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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., Plaintiff, v. SPINAL KINETICS, INC., Defendants.	No. C-09-01201 RMW ORDER DENYING MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS 29-31 OF U.S. PATENT NO. 7,429,270 UNDER 35 U.S.C. § 112 ¶ 1 **[Re Docket Nos. 125 and 143]**

Defendant Spinal Kinetics, Inc. ("Spinal Kinetics") moves for summary judgment of invalidity of claims 29-31 of U.S. Patent No. 7,429,270 ("the '270 patent") under 35 U.S.C. § 112 ¶ 1. Spinal Kinetics also objects to the declaration of David Koch in support of Synthes' opposition to Spinal Kinetics' motion for summary judgement. On February 11, 2011, the court held a hearing to consider defendant's motion. Having considered the papers submitted by the parties and the arguments of counsel, and for the reasons set forth below, the court agrees in part with defendant's objections and denies the motion for summary judgment.

I. BACKGROUND

The invention claimed in the '270 patent is directed to an intervertebral implant. More specifically, the patent describes a prosthetic device designed to replace a diseased or damaged disc located between adjacent vertebrae, *i.e.* an "artificial disc." Synthes asserts that Spinal Kinetics' device infringes claims 29, 30, and 31 of the '270 patent. The claims recite the following:

> 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.
>
> 30. The intervertebral implant of claim 29, wherein the first and second **bone contacting plates** are made from titanium or a titanium alloy.
>
> 31. The intervertebral implant of claim 30, wherein the **fiber system** is constructed of an ultra high molecular weight polyethylene (UHMWPE) material.

'270 patent, col.8 ll.18-54. (emphasis added). This court has already construed the disputed claim terms. Dkt. No. 84.

Spinal Kinetics now moves for summary judgment that claims 29-31 of the '270 patent are invalid under 35 U.S.C. § 112 because the specification fails to disclose the best mode contemplated by the inventors to practice the claimed subject matter at the time the application was filed.

II. ANALYSIS

A. Summary judgment of best mode violation

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). Summary judgment is improper "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001).

Compliance with the best mode requirement is a question of fact. *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1312 (Fed. Cir. 2002). "To grant summary judgment on a factual question, all disputed material facts must be resolved in favor of the non-movant." *High Concrete Structures, Inc. v. New Enterprise Stone and Lime Co., Inc.*, 377 F.3d 1379, 1382 (Fed. Cir. 2004) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252-53 (1986)). The test for compliance with the best mode requirement involves a two-prong inquiry:

> First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. Second, if the inventor possessed a best mode, the factfinder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it. The first prong involves a subjective inquiry, focusing on the inventor's state of mind at the time of filing. The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art.

Eli Lilly & Co., 251 F.3d at 963 (citations omitted). With regard to both prongs, "the contours of the best mode requirement are defined by the scope of the claimed invention . . . the party asserting invalidity must show that the asserted best mode relates directly to the claimed invention." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1330 (Fed. Cir. 2002) (quoting *Northern Telecom Ltd. v. Samsung Electronics Co., Ltd.*, 215 F.3d 1281, 1286 (Fed. Cir. 2000)). Moreover, "[r]outine details need not be disclosed because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention." *Teleflex*, 299 F.3d at 1332. Best mode violations are found where there is either a "failure to disclose a preferred

embodiment, or else failure to disclose a preference that materially affected making or using the invention." *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1316 (Fed. Cir. 2002).

B. Best mode for "bone contacting plate"

Spinal Kinetics argues that in their February 2002 thesis, inventors Adrian Burri ("Burri") and Daniel Baumgartner ("Baumgartner") contemplated "bone contacting plates" having a structure different from the structure disclosed in the '270 patent as the best mode at the time the patent application was filed (April 14, 2003). *See* Jansen Decl., Exh. 3, A. Burri and D. Baumgartner, *New Development of an Implant for Total Disc Replacement* ("Thesis Report"). In the Thesis Report, the authors describe three conceptual solutions focused on the conservation of movement. *Id.* pg. 73 ("The three proposed concepts have been elaborated deliberately with a view only to the nature of conserved mobility. In terms of endplate geometry, different solutions are feasible for all three concepts."). These are identified as "Solution 1" or "S.1," "Solution 2" or "S.2" and "Solution 3" or "S.3" as shown below:

