Synthes (USA) v. Spinal Kinetics Inc. Doc. 84

United States District Court
For the Northern District of California

E-FILED on 6/23/10

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

SYNTHES USA, LLC (f/k/a SYNTHES (U.S.A.)); SYNTHES USA SALES, LLC; and SYNTHES, INC., Plaintiffs, v. SPINAL KINETICS, INC., Defendant.	No. C-09-01201 RMW ORDER CONSTRUING DISPUTED CLAIM LANGUAGE OF UNITED STATES PATENT NO. 7,429,270

Plaintiffs Synthes USA, LLC, Synthes USA Sales, LLC and Synthes, Inc. (collectively, "Synthes") bring this suit against defendant Spinal Kinetics, Inc. alleging infringement of United States Patent No. 7,429,270 ("'270 Patent"). Spinal Kinetcs by counterclaim seeks declaratory judgment of noninfringement and invalidity. The parties now seek construction of claim terms and other language in the '270 Patent for which they assert different interpretations. The court held a claim construction hearing on March 17, 2010. The court has reviewed the claims, specification, prosecution history, and other relevant evidence, considered the briefing submitted (including supplemental briefing on an issue raised at the hearing) and listened to the arguments of the parties. It now construes the terms and other language at issue.

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I. ANALYSIS

A. The '270 Patent

The invention claimed in the '270 Patent is directed to an intervertebral implant. More specifically, it is a prosthetic device designed to replace a diseased or damaged disc located between adjacent vertebrae, *i.e.* an "artificial disc." Three claims are at issue, specifically, independent Claim 29 and dependent Claims 30 and 31. Claim 29 claims the following, with the language subject to disputed construction highlighted:

> **29**. An intervertebral implant for implantation between an upper and lower vertebrae, the implant having a central axis, the implant comprising:
>
> a first substantially rigid bone contacting plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the upper vertebra;
>
> a second substantially rigid bone contacting plate having an external surface extending generally transversely to the central axis for contacting at least a portion of the lower vertebra;
>
> ***a third plate operatively coupled to the first bone contacting plate, the third plate including a plurality of openings***;
>
> ***a fourth plate operatively coupled to the second bone contacting plate, the fourth plate including a plurality of openings***;
>
> ***a central part*** substantially located between the third and fourth plates, the central part including a ***flexible core*** and ***a fiber system, wherein the core is substantially cylindrical*** and includes a top surface and a bottom surface, ***the top surface of the core being in contact with the third plate and the bottom surface of the core being in contact with the fourth plate***, and ***wherein the fiber system at least partially surrounds the core***, and ***is at least partially received within the plurality of openings formed in the third and fourth plates so that the fiber system is joined to the third and fourth plates***; and
>
> ***an elastic sheathing body at least partially surrounding the fiber system and the core***, and connected to the third and fourth plates.

Dependent Claim 30 claims:

> **30.** The intervertebral implant of claim **29**, wherein the first and second bone contacting plates are made from titanium or a titanium alloy.

Dependent Claim 31 claims:

> **31.** The intervertebral implant of claim **30**, wherein the fiber system is constructed of an ultra high molecular weight polyethylene (UHMWPE) material.

B. Construction Principles

Claim terms are generally construed to mean what a person of ordinary skill in the art at the time of the invention would have understood the terms to mean. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). When the meaning of a claim term, as understood by persons of ordinary skill in the art, is not immediately apparent, courts are to look to sources available to the public to determine what the disputed claim language means. *Id.* at 1314. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

The court thus begins by looking at the words of the claims themselves. *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The court may consider the claim terms and the context in which they are used, including the language of other claims of the patent, both asserted and unasserted. These other claims may provide enlightenment as to the meaning of a disputed claim term because claim terms are normally used consistently throughout a patent and the usage of a term in one claim may illuminate the meaning of the same term in another claim, and differences between claims may also be a useful guide in understanding the meaning of the particular claim terms at issue. *Phillips*, 415 F.3d at 1314.

Consideration of the specification is also essential, however. As recognized by the Federal Circuit:

> The specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs. In other cases, the specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive.

Id. at 1316 (internal citations omitted).

Similarly, the prosecution history should also be considered, and it may provide evidence of how the PTO and the inventor understood the patent, and may "inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor

limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* at 1317 (internal citations omitted).

