PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 7115/94465	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2009/042882	International filing date *(day/month/year)* 05 May 2009 (05.05.2009)	Priority date *(day/month/year)* 05 May 2008 (05.05.2008)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant PIONEER SURGICAL TECHNOLOGY, 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 November 2010 (09.11.2010)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Nora Lindner e-mail: pt11.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)*	22 JUN 2009
Applicant's or agent's file reference 7115/94465	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 09/42882	05 May 2009 (05.05.2009)	05 May 2008 (05.05.2008)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61F 2/44 (2009.01)
USPC - 623/17.16

Applicant PIONEER SURGICAL TECHNOLOGY, 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.

3. For further details, see notes to 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	08 June 2009 (08. 06. 2009)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 09/42882

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. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished 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 and/or table(s) relating thereto 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. 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	1-23	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-23	NO
Industrial applicability (IA)	Claims	1-23	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 4-12, 15-18, 22 lack inventive step under PCT Article 33(3) as being obvious over US 2008/0103598 A1 to Trudeau et al. (hereinafter . Trudeau.) in light of US 2006/0195191 A1 Sweeney II et al. (hereinafter . Sweeney.)

As per claim 1, Trudeau discloses a weight-bearing implant comprising: a first bearing member (abstract, para [0189] .Fig. 72 :1518); a second bearing member (para [0189] .Fig. 72 :1522); a body of the first bearing member having an outer bearing surface for being disposed adjacent a first bone to extend laterally therealong (para [0021], abstract, para [0189] .Fig. 72 :1518); a body of the second bearing member having an outer bearing surface for being disposed adjacent to a second bone to extend laterally therealong (para [0021], para [0189] .Fig. 72 :1522); an interface between the first and second bearing members for allowing at least relative translational movement along a predetermined lateral direction therebetween (para [0012]-[0013], [0018], [0165] .Fig. 41 : 1316.); However, does not specifically disclose a biasing member between the first and second bodies that resiliently opposes the relative translational movement between the first and second bearing members. Sweeney teaches wherein biasing members may be used between elements of modular disc to increase the stability by and facilitate returning the elements to the neutral position. (abstract, para [0037] .Fig. 7.) . It would have been obvious to one of ordinary skill in the art to utilize the teaching of Sweeney and utilize a biasing member between the first and second bodies in the device taught by Trudeau to resiliently oppose the relative translational movement between the first and second bearing members.

As per claim 4, Trudeau and Sweeney teach the implant of claim 1, however, do not specifically teach wherein further comprising a translatable articulation member disposed between the first and second bodies and operably connected to the biasing member such that the translatable articulation member is translatably biased by the biasing member. Trudeau teaches wherein articulation surface facilitates the relative motion of upper and lower members (para [0165] .Fig. 41 : 1316.). Sweeney teaches wherein an articulating spacer is located between two members and act as a biasing member as well (para [0038]). It would have been obvious to one of ordinary skill in the art to utilize the teaching of Sweeney and utilize a separate articulating member between two bodies, while it is connected to biasing member to create the articulation surface described by Trudeau since it allows relative motion of upper and lower bodies that is controlled by biasing member.

As per claim 5, Trudeau further discloses wherein the translatable articulation member further comprises an arcuate articulation surface and one of the first and second bodies has a corresponding arcuate articulation surface and the implant further comprises: an articulation interface formed by the arcuate articulation surface of the translatable articulation member and the corresponding arcuate articulation surface of the one body for allowing polyaxial articulation therebetween (para [0165] .Fig. 41 : 1316. and .Fig. 42.).

As per claim 6, Trudeau and Sweeney teach the implant of claim 4, however, does not specifically disclose further comprising a biasing member mounting portion of the translatable articulation member for receiving at least a portion of the biasing member. Trudeau teaches wherein the restraining portion may be located on each shells or bearing members (para [0142]). Sweeney teaches engagement portions (para [0040]). It would have been obvious to one of ordinary skill in the art to utilize a mounting portion for a biasing member of the translatable articulation member taught by Trudeau to engage the biasing member and prevent unwanted motion while providing neutral position of the disc.

As per claim 7, Trudeau further teaches wherein the translatable articulation member includes an articulation surface opposite the arcuate articulation surface and the implant further comprises: an inner articulation surface of the at least one body engaged with the biasing member, wherein the opposite articulation surface of the translatable articulation member and the inner articulation surface form the interface between the first and second bearing members (para [0018], [0140]-[0141], [0165]).