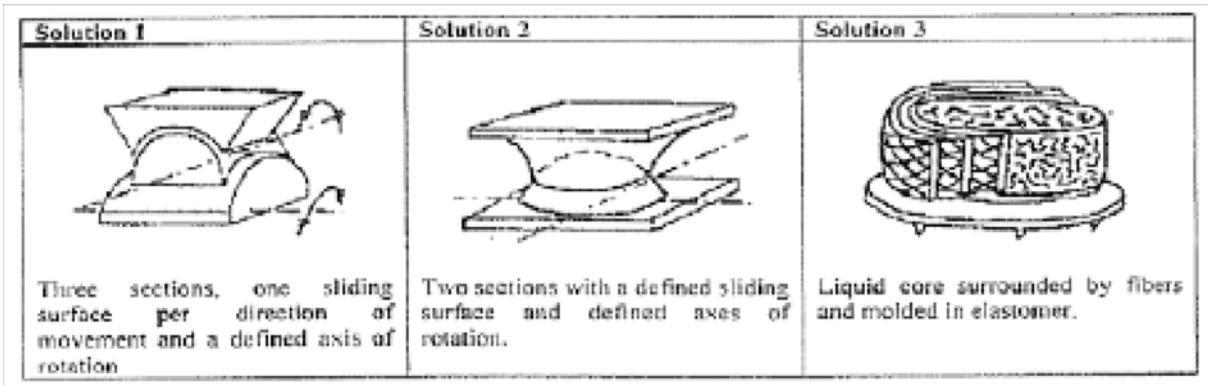

Table 10.2 Conceptual solutions for conservation of movement which are elaborated in more detail

Id. at pg. 62. The Thesis Report goes on to explain that S.1 and S.2 are "Mechanical solutions" that are "based on diverse sliding surfaces." *Id.* at § 9.6.1, Figures 9.1 and 9.2, pgs. 57 and 58. In contrast, the S.3 implant is described as an "Elastomer solution" using fibers in which "the implant consists of a nucleus–such as an incompressible water nucleus or elastomer enveloped by various fiber layers." *Id.* at § 9.6.2.1, Figure 9.3, pg. 58. Inventor Baumgartner testified that S.3 is embodied in claims 29-31 of the '270 patent. Baumgartner Depo. Tr. at 158:10-163:22.

The Thesis Report discusses both primary and secondary stabilization or fixation. Primary stabilization refers to macroscopic, mechanical structures for fastening the implant to adjacent vertebrae while secondary stabilization refers to stabilization via eventual growth of vertebral bone onto the implant itself. With regard to S.2, the Thesis Report states the following:

> **10.5.3.1 Primary Stabilization**
> Primary stabilization is guaranteed by two anchors protruding into the endplates of the adjacent vertebral bodies. On lateral shear, the resulting force is absorbed by the surfaces of these two anchors. On dorsal or ventral forces, the teeth transfer the reaction force to the partly comprised spongiosa structure in the vertebral body.
>
> **10.5.3.2 Secondary Stabilization**
> Long-term growth, and thus permanent attachment to the endplate structure of the vertebrae is guaranteed by a coated titanium surface. In analogy to Prodisc, the proven "plasma spray coating" is the optimal solution-variant for problem-free osteointegration.[1]

Thesis Report at pgs. 68-69. Table 4.1 of the Thesis Report further describes ProDisc as having endplates of titanium with plasma spray coating. *Id.* at § 4.1, pg. 19.

Critical to Spinal Kinetics' argument, the Thesis Report describes the S.3 (claimed in the '270 patent) as having "the same endplates as for the second solution." *Id.* at § 10.6.3, pg. 71. According to Spinal Kinetics, the only structural designs for the bone contacting plates of S.3 found in the Thesis Report show a central planar keel extending axially outwards on the opposite sides of the intervertebral implant. *Id.* at Figures 10.14-10.15. Each central planar keel has multiple jagged edges extending longitudinally outwards along the same plane as the keel. *Id.* Based on these statements and figures in the Thesis Report, Spinal Kinetics argues that plasma spray coating and a central planar keel are the best modes contemplated by the inventors for the claimed "bone contacting plates."