One of the greatest challenges in claim construction is to consider the claim language in light of the specification in order to interpret the meaning of the claim language, while at the same time avoiding the trap of importing limitations from the specification into the claim language. As recognized by the Federal Circuit, "the distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim can be a difficult one to apply in practice." *Id.* at 1323.

With these principles in mind, the court turns to the disputed claim language.

C. Construction of Claim Language at Issue

1. "a third [fourth] plate operatively coupled to the first [second] bone contacting plate"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"a third [fourth] plate operatively coupled to the first [second] bone contacting plate" ('270 Pat. 8:30-34)	a third [fourth] plate fastened, so as to receive forces, to the first [second] bone contacting plate	a cover plate made of a synthetic material and fixed to a plate of titanium or a titanium alloy closing plate	a third [fourth] plate that works together with the first [second] bone contacting plate to transmit forces

The parties agreed at the hearing that "operatively coupled" means that the third [fourth] plate and the first [second] bone contacting plates work together to transmit forces. The dispute centers on whether the cover plate is limited to one of synthetic material and the closing plate can only be titanium or a titanium alloy. Spinal Kinetics argued that the only language in the specification describing the cover plates says that they are made from synthetic material and in the same sentence says that the closing plates are made from titanium or titanium allow. '270 Pat. 6:3-5. However, the claim language does not specify the material of the plates and nothing in the specification suggests that only a cover plate of a synthetic material and a closing plate of titanium or a titanium alloy have to be used. The Federal Circuit has rejected the contention that a claim must be limited to what is described in the specification even if the specification contains only a single embodiment. "In particular, we have expressly rejected the contention that if a patent describes only a single

embodiment, the claims of the patent must be construed as being limited to that embodiment. *Phillips*, 415 F.3d at 1323.

The court concludes that "a third [fourth] plate operatively coupled to the first [second] bone contacting plate" ('270 Pat. 8:30-34) means a third [fourth] plate that works together with the first [second] bone contacting plate to transmit forces.

2. "the third [fourth] plate including a plurality of openings"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"the third [fourth] plate including a plurality of openings" ('270 Pat. 8:32 and 33-34)	a third [fourth] plate including two or more openings	a cover plate including more than one grove distributed on the circumference and radially penetrating into the lateral surface of the cover plate	the third [fourth] plate including two or more openings to allow the fiber[1] system to be joined or anchored to that plate.

The dispute as to what is meant by "the third [fourth] plate including a plurality of openings" primarily concerns the placement of the openings or grooves. Neither party disputes that "plurality" means "two or more." From the pre-hearing briefing, it appeared that Spinal Kinetics was primarily distinguishing between "opening" (used in Claim 29 but not in the specification) from "groove" (used in specification but not in claim). However, Spinal Kinetics made clear at the hearing that the location of the "openings" was more its concern.

> Mr. Geriak (Spinal Kinetics' Counsel): It – I don't want to belabor the point, but if our fibers were on the peripheral surface of the, of our plates, they'd be quite happy with the word "grooves" because presumably we would have grooves, too. But we don't.
>
> And we don't have peripheral openings. We have a different type of construction, and that parts company with what the inventors purported to invent here.
>
> The Court: Just to follow up to make sure I understand your position, if you took your construction and you put in opening, openings – "opening" rather than "groove" in your construction, are you saying you would or would not have a problem with that?
> . . .
> Mr. Geriak: I said yes, I am.
> In other words, if you substituted "opening" for "groove" in our proposed construction, that would be agreeable to us and that would accomplish just what I've been talking about.

[1] The patent sometimes spells "fiber" with an "re" as opposed to an "er." The court has used the "fiber" version except when quoting the patent where "fibre" is used.

The Court: So you're concerned with the placement of the opening or groove, as opposed to whether or not something constitutes an opening or groove?

Mr. Geriak: Yes, in that context, yes.

Transcript at 79:10-80:14.

Spinal Kinetics argues that the specification never describes any structure that contains a hole or slot in the cover plate and instead describes only grooves and furthermore that the embodiments in the specification only disclose grooves on the circumference of the cover plate that radially penetrate into the lateral surface of the cover plate. Thus, according to Spinal Kinetics, the subject language must be construed to mean grooves distributed on the circumference of, and that radially penetrate into the lateral surface of, the cover plate.

