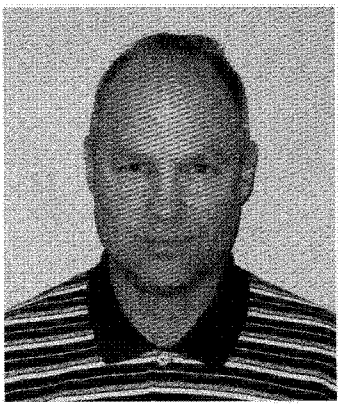
A Brief Review Of Two Pedicle Screw Patents



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The battle in the marketplace is *increasingly fought on issues of intellectual property, especially in the spine segment. Key patents involving polyaxial pedicle screws have come to the front lines. Through its acquisition of Interpore Cross, Biomet came to own the now-legendary* '555 *patent, and continued Interpore* s *efforts to enforce it vigorously. Recently, Johnson & Johnson began to enforce its* '678 *patent. In order to provide some clarity, we requested the following summary. We will continue this feature in the future as need arises. -Editor*

Many OPN readers have requested a review of U.S. Patent No. 5,474,555 to Puno *et al.* (the '555 Patent) and U.S. Patent No. 5,207,678 to Harms *et al.* (the '678 Patent). In response to these requests, we have looked at both patents and have attempted to provide here a general review of the structural limitations defined in the independent and dependent claims that have issued. This review should not be interpreted as legal advice or a legal opinion, as the contents and positions stated in this article are provided for informational purposes only. This review does not make any comparisons of commercially available product to either the '555 Patent or the '678 Patent, and no opinions as to invalidity, infringement or freedom to operate have been provided.

A person usually seeks the advice of a patent attorney when he wants an opinion as to whether his invention infringes a previously issued patent or would like to know the likelihood of obtaining a patent for his invention in view of the known prior art. For both of these scenarios, before any comparisons can be made, the patent attorney must first look at the identified prior art and properly construe the claims to determine their meaning and scope. This article will attempt to construct the limitations defined within the claims of the '555 and '678 Patents.

Because of space restraints, the legal precedent that defmes the standards for claim construction review will not be discussed in this article. The author is happy to share with any interested reader the role of the court as the determinator of claim construction, as well as the use of intrinsic and extrinsic evidence when attempting to define what a claim means.

It must be noted that many of the claims in the '555 Patent include elements that have been claimed using "means-plus-function" language. Briefly, Section 112, paragraph 6 of Title 35 ofthe U.S. Code provides that an element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of a structure, or material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the
specification and equivalents thereof. As a side note, a patent attorney, if performing a non-infringement analysis, would understand that for such a "means-plus-function" limitation to read on an accused device, the accused device must employ a structure identical to or the equivalent of the structure, material, or acts described in the patent specification. In addition, the accused device must also perform the identical function as specified in the claim. *Valmont Indus., Inc.* v. *Reinke Mfg. Co.,* 983 F.2d 1039, 104142,25 USPQ2d 1451, 1454 (Fed. Cir. 1993).

Based on well established legal standards, a detailed review of the claims and the defined limitations of the '555 and '678 Patents has been provided. It should be emphasized that neither of the prosecution history files for these two patents were reviewed nor examined for this article. Further, when the independent claims of a particular patent contain identical claim limitations, such limitations will be interpreted to be the same in each subsequent independent claim. Therefore, for inquiry purposes, the definition of a particular term that is contained within any subsequent claim of the same patent will not be re-analyzed.

1. U.S. Patent 5.474.555 to Puno *et af.*

The '555 Patent issued on December 12, 1995, from U.S. Application No. 08/285,226 that was filed on August 3, 1994, and is a Continuation of Application No. 07/946,316, filed onApril26, 1990. The '555 Patent claims priority from U.S. Application No. 07/946,316, which is now U.S. Patent No. 5,360,431 (the" '431 Patent").

A terminal disclaimer was approved by the United States Patent and Trademark Office (USPTO) that required the term of the '555 Patent to not extend beyond the November 1, 2011 expiration date of the '431 Patent. On its face, the '555 Patent is assigued to Cross Medical Products. All maintenance fees for the '555 Patent are current as of the date ofthis article.

