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 DEC 2009
Applicant's or agent's file reference 578492003740	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2009/060202	09 October 2009	10 October 2008

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 17/04 (2009.01)
USPC - 606/232

Applicant GUIDED DELIVERY SYSTEMS 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	02 December 2009	Blaine R. Copenheaver 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:

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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	4-8, 10-16, 21-24, 28, 38-39, 43, 50-51, 60	YES
	Claims	1-3, 9, 17-20, 25-27, 29-37, 40-42, 44-49, 52-59	NO
Inventive step (IS)	Claims	60	YES
	Claims	1-59	NO
Industrial applicability (IA)	Claims	1-60	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-3, 9, 17-20, 25-27, 29-37, 40-42, 47-49 and 52-58 lack novelty under PCT Article 33(2) as being anticipated by Jackson et al.

Regarding claim 1, Jackson discloses a device for securing a tether comprising: a locking member (block of material 12) configured to receive a plug (Fig. 1, see rotatable element 14 received in block 12) and comprising a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14); and a plug (rotatable element 14) rotatable within the lumen of the locking member to secure a portion of a tether within the lumen (para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together), the plug comprising an exterior surface (Fig. 1, see exterior surface of rotatable element 14), wherein the locking member comprises a wall portion comprising an interior surface (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), and wherein the exterior surface of the plug has at least one contour alignable with the interior surface of the wall portion when the plug is at least partially disposed within the lumen of the locking member (Fig. 1, see complimentary contours of rotatable element 14 and hole in block 12 that receives rotatable element 14; para. [0033]- element 14 is made to a dimension such that it is preferably "friction-fit" or "press-fit" into block 12 such that element 14 may be rotated, but does not tend to fall out of block 12).

Regarding claim 2, Jackson discloses that as applied to claim 1 further comprising an elongated member (elongated member 200) comprising a distal portion (Fig. 13, see end of elongated member 200 that receives system 100) to which the locking member is releasably coupled (para. [0043]- Optionally, rod 130 may be advanced distally such that system 100 can easily be pushed out of the distal end of elongated member 200).

Regarding claim 3, Jackson discloses that as applied to claim 1 wherein the wall portion of the locking member comprises first (Fig. 3A, see leftmost hole 13) and second apertures (Fig. 3A, see rightmost hole 13) alignable for passage of a tether therethrough (Fig. 3A, see holes 13 aligned with hole 15 to allow suture pair 20 and 22 to pass through).

Regarding claim 9, Jackson discloses that as applied to claim 1 wherein the plug is rotatable within the lumen of the locking member by tensioning a tether passing through the lumen of the locking member (It is inherent that the suture pair 20 and 22 would be tensioned prior to rotating the plug in order to properly take up the slack in the suture pair to lock and keep the sutured structure closed; para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 17, Jackson discloses a method for securing a tether when at least a portion of the tether is disposed within a lumen of a locking member, the method comprising: tensioning the tether to rotate a plug at least partially disposed within the lumen of the locking member (It is inherent that the suture pair 20 and 22 would be tensioned prior to rotating the plug in order to properly take up the slack in the suture pair to lock and keep the sutured structure closed; para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together), wherein the locking member comprises a wall portion having an interior surface (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), and the plug comprises an exterior surface having at least one contour which is aligned with the interior surface of the wall portion when the plug is rotated (Fig. 1, see complimentary contours of rotatable element 14 and hole in block 12 that receives rotatable element 14; para. [0033]- element 14 is made to a dimension such that it is preferably "friction-fit" or "press-fit" into block 12 such that element 14 may be rotated, but does not tend to fall out of block 12).

Regarding claim 18, Jackson discloses that as applied to claim 17 further comprising advancing the plug at least partially into the lumen of the locking member (Fig. 1 and Fig. 2, see rotatable element 14 partially received in the hole in block 12).

Regarding claim 19, Jackson disclosex that as applied to claim 17 wherein the wall portion of the locking member comprises first (Fig. 3A, see leftmost hole 13) and second apertures (Fig. 3A, see rightmost hole 13), and the method comprises rotating the plug when the tether passes through the first and second apertures (para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 20, Jackson et al. disclose that as applied to claim 17 wherein rotating the plug secures the portion of the tether between the exterior surface of the plug and the interior surface of the wall portion of the locking member (para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12).

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Regarding claim 25, Jackson discloses that as applied to claim 17 wherein the locking member is releasably coupled (para. [0043]- Optionally, rod 130 may be advanced distally such that system 100 can easily be pushed out of the distal end of elongated member 200) to a distal portion (Fig. 13, see end of elongated member 200 that receives system 100) of an elongated member (elongated member 200).