----------See Supplemental Sheets----------

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Supplemental Box

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Box V.2: Citations and Expalanations:

As per claim 8, Trudeau discloses a weight-bearing implant comprising: a first bearing member; a body of the first bearing member having an outer bearing surface (abstract, para [0189] .Fig. 72 :1518); a second bearing member (para [0189] .Fig. 72 :1518 and 1522); a body of the second bearing member having an outer bearing surface (para [0189] .Fig. 72 :1518 and 1522); However, does not specifically disclose a translatable member disposed between the first and second bearing members having a predetermined position with respect thereto; a resilient connection between the translatable member and at least one of the first and second bearing members to allow the translatable member to translate with respect to the one bearing member; and bearing surfaces of the translatable member and the other bearing member that engage one another and allow for relative motion therebetween with the resilient connection permitting the bearing surfaces to shift relative to the one bearing member to allow the relative motion between the other bearing member and the translatable member to occur at different positions relative to the one bearing member.
Trudeau teaches wherein articulation surface, which facilitates the relative motion of upper and lower members (para [0165] .Fig. 41 : 1316.). Sweeney teaches wherein an articulating spacer is located between two members and act as a biasing member as well to increase the implant stability and facilitate returning the elements to the neutral position. (abstract, para [0037]-[0038] .Fig. 7.) . It would have been obvious to one of ordinary skill in the art to utilize the teaching of Sweeney and utilize a separate articulating element between two bearing bodies, while it is connected to biasing member to create the articulation surface described by Trudeau since it allows relative motion of upper and lower bodies that is controlled by biasing member. .

As per claim 9, Trudeau further discloses wherein the bearing surfaces of the translatable member and the other bearing member comprise dome-shaped surfaces, and the implant further comprises: an arcuate interface formed by the bearing surfaces of the translatable member and the other bearing member to allow the translatable member and the other bearing member to undergo polyaxial articulation with respect to one another and together with the resilient connection permit the polyaxial articulation to occur at different positions relative to the one bearing member (para [0140]-[0141], [0165] .Fig. 41 : 1316. and .Fig. 42.).

As per claim 10, Trudeau and Sweeney teach the weight-bearing implant of claim 8, however, do not specifically disclose wherein the resilient connection comprises a biasing member operably connected to the translatable member to resist translation of the translatable member with respect to the one bearing member and to bias the translatable member towards the predetermined position thereof. Sweeney teaches wherein biasing members may be used between elements of modular disc to increase the stability by and facilitate returning the elements to the neutral position. (abstract, para [0037] .Fig. 7.) . It would have been obvious to one of ordinary skill in the art to utilize the teaching of Sweeney and utilize a biasing member between the first and second bodies in the device taught by Trudeau to resiliently oppose the relative translational movement between the first and second bearing members.

As per claim 11, Trudeau teaches the weight-bearing implant of claim 10, however, does not specifically disclose wherein the translatable member comprises a recess portion with the biasing member disposed at least partially therein and operably connected to the second bearing member to provide the resilient connection between the translatable member and the second bearing member. Trudeau teaches wherein the restraining portion may be located on each shells or bearing members (para [0142]). Sweeney teaches the use of recessed slot for engagement of middle element (para [0033]) and mounting of biasing member or spacer in upper and lower elements (para [0037]-[0038], [0040]. Fig. 7). It would have been obvious to one of ordinary skill in the art to use the teaching of Sweeney utilize a recess portion with the biasing member disposed at least partially therein and operably connected to the second bearing member taught by Trudeau since this configuration allows for controlled movement between the translatable member and the second bearing member.

As per claim 12, Trudeau further discloses further comprising: an opposite bearing surface of the translatable member opposite the dome-shaped bearing surface (para [0140]-[0141], [0165] .Fig. 41 : 1316. and .Fig. 42.); an inner facing bearing surface of the at least one bearing member (para [0140]-[0141], [0165] .Fig. 41 : 1316. and .Fig. 42.); and a sliding interface formed by the opposite bearing surface of the translatable member and the inner facing articulation surface that allows the translatable member to translate laterally with respect to the at least one bearing member (para [0165] .Fig. 41 : 1316. and .Fig. 42.).

As per claim 15, Trudeau discloses an intervertebral implant for being inserted between adjacent upper and lower vertebrae, the intervertebral implant comprising: an upper body (abstract, para [0140]-[0141]); a lower body (abstract, para [0140]-[0141]); an articulation interface between the upper and lower bodies (para [0165] .Fig. 41 : 1316.); a concave articulating surface of the articulation interface having first and second radii of curvature in at least one plane, wherein the first radius of curvature is smaller than the second and neither of the first and second radii of curvatures are infinite (para [0141]); and a convex articulating surface of the articulation interface having a radius of curvature corresponding substantially with the first radius of curvature in the at least one plane, such that the articulation interface provides for polyaxial pivoting as well as translation of the upper and lower bodies with respect to each other (para [0140]-[0141], [0165]).

