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Paper 9
Entered: October 17, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW, INC. and
ARTHROCARE CORP.,
Petitioner,

v.

ARTHREX, INC.,
Patent Owner.

Case IPR2016-00918
Patent 8,821,541 B2

Before WILLIAM V. SAINDON, BARRY L. GROSSMAN, and TIMOTHY J. GOODSON, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Petitioner requests an *inter partes* review of claims 10 and 11 of U.S. Patent No. 8,821,541 B2 (Ex. 1101, "the '541 patent"). Paper 2 ("Petition" or "Pet."). Patent Owner filed a Preliminary Response to the Petition. Paper 8 ("Prelim. Resp.").

This Decision is made under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition and Patent Owner's Preliminary Response, we institute an *inter partes* review on both challenged claims of the '541 patent.

Our factual findings and conclusions at this stage of the proceeding, including claim constructions, are preliminary, and based on the evidentiary record developed thus far. This is not a final decision as to the patentability of claims for which *inter partes* review is instituted. Our final decision will be based on the record as fully developed during trial.

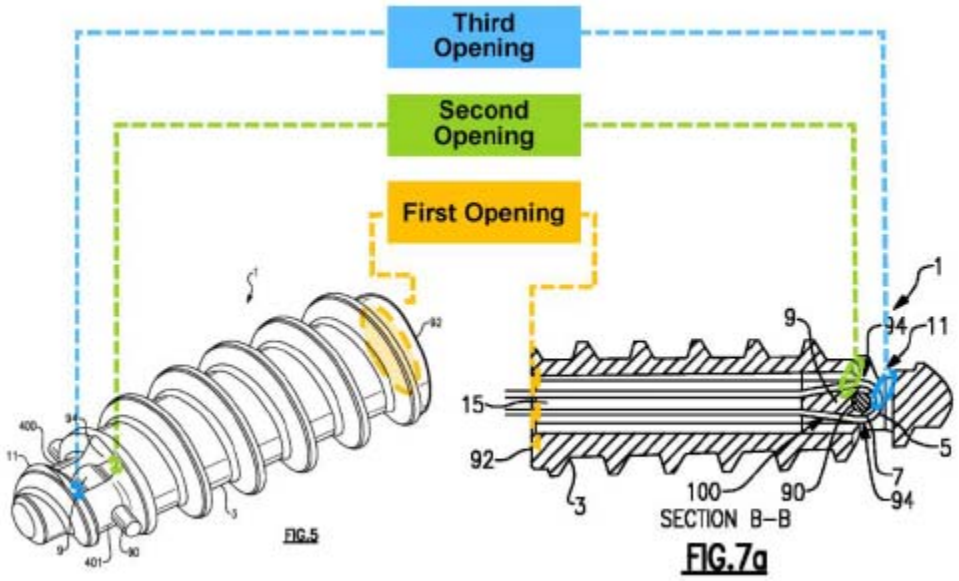
A. Related Matters

The '541 patent has been asserted in the U.S. District Court for the Eastern District of Texas, *Arthrex, Inc. v. Smith & Nephew, Inc.*, Civil Action No. 2:2015-cv-01047. Pet. 7; Paper 5, 2. There are several related petitions for *inter partes* review: IPR2015-00505 (involving U.S. Patent No. 8,343,186, the parent of the '541 patent), IPR2015-00506 (involving U.S. Patent No. 8,623,052, a child of the '186 patent), and IPR2016-00507 and 508 (involving U.S. Patent No. 8,801,755, a child of the '052 patent). Pet. 7;

Paper 5, 1. There are also a number of related patents and patent applications not presently at issue. Pet. 7; Paper 5, 2.

B. The '541 Patent

The '541 patent is directed to a suture anchor having a transverse anchor pin inside the body of the anchor. Ex. 1001, 1:25–28. Petitioner provides the following annotated versions of Figures 5 and 7a of the '541 patent:



Pet. 4. Petitioner's annotated version of Figure 5 of the '541 patent is a perspective view of a suture anchor having a transverse anchor pin. Petitioner's annotated version of Figure 7a of the '541 patent is a cross section view of the same. The annotations identify three openings through which suture passes. Notably, the locations of the second and third openings are defined by the location of the pin.

C. Challenged Claims

Petitioner challenges independent claims 10 and 11. Claim 10 is reproduced below.