Regarding claim 26, Jackson discloses that as applied to claim 25 further comprising decoupling the locking member from the distal portion of the elongated member (para. [0043]- Optionally, rod 130 may be advanced distally such that system 100 can easily be pushed out of the distal end of elongated member 200).

Regarding claim 27, Jackson discloses that as applied to claim 26 wherein decoupling the locking member from the distal portion of the elongated member comprises applying force to the locking member with a pushing member (para. [0043]- Optionally, rod 130 may be advanced distally such that system 100 can easily be pushed out of the distal end of elongated member 200).

Regarding claim 29, Jackson discloses a device for securing a tether comprising: a locking member (block of material 12) configured to receive a plug (Fig. 1, see rotatable element 14 received in block 12) and comprising a wall portion (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14) comprising first (Fig. 3A, see leftmost hole 13) and second apertures (Fig. 3A, see rightmost hole 13) and a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14); and a plug (rotatable element 14) comprising a third aperture (hole 15) alignable with the first and second apertures for passage of a tether therethrough (para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 30, Jackson et al. discloses that as applied to claim 29 wherein the third aperture can be misaligned from at least one of the first and second apertures to secure a tether passing therethrough (Fig. 4A, see holes 13 and 15 in misalignment; para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 31, Jackson discloses a method for securing a tether using a device comprising a locking member (block of material 12) comprising a wall portion (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14), and a plug (rotatable element 14) comprising first and second apertures (Fig. 1 and Fig. 3A, see apertures at both ends of hole 15), the method comprising: advancing the plug at least partially into the lumen of the locking member when the tether has been routed through the first and second apertures to secure the tether between the plug and the locking member (Fig. 4A, see holes 13 and 15 in misalignment; para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 32, Jackson discloses that as applied to claim 31 further comprising advancing the tether through the first aperture (Fig. 3A, see suture pair 20 and 22 entering leftmost aperture of hole 15).

Regarding claim 33, Jackson discloses that as applied to claim 32 wherein the tether is advanced through the first aperture while the plug is at least partially disposed within the lumen of the locking member (Fig. 3B, see rotatable element 14 disposed within the hole in block 12; Fig. 3A, see suture pair 20 and 22 entering leftmost aperture of hole 15; para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 34, Jackson discloses that as applied to claim 32 further comprising advancing the tether through the second aperture (Fig. 3A, see suture pair 20 and 22 exiting rightmost aperture of hole 15).

Regarding claim 35, Jackson discloses that as applied to claim 32 wherein the tether is advanced through the second aperture while the plug is at least partially disposed within the lumen of the locking member (Fig. 3B, see rotatable element 14 disposed within the hole in block 12; Fig. 3A, see suture pair 20 and 22 exiting rightmost aperture of hole 15; para. [0034]- As seen in FIGS. 3A and 3B, a suture pair 20 and 22 is first fed through holes 13 and 15, thereby passing fully through system 10. Then, as shown in Fig. 4A, element 14 is rotated (here, by 90 degrees from Fig. 3A) thereby forming a tortuous path for suture pair 20 and 22. As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together).

Regarding claim 36, Jackson discloses a device for securing a tether comprising: a locking member (block of material 12) comprising a wall portion (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14); and a plug (rotatable element 14) comprising at least one protrusion (curved bar 19) configured to engage a groove or first aperture in the wall portion of the locking member when the plug is at least partially disposed within the lumen of the locking member (Fig. 5 and Fig. 6, it is inherent that there must be a groove to allow the barb 19 to move in a forward direction or that the barb 19 engages with either hole 13), wherein the plug and the locking member are configured to secure a tether therebetween (para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12).

Regarding claim 37, Jackson discloses that as applied to claim 36 wherein the at least one protrusion of the plug is configured to form a snap-fit with the groove or first aperture in the wall portion of the locking member (Fig. 5 and Fig. 6, it is inherent that there must be a groove to allow the barb 19 to snap into to allow movement in a forward direction or that the barb 19 engages with either hole 13).