As per claim 16, Trudeau further discloses wherein the concave articulating surface is disposed on the upper body (para [0140]-[0141]).

As per claim 17, Trudeau further discloses wherein the convex articulating surface is disposed on the lower body (para [0140]-[0141]).

----------See Supplemental Sheets---

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Supplemental Box

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As per claim 18, Trudeau teaches the intervertebral implant of claim 15, however, does not specifically disclose wherein the at least one plane is a sagittal plane, such that the upper and lower bodies may translate with respect to each other in an anterior-posterior direction to provide for natural movement of the upper and lower vertebrae in flexion and extension. Trudeau teaches wherein the radius of curvature of the concave recess 1318 and convex dome 1322 are the same for smooth sliding engagement therebetween (para [0165]) and wherein the implant is typically inserted from an anterior to posterior approach (para [0154]). It would have been obvious to one of ordinary skill in the art to design the disc so that the upper and lower bodies having first and second radii of curvature in at least one plane to allow relative translation with respect to each other in an anterior-posterior direction and provide natural movement of the upper and lower vertebrae in flexion and extension since the implant is typically inserted from an anterior to posterior approach.

As per claim 22, Trudeau teaches the implant of claim 15, however, does not specifically disclose further discloses wherein the concave and convex articulation surfaces have the first radius of curvature in a coronal plane. Trudeau teaches wherein the radius of curvature of the concave recess 1318 and convex dome 1322 are the same for smooth sliding engagement therebetween (para [0165]). It would have been obvious to one of ordinary skill in the art to the concave and convex articulation surfaces have the similar first radius of curvature in coronal plane to allow for smooth sliding engagement therebetween.

Claims 2-3, 13-14 lack inventive step under PCT Article 33(3) as being obvious over Trudeau and Sweeney in light of US 2006/0116767 A1 to Magerl et al. (hereinafter . Magerl.)

As per claim 2, Trudeau and Sweeney teach the implant of claim 1, however do not specifically disclose wherein the biasing member is an elongate flat spring that normally extends generally orthogonal to the predetermined lateral direction to position the bearing members at a predetermined neutral position relative to each other in the lateral direction. Sweeney teaches wherein the biasing member can be a leaf spring (para [0037] . Fig.7.). Magerl teaches wherein a flat spring can be used in order to increase the elasticity of the entire implant (para [0090]-[0091]). It would have been obvious to one of ordinary skill in the art to use the teaching of Magerl and utilize a flat spring in the devide taught by Trudeau and Sweeney , which normally extends generally orthogonal to the predetermined lateral direction to increase the implant elasticity and position the bearing members at a predetermined neutral position relative to each other in the lateral direction.

As per claim 3, Trudeau, Sweeney and Magerl teach the implant of claim 2, however do not specifically disclose further comprising a spring mounting portion of one of the first and second bodies for engaging with the spring; and a channel of the spring mounting portion for receiving the spring and providing engagement surfaces on opposing sides thereof. Trudeau teaches wherein the restraining portion may be located on each shells or bearing members (para [0142]). Sweeney teaches the use of recessed slot for engagement of middle element (para [0033]) and mounting of biasing member or spacer in upper and lower elements (para [0037]-[0038], [0040]. Fig. 7). It would have been obvious to one of ordinary skill in the art to use the teaching of Sweeney utilize a recess portion with the biasing member disposed at least partially therein and operably connected to the second bearing member taught by Trudeau and Magerl since this configuration allows for controlled movement between the translatable member and the second bearing member.

As per claim 13, Trudeau and Sweeney teach the implant of claim 10, however do not specifically disclose wherein the resilient connection allows the translatable member to translate along a predetermined first direction and the biasing member is a flat spring having a longitudinal axis disposed generally orthogonal to the first direction. Magerl teaches wherein a flat spring can be used in order to increase the elasticity of the entire implant (para [0090]-[0091]). Trudeau teaches wherein dynamic securing mechanisms create a much more reliable and stable connection between the implant and the vertebra (para [0217], [0165] .Fig. 41 : 1316.). Sweeney teaches wherein the biasing member can be a spring (para [0037] . Fig.7.). It would have been obvious to one of ordinary skill in the art to combine the teaching of Trudeau and utilize the resilient connection to allow the translatable member to translate along a predetermined first direction with teaching of Magerl and Sweeney and utilize flat spring that normally extends generally orthogonal the first direction to simultaneously allow for stable translate of translatable member and spring to position the bearing members at a predetermined neutral position relative to each other in the lateral direction