> 10. A structure anchor assembly comprising an anchor body including a longitudinal axis, a proximal end, a distal end, and a central passage extending along the longitudinal axis from an opening at the proximal end of the anchor body through a portion of a length of the anchor body, wherein the opening is a first suture opening, the anchor body including a second suture opening disposed distal of the first suture opening, and a third suture opening disposed distal of the second suture opening, wherein a helical thread defines a perimeter at least around the proximal end of the anchor body;
>
> a rigid support extending across the central passage, the rigid support having a first portion and a second portion spaced from the first portion, the first portion branching from a first wall portion of the anchor body and the second portion branching from a second wall portion of the anchor body, wherein the third suture opening is disposed distal of the rigid support;
>
> at least one suture strand haying a suture length threaded into the central passage, supported by the rigid support, and threaded past the proximal end of the anchor body, wherein at least a portion of the at least one suture strand is disposed in the central passage between the rigid support and the opening at the proximal end, and the at least one suture strand is disposed in the first suture opening, the second suture opening, and the third suture opening; and
>
> a driver including a shaft having a shaft length, wherein the shaft engages the anchor body, and the suture length of the at least one suture strand is greater than the shaft length of the shaft.

D. Prior Art and Asserted Grounds

Petitioner asserts that claims 10 and 11 of the '541 patent are unpatentable under the following grounds:

References	Basis	Claim(s) Challenged
Gordon[1] and West[2]	§ 103	10 and 11
Curtis[3]	§ 102	11
Curtis and Overaker[4]	§ 103	10
Curtis, Overaker, and DiPoto[5]	§ 103	10

Petitioner also relies on the declaration Mark A. Ritchart (Ex. 1103), who holds a degree in mechanical engineering and is the president of a medical device company (*id.* ¶ 2).

II. ANALYSIS

A. Claim Construction

We interpret the claims of an unexpired patent using the broadest reasonable interpretation in light of the specification of the patent. 37 C.F.R. § 42.100(b). Under that standard, a claim term generally is given its ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic*

[1] U.S. Pub. No. 2006/0271060 A1, published Nov. 30, 2006, Filed May 26, 2006 (Ex. 1105).

[2] U.S. Patent No. 7,322,978 B2, issued Jan. 29, 2008, filed June 22, 2004 (Ex. 1106).

[3] U.S. Patent No. 5,464,427, issued Nov. 7, 1995 (Ex. 1107).

[4] U.S. Pub. No. 2003/0187444 A1, pub. Oct. 2, 2003, filed Mar. 29, 2002 (Ex. 1124).

[5] U.S. Patent No. 5,690,676, issued Nov. 25, 1997 (Ex. 1125).

Tech., Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Although our claim interpretation cannot be divorced from the specification, *see Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1298 (Fed. Cir. 2015) (quoting *In re NTP, Inc.*, 654 F.3d 1279, 1288 (Fed. Cir. 2011)), we must be careful not to import limitations from the specification that are not part of the claim language, *see SuperGuide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

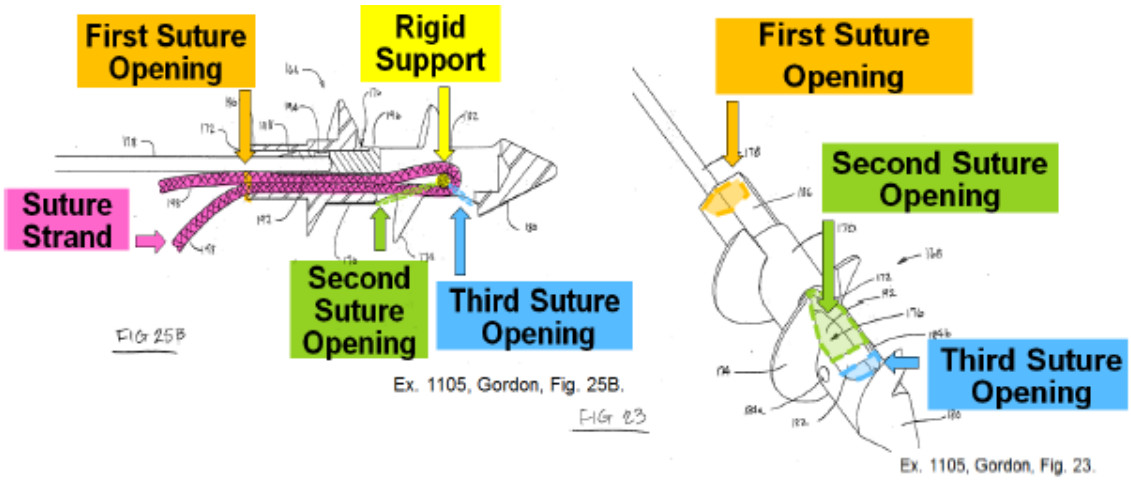
Petitioner proposes constructions for a number of terms, "suture opening," "rigid support," "central passage," "suture passage," "branching," and "a rigid support integral with the anchor body to define a single-piece component." Pet. 19–24. Patent Owner offers its discussion of the terms, but argues that it does not believe constructions of the terms are warranted. Prelim. Resp. 12–19.