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Regarding claim 40, Jackson discloses a device for securing a tether comprising: a locking member (block of material 12) comprising a wall portion (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14); and a plug (rotatable element 14) comprising a body portion (Fig. 1 and Fig. 2, see portion of rotatable element 14 below distal end 11) and a head portion (Fig. 1 and Fig. 2, see distal end 11 of rotatable element 14) comprising a one-way feature (curved barb 19; para. [0040]- FIGS. 10 and 11 show an embodiment of the invention in which rotatable element 14 has a distal end 11 with a symmetric, non-circular cross section. As illustrated in Fig. 11, end 11 may be hexagonal, but square, octagonal or other shaped ends are also contemplated. As can be appreciated, rotating element 14 around axis A will tend to result in element 11 clicking from one position to the next. The symmetric, non-circular cross section provides resistance such that element 14 will not inadvertently rotate backwards and thus unwind) allowing translation of the head portion in a first direction once within the lumen of the locking member (para. [0036]- as illustrated in FIGS. 5 and 6, rotatable element 14 includes a projection such as curved barb 19 which inhibits rotation of element 14 in one direction; para. [0040]- FIGS. 10 and 11 show an embodiment of the invention in which rotatable element 14 has a distal end 11 with a symmetric, non-circular cross section. As illustrated in Fig. 11, end 11 may be hexagonal, but square, octagonal or other shaped ends are also contemplated. As can be appreciated, rotating element 14 around axis A will tend to result in element 11 clicking from one position to the next. The symmetric, non-circular cross section provides resistance such that element 14 will not inadvertently rotate backwards and thus unwind), but not in a second direction opposite the first direction (para. [0036]- as illustrated in FIGS. 5 and 6, rotatable element 14 includes a projection such as curved barb 19 which inhibits rotation of element 14 in one direction; para. [0040]- FIGS. 10 and 11 show an embodiment of the invention in which rotatable element 14 has a distal end 11 with a symmetric, non-circular cross section. As illustrated in Fig. 11, end 11 may be hexagonal, but square, octagonal or other shaped ends are also contemplated. As can be appreciated, rotating element 14 around axis A will tend to result in element 11 clicking from one position to the next. The symmetric, non-circular cross section provides resistance such that element 14 will not inadvertently rotate backwards and thus unwind), wherein the plug and the locking member are configured to secure a tether therebetween when the plug is at least partially disposed within the lumen of the locking member (Fig. 4A and Fig. 4B; para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12).

Regarding claim 41, Jackson et al. disclose that as applied to claim 40 further comprising a pushing member configured to push the plug in the first direction (para. [0040]- FIGS. 10 and 11 show an embodiment of the invention in which rotatable element 14 has a distal end 11 with a symmetric, non-circular cross section. As illustrated in Fig. 11, end 11 may be hexagonal, but square, octagonal or other shaped ends are also contemplated. As can be appreciated, rotating element 14 around axis A will tend to result in element 11 clicking from one position to the next. The symmetric, non-circular cross section provides resistance such that element 14 will not inadvertently rotate backwards and thus unwind; the different shaped ends of end 11 allow a pushing/rotational force to be applied to the rotatable element 14).

Regarding claim 42, Jackson discloses a device for securing a tether comprising: a locking member (block of material 12) configured to receive a plug (Fig. 2, see rotatable element 14 recevied in block 12) and comprising a wall portion (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14); and a plug comprising a body portion (Fig. 1 and Fig. 2, see distal end 11 of rotatable element 14) and an anchor portion (Fig. 1 and Fig. 2, see portion of rotatable element 14 below distal end 11) extending from the body portion (Fig. 1), wherein the plug and the locking member are configured to secure a tether therebetween (para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12).

Regarding claim 47, Jackson discloses, as best understood, a method for securing a first tether (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see left half of suture loop 120) is wrapped around the suture pair to be clamped) using a plug (rotatable element 114) comprising a first ring portion (hole 115; para. [0041]- Rotatable element 14 has a hole 115 passing therethrough) and a locking member (block 112) comprising a wall portion (Fig. 12, see interior surface of hole in block 112 that receives rotatable element 114), a proximal end (Fig. 12, see top end of block 112), a distal end (Fig. 12, see bottom end of block 112), and a lumen therethrough (Fig. 12, see hole in block 112 that receives rotatable element 114), the method comprising: advancing the plug at least partially into the lumen of the locking member (Fig. 12, see rotatable member 114 advanced into the hole in block 112) to secure the first tether between the plug and the wall portion of the locking member (para. [0042]- Specifically, such rotation will wrap the suture around rotatable element 114 in the same way that sutures 20 and 22 were wrapped around rotatable element 14 in clamping system 10, previously described; para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12); passing a second tether through the first ring portion (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see right half of suture loop 120 passed through hole 115; para. [0041]- Rotatable element 14 has a hole 115 passing therethrough); and securing the second tether to tissue of a subject (para. [0012]- The present system can minimize the extent to which suture at the surgical site is pulled as it secures the suture(s). As the present system is deployed, it simply tightens together the suture(s) at the operative site. In contrast, when tying together a suture pair, it is typically difficult to tie a knot very close to the operative site without excessively pulling on the tissues being tied together; Fig. 12, both halves of the suture loop 120 would be secured to the tissue of the patient).

Regarding claim 48, Jackson discloses that as applied to claim 47 wherein the locking member further comprises a second ring portion (loop holder extension 117), and the method further comprises passing the second tether through the second ring portion (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see right half of suture loop 120 passed through loop holder extension 117).