As per claim 14, Trudeau, Sweeney and Magerl teach the weight-bearing implant of claim 13, however do not specifically disclose wherein the one bearing member comprises a spring-receiving portion including a channel for receiving the spring therein and offering support to opposing sides thereof. Trudeau teaches wherein the restraining portion may be located on each shells or bearing members (para [0142]). Sweeney teaches the use of recessed slot for engagement of middle element (para [0033]) and mounting of biasing member or spacer in upper and lower elements (para [0037]-[0038], [0040]. Fig. 7). It would have been obvious to one of ordinary skill in the art to use the teaching of Trudeau and utilize a spring receiving portion in one of bearing elements including a channel for receiving the spring taught by Magerl and Sweeney to offer support to opposing sides thereof and allow for controlled movement between the translatable member and the second bearing member.

----------See Supplemental Sheets------

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Supplemental Box

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Claims 19-21 lack inventive step under PCT Article 33(3) as being obvious over Trudeau and Sweeney in light of US 2004/0006394 A1 to Lipman et al. (hereinafter. Lipman.)

As per claim 19, Trudeau and Sweeney teach the intervertebral implant of claim 18, however, do not specifically disclose wherein a posterior portion of the concave articulation surface comprises the first radius and an anterior portion of the concave articulation surface comprises the second radius to allow the upper and lower bodies to translate with respect to one another with the adjacent vertebrae in extension. Lipman teaches wherein a self aligning knee prosthesis has two different radius of curvature at anterior versus posterior side (para [0032]-[0034] .Fig 2B. and 3A.). It would have been obvious to one of ordinary skill in the art to use the teaching of Lipman and utilize two different radius of curvature designs at anterior versus posterior sides of the intervertebral implant taught by Trudeau and Sweeney to facilitate the movement at different degrees of flexion or extension.

As per claim 20, Trudeau, Sweeney and Lipman teach the intervertebral implant of claim 19, however, do not specifically disclose wherein the first and second radii intersect one another, such that concave articulation surface includes a line interface wherein the radius of curvature of the concave articulation surface changes between the first and second radii of curvature. Lipman teaches wherein a self aligning knee prosthesis has two different radius of curvature at anterior versus posterior side (para [0032]-[0034] .Fig 2B and 3A.). It would have been obvious to one of ordinary skill in the art to use the teaching of Lipman and utilize two different radius of curvature designs at anterior versus posterior sides of the intervertebral implant taught by Trudeau and Sweeney while there is a transitional interface line to change from first radius of curvature to another since this confirguration allows for customized movement of the implant at at different degrees of flexion or extension.

As per claim 21, Trudeau and Sweeney teach the intervertebral implant of claim 17, however does not wherein the line interface is located generally at a midpoint of the articulation interface. Lipman teaches wherein a self aligning knee prosthesis has two different radius of curvature at anterior versus posterior side (para [0032]-[0034] .Fig 2B and 3A.). It would have been obvious to one of ordinary skill in the art to use the teaching of Lipman and utilize two different radius of curvature designs at anterior versus posterior sides of the intervertebral implant taught by Trudeau and Sweeney while the transitional region is located in between anterior and posterior region to allow for customized movement of the implant at at different degrees of flexion or extension. It would have been obvious to one of ordinary skill in the art to design the line interface in the midpoint of the articulation interface to symmetrically change the radius of curvature from anterior side to the posterior side.

Claim 23 lacks inventive step under PCT Article 33(3) as being obvious over Trudeau and Sweeney in light of US 6,146,421 A to Gordon et al. (hereinafter .Gordon.)

As per claim 23, Trudeau and Sweeney teach the intervertebral implant of claim 15, however do not specifically disclose wherein the articulating surfaces have a neutral orientation with the convex articulation surface in contact with a portion of the concave articulating surface having the first radius of curvature in the one plane for providing a compact configuration of the implant which operates to self-center the articulation surfaces. Trudeau teaches wherein the radius of curvature of the concave recess 1318 and convex dome 1322 are the same for smooth sliding engagement therebetween (para [0165]). Gordon teaches a self-centering intervertebral implant (Col 2, ln 39-60) and shows the device at normal resting position (Col 6, ln 40-47). It would have been obvious to one of ordinary skill in the art to use the teaching of Gordon and design a self-centering intervertebral implant wherein the articulating surfaces have a neutral orientation with the convex articulation surface in contact with a portion of the concave articulating surface having the first radius of curvature in the one plane as taught by Trudeau and Sweeney for providing a compact configuration of the implant which operates to self-center the articulation surfaces.

Claims 1-23 have industrial applicability as defined by PCT Article 33 (4) because the subject matter can be made or used in industry.