Spinal Kinetics' proposed construction is too limiting. The patent discloses different ways in which the fiber system may be joined or anchored to the cover plates but there is no limitation in Claim 29 or disclosure in the specification that restricts the manner in which that may be accomplished. The specification indicates that "the anchoring of the fiber system is possible by various means." '270 Pat. 2:4-5. Claim 29 merely requires openings in the third [fourth] plate to allow the fiber system to be joined or anchored to that plate. It has no further restriction. Accordingly, the court construes "the third [fourth] plate including a plurality of openings" to mean two or more openings to allow the fiber system to be joined or anchored to that plate.

3. "a central part"

Disputed Claim Language	**Synthes' Proposed Construction**	**Spinal Kinetics' Proposed Construction**	**Court's Construction**
"a central part" ('270 Pat. 8:35)	a part near the center	an assembly of an elastically deformable structure containing a cavity with an incompressible material, a sheathing, a homogeneous elastic sheathing body, and a fiber system embedded therein	the portion of the implant located substantially between the third and fourth plates and which includes a flexible core and a fiber system

Synthes contends that the term "a central part" needs no construction, but that if any construction is warranted, the term should be construed to mean "a part near the center." Spinal Kinetics, in turn, argues that the term should be construed to include "an assembly of an elastically deformable structure containing a cavity with an incompressible material, a sheathing, a homogeneous elastic sheathing body, and a fiber system embedded therein."

Claim 29 identifies the "central part" both by location and by what it must include. "[A] central part substantially located between the third and fourth plates, the central part including a flexible core and a fiber system . . . ." *Id.* at 8:35-37. This interpretation is consistent with the specification and drawings, which depict central part 10 as the portion between the cover plates 3 and 4. *See, e.g., id.* at Fig 4. The fact that the specification discloses an embodiment which includes additional components of the "central part," such as "an elastic formed body . . . with an incompressible core" (*id.* at 5:29-30) does not mean that "central part" as used in Claim 29 should be defined to include a limitation of "an incompressible core." As pointed out by the Federal Circuit on numerous occasions, "although the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." *Phillips*, 415 F.3d at 1323.

The court construes the term "central part" using the language of the claim. "Central part" means the portion of the implant located substantially between the third and fourth plates and which includes a flexible core and a fiber system.

4/5. "flexible core" and "core"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"flexible core" ('270 Pat. 8:36)	elastic (deformable) core	The term "flexible" is new matter and cannot be construed based on the intrinsic disclosure of the '270 patent. Flexible means bendable or capable of being bent and no bendable core is disclosed in the '270 patent.	the deformable central part of the implant substantially located between the third and fourth plates

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"core" ('270 Pat. 8:37, 38, 40 and 42)	central portion	an incompressible material such as a liquid, which is capable of expanding radially upon the application of force to the central axis and which is contained in an elastic material	no construction necessary because only term used in patent claim is "flexible core" which is defined above

As claimed in Claim 29, the "central part" includes "a flexible core." '270 Pat. 8:36. The "central part" limitation goes on to refer to "the core" four times. *Id.* at lines 37, 39, 40 and 42. Spinal Kinetics contends that the specification defines the term "core" and that the use of the term "flexible core" in the claim is inconsistent with that definition. Therefore, since "core" refers to an incompressible material, the addition of a "flexible core" is new matter not supported in the specification. Synthes, in turn, contends that the "central part" limitation only refers to a "flexible core" and that the references to "the core" refer to the "flexible core."

Claim 29 refers only to a "flexible core." The grammatical structure of the claim limitation language makes this clear. Claim 29 in relevant part states:

> a central part . . . including ***a flexible core*** and a fiber system wherein ***the core*** is substantially cylindrical and includes a top surface an a bottom surface, the top surface of ***the core*** being in contact with the third plate and the bottom surface of ***the core*** being in contact with the fourth plate, and where in the fiber system at least partially surrounds ***the core*** . . . .

Id. at 8:35- 42. The limitation first uses the term "flexible core" and the subsequent references to "the core" clearly refer back to the earlier recited "flexible core." Therefore, the only "core" described is the "flexible core."