Regarding claim 49, Jackson discloses that as applied to claim 48 further comprising securing the second tether to tissue of the subject (para. [0012]- The present system can minimize the extent to which suture at the surgical site is pulled as it secures the suture(s). As the present system is deployed, it simply tightens together the suture(s) at the operative site. In contrast, when tying together a suture pair, it is typically difficult to tie a knot very close to the operative site without excessively pulling on the tissues being tied together; Fig. 12, both halves of the suture loop 120 would be secured to the tissue of the patient).

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Regarding claim 52, Jackson discloses that as applied to claim 47 wherein the first and second tethers are the same tether (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped).

Regarding claim 53, Jackson discloses that as applied to claim 47 wherein the first tether passes through at least one aperture in the wall portion of the locking member (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see left half of suture loop 120 passing through hole 113; para. [0041]- block 112 has a hole 113 passing therethrough)).

Regarding claim 54, Jackson discloses, as best understood, a method for securing a first tether (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see left half of suture loop 120) using a plug (rotatable element 114) and a locking member (block 112) comprising a wall portion (Fig. 12, see interior surface of hole in block 112 that receives rotatable element 114), a first ring portion (hole 115; para. [0041]- Rotatable element 14 has a hole 115 passing therethrough), a proximal end (Fig. 12, see top end of block 112), a distal end (Fig. 12, see bottom end of block 112), and a lumen therethrough (Fig. 12, see hole in block 112 that receives rotatable element 114), the method comprising: advancing the plug at least partially into the lumen of the locking member (Fig. 12, see rotatable member 114 advanced into the hole in block 112) to secure the first tether between the plug and the wall portion of the locking member (para. [0042]- Specifically, such rotation will wrap the suture around rotatable element 114 in the same way that sutures 20 and 22 were wrapped around rotatable element 14 in clamping system 10, previously described; para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12); passing a second tether through the first ring portion portion (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see right half of suture loop 120 passed through hole 115; para. [0041]- Rotatable element 14 has a hole 115 passing therethrough); and securing the second tether to tissue of a subject (para. [0012]- The present system can minimize the extent to which suture at the surgical site is pulled as it secures the suture(s). As the present system is deployed, it simply tightens together the suture(s) at the operative site. In contrast, when tying together a suture pair, it is typically difficult to tie a knot very close to the operative site without excessively pulling on the tissues being tied together; Fig. 12, both halves of the suture loop 120 would be secured to the tissue of the patient).

Regarding claim 55, Jackson discloses that as applied to claim 54 wherein the locking member further comprises a second ring portion (loop holder extension 117), and the method further comprises passing the second tether through the second ring portion (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see right half of suture loop 120 passed through loop holder extension 117).

Regarding claim 56, Jackson discloses that as applied to claim 55 further comprising securing the second tether to tissue of the subject (para. [0012]- The present system can minimize the extent to which suture at the surgical site is pulled as it secures the suture(s). As the present system is deployed, it simply tightens together the suture(s) at the operative site. In contrast, when tying together a suture pair, it is typically difficult to tie a knot very close to the operative site without excessively pulling on the tissues being tied together; Fig. 12, both halves of the suture loop 120 would be secured to the tissue of the patient).

Regarding claim 57, Jackson discloses that as applied to claim 54 wherein the first and second tethers are the same tether (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped).

Regarding claim 58, Jackson discloses that as applied to claim 54 wherein the first tether passes through at least one aperture in the wall portion of the locking member (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see left half of suture loop 120 passing through hole 113; para. [0041]- block 112 has a hole 113 passing therethrough)).

Claim 44 lack novelty under PCT Article 33(2) as being anticipated by Gallagher et al.

Regarding claim 44, Gallagher et al. disclose a method for securing a tether using a locking member comprising a first portion (first leg 102) having a first surface (concave inner surface 108, ridge 134 and eyelet 136) and a second portion (second legs 104) having a second surface (Convex inner surface 112 and groove 138), the first and second portions coupled to each other by a hinge (hinge section 106; para. [0021]- First and second legs 102 and 104 are joined at their proximal ends by an integral hinge section, generally designated 106), the method comprising: positioning the tether on one of the first and second surfaces when the first surface is not in contact with the second surface (Fig. 4 shows suture thread "T" in contact with the ridge 134 and eyelet 136 but not in contact with groove 138); and contacting the first surface with the second surface to secure a portion of the tether between the first and second portions of the locking member (para. [0031]- Fig. 6 is an enlarged, vertical cross-sectional view of clip 100 engaged around a portion of suture thread T. In the area where clip 100 is applied to suture thread T, ridge 134 pushes suture thread T into groove 138. The portion of suture thread T in contact with ridge 134 conforms around ridge 134 as suture thread T is pushed into groove 138. The desired amount of tension is maintained on suture thread T primarily by the interaction between ridge 134, suture thread T, and the interior walls of groove 138).

