

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year)		05 NOV 2012
Applicant's or agent's file reference P027PCT		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US 12/48709	International filing date (day/month/year) 27 July 2012 (27.07.2012)	Priority date (day/month/year) 28 July 2011 (28.07.2011)
International Patent Classification (IPC) or both national classification and IPC IPC(8) - A61B 17/32 (2012.01) USPC - 606/170		
Applicant SPINE VIEW, 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 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 Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 25 October 2012 (25.10.2012)	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/US 12/48709

Box No. 1 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. (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:

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

1. Statement

Novelty (N)	Claims	<u>1-14</u>	YES
	Claims	<u>15-18</u>	NO
Inventive step (IS)	Claims	<u>None</u>	YES
	Claims	<u>1-18</u>	NO
Industrial applicability (IA)	Claims	<u>1-18</u>	YES
	Claims	<u>None</u>	NO

2. Citations and explanations:

Claims 15-18 lack novelty under PCT Article 33(2) as being anticipated by US 2008/0125783 A1 to Perez-Cruet et al. (hereinafter Perez-Cruet).

As per claim 15, Perez-Cruet teaches a tissue removal device comprising:

a handheld housing (12, para [0020]; Fig. 1);
a motor (22, para [0020]; Fig. 1, 2); and
a tissue removal mechanism coupled to the handheld housing (14/16, para [0020]; Fig. 1, 2), the tissue removal mechanism comprising:
a tubular member (32, para [0023]; Fig. 1, 2);
a rotatable elongated member disposed within a lumen of the tubular member (36, para [0021]; Fig. 3);
an impeller housing (16) coupled to a distal end of the tubular member (para [0022]; Fig. 3); and
an impeller (38) disposed within the impeller housing and coupled to the rotatable elongated member (para [0021]; Fig. 3),
wherein the impeller housing comprises a side wall portion having first and second apertures therethrough, and wherein the first and second apertures are configured to expose the impeller to tissue during use (para [0022]; Fig. 3).

As per claim 16, Perez-Cruet teaches the tissue removal device of claim 15, wherein at least one of the first and second apertures defines a cutting edge (para [0022]; Fig. 3).

As per claim 17, Perez-Cruet teaches the tissue removal device of claim 16, wherein the cutting edge has a serrated configuration (para [0022]; Fig. 3).

As per claim 18, Perez-Cruet teaches the tissue removal device of claim 15, wherein the first aperture is opposite the second aperture along a circumference of the impeller housing (para [0022]; Fig. 3).

Claims 1-14 lack an inventive step under PCT Article 33(3) as being obvious over Perez-Cruet in view of US 2010/0145343 A1 to Johnson et al. (hereinafter Johnson).

As per claim 1, Perez-Cruet teaches a tissue removal device comprising:

a handheld housing (12, para [0020]; Fig. 1);
a motor (22, para [0020]; Fig. 1, 2); and
a tissue removal mechanism coupled to the handheld housing (14/16, para [0020]; Fig. 1, 2), the tissue removal mechanism comprising:
a tubular member (32, para [0023]; Fig. 1, 2);
a rotatable elongated member disposed within a lumen of the tubular member (36, para [0021]; Fig. 3);
a first impeller attached to the rotatable elongated member (38, para [0021]; Fig. 3).

While Perez-Cruet does not specify the impeller distal to the rotatable elongated member, it would have been obvious to one of ordinary skill in the art to optimize the impeller to be distal to the rotatable elongated member, to permit the removal and replacement of worn-out or damaged impellers without necessitating replacement of the entire elongated member.

Perez-Cruet does not show a second impeller adjacent the first impeller.

Johnson teaches a second impeller adjacent the first impeller (6108, para [0187]; Fig. 67, 68). It would have been obvious for one of ordinary skill in the art to combine the multiple impellers of Johnson with the device of Perez-Cruet in order to provide means for removing a larger area of tissue while affording greater control of the area removed based on using two smaller individual impellers, as opposed to one larger impeller.

As per claim 2, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 1. Johnson further teaches wherein the second impeller is configured to counter-rotate with respect to the first impeller ("spline gears 6113 rotate adjacent cutting elements 6107 and 6108 in opposite directions," para [0187]; Fig. 67, 68).

As per claim 3, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 1. Perez-Cruet further teaches wherein rotation of the rotatable elongated member effects rotation of the first impeller (para [0021]).

---See supplemental sheet---

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Supplemental Box

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

Continuation of:
---Box V.2---

As per claim 4, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 3. Johnson further teaches wherein rotation of the first impeller effects rotation of the second impeller ("spline gears 6113 rotate adjacent cutting elements 6107 and 6108 in opposite directions," para [0187]; Fig. 67, 68).

As per claim 5, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 3. Perez-Cruet further teaches a helical member disposed around at least a portion of the rotatable elongated member (38, para [0021]; Fig. 2).

As per claim 6, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 5. Perez-Cruet further teaches wherein rotation of the rotatable elongated member also effects rotation of the helical member (para [0021]; Fig. 2).

As per claim 7, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 1. Perez-Cruet further teaches an impeller housing (16), wherein the first impeller is disposed within the impeller housing (para [0022]; Fig. 3). Johnson teaches a second impeller adjacent the first impeller (para [0187]; Fig. 67, 68). It would therefore have been obvious for one of ordinary skill in the art to dispose the second impeller within the impeller housing adjacent to the first impeller.

As per claim 8, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 7. Perez-Cruet further teaches wherein the impeller housing comprises a side wall portion including a first aperture therethrough (para [0022]; Fig. 3).

As per claim 9, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 8. Perez-Cruet further teaches wherein the side wall portion further includes a second aperture therethrough (para [0022]; Fig. 3).

As per claim 10, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 9. Perez-Cruet further teaches wherein the first and second apertures are configured to expose the first impeller to tissue during use (para [0022]; Fig. 3). Johnson teaches a second impeller adjacent the first impeller (para [0187]; Fig. 67, 68). It would therefore have been obvious for one of ordinary skill in the art to expose an adjacent second impeller via the first and second apertures.

As per claim 11, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 9. Perez-Cruet further teaches wherein at least one of the first and second apertures defines a cutting edge (para [0022]; Fig. 3).

As per claim 12, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 11. Perez-Cruet further teaches wherein the cutting edge has a serrated configuration (para [0022]; Fig. 3).

As per claim 13, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 7, but does not specify a sheath disposed within the impeller housing, wherein the first and second impellers are disposed within the sheath. However, it would have been obvious to one of ordinary skill in the art to optimize the sheath to be disposed within the impeller housing, wherein the first and second impellers are disposed within the sheath to permit incremental control over the amount of tissue removed as well as a means for dislodging any captured tissue.

As per claim 14, the combination of Perez-Cruet and Johnson teaches the tissue removal device of claim 11. Perez-Cruet also teaches a tissue removal chamber (60) coupled to a portion of the handheld housing (para [0025]; Fig. 2). While Perez-Cruet does not specify distal collection, it would have been obvious to one of ordinary skill in the art to optimize the collection to be distal collection, to permit immediate evaluation of the amount of tissue collected.

Claims 1-18 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.