According to Spinal Kinetics, since the specification refers to "an elastically deformable formed body . . . [ ] with an ***incompressible core***, preferably a liquid core" (*id*. at 5:15-16), claiming a "flexible core" improperly attempts to claim new matter. Spinal Kinetics, however, is equating the word "core" with the composition of the core. The word "core" has an ordinary and customary meaning, namely "the central and often foundational part of a body, mass or construction usu. distinct from the enveloping part by a difference in nature or by being cut out or separated." WEBSTER'S

THIRD NEW INTERNATIONAL DICTIONARY, Merriam-Webster Inc. (1993), p. 506 ("core"). "Claim terms are 'generally given their ordinary and customary meaning,' the meaning that the term would have to 'a person of ordinary skill in the art . . . at the time of the invention.'" *Power-One, Inc. v. Artesyn Technologies, Inc.*, 599 F.3d 1343, 1348 (Fed. Cir. 2010), quoting *Phillips*, 415 F.3d at 1312-13.

In this case, the intrinsic evidence, the primary resource for construing claims, is consistent with the customary definition of "core." *See id.* As defined in Claim 29, the central part or "core" of the central part of the implant located substantially between the third and fourth plates includes a "flexible core." The specification discloses embodiments which have a flexible core ("an elastically deformable body") which contains "an incompressible core" or center part. The reference to "core"in the specification merely refers to the center part of a particular component of the implant and descriptive language such as "flexible" or "incompressible" discloses the composition of that particular core.

Spinal Kinetics also contends that "flexible core" cannot be referring to an "elastically deformable formed body" such as item 9 in the specification because "elastic" and "flexible" have different meanings. However, in the context of the patent, it would be clear to one skilled in the art that "flexible" does describe the "elastic" or "deformable" nature of the elastic body 9. This conclusion would be clear from the description of how the implant is designed to work. *See* '270 Pat. 5:14-22 and 5:46-53.

The court construes the term "flexible core" to refer to the deformable central part of the implant substantially located between the third and fourth plates.

6. "a fiber system"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction

"a fiber system" ('270 Pat. 8:37, 41-42, and 44-45)	a fiber system capable of being joined to the third and fourth plates	fibers anchored in grooves distributed on the circumference and radially penetrating into the lateral surfaces of the cover plates and constraining an incompressible core from radial expansion	a collection of fiber strands joined to the third and fourth plates and capable of absorbing tensile forces and constraining radial expansion of the flexible core

Synthes asserts that no construction of the term "a fiber system" is necessary, but that if the court deems construction appropriate, a fiber system should merely be defined as "a fiber system capable of being joined to the third and fourth plates." Spinal Kinetics' proposed construction — "fibers anchored in grooves distributed on the circumference and radially penetrating into the lateral surfaces of the cover plates and constraining an incompressible core from radial expansion" — seeks to limit the term by requiring that the fibers of the system be attached to the cover plates in grooves distributed at the circumference of the plates and that the fibers constrain the incompressible core from radial expansion. As discussed above, such proposed restrictions result from Spinal Kinetic's attempt to inappropriately narrow the generic word "core" to a particular type of core and to improperly import a limitation on the location of grooves or openings in the plates.

Synthes' proposal, however, affords no explanation of what is meant by "a fiber system" in the context of the claimed invention. The specification makes clear that the fiber system in the claimed invention is a collection of fibers that is capable of absorbing tensile forces and constraining the radial expansion of the flexible core. What is meant by "a fiber system" is clear from the discussion of fiber systems in the prior art and in contrasting how the system is used in embodiments of the claimed invention. *See, e.g.*, '270 Pat. 1:22-28, 43-48, 2:26-39, and 3:15-21.

Based on the discussion in the specification, the term "a fiber system" as claimed in Claim 29, is a collection of fiber strands joined to the third and fourth plates and capable of absorbing tensile forces and constraining radial expansion of the flexible core. The anchoring of the fiber system to the plates is an important aspect of the claimed invention, but the means by which this is to be accomplished is not a limitation of the term "a fiber system." This construction of fiber system does not violate the principle discussed in *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F3d

1318, 1324 (Fed. Cir. 2002), that "[w]here a claim uses clear structural language, it is generally improper to interpret it as having functional requirements." In Claim 29 there is no structural description of a "fiber system" and review of the specification is necessary to understand what a fiber system is in the context of the claimed invention. Therefore, some description of what the fiber system does is necessary to understand its structure.