Claims 45 and 46 lack novelty under PCT Article 33(2) as being anticipated by Golds et al.

Regarding claim 45, Golds et al. disclose a device for securing a tether comprising: a locking member (bead member 12) configured to receive a plug (Fig. 9, see anchor 16 received in bead member 12) and comprising a proximal end (Fig. 3, see top end of anchor 16), a distal end (Fig. 3, see bottom end of anchor 16), and a lumen therethrough (Fig. 1 and Fig. 2, see aperture 22); a plug (anchor 16); and a coupling member (outwardly extending flange portions 30, 32) extending between the plug and the locking member to couple the plug to the locking member (Fig. 9, see the outwardly extending flange portions 30, 32 allowing coupling engagement of the anchor 16 and bead member 12 to clamp suture 40; Col. 4, Lns. 13-16).

Regarding claim 46, Golds et al. disclose a method for securing a tether (suture 40) using a locking member (bead member 12) and a clamping member (anchor 16) slidably disposed within the lumen of the locking member (Figs. 4 thru 9, see anchor 16 sliding within the bore 14 of bead member 12), the method comprising: clamping the tether (Fig. 2 and Fig. 4, see suture 40 placed into the aperture 22 and into contact with the arcuate wedging surfaces 28; Col. 4, Lns. 13-16) with the clamping member (arcuate wedging surfaces 28); and withdrawing the clamping member into the lumen of the locking member (Fig. 9, see anchor 16 withdrawin in the bore 14 of the bead member 12).

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Claim 59 lacks novelty under PCT Article 33(2) as being anticipated by Del Rio et al.

Regarding claim 59, Del Rio et al. disclose a method for securing a tether comprising: advancing the tether (suture 24) through a tubular member (Fig. 3, see frangible shaft 14; Fig. 1, see suture advanced through the opening created between the guide pin 42 of frangible shaft 14 and aperture 46) while the tubular member is at least partially disposed within a hollow region of a locking member (anchor 12; see frangible shaft 14, distal tip 16 and guide pin 42 disposed within the hollow region of the anchor 12) in an open configuration (Fig. 5A, shows an open configuration between the guide pin 42 and the top surface 61 of recess 62 which allows the suture 24 to freely slide in the opening); and withdrawing the tubular member from the hollow region without also withdrawing the tether from the hollow region (Fig. 5C, see frangible shaft 14 withdrawn from the hollow region of the anchor 12), wherein the locking member assumes a closed configuration (Fig. 9 and Fig. 7, show an closed configuration between the guide pin 42 and the top surface 61 of recess 62 which squeezes the suture 24 to lock it in place) when the tubular member has been withdrawn from the hollow region (Fig. 9 and Fig. 7; para. [0031]- The action of the tool 41 forces the pin to ride in the grooves 40 as it proceeds toward the top of the main body 28 until it fits into the recess 62. The top surface 61 of recess 62 may be serrated as shown by reference numeral 64 so that when the pin is moved to its most upward position the suture reaches are forced against the serrated surface 61 where the force of the pin binds the surface of the suture against the serration, squeezing the suture therein so as to tie and lock the suture in place without the necessity of having the surgeon knot the suture), such that the locking member clamps down on the tether and thereby secures the tether (Fig. 9 and Fig. 7; para. [0031]- The action of the tool 41 forces the pin to ride in the grooves 40 as it proceeds toward the top of the main body 28 until it fits into the recess 62. The top surface 61 of recess 62 may be serrated as shown by reference numeral 64 so that when the pin is moved to its most upward position the suture reaches are forced against the serrated surface 61 where the force of the pin binds the surface of the suture against the serration, squeezing the suture therein so as to tie and lock the suture in place without the necessity of having the surgeon knot the suture).

Claims 4-8, 21-24, 38, 39, 50 and 51 lack an inventive step under PCT Article 33(3) as being obvious over Jackson.

Regarding claim 4, Jackson discloses that as applied to claim 3. Jackson does not explicitly teach wherein the first and second apertures are located such that a tether passing therethrough would not cross the center of the lumen of the locking member. Jackson further discloses wherein the first and second apertures are located such that a tether passing therethrough would cross the center of the lumen of the locking member (Fig. 3A, see suture pair 20 and 22 crossing the center of the hole in block 12 that receives rotatable element 14). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the first and second apertures are located such that a tether passing therethrough would not cross the center of the lumen of the locking member, since rearranging parts of an invention only involves routine skill in the art and for the purpose of providing an alternate locking arrangement.

Regarding claim 5, Jackson disclose that as applied to claim 1. Jackson does not explicitly teach wherein the locking member comprises a tubular member. Jackson further discloses wherein the locking member comprises a block shaped member (Fig. 1, block of material 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the locking member to comprise a tubular member, since a change in shape of an element involves only routine skill in the art and for the purpose of optimizing/ minimizing the overall size of the device.