The '555 Patent was the subject of litigation between Cross Medical Products and Medtronic Sofamor Danek, with the case being decided on September 30, 2005, by the U.S. Court of Appeals, Federal Circuit. *(See Cross Medical Prods., Inc. v. Medtronic Sofamor Danek, Inc.,* 424 F.3d 1293 (Fed. Cir. 2005).) The court, in making its decision, considered several claim limitations that will be discussed below. The holdings of the court should be looked at as being dispositive relative to those particular limitations analyzed. It is assumed that all the other claim limitations in the independent claims of the '555 Patent not reviewed by the court were agreed to by the parties. These other limitations have also been listed below.

The '555 Patent includes three independent claims. As a rule, the independent claims are the focal point when reviewing a pa!ent, because if one doesn't infringe an independent claim, then the narrower or more limiting dependent claims will also not be infringed. For this article, we will only look at claims 1,5 and 7 of the '555 Patent. In addition, as a general rule, claim limitation utilizing identical language in subsequent claims is interpreted the same. Therefore, for the purposes of this article, if a claim limitation has been examined in claim 1, this same analysis is applicable to claims 5 or 7 if that same claim limitation has been defmed in those claims.

Claim I provides:

1. A fixation device for the stabilization of one or more spinal bone segments, comprising:

> at least two anchors and an elongated stabilizer, said stabilizer having a cross-sectional depth, said anchors each comprising screw means which secure said anchor to said spinal bone segment;
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> anchor seat means which has a lower bone interface surface which is operatively joined to said spinal bone segment by said screw means and has external threads on a portion spaced apart trom said bone interface surface and said anchor seat means having an internal bore through which said screw means projects and the screw means has a rounded head which cooperates with said internal bore to permit limited motion between said screw means and said anchor seat means, said anchor seat means further having a stabilizer receiving channel with a stabilizer interface surface to receive said stabilizer and said external threads extending toward said stabilizer interface surface beyond the cross-sectional depth of the stabilizer; and
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> a nut having a relatively constant diameter through bore having internal threads which cooperate with the threads of said anchor seat which is exterior to said elongated stabilizer and said seat and said screw means cooperating to allow relative limited motion whereby alignment of the means to receive the stabilizer is facilitated and transfer of load trom the stabilizer to the interface of the spine and the screw is inhibited.

The key elements of the fixation device claimed in claim I include:

(a) "at least two anchors" - This generally means that the invention must have two or more anchors present. One may take the position that the term "anchor" is not clear trom the plain language of the claim. Thus, relying on the description provided by the specification (see Column 4, lines 2-7), the Patentee states that the "anchor" element is comprised of three members: an anchor seat, a cap and a nut. The Patentee further provides that the anchor includes a "transpedicular screw" (Column 5, line 4) and is made trom a suitable strong biocompatible material. (Column 5, line 6-7)

(b) "elongated stabilizer" that has a "cross-sectional depth" - The term "stabilizer" can be construed very broadly to include a wire, tether, rod, cable or band. The specification does describe the use of a rod in conjunction with the anchor element (Column 3, line 26), but for the purposes of claim I any elongated stabilizer may be applicable.

(c) "screw means" - This limitation is provided in a "means-plus-function" format. The corresponding function is to "secure said anchor to said spinal bone segment." (Column 7, lines 61-62) The structure that corresponds to the claimed function in the specification is a transpedicular screw. (Column 3, lines 27-28, line 58-60) The claim thus appears to cover the transpedicular screw structure and equivalents thereof. Also note that the "screw means" structure is further limited in claim I to include a "rounded head." (Column 8, line 2)

(d) "anchor seat means" - The Federal Circuit in *Cross Medical Prods., Inc.* concluded that this claim element should not be treated as a "means-plus-function" limitation because of the sufficient structural limitations provided in the claim. Therefore, trom this holding it may be concluded that the anchor seat means limitation has a lower bone interface surface which is operatively joined to said spinal bone segment when the interface and the bone segment are connected and in contact such that the device is effective to perform posterior stabilization. *Cross Medical Prods. Inc.,* 424 F.3d. at 1306.