7. "wherein the core is substantially cylindrical"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"wherein the core is substantially cylindrical" ('270 Pat. 8:37-38)	wherein the core has a generally cylindrical shape	The terms "substantially cylindrical" as applied to the core in the '270 patent are new matter. The patent describes the "central part," not the "core," as being "essentially hollow-cylindrical." The shape of the core in the '270 patent is defined by the cavity in which it resides. "Substantially cylindrical" excludes "barrel shaped," "ellipsoid" and "partial sphere."	No construction necessary

Synthes argues that "where in the core is substantially cylindrical" should be construed to mean "wherein the core has a generally cylindrical shape." This merely rephrases what is already stated in ordinary language. Spinal Kinetics, on the other hand, contends that "substantially cylindrical" as applied to the core in the '270 patent presents new matter because the patent describes the "central part," not the "core," as being "essentially hollow-cylindrical." '270 Pat. 3:55-56. Spinal Kinetics again asserts that "core" refers only to the incompressible liquid core which is contained in the flexible core of an embodiment and therefore the shape of the core is defined by the cavity in which it resides. For the reasons previously discussed, the assertion that the only "core" is the incompressible liquid core of a particular embodiment is wrong.

Spinal Kinetics further argues that "substantially cylindrical" excludes "barrel-shaped," "ellipsoid" and "partial sphere." This assertion is based upon the description of an embodiment of the patent where "the central part is essentially hollow-cylindrical, hollow-prismatic or is a body of rotation, an ellipsoid, a partial sphere or barrel-shaped with an axis of rotation that is coaxial with the central axis." *Id.* at 3:55-58. Nothing in the specification, however, suggests that these descriptions of shapes are mutually exclusive. For example, something that is "substantially cylindrical" may also be, but is not necessarily required to be, "barrel-shaped." The two are not mutually exclusive. Further, words of approximation, such as "substantially," are descriptive terms commonly used in patent claims to avoid precise constraints. *See, e.g., Playtex Products, Inc. v. Proctor & Gamble Co.*, 400 F.3d 901, 907 (Fed. Cir. 2005).

"Substantially cylindrical" needs no construction.

8. "the top surface of the core being in contact with the third plate and the bottom surface of the core being in contact with the fourth plate"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"the top surface of the core being in contact with the third plate and the bottom surface of the core being in contact with the fourth plate" ('270 Pat. 8:39-41	the top surface of the core is in contact with the third plate and the bottom surface of the core is in contact with the fourth plate	The recited relationship between the core surfaces and the plates is new matter because no disclosure in the '270 patent exists for a flat top surface of incompressible material which contacts the top closing plate or a flat bottom surface of incompressible material which contacts the bottom cover plate.	No construction necessary

Spinal Kinetics' argument that the subject limitation brings new matter into the claim is premised upon its fundamental contention that "core" as used in the patent specification refers to the incompressible liquid core at the center of the center part. Therefore, no portion of the core, Spinal

Kinetics contends, is in contact with either the third or fourth plates because the "core" is completely surrounded by the "elastically deformed body 9" of which it is a part. Thus, Spinal Kinetics argues that the recited relationship between the core surfaces and the plates is new matter.

As discussed above, however, "core" as used in Claim 29 refers to "flexible core" and does not refer to the incompressible core described in the specification. "Flexible core" refers to an elastic formed body. '270 Pat. 5:29-31 and Figs. 1 & 4. Figure 4 shows that the flexible core is in contact with the third and fourth plates.

Spinal Kinetics further argues that even if "core" refers to the deformable body, there is no contact between the third and fourth plates and the deformable body because the deformable body is surrounded by a sheath. This contention has no merit and is refuted by Figure 4.

The language "the top surface of the core being in contact with the third plate and the bottom surface of the core being in contact with the fourth plate" needs no construction. *Id.* at 8:39-41 The words in the phrase have their ordinary and customary meanings.

9. "wherein the fiber system at least partially surrounds the core"

Disputed Claim Language	**Synthes' Proposed Construction**	**Spinal Kinetics' Proposed Construction**	**Court's Construction**
"wherein the fiber system at least partially surrounds the core" ('270 Pat. 8:41-42)	where the fiber system is situated around, about, or in a ring around at least a portion of the core	Indefinite; construction not possible	fiber system at least partially surrounds the core such that it is capable of absorbing tensile forces and constraining radial expansion of the flexible core.