Based on our analysis of the disputes between the parties at this time, we agree with Patent Owner that none of these terms require construction at this time. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Accordingly, we do not adopt an express claim construction of any claim term in this Decision.

B. Obviousness in View of Gordon and West (Claims 10 and 11)

1. Petitioner's Ground

Petitioner asserts that the subject matter of claims 10 and 11 would have been obvious to a person of ordinary skill in the art in view of Gordon and West. Pet. 24–43. Petitioner asserts that Gordon discloses a suture anchor having an anchor body with a central passage, a rigid support for the suture, a suture, and three openings, as depicted in Petitioner's annotated versions of Figures 25B and 23 of Gordon, reproduced below:



Pet. 33. Petitioner's annotated version of Figure 25B depicts a cross section of Gordon's anchor. Petitioner's annotated version of Figure 23 depicts a perspective view of Gordon's anchor.

According to Petitioner, two aspects of the claims are missing from Gordon. First are helical threads defining a perimeter at least around the proximal end of the anchor body. Pet. 28. In Gordon, the proximal end of the anchor body is a male drive head, precluding the presence of threads at the proximal end. *Id.*; *see, e.g.*, Ex. 1105, Fig. 23. Petitioner asserts that substituting a female socket, as shown in West, would allow for the presence

of threads on the proximal end, and would have been a known and predictable substitution. Pet. 28. Further, the female socket in West "provides the bone anchor with the ability to better engage the cortical bone near the surface of the bone," due to the extra threads. Ex. 1106, 2:65–67; Ex. 1103 ¶¶ 162–166.

The second modification, relevant only to claim 11, is to manufacture Gordon using a casting process, such as to make the rigid support (the pin around which the suture is threaded) an integral component of the anchor body. Pet. 28–30. According to Petitioner, West describes a similar anchor body having pins to thread suture over, and that West describes making it using a casting process. *Id.* at 28–29 (citing Ex. 1106, 5:31–33, 6:48–50, 7:41–43). Petitioner also asserts that this implementation is consistent with Gordon because Gordon incorporates Foerster, which describes how a pulley (like Gordon) may be a "fixed structure." *Id.* (citing Ex. 1108 ¶ 70; Ex. 1103 ¶¶ 25, 83, 167). Lastly, Petitioner asserts several other reasons to cast the structures, because it would minimize the materials used (allegedly useful in FDA approvals), because casting was well known, and because this would be more secure than an attached support. *Id.* at 29–30 (citing Ex. 1103 ¶¶ 169–171, 210).

2. Patent Owner's Preliminary Response

Patent Owner's Preliminary Response argues that Petitioner relies on multiple embodiments of Gordon's suture (Prelim. Resp. 34–35), and on multiple embodiments of Gordon's driver (*id.* at 36–37). Patent Owner also argues that modifying Gordon in view of West would render Gordon unsatisfactory for its intended purpose, due to size constraints. *Id.* at 38–40.

Specifically for claim 11, Patent Owner argues that Petitioner has not shown sufficiently that Gordon's rigid support can be cast with the body. *Id.* at 41–43.