In this case, both "plasma spray coating" and "a central planar keel" are directly related to primary function of the "bone contacting plates." Specifically, "a central planar keel" is a description of the shape and design of a bone contacting plate while "plasma spray coating" describes the surface condition of a bone contacting plate. Therefore, the court finds that the asserted best modes relate directly to the claimed invention.

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[1] Spinal Kinetics' translation of § 10.5.3.2 is different: "In a similar way to Prodisc, the proven "plasma spray coating" is the optimal solution for perfect osteointegration." In its reply brief, Spinal Kinetics does not dispute Synthes' corrected translation.

Having determined that the alleged best modes are within the scope of the asserted claims, the court must next determine whether the inventors actually considered plasma spray coating and a central planar keel to be a best mode for "bone contacting plates." The court finds that the evidence is not as indisputable as Spinal Kinetics contends. As Synthes points out, the Thesis Report focuses on conserving mobility rather than fixation:

> It was discovered that solutions to the subfunctions of fixation and force transmission can in principle be combined with every solution for conserving mobility. In-depth knowledge of osteointegration is needed for the purposes of detailed elaboration of the fixation of the implant and choice of implant surface with a view to optimal growth onto the bone. Such knowledge is available within the company and there are successful products on the market. For this reason, no new solution is being sought in this paper to this aim.
>
> Subsequently, we concentrate specifically on finding a solution for maintaining the physiological movement pattern. The systems used in the following solutions for osteointegration are examples of existing products and have not undergone more thorough investigation for feasibility.

Id. at § 9.5, pg. 57. These statements suggest that the discussed fixation techniques are only examples, not best modes. Notably, the inventors "concentrate specifically on finding a solution for maintaining the physiological movement pattern." Moreover, the concluding section of the Thesis Report makes clear that the "elaborated concepts are a good basis for further development." *Id.* § 11, pg. 74. Even more to the point, the inventors note that "[i]n terms of endplate geometry, different solutions are feasible for all three concepts." *Id.* at pg. 73. These statements are not indicative of a "preferred embodiment" or a "failure to disclose a preference that materially affected making or using the invention." *Bayer AG*, 301 F.3d at 1316. Indeed, with respect to the planar keel, the inventors merely note that stabilization is "guaranteed by two anchors protruding into the endplates." This does not mean that a central planar keel was "considered to be better than any other" approach. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927-28 (Fed. Cir. 1990). With these limiting statements in mind, a reasonable juror could find that the inventors did not have a best mode for fixation.

To be sure, section 10.5.3.2 states that "plasma spray coating is the optimal solution-variant for problem-free osteointegration." But the fixation techniques described in 10.5.3.1 and 10.5.3.2 refer to S.2, not S.3. While Spinal Kinetics is correct in noting that the Thesis Report describes elastomeric S.3 as using the same endplates that were used in the mechanical S.2, the Thesis Report also presents an alternative fixation for the elastomeric S.3:

> According to the description above, the same endplates were used as for the second solution. An alternative would be the following: the enveloped endplates are positioned on one side where they abut the vertebral bodies, covered with silicone. On implantation, the layer adapts exactly to the form of the vertebral endplate. There is the question of abrasion properties and particle release, however, if an elastomer comes into direct contact with the vertebral body endplates.

Thesis Report at § 10.6.3, pg. 71. The Thesis Report does not claim that central planar keels and plasma spray coating are the optimal fixation choices with regard to the elastomeric S.3. Rather, the Thesis Report gives an alternative fixation method for S.3 without commenting on which method is better. Other depictions of the elastomeric design of S.3 show yet another fixation alternative, specifically a multiple-pin approach (Figures 9.3 and 10.2 at pgs. 58 and 62) similar to that used with the S.1 design (Figure 10.4 at pg. 64). In light of the narrow scope of the Thesis Report as well as the alternative S.3 fixation examples, a reasonable juror could find that plasma spray coating and a central planar keel were not considered best modes by the inventors.

Since it appears that the inventors did not have a best mode, the court does not reach the issue of whether or not plasma spray coating and a central planar keel are disclosed in the '270 patent.

C. Best mode for "fiber system"

Spinal Kinetics also argues that the calculation appearing in the appendix to the Thesis Report represents a best mode for optimizing the "fiber system" in the asserted claims. Spinal Kinetics relies on the following statement in the Thesis Report to support its theory:

> By varying the number of fibrous layers, fibrous material, fiber orientation, core size, etc, exact reproduction of the physiological rations can be achieved. These parameters can be partly compute, and partly achieved with experimentation. Hence there is a problem of optimization with several unknown factors. For the first prototype, a simple calculation was made for torsion stiffness (see appendix, section 13.5).