Spinal Kinetics, again based upon its interpretation of "core" which the court has rejected, asserts that the phrase "wherein the fiber system at least partially surrounds the core" is indefinite and not capable of construction. *Id.* at 8:41-42. The court finds no merit to Spinal Kinetics' contention that the claim is indefinite.

The purpose of the fiber system surrounding the core is to restrict the expansion of the central part and to absorb the radial compression forces when vertical compression forces are applied to the top and bottom plates. *Id.* at 2:26-39; 5:46-56. Given this recited purpose, a fiber system that "at

least partially surrounds the core" would be understood by one of ordinary skill in the art to mean that the fiber system at least partially surrounds the core such that it is capable of absorbing tensile forces and constraining radial expansion of the flexible core.

10/11. "wherein the fiber system . . . is at least partially received within the plurality of openings formed in the third and fourth plates so that the fiber system is joined to the third and fourth plates"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"[wherein the fiber system . . . is at least partially received within the plurality of openings formed in the third and fourth plates] [so that the fiber system is joined to the third and fourth plates"] ('270 Pat. 8:41-45). Spinal Kinetics contends that the two bracketed phrases should be separately construed.	wherein at least a portion of the fiber system is received or passed through the openings formed on the third and fourth plates so that the fiber system is anchored to the third and fourth plates	[1] the fibers are anchored in grooves distributed on the circumference and radially penetrating into the lateral surfaces in the outer edge of the cover plates to anchor the fiber system. The terms "at least partially received" are new matter because the terms do not appear in the '270 patent and must be construed to mean anchored. [2] each fiber is anchored in at least two grooves distributed on the circumference and radially penetrating the lateral surfaces in the outer edges of both cover plates.	wherein at least a portion of the fiber system is taken into or passed through the openings formed on the third and fourth plates so that the fiber system is anchored to the third and fourth plates

Synthes argues initially that the language quoted above needs no construction but nevertheless proposes a construction if the court believes one is necessary.

Spinal Kinetics, on the other hand, contends that the subject language should be broken into two parts and each part separately construed. It contends that "at least partially received" is not supported by the specification and that the only relationship between the "fiber" system and the "grooves" disclosed in the patent is that the fibers are anchored in the grooves. Spinal Kinetics

repeats its argument that "openings" are grooves located at the circumference of the cover plates and radially penetrating into the lateral surface of the plates.

The court, however, has rejected that construction of "opening." "At least partially received within," given its ordinary meaning, explains that at least a portion of the fiber system is brought into or passed through the openings so that the fiber system can be joined to the plates. The fiber system is joined, not each individual fiber.

The term "is joined" refers to the fastening or anchoring of the fiber system to the plates. The specification discloses several ways that this can be done and Claim 29 contains no requirement limiting the manner in which the fiber system is anchored or fastened to the plates. *See, e.g., id.* at 3:22-35 (three examples of how the fibers may be anchored on the cover plates).

The court construes the subject language to mean wherein at least a portion of the fiber system is taken into in or passed through the openings formed on the third and fourth plates so that the fiber system is anchored to the third and fourth plates.

12. "an elastic sheathing body at least partially surrounding the fiber system and the core"

Disputed Claim Language	Synthes' Proposed Construction	Spinal Kinetics' Proposed Construction	Court's Construction
"an elastic sheathing body at least partially surrounding the fiber system and the core" ('270 Pat. 8:46-7)	an elastic cover situated around, about, or in a ring around at least a portion of the fiber system and the core	a homogeneous elastic sheathing body in which at least a portion of each of the fibers is embedded	a homogeneous elastic sheathing body at least partially surrounding the fiber system and flexible core

The final construction dispute concerns whether the "elastic sheathing body" referred to in the last limitation of Claim 29 must be made of a homogeneous material in which at least a portion of the fibers are embedded. Spinal Kinetics submits that the specification makes clear that the elastic sheathing must consist of a homogeneous material and that the fiber system must be either partially or completely embedded in the sheathing body. Spinal Kinetics also asserts that statements made by Synthes during prosecution further compel these conclusions. Synthes disagrees and asserts that Spinal Kinetics is again trying to import limitations from the preferred embodiments into the claim and is mis-characterizing Synthes' statements during prosecution.