Further, structure limitations of the anchor seat means as provided in claim I include external threads on a portion spaced apart trom the bone interface surface and an internal bore through which the screw projects, allowing limited motion between these two structures. The anchor seat means also comprises a stabilizer receiving channel with an included interface surface that contacts the stabilizer. Additional structural limitations are provided as to the external threads, wherein the threads extend in the direction towards the stabilizer interface surface beyond the dimension of the cross-sectional depth of the stabilizer. The anchor seat means is described further as being exterior to the stabilizer with the seat and the screw means cooperating to allow relative limited motion, whereby alignment of the means to receive the stabilizer is facilitated and transfer of the load trom the stabilizer to the bone-screw interface is inhibited. The "means to receive" a stabilizer may be treated as a "means-plus-function" limitation. The claimed function of the ability to receive the stabilizer is not supported by any structure in the claims. The only embodiment described in the specification to perform the function of receiving the stabilizer is the opposing channels. (Column 5, lines 21-23)

(e) "operatively joined" - This limitation is contained within the above "anchor seat means" element. The court in *Cross Medical Prods., Inc.* held that this limitation should be construed as meaning (in the context of claim I) that the lower bone interface is operatively joined to the bone segment when the interface and the bone segment are connected and in contact such that the device is effective to perform posterior stabilization. *Id.* (emphasis added). Thus, to be operatively connected, the elements must connect and be in contact and be effective in the function of achieving posterior stabilization.

(f) a "nut" - This element appears to be comprised of a through bore with internal threads that engage the external threads of the anchor seat.

The second independent claim of the '555 Patent is claim 5.

Claim 5 provides:

5. A fixation device for the posterior stabilization of one or more bone segments of the spine, comprising:

> at least two anchors and an elongated stabilizer comprising a rod having a diameter and a longitudinal axis, said anchors each comprising anchoring means which secure said anchors to said bone segment and an anchor seat means which has a lower bone interface operatively joined to said bone segment and an anchor seat portion spaced apart trom said bone interface including a channel to receive said rod; and
>
> securing means which cooperate with each of said anchor seat portions spaced apart from said bone interface and exterior to the bone relative to said elongated rod, said seat means including a vertical axis and first threads which extend in the direction of said vertical axis toward said lower bone interface to a depth below the diameter of the rod when it is in the rod receiving channel, and said securing means including second threads which cooperate with the first threads of the seat means to cause said rod to bear against said channel through the application of substantially equal compressive

forces by said securing means in the direction of the vertical axis and applied on either side along said longitudinal axis of said channel.

The key claim elements of claim 5 includes:

(a) "at least two anchors" - As discussed in claim I above, this generally means two or more anchors are present in the invention. From above, the "anchor" element appears to be comprised of three elements: an anchor seat, a cap and a nut. It is not entirely clear whether the anchor includes a "transpedicular screw" because of the inconsistencies seen in the specification.

(b) "elongated stabilizer" - This element appears to comprise a rod with a diameter. (Column 8, line 37)

(c) "anchoring means" - The Federal Circuit Court in *Cross Medical Prods., Inc.* held that the structure to secure the anchor was a polyaxial screw. The court expressly rejected the argument to expand this structure to include a monoaxial screw.

(d) "operatively joined" - See claim I above for the court's analysis and holding for this claim limitation.

(e) "anchor seat means" - The court found that the claim language was sufficiently structural so as to remove the limitation from being interpreted as a "means-plus-function limitation." See claim I above for the analysis of this claim limitation.

(f) "securing means" - The court construed this "means-plusfunction" limitation to be the structure that functions to secure the rod within the channel. They concluded that the corresponding structure was the disclosed nut with internal threads cooperating with the external threads of the anchor seat.

(g) "channel" - The court held that there was nothing in the written description that would limit the channel element to be formed as a single component structure. Therefore, the court found that the "bear against said channel" language does not exclude any "anchor seat portion" composed of multiple components. *Id.* at 1309.

The last independent claim of the '555 Patent is claim 7.

Claim 7 provides:

7. A device for the stabilization of one or more bone segments, comprising:

at least two anchors and a rod having a diameter, said anchors each comprising screw means, an anchor seat, and a nut, said anchor seat including external threads and a channel to receive said rod and having a rod contacting surface in the bottom ofthe channel and said threads extending toward the rod contacting surface to a thread run-out, the distance between the rod contacting surface and the thread run-out being less than the diameter of the rod; and

said nut including top and bottom surfaces and a relatively constant diameter through bore having threads which mate with the threads of the anchor seat and said nut being exterior to said rod and tightening down toward the rod whereby said bottom surface applies a compressive force to said rod.

The key elements of claim 7 include:

(a) "at least two anchors" - See claims 1 and 5 above.

(b) "a rod having a diameter" - It would appear that the plain language of this claim limitation is unambiguous.

(c) "screw means" - As found in the specification, this limitation would likely be treated as a "means-plus-function" limitation. Thus, from reviewing the specification, the structure that performs this function is a polyaxial screw.

