wall segments allowing the body to have a compressed and uncompressed cross section, which is not present in the claims of Groups I, III-V.
The special technical feature of the Group III claims is a tapered distal portion having expandable blade portions that rotate outwards, which is not present in the claims of Groups I-II, IV-V.
The special technical feature of the Group IV claims is a guide pin with outwardly biased prongs, sequential dilators and an outer cannula with stabilizing pins, which is not present in the claims of Groups I-III, V.
The special technical feature of the Group V claims is a handle quick connect feature, which is not present in the claims of Groups I-IV.

Common Technical Features
Groups I-V share the technical feature of a cannula, dilator or longitudinal body having a distal end, a proximal end and a wall with an inner surface that defines a passage extending through the cannula, dilator or longitudinal body. This generic feature does not avoid the prior art, as evinced by US 2003/0083688 A1 to Simonson which teaches a typical example of a dilator comprising a series of cannulated dilators formed of longitudinal bodies that define a pasage therethrough (para [0033], fig 2, dilators 12).

Groups II and IV further share the technical feature of an expandable dilator which expands from a compressed/contracted configuration to an expanded configuration. This generic feature does not avoid the prior art, as evinced by US 4,350,151 A to Scott which teaches a typical example of an expandable dilator which expands from a compressed configuration to an expanded configuration (col 2, ln 39-51, col 3, ln 1-20, fig 1, 6-9, dilator 10 having portions 11, 12 which start in a radially closed/compressed configuration and expand when urged apart by inner member 16).

Therefore, the listed inventions lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-9, 29-30

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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	3-5, 9	YES
	Claims	1-2, 6-8, 29-30	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-9, 29-30	NO
Industrial applicability (IA)	Claims	1-9, 29-30	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2, 6-8 and 29-30 lack novelty under PCT Article 33(2) as being anticipated by US 2007/0233146 A1 to Henniges, et al. (hereinafter Henniges).

Regarding claim 1, Henniges discloses a soft tissue protector system for coating an implant with a biologic aid, the system comprising:
a longitudinal body (18) having a distal end (top end, fig 25), a proximal end (bottom end, fig 25) and a wall (inner wall separating lumens 34A, 34B, fig 25) with an inner surface that defines a passage (34B) extending through the longitudinal body, wherein the passage is configured to receive the implant (20, fig 25, para [0094]);
at least one port (where 34A, 34B merge near distal end, fig 25) located on the inner surface of the wall proximal the distal end of the longitudinal body (18, fig 25, para [0094]); and
at least one channel (34A) in fluid communication with the at least one port (fig 25), wherein the at least one channel is configured to contain the biologic aid (22, fig 25, para [0094]).

Regarding claim 2, Henniges further discloses the system of claim 1 further comprising a pusher (24A, fig 25), wherein the pusher is configured to be inserted into both the passage (via connected rod 24C, fig 25) and the at least one channel (via connected rod 24B, fig 25) such that the pusher is capable of pushing out the implant from within the passage and pushing out the biologic aid from at least one channel through the at least one port to coat the implant as the implant is pushed out of the passage (para [0094]).

Regarding claim 6, Hennieges further discloses the system of claim 1, wherein the port (where 34A, 34B merge near distal end, fig 25) is a slot oriented transversely to the longitudinal body (18, fig 25).

Regarding claim 7, Henniges further discloses the system of claim 1, wherein the channel is pre-loaded with the biologic aid (22, fig 25, para [0094]).

Regarding claim 8, Henniges further discloses the system of claim 7, wherein the biologic aid is selected from the group consisting of bone morphogenetic proteins, hydroxyapatite, demineralized bone, morselized autograft bone, morselized allograft bone, analgesics, antibiotics, and steroids (para [0073], [0094]).

Regarding claim 29, Henniges discloses a method of inserting an implant into a bone cavity, the method comprising:
providing an implant (20, fig 25) loaded into a lumen (34B) of a dilator (130 tool has tapered distal ends and will act to dilate tissue when entering tissue) having a proximal end (bottom end, fig 25) and a distal end (top end, fig 25, para [0094]), the lumen of the dilator defined by a wall having an interior surface with one or more ports (where 34A, 34B merge near distal end, fig 25) located proximal to distal end of the dilator (fig 25), the one or more ports in communication with one or more channels (34A) within the wall (fig 25), the one or more channels containing a biologic aid (22, fig 25, para [0094]);
positioning the distal end of the dilator adjacent to the bone cavity (fig 25, para [0094]);
advancing a pusher (24A) simultaneously through the lumen of the dilator and the one or more channels to simultaneously advance the implant into the bone cavity and eject the biologic aid out of the one or more ports, thereby coating the implant with the biologic aid as the implant is advanced into the bone cavity (para [0094]).

Regarding claim 30, Henniges discloses a method of inserting an implant into a bone cavity, the method comprising:
providing an implant (20) loaded into the lumen (34B) of a dilator (130) tool has tapered distal ends which act to dilate tissue, fig 25) having a proximal end (bottom end, fig 25) and a distal end (top end, fig 25), the dilator including a reservoir (34A) of biologic aid (22, fig 25, para [0094]);
positioning the distal end of the dilator adjacent to the bone cavity (fig 25, para [0094]); and
advancing the implant into the bone cavity while simultaneously coating the implant with the biologic aid (para [0094]).

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V, Part 2: Citations and Explanations

Claim 1 lacks novelty under PCT Article 33(3) as being obvious over US 5,197,961 A (CASTLE).