Regarding claim 6, Jackson discloses that as applied to claim 1. Jackson does not explicitly teach wherein the plug is rotatable by at least about 1° to secure a portion of a tether within the lumen of the locking member. Jackson further discloses wherein the plug is rotatable greater or less than 90° (para. [0034]- As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together. It is to be understood that, although element 14 is illustrated as being rotated by 90 degrees from Fig. 3A to Fig. 4A, greater or lesser amounts of rotation may instead be used). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to be rotatable by at least about 1° to secure a portion of a tether within the lumen of the locking member, since discovering the optimum value of a result effective variable involves only routine skill in the art and for the purpose of providing a sufficient amount of locking force.

Regarding claim 7, Jackson discloses that as applied to claim 6. Jackson does not explicitly teach wherein the plug is rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member. Jackson further discloses wherein the plug is rotatable greater or less than 90° (para. [0034]- As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together. It is to be understood that, although element 14 is illustrated as being rotated by 90 degrees from Fig. 3A to Fig. 4A, greater or lesser amounts of rotation may instead be used). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to be rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member, since discovering the optimum value of a result effective variable involves only routine skill in the art and for the purpose of providing a sufficient amount of locking force.

Regarding claim 8, Jackson discloses that as applied to claim 1. Jackson does not explicitly teach wherein the plug is rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member. Jackson further discloses wherein the plug is rotatable greater or less than 90° (para. [0034]- As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together. It is to be understood that, although element 14 is illustrated as being rotated by 90 degrees from Fig. 3A to Fig. 4A, greater or lesser amounts of rotation may instead be used). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to be rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member, since discovering the optimum value of a result effective variable involves only routine skill in the art and for the purpose of providing a sufficient amount of locking force.

Regarding claim 21, Jackson disclose that as applied to claim 17. Jackson does not explicitly teach wherein the locking member comprises a tubular member. Jackson further discloses wherein the locking member comprises a block shaped member (Fig. 1, block of material 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the locking member to comprise a tubular member, since a change in shape of an element involves only routine skill in the art and for the purpose of optimizing/ minimizing the overall size of the device.

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Regarding claim 22, Jackson discloses that as applied to claim 17. Jackson does not explicitly teach wherein the plug is rotatable by at least about 1° to secure a portion of a tether within the lumen of the locking member. Jackson further discloses wherein the plug is rotatable greater or less than 90° (para. [0034]- As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together. It is to be understood that, although element 14 is illustrated as being rotated by 90 degrees from Fig. 3A to Fig. 4A, greater or lesser amounts of rotation may instead be used). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to be rotatable by at least about 1° to secure a portion of a tether within the lumen of the locking member, since discovering the optimum value of a result effective variable involves only routine skill in the art and for the purpose of providing a sufficient amount of locking force.

Regarding claim 23, Jackson discloses that as applied to claim 22. Jackson does not explicitly teach wherein the plug is rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member. Jackson further discloses wherein the plug is rotatable greater or less than 90° (para. [0034]- As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together. It is to be understood that, although element 14 is illustrated as being rotated by 90 degrees from Fig. 3A to Fig. 4A, greater or lesser amounts of rotation may instead be used). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to be rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member, since discovering the optimum value of a result effective variable involves only routine skill in the art and for the purpose of providing a sufficient amount of locking force.

Regarding claim 24, Jackson discloses that as applied to claim 7. Jackson does not explicitly teach wherein the plug is rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member. Jackson further discloses wherein the plug is rotatable greater or less than 90° (para. [0034]- As can be appreciated, rotation of element 14 within block 12 will tightly hold suture pair 20 and 22 together. It is to be understood that, although element 14 is illustrated as being rotated by 90 degrees from Fig. 3A to Fig. 4A, greater or lesser amounts of rotation may instead be used). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to be rotatable by at most about 180° to secure a portion of a tether within the lumen of the locking member, since discovering the optimum value of a result effective variable involves only routine skill in the art and for the purpose of providing a sufficient amount of locking force.