Claim 29 expressly requires only that the "sheathing body at least partially surround[ ] the fiber system." *Id.* at 8:46-7. It says nothing about a homogeneous material or embedding. Therefore, the questions are (1) whether Synthes defined "sheathing body" in the specification as being composed of a homogeneous material and as having a fiber system at least partially embedded in it and (2) whether Synthes used those limitations during prosecution to obtain the patent.

A. *Homogeneous*

Spinal Kinetics points to a statement in the '270 Patent to establish that the invention is limited to a sheathing body comprised of a homogeneous material. Specifically, at lines 56-61 of column 1, the '270 Patent states that the invention solves the problem it addresses by, in part, use of a homogeneous material.

> This is where the invention wants to provide a remedy. The object of the invention is to produce an intervertebral implant, that comprises a fibre system joined with cover plates, by virtue of which a sheathing body, surrounding the central part and **made from a homogeneous material**, will be reinforced.

Id. (emphasis added). Spinal Kinetics also points to a statement at lines 61-62 of column 1 which describes how the claimed invention achieves the recited object of the invention, namely "with an intervertebral implant having the features of claim 1." The "claim 1" which is referenced in the specification is claim 1 of the original application, which recited among other things, that the sheathing body is made from a homogeneous material." *See* Mulville Dec. Ex 1 (Docket 70-10)

Synthes argues that it withdrew the homeogeneous limitation during prosecution and "made explicitly clear to the Examiner (and the public) that the claimed invention was not limited to an embodiment in which 'the sheathing body is made from a homogeneous material...." Reply at 28, citing February 19, 2008 Response to Non-Final Office Action (Meier Decl. Exh. B).

When the specification of a patent describes what the invention is (or here what remedies the problem existing in the prior art), the inventors are describing more than merely a preferred embodiment of the claimed invention. *See Honeywell Intern., Inc. v. ITT Industries, Inc.*, 452 F.3d 1312, 1318-19 (Fed. Cir. 2006). Therefore, here, despite the applicant's statement during prosecution that the inventors were deleting the limitation of the "sheathing body [being] made from a homogeneous material," a representation made during prosecution cannot enlarge the content of the

specification. *Id.* at 1319; *Biogen, Inc. v. Berlex Labs.*, 318 F.3d 1132, 1140 (Fed. Cir. 2003). Therefore, "sheathing body" is properly limited to one made from a homogeneous material.

B. Embedded Fiber System

The court, however, comes to a different conclusion with respect to whether the fiber system must be partially or completely embedded in the sheathing body. The specification describes several embodiments, one that has the entire fiber system embedded in the sheathing body, another that has it only partially embedded, and still other embodiments that do not say. '270 Pat. 2:41-3:62. Thus, the court does not read the specification as defining "sheathing body" or any other term in Claim 29 as requiring an embedded fiber system.

Spinal Kinetics points to lines 49-55 of column 1 and argues that the inventors represented that a disadvantage of the Stubstad prosthesis (U.S. Pat. No. 3,867,728) is that its fiber system is not embedded in the sheathing body and that the claimed invention provides a remedy by requiring a fiber system embedded in the sheathing body. However, that portion of the specification cited by Spinal Kinetics points out that one embodiment of the Stubstad patent has an embedded system. *Id.* at 1:53-55. Moreover, the examiner understood Stubstad as having a fiber system embedded in a sheathing body, commenting in reference to Stubstad that "[t]he sheath 13 is made of a plurality of layers 14 of silicone elastomer that is passed through by a mesh of filaments or **what is considered to be the fiber system that is entirely imbedded** [*sic*] in the sheathing body 13." Office Action dated 5/13/08 at 3 (Doc. 70-8 Mulville Decl. Ex. 4) (emphasis added). The "express disclaimer of any fibre system that is not embedded in the sheathing body" suggested by Spinal Kinetics is not unequivocally clear.

The doctrine of claim differentiation also supports Synthes' contention that an embedded fiber system is not a limitation of Claim 29. Claim 2 of the patent is a dependent claim which adds to independent Claim 1 "wherein the fiber system is embedded in the elastic sheathing body." '270 Pat. at 7:3-4. "[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1315. Thus, the fiber system in Claim 1 is not necessarily embedded in the elastic sheathing body. Here, although we are dealing with Claim 29 rather than Claim 1, claim differentiation suggests that

embedding of the fiber system in the sheathing body is not required in all the claims, contrary to what is in effect Spinal Kinetics' assertion.