Regarding claim 1, Castle discloses a soft tissue protector system for coating an implant with a biologic aid, the system comprising:
a longitudinal body (14) having a distal end (right end, fig 1), a proximal end (left end, fig 1) and a wall (wall that separates 15 from 16, fig 2) with an inner surface that defines a passage extending through the longitudinal body, wherein the passage is configured to receive the implant (11, fig 1, 2, col 2, ln28-50);
at least one port (opening where channels 15 and 16 connect as distal end, fig 2) located on the inner surface of the wall proximal the distal end of the longitudinal body (fig 2); and
at least one channel (15) in fluid communication with the at least one port, wherein the at least one channel is configured to contain the biologic aid (19, fig 2, col 2, ln 28-41).

Claims 3-5 lack an inventive step under PCT Article 33(3) as being obvious over Henniges in light of US 2003/0083688 A1 to Simonson

Regarding claim 3, Henniges teaches the system of claim 1, but does not specifically teach wherein the inner surface defines a passage having a rectilinear transverse cross-sectional profile that is configured to receive an implant having a corresponding rectilinear transverse cross-sectional profile. Henniges does teach a variety of other embodiments having various implant shapes including rectilinear (para [0068], fig 12C) while the passage is generally illustrated as circular further embodiments teach a variety of internal features (para [0064], [0065], fig 9-11). Polygonal access cannula are well known in the art, Simonson teaches one such example (para [0033]-[0037]). It would have been obvious to one skilled in the art that Henniges could have been modified to include the cannula of Simonson as claimed in order to provide a cannula that matches the profile of the implant.

Regarding claim 4, Henniges and Simonson teach the system of claim 3, but do not specifically teach wherein the passage and the implant each have a transverse triangular cross-sectional profile. Henniges illustrates a box shaped implant (para [0068], fig 12C), Simonson a polygonal cannula (para [0033]-[0037]). It would have been obvious to one skilled in the art that Henniges and Simonson could have been modified as claimed in order to provide an implant profile as needed.

Regarding claim 5, Henniges and Simonson teach the system of claim 3, but do not specifically teach wherein the inner surface comprises a plurality of planar surfaces, each planar surface defining one side of the rectilinear cross-sectional profile of the passage, wherein each of the plurality of planar surfaces comprises at least one port located proximal to the distal end of the longitudinal body and configured to deliver the biologic aid. Henniges generally teaches the passage being illustrated as circular however further teaches embodiments with a variety of internal features that aid in supplying the biologic on all sides (para [0064], [0065], fig 9-11). It would have been obvious to one skilled in the art that Henniges and Simonson could have been modified as claimed in order to provide an even supply of biologic.

Claims 3-5 lack an inventive step under PCT Article 33(3) as being obvious over Castle in view of US 2011/0046737 A1 (TEISEN).

Regarding claim 3, Castle teaches the system of claim 1, but does not teach wherein the inner surface defines a passage having a rectilinear transverse cross-sectional profile that is configured to receive an implant having a corresponding rectilinear transverse cross-sectional profile. However, Castle teaches wherein the inner surface defines a passage with a u-shape cross-sectional profile (16, fig 3, col 2, ln 42-46). Additionally, Teisen teaches an implant has a triangular transverse cross-sectional profile (para [0114]). It would have been obvious to one of ordinary skill in the art that Castle would have been modified by the teachings of Teisen because the use of a triangular implant provides a functional shape for an implant. Furthermore, it would have been obvious to one of ordinary skill in the art that the inner surface would have have the same transverse cross-sectional shape as the implant in order to securely hold and prevent the implant from rotating while stored within the inner surface in order to maintain a desired orientation of the implant for implantation by a surgeon, as optimizing the shape of an element for a particular use is within the ordinary skill of one in the art.

Regarding claim 4, Castle and Teisen teach the system of claim 3, and Teisen further teaches wherein the implant has a transverse triangular cross-sectional profile (para [0114]), but does not teach the passage having a transverse triangular cross-section. It would have been obvious to one of ordinary skill in the art that the inner surface would have also had a transverse cross-sectional shape as the implant in order to prevent the implant from rotating while stored/moved within the inner surface in order to maintain a desired orientation of the implant for implantation by a surgeon, as optimizing the shape of an element for a particular use is within the ordinary skill of one in the art.

Regarding claim 5, Castle and Teisen teach the system of claim 3, and Castle further teaches wherein the inner surface (16) comprises a plurality of planar surfaces (top, right and left surfaces, fig 3), each planar surface defining one side of the [rectilinear] cross-sectional profile of the passage (fig 3), but does not teach wherein each of the plurality of planar surfaces comprises at least one port located proximal to the distal end of the longitudinal body and configured to deliver the biologic aid. However, Castle teaches wherein the upper planar surfaces comprises at least one port (where 15 and 16 connect at distal end, fig 2) located proximal to the distal end of the longitudinal body and configured to deliver the biologic aid (col 2, ln 28-50). It would have been obvious to one of ordinary skill in the art that the other planar surfaces would also have ports in order to allow application of biologic aid to the other sides of the implant, as mere duplication of an element is within the ordinary skill of one in the art.

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INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of: –
Box V, Part 2: Citations and Explanations

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Henniges in view of US 2001/0046518 A1 (SAWHNEY).

Regarding claim 9, Henniges teaches the system of claim 7, but does not teach wherein the biologic aid is incorporated into a controlled release formulation to provide sustained release of the biologic aid over time. However, Sawhney teaches wherein the biologic aid is incorporated into a controlled release formulation to provide sustained release of the biologic aid over time (para [0094]-[0096]). It would have been obvious to one of ordinary skill in the art that Henniges would have been modified by the teachings of Sawhney because the use of a controlled release formulation provides for the therapuetic effect of the biologic aid to last longer.

Claims 1-9 and 29-30 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.