Regarding claim 38, Jackson discloses a method for securing a tether using a device comprising a plug (rotatable element 14) and a locking member (block of material 12) comprising a wall portion having an interior surface (Fig. 1, see interior surface of hole in block 12 that receives rotatable element 14), a proximal end (Fig. 1, see top surface of block 12), a distal end (Fig. 1, see bottom surface of block 12), and a lumen therethrough (Fig. 1, see hole in block 12 that receives rotatable element 14), the method comprising: at least partially fitting the plug within the lumen of the locking member (Fig. 2 and Fig. 3B, see rotatable element partially disposed within the block 12). Jackson does not explicitly teach engaging a groove or first aperture in the plug with at least one protrusion on the interior surface of the wall portion of the locking member while a portion of the tether is disposed within the lumen of the locking member to secure the tether between the plug and the locking member. Jackson further discloses a plug (rotatable element 14) comprising at least one protrusion (curved bar 19) configured to engage a groove or first aperture in the wall portion of the locking member when the plug is at least partially disposed within the lumen of the locking member (Fig. 5 and Fig. 6, it is inherent that there must be a groove to allow the barb 19 to move in a forward direction or that the barb 19 engages with either hole 13), wherein a portion of the tether is disposed within the lumen of the locking member to secure the tether between the plug and the locking member (para. [0034]- Preferably, therefore, block 12 will deform to a degree to receive suture pair 20 and 22 between the outer surface of element 14 and the inner surface of block 12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to engage a groove or first aperture in the plug with at least one protrusion on the interior surface of the wall portion of the locking member while a portion of the tether is disposed within the lumen of the locking member to secure the tether between the plug and the locking member, since a mere reversal of essential working parts of a device involves only routine skill in the art and for the purpose of providing an alternate locking arrangement.

Regarding claim 39, Jackson discloses that as applied to claim 38. Jackson does not explicitly teach wherein the at least one protrusion on the interior surface of the wall portion of the locking member forms a snap-fit with the groove or first aperture in the plug. Jackson further discloses wherein the at least one protrusion of the plug is configured to form a snap-fit with the groove or first aperture in the wall portion of the locking member (Fig. 5 and Fig. 6, it is inherent that there must be a groove to allow the barb 19 to snap into to allow movement in a forward direction or that the barb 19 engages with either hole 13). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the at least one protrusion on the interior surface of the wall portion of the locking member forms a snap-fit with the groove or first aperture in the plug, since a mere reversal of essential working parts of a device involves only routine skill in the art and for the purpose of providing an alternate locking arrangement.

Regarding claim 50, Jackson discloses that as applied to claim 47. Jackson does not explicitly teach wherein the plug further comprises a second ring portion, and the method further comprises passing the second tether through the second ring portion. Jackson further discloses wherein the locking member further comprises a second ring portion (loop holder extension 117), and the method further comprises passing the second tether through the second ring portion (para. [0044]-Specifically, loop 120 (or a loop formed by sutures 20 and 22) is wrapped around the suture pair to be clamped; Fig. 12, see right half of suture loop 120 passed through loop holder extension 117). It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug further comprises a second ring portion, and the method further comprises passing the second tether through the second ring portion, since a mere reversal of essential working parts of a device involves only routine skill in the art and for the purpose of providing an alternate securing method.

Regarding claim 51, Jackson discloses that as applied to claim 50 further comprising securing the second tether to tissue of the subject (para. [0012]- The present system can minimize the extent to which suture at the surgical site is pulled as it secures the suture(s). As the present system is deployed, it simply tightens together the suture(s) at the operative site. In contrast, when tying together a suture pair, it is typically difficult to tie a knot very close to the operative site without excessively pulling on the tissues being tied together; Fig. 12, both halves of the suture loop 120 would be secured to the tissue of the patient).

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Claim 10 lacks an inventive step under PCT Article 33(3) as being obvious over Jackson in view of Coe et al.
Regarding claim 10, Jackson discloses that as applied to claim 1 further comprising a pullwire for rotating the plug within the lumen of the locking member.
Coe et al. teach the concept of using a pullwire (pullwire 15) to actuate rotation (Fig. 6; para. [0039]- As shown in Fig. 6, force can be applied to the pull wire 15 to rotate the cap 13 with respect to the cylindrical member) of an element (cap 13).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a pullwire for rotating the plug within the lumen of the locking member as taught by Coe et al. with the invention of Jackson for the purpose of providing an alternate means for externally rotating the plug.