(d) "anchor seat" - This element appears to comprise external threads and a channel to receive the rod, with a rod contacting surface in the bottom of the channel. The external threads extend in the direction of the rod contacting surface to a thread run out with this distance being less than the diameter of the rod.

(e) a "nut" - This claim element appears to include top and bottom surfaces with a relatively constant diameter through bore with internal threads that engage with the extemal threads of the anchor seat. The nut appears to be located exterior to the rod and functions by tightening down onto the rod causing the bottom surface to apply a pressure force to the rod.

In summary, the three independent claims of the '555 Patent generally provide claim coverage for a device that comprises at least two anchors and an elongated stabilizer, which in two of the claims has been narrowed to a rod. The anchors each appear to have a means to hold the anchor to the bone, which will likely be a polyaxial screw that has been inserted through a bone in an anchor seat, and a nut that threads onto the external threads of the anchor seat.

2. U.S. Patent 5.207.678 to Harms *et al.*

The '678 Patent issued on May 4, 1993, ITom U.S. Application No. 07/817,659 that was filed on January 7,1992. The '678 Patent claims priority ITom German Patent No. 3923996, which was filed on July 20, 1989.

On its face, the '678 Patent is assigned to Prufer of Munich, Germany. All maintenance fees for the '678 Patent are current as ofthe date ofthis article.

The '678 Patent includes only one independent claim. The review of this claim is facilitated because Patentee has labeled each ofthe elements with the associated reference number of the structure in the patent figures. (See Figure 1.)

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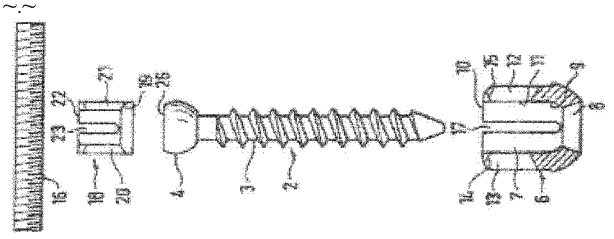

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Figure 1: Labeled elements with associated reference numbers

Claim 1 provides:

1. Device for stabilizing spinal column segments, comprising a pedicle screw (1) having a threaded shaft portion (3) and a spherically-shaped head (4) at the end of said threaded shaft portion, a receiver member (5) flexibly connected to said head (4), said receiver member being provided with two holes for receiving a rod (16), a receiver chamber (7) being provided within said receiver member (5), the receiver chamber (7) having at one end thereof a bore (8) for passing the threaded shaft portion (3) therethrough and an inner hollow spherically-shaped portion (9) for receiving the head (4) of said screw (1), an opening (10) being provided opposite said bore (8) for inserting said screw (1), said device further comprising a compression member (18) for exerting a force onto said head (4) such that said head is pressed against the hollow spherically-shaped portion (9).

The key claim elements of claim 1 include:

(a) a "pedicle screw" (1) - It would appear that this element is comprised of a threaded shaft portion (3) and a spherically-shaped head (4) at the end of the threaded shaft.

(b) a "receiver member" (5) - It appears that this element is flexibly connected to the pedicle screw head (4) and includes two holes for receiving a rod (16).

(c) a "rod" (16) - The plain language of the claim is unambiguous as to this limitation.

(d) a "receiver chamber" (7) - This element appears to include one end having a bore (8) through which the threaded shaft portion (3) of the screw (1) is passed. Further, the receiver chamber includes an inner hollow spherically-shaped portion (9) for receiving the pedicle screw head (4) and an opening (10) that is opposite the bore (8) for inserting the pedicle screw (1).

(e) a "compression member" (18) - It would appear that this element is used to apply a force to the pedicle screw head (4) causing the head (4) to be pressed against the hollow spherically-shaped portion (9) of the receiver chamber (7).

Claim 1 of the '678 Patent generally provides claim coverage for a device that includes a pedicle screw that connects to a receiver member. The receiver member is comprised of a receiver chamber that appears to include a through bore, an opening and a hollow spherically-shaped portion. It appears that a receiver member receives a rod. Lastly, the device includes a compression member for applying a force on the pedicle screw head.

In closing, the readers of this article should remember that this review of the '555 and the '678 Patents is only an examination of the possible claim interpretations and should not be interpreted as a legal opinion or advice from this author or the firm with which he is associated. If a person has a device that they would like to specifically compare to the claims of the '555 and the '678 Patents, appropriate legal counsel should be retained to seek such a review and evaluation.

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