Thesis Report § 10.6.2, pg. 71. The torsion stiffness calculation in § 13.5 shows: (a) a cross-section of PE fiber A = 0.723 mm^2; (b) a radius of innermost fiber layer R_i = 10 mm; (c) a radius of outermost fiber layer R_a = 13mm; (d) a height of core h = 8 mm; (e) an angle of fiber around core = 30 degrees; and (f) a length of fiber c = 16mm.

In response, Synthes cites to other portions of the Thesis Report indicating that the calculation in the appendix is nothing more than an example demonstrating a wide range of ways in which a fiber system might be constructed to achieve a desired "torsion stiffness" similar to that of one of the segments of the spine:

10.6.6 Perspectives, possibilities

There is a lot of leeway when it comes to further elaboration and design. On the one hand, the fiber thickness can be varied, and on the other hand the dimensions of the fluid-filled chamber modified to enable approximation of the physiological reality. The technical side of manufacturing needs to be clarified; industrial winding technology was first used with the dynesis system (dorsal stabilization element, section 4.2). Some problems may arise with sterilization methods, as well as issues with aging the integrated elastomer. In summary, the following parameters can be freely selected:

- Number of fibrous layers
- Number of fibers in a fiber bundle
- Angle of the fibers around the core
- Geometry of the core
- Viscosity of the fluid

Id. at pg. 72.

Considering the Thesis Report as a whole, the court finds that Spinal Kinetics has not shown by clear and convincing evidence that no reasonable juror could find that the torsion stiffness calculation in § 13.5 does not represent the inventors' best mode. The Thesis Report notes that the fiber parameters can be "freely selected" and that "[t]here is a lot of leeway when it comes to further elaboration and design." Critically, Spinal Kinetics fails to point out any language in the Thesis Report claiming that the values used for the calculation in § 13.5 are the best or even preferred. Moreover, nothing in the Thesis Report suggests that the values in § 13.5 represent the only prototype. To the contrary, the language of § 10.6.6 teaches that values can be freely selected. And while an E module of 200-1200 N/mm^2 was selected based on a "tractive test of the PE fibers used in the prototype," nothing suggests that the PE fibers tested were the best or necessary fibers.

Even if the values employed in § 13.5 were representative of a best mode fiber system, a material issue of fact remains as to whether the '270 patent discloses the alleged best mode to those skilled in the art. The '270 patent specification discloses ranges of parameter values for each of the following variables used in the torsion stiffness calculation of the Thesis Report: (a) a fiber winding angle of 15-60 degrees; (b) 2-6 fiber layers; (c) a fiber diameter 0.005-0.025 mm; (d) 500-2000 fibers in the fiber yarn; and (e) a yarn cross-section of 0.5-2.0 mm^2. '270 patent col.4 ll.11-40. Other than production details such as the size of the implant (which will vary depending on position), and factors imposed by the natural characteristics of the spine or the chosen fiber material, Synthes has presented evidence that all of the parameter values appearing in connection with the torsion stiffness calculation

are described or depicted in the '270 patent. *See* Dkt. No. 135-2 at ¶¶ 22-23.[2] In sum, Spinal Kinetics has not shown that a reasonable juror could not find that the '270 patent discloses the alleged best mode for a "fiber system" such that one reasonably skilled in the art could practice it.

III. ORDER

For the foregoing reasons, and recognizing that best mode is a question of fact for which Spinal Kinetics has the burden of showing a failure to disclose by clear and convincing evidence, the court denies Spinal Kinetics' motion for summary judgment of invalidity.

DATED: 2/11/2011

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge

[2] Spinal Kinetics objects to the Koch Declaration insofar as it contains conclusory assertions in the absence of supporting evidence. The court agrees in part. Several items in the Koch Declaration are merely speculative as to the inventors' state of mind. That said, some of the content regarding the prior art and the Thesis Report is supported by admissible evidence. Insofar as the Koch Declaration contains unsupported conclusions and arguments regarding the inventors' state of mind, the court declines to consider it. Otherwise, Spinal Kinetics' objection is overruled.