3. Discussion

We are persuaded that Petitioner has shown a reasonable likelihood of success in demonstrating claims 10 and 11 to be unpatentable in view of Gordon and West. In Petitioner's proposed combination, Gordon's anchor is modified to have a female proximal end socket instead of a male proximal end. Both are known, and the benefits of having a female end socket over a male socket in particular are known. The background portion of West explains:

> Bone anchors can fail for various reasons. One reason is that existing bone anchors are not threaded to the proximal end of the anchor where the anchor meets the surface of the bone in the hard cortical bone region. In existing bone screws, the proximal end is not threaded because the driver tool used to insert the bone anchor fits over a hex shaped protrusion. The hex protrusion cannot extend above the bone surface so the screw is driven into the bone until the protrusion is below the surface. Since the protrusion has no threads, the bone anchor does not engage the bone near the surface, but only the soft cancellous bone beneath the cortical bone layer. This feature of existing bone anchors is very problematic because it prevents a practitioner from placing the threads of the bone anchor in the harder cortical bone, which is near the bone surface.

Ex. 1106, 1:50–64. Accordingly, we are persuaded by Petitioner's assertion, on this record, that a person of ordinary skill in the art would have considered it obvious to switch to a female socket, which would then result in the proximal end being threaded on the outside. Patent Owner argues that this would be unsatisfactory because "*Gordon* cannot accommodate an

internal drive head." Prelim. Resp. 38. Patent Owner's line of reasoning here is speculative and based on precise measurements of drawings that are not necessarily to scale. On this record, this argument is not persuasive.

The second modification to Gordon is to manufacture it by casting. West states that its anchor, which also includes a central passage and two rigid supports, "can be cast and formed in a die." Ex. 1106, 7:41–43. West also describes an embodiment where the anchor body is cast, and then pins are inserted for the two rigid supports. *Id.* at 7:43–47. On this record, this shows that anchors having rigid supports can be cast as a whole, or the supports can be added separately. Patent Owner argues that "*West* has a much simpler design with greater wall thickness that would lend itself more to casting [than] compared to the complex geometries and thin walls of . . . *Gordon*." Prelim. Resp. 41. First, Patent Owner's argument regarding the relative sizes is speculative, as we noted above. Second, there is no persuasive evidence suggesting that Gordon is any more complex than West. West, notably, has two rigid members offset by 90 degrees, which would appear, in our view, to be more difficult (or at least as difficult) to cast than a structure like Gordon, which only has one rigid member. On this record, Patent Owner's arguments are not persuasive.

Patent Owner also argues that Petitioner mixes embodiments when referencing the suture and driver. Although we agree that Gordon describes two different tools for driving the same suture anchor, it is not apparent that this makes any difference to the ground. That the suture is given one number or another in different drawings does not change that Gordon describes the suture as claimed. Further, that there are different drivers does not change that a driver as claimed is disclosed. *See EWP Corp. v. Reliance*

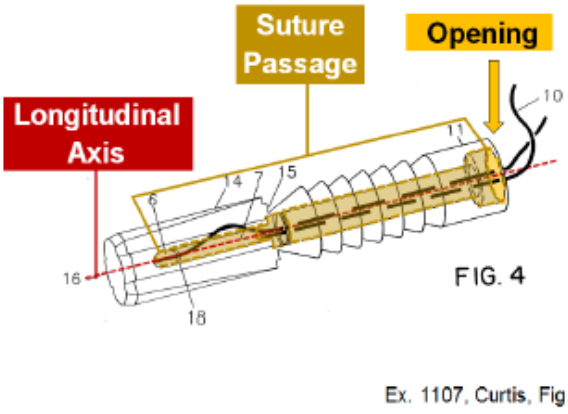
Universal Inc., 755 F.2d 898, 907 (Fed. Cir. 1985) ("A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect."). Based on our review of the ground and the prior art, these alleged distinctions are immaterial as both the driver in Fig. 13 or the combination driver/tensioner in, e.g., Fig. 7 have a shaft shorter than the suture.

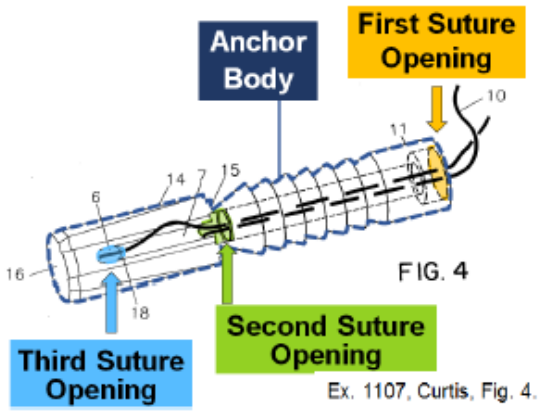
4. Conclusion

Reviewing the Petition, Preliminary Response, and the evidence cited therein, we are persuaded that Petitioner has demonstrated a reasonable likelihood of showing claims 10 and 11 to be unpatentable in view of Gordon and West.