Claims 11, 15, 16 and 28 lack an inventive step under PCT Article 33(3) as being obvious over Jackson in view of Goble et al.
Regarding claim 11, Jackson discloses that as applied to claim 1. Jackson does not explicitly teach further comprising a cutting member configured to cut a tether.
Goble et al. teach a suture anchor (title) comprising a cutting member configured to cut a tether (abstract- the excess suture or shaft can be cut away, permanently mounting the graft ; Col. 14, Lns. 10-13).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a cutting member configured to cut a tether as taught by Goble et al. with the invention of Jackson for the purpose of providing an alternate means for removing the excess suture.
Regarding claim 15, Jackson discloses that as applied to claim 1. Jackson does not explicitly teach wherein the plug comprises a gear-shaped portion.
Goble et al. teach a suture anchor (title) wherein a plug (bone anchor 100) comprises a gear-shaped portion (Fig. 18 and Fig. 19, see cylinder 107 and grooves, serrations or the like 107b).
It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug comprises a gear-shaped portion as taught by Goble et al. with the invention of Jackson for the purpose of providing an alternate means for locking the tether.
Regarding claim 16, Jackson in view of Goble et al. disclose that as applied to claim 15. Jackson does not explicitly teach wherein the gear-shaped portion comprises a plurality of teeth.
Goble et al. teach wherein the gear-shaped portion comprises a plurality of teeth portion (Fig. 18 and Fig. 19, see grooves, serrations or the like 107b).
It would have been obvious to one of ordinary skill in the art at the time the invention was made for the gear-shaped portion to comprise a plurality of teeth as taught by Goble et al. with the invention of Jackson for the purpose of providing an alternate means for locking the tether. Neither Jackson or Goble et al. explicitly teach each tooth being progressively longer than the previous tooth. It would have been obvious to one of ordinary skill in the art at the time the invention was made for each tooth being progressively longer than the previous tooth, since such a modification would involve a mere change in the size of a component and for the purpose of increasing the frictional force between the tooth and the tether.
Regarding claim 28, Jackson discloses that as applied to claim 17. Jackson does not explicitly teach further comprising cutting the tether.
Goble et al. teach a suture anchor (title) comprising a cutting member configured to cut a tether (abstract- the excess suture or shaft can be cut away, permanently mounting the graft ; Col. 14, Lns. 10-13).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a cutting member configured to cut a tether as taught by Goble et al. with the invention of Jackson for the purpose of providing an alternate means for removing the excess suture.

Claims 12-14 lack an inventive step under PCT Article 33(3) as being obvious over Jackson in view of Toso et al.
Regarding claim 12, Jackson discloses that as applied to claim 1. Jackson does not explicitly teach wherein the plug comprises at least one protrusion configured to engage a portion of a tether within the lumen of the locking member.
Toso et al. teach a suture clip (title) wherein a plug (first member 110) comprises at least one protrusion (legs 112, 113 and locking barbs 115, 116) configured to engage a portion of a tether within the lumen of the locking member (Fig. 3, see locking barbs 115, 116 engaging with suture 130 within the lumen of retainer member 120).
It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to comprise at least one protrusion configured to engage a portion of a tether within the lumen of the locking member as taught by Toso et al. with the invention of Jackson for the purpose of providing an alternate means for retaining the suture in the lumen.
Regarding claim 13, Jackson in view of Toso et al. disclose that as applied to claim 12. Jackson does not explicitly teach wherein the at least one protrusion is in the form of at least one ridge.
Toso et al. teach wherein the at least one protrusion is in the form of at least one ridge (Fig. 3, see ridge shaped locking barbs 115, 116).
It would have been obvious to one of ordinary skill in the art at the time the invention was made for the at least one protrusion to be in the form of at least one ridge as taught by Toso et al. with the invention of Jackson for the purpose of providing an alternate means for retaining the suture in the lumen.
Regarding claim 14, Jackson discloses that as applied to claim 1. Jackson does not explicitly teach wherein the plug comprises multiple protrusions that form a stepped configuration.
Toso et al. teach a suture clip (title) wherein a plug (first member 110) wherein the plug comprises multiple protrusions (legs 112, 113 and locking barbs 115, 116) that form a stepped configuration (Fig. 3, see stepped configuration formed by legs 112, 113 and locking barbs 115, 116 to the flat surface of base 111).
It would have been obvious to one of ordinary skill in the art at the time the invention was made for the plug to comprise multiple protrusions that form a stepped configuration as taught by Toso et al. with the invention of Jackson for the purpose of providing an alternate means for retaining the suture in the lumen.

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Claim 43 lacks an inventive step under PCT Article 33(3) as being obvious over Jackson in view of Denham et al.
Regarding claim 43, Jackson discloses that as applied to claim 42. Jackson does not explicitly teach further comprising advancing the anchor portion into tissue so that the anchor portion engages the tissue.
Denham et al. teach advancing an anchor portion (Fig. 4A, see tip 32 of the suture receiving portion 22) into tissue so that the anchor portion engages the tissue (Fig. 4A, see tip 32 of suture receiving portion 22 engaged with the boney structure 16).
It would have been obvious to one of ordinary skill in the art at the time the invention was made to advancing the anchor portion into tissue so that the anchor portion engages the tissue as taught by Denham et al. with the invention of Jackson for the purpose of further securing the device to the tissue.

Claim 60 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest:
Regarding claim 60, The cited prior art does not teach or fairly suggest a method for securing a tether comprising: advancing the tether through a coil while the coil is in a primary configuration and at least partially disposed within a lumen of a tubular member; and translating the coil relative to the tubular member so that the coil exits the lumen of the tubular member and assumes a secondary configuration in which the coil secures the tether.

Claims 1-60 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.