C. Prosecution History

Turning to the prosecution history, Spinal Kinetics points to the applicants response to an Office Action in which the applicant amended claims and sought to overcome prior art rejections on the basis that the prior art did not disclose, teach or suggest a fiber system that is at least partially embedded within an elastic sheathing body. Defendant's Brief at 29, citing July 10, 2007 Response to Non-Final Office Action at 12 (Mulville Decl. Ex 2). From this, Spinal Kinetics argues that "having gained allowance of the patent over Stubstad based on the fibres being embedded in the sheath, the '270 patentees cannot now broaden the patent to ignore this limitation." Def. Brief at 29.

Spinal Kinetics' argument, however, takes this statement in the prosecution history out of its proper context. The Examiner had rejected the claims as being anticipated by Stubstad and as obvious in view of Stubstad and Dickman, and the applicant amended the claims to recite that the fiber system was at least partially embedded within the elastic sheathing body and argued that the cited prior art did not disclose, teach or suggest that the fiber system was at least partially embedded in the sheathing body. July 17, 2007 Response to Non-Final Office Action. This is the office action cited by Spinal Kinetics. Thereafter, the examiner again rejected the claims, again based on Stubstad and Dickman, as well as other prior art.[2] In turn, on February 19, 2008, the applicant filed a Response, which amended the claims again, added new claims to the application, and argued for allowance. Among other things, however, the applicant stated that he had deleted the limitations previously added by the July 10, 2007 response, stating:

> In particular, Applicants have deleted the limitation, and the accompanying Remarks distinguishing the prior art based on, *inter alia*, that the fiber system is guided over the external surfaces of both cover plates, that the sheathing body is made from a homogeneous material, and that the fibre system is at least partially embedded within the elastic sheathing body. As such, these limitations, either alone or in combination, no longer exist and should not be relied upon, as creating an estoppel or otherwise limiting the scope of these claims.

[2] The October 18, 2007 Office Action was not included with the parties' submissions, but the general content and effect of the Office Action can be discerned from the applicant's February 19, 2008 Response, which has been submitted to the court.

February 19, 2008 Response to Non-Final Office Action at 13. In response, the examiner issued his Final Office Action, rejecting most of the original and amended claims, but allowing newly added claims 47-50. Claim 47 issued as Claim 29 of the '270 Patent.

Thus, although there may have been a disclaimer had the claims then pending issued following the July 10, 2007 Office Action, the patent did not issue based on these amendments and remarks. Instead, further prosecution ensued, including an express withdrawal of the amendments and the remarks seeking to distinguish the prior art on the basis of the embedded system limitation. Thus, it cannot be fairly said that the patentee "gained allowance of the patent over Stubstad based on the fibers being embedded in the sheath." No competitor reading the prosecution history as a whole would reasonably conclude that the applicant had limited the invention to one in which the fiber system was embedded within the sheathing body. Thus, no disclaimer occurred. *See Schindler Elevator Corp. v. Otis Elevator Co.*, 593 F.3d 1275, 1285 (Fed. Cir. 2010).

Finally, Spinal Kinetics argues that examiner distinguished Stubstad and the claimed invention in his May 13, 2008 office action on the basis that the fiber system in Stubstad was not an embedded system. Spinal Kinetics infers that the examiner made this distinction from the examiner's statement that "Stubstad et el. does not disclose fiber system of the top and bottom cover plates and the fiber system in the sheathing body to be a **single entity**." Office Action dated 5/13/08 at 3 (Doc. 70-8 Mulville Decl. Ex. 4) (emphasis added). Although it is unclear what the examiner meant when he referred to a "single entity," it seems nonsensical to conclude that the examiner viewed Stubstad as not having an embedded fiber system since earlier in the same paragraph he refers to what is considered in Stubstad to be "the fiber system that is entirely imbedded [sic] in the sheathing body 13." *Id.*

For the above reasons, the court construes "an elastic sheathing body at least partially surrounding the fiber system and the core" as meaning a homogeneous elastic sheathing body at least partially surrounding the fiber system and flexible core.

II. ORDER

It is hereby ordered that the disputed claim language is construed as set forth above.

DATED: 6/23/10

RONALD M. WHYTE
United States District Judge