C. Anticipation by Curtis (Claim 11)

Petitioner asserts that claim 11 is anticipated by Curtis. Pet. 43–52. Petitioner addresses each element in a chart. *Id.* at 50–52. Petitioner provides the following annotated versions of Figure 4 of Curtis to show most of the claimed features:





Pet. 46. Petitioner's two annotated Figure 4s depict perspective views of the Curtis suture anchor.

Patent Owner argues that Curtis does not disclose "a rigid support integral with the anchor body" because "the main body 11 and the conical body 14 are temporarily attached to each other." Prelim. Resp. 46–47; *see also id.* at 43–47 (setting forth the entire argument).

On this record, we are not persuaded that a temporary attachment precludes the rigid support from being "integral with the main body." The claim has no duration or deployment constraints. Further, as Petitioner points out, the connection between main body 11 and conical body 14 is one that "breaks away" if enough pulling force is applied. Pet. 51–52 (quoting Ex. 1107, 2:60–3:8). The description that the two can be *broken* apart due to force reasonably implies, on this record, that they were integrally connected. Accordingly, Petitioner has made a sufficient showing that the rigid support in Curtis is integral with the anchor body as required by claim 11. Similarly, we are persuaded Petitioner has made a sufficient showing regarding the remaining claim limitations. Reviewing the Petition, Preliminary Response, and the evidence cited therein, we are persuaded that Petitioner has demonstrated a reasonable likelihood of showing claim 11 to be unpatentable in view of Curtis.

D. Curtis, Overaker, and DiPoto (Claim 10)

Petitioner asserts that claim 10 is unpatentable in view of Curtis and Overaker, or Curtis, Overaker, and DiPoto. Pet. 53–60. We consider the Curtis/Overaker ground to be subsumed within the Curtis/Overaker/DiPoto ground, and thus only address the latter. We consider Petitioner's arguments

and discussion concerning the Curtis/Overaker ground to be included in Petitioner's ground of Curtis/Overaker/DiPoto.

Petitioner asserts that Curtis does not disclose the claimed helical threads of claim 10, but that Overaker does. Pet. 53–54. Petitioner asserts modifying Curtis's barbs to be helical as shown in Overaker would be a known substitution to yield a predictable result. *Id.* at 54–55. Petitioner asserts that DiPoto describes suture threads extending past the driver's shaft length. *Id.* at 58–60. Petitioner asserts that such an arrangement may be understood from Curtis's disclosure, but that DiPoto shows such features explicitly. *Id.*; *id.* at 57–58.

Patent Owner argues that "rotating the main body 11 [of Curtis] in order to thread the anchor into bone would [be problematic]." Prelim. Resp. 52–53; *see also id.* at 53–54, 56 (similar arguments). This argument is in the context of Petitioner's proposed modification of Curtis's barbs into a helical form. Patent Owner does not explain clearly why rotation is an issue, as claim 10 does not appear to require an anchor that is rotated. Modifying barbs that are parallel to each other to be helical does not mean that that modification would turn the anchor into a screw or that it would be rotated into place. Overaker, like Curtis, is not a screw anchor but an expandable anchor. Ex. 1124, (54). Overaker describes barbs or ribs in parallel, like Curtis (*see id.* at Fig. 1) but also describes them as helical (*id.* ¶ 20). Accordingly, Overaker shows that it is appropriate for expandable anchors to have either configuration; i.e., the helix shape is also appropriate for these types of anchors and does not imply rotational installment.

Reviewing the Petition, Preliminary Response, and the evidence cited therein, we are persuaded that Petitioner has demonstrated a reasonable

likelihood of showing claim 10 to be unpatentable in view of Curtis, Overaker, and DiPoto.

III. ORDER

In view of the foregoing, it is hereby:

ORDERED that *inter partes* review of the ’541 patent is instituted on the following grounds set forth in the Petition:

Whether claims 10 and 11 would have been obvious in view of Gordon and West;

Whether claim 11 is anticipated by Curtis;

Whether claim 10 would have been obvious in view of Curtis, Overaker, and DiPoto;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, *inter partes* review shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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