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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., Plaintiffs, v. SPINAL KINETICS, INC., Defendant.	No. C-09-01201 RMW ORDER ON PARTIES' PRETRIAL MOTIONS **[Re Docket Nos. 206, 217, 218, 224, 225, 236, 267, and 281]**

Defendant Spinal Kinetics, Inc. ("Spinal Kinetics") moves (1) to dismiss plaintiffs Synthes, Inc. and Synthes USA Sales, LLC for lack of standing; (2) for summary adjudication precluding plaintiffs Synthes, Inc. and Synthes USA Sales, LLC from recovering any damages and precluding plaintiff Synthes USA, LLC from recovering any lost profit damages; (3) for partial summary judgment that none of claims 29-31 of U.S. Patent No. 7,429,270 ("the '270 patent") is entitled to the effective filing date of the PCT application under 35 U.S.C. § 120; and (4) for summary judgment of invalidity under § 102(b) based on public accessability of the inventors' thesis work.

Plaintiffs Synthes USA, LLC, Synthes USA Sales, LLC, and Synthes, Inc. (collectively "Synthes") move (1) for partial summary judgment dismissing invalidity defenses based on 35

U.S.C. § 112 and 35 U.S.C. § 101; (2) for summary judgment dismissing anticipation and obviousness defenses; (3) to strike or otherwise exclude the testimony of Spinal Kinetics' experts George Strong, Nicholas Koske, and Thomas Smegal on certain issues; and (4) to exclude untimely evidence at trial and for all other purposes.

On July 29, 2011, the court held a hearing to consider the parties' motions. The court has considered the papers submitted by the parties and the arguments of counsel and hereby issues its rulings.

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;
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> a third plate operatively coupled to the first bone contacting plate, the third plate including a plurality of openings;
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> 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. The court has construed the disputed claim terms. Dkt. No. 84. Additionally, the court previously denied two summary judgment motions brought by the defendants. *See* Dkt. No. 137 (Order Denying Motion for Summary Judgment of Non-Infringement) and Dkt. No. 153 (Order Denying Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 112 ¶ 1).

The court now considers the parties' currently pending motions.

II. ANALYSIS

A. Motion to Dismiss Synthes, Inc. and Synthes USA Sales, LLC for Lack of Standing

Synthes, Inc., Synthes USA Sales, LLC, and Synthes USA, LLC are closely-tied affiliated companies. Synthes USA, LLC and Synthes USA Sales, LLC are both wholly-owned subsidiaries of Synthes, Inc. Dkt. No. 265 Exh. 2. Synthes USA, LLC is the record assignee of the '270 patent. Synthes USA, LLC acquires Synthes products, including the Prodisc artificial disc devices, from Synthes USA Products, LLC, a related contract manufacturing facility, and transfers them (at a profit) to Synthes USA Sales, LLC for distribution. *Id.* at Exh. 4. This structure guarantees Synthes USA, LLC a significant profit from every sale. Spinal Kinetics manufactures its M6 devices within the United States and then sells them to distributors for sale outside the United States in competition with the Synthes ProDisc devices. *Id.* Exh. 3. Spinal Kinetics M6 devices allegedly infringe the '270 patent. Although Synthes ProDisc devices are not embodiments of the '270 patent, sales of the Synthes ProDisc devices have allegedly been hurt by the sale of Spinal Kinetics M6 devices.

Spinal Kinetics moves to dismiss Synthes, Inc. and Synthes USA Sales, LLC for lack of standing. Both Spinal Kinetics and Synthes recognize that current Federal Circuit precedent states that "[o]nly a patent owner or an exclusive licensee can have constitutional standing to bring an infringement suit; a non-exclusive licensee does not." *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, 620 F.3d 1305, 1317 (Fed. Cir. 2010) (citing *Mars, Inc. v. Coin Acceptors, Inc.*, 527 F.3d 1359, 1367 (Fed. Cir. 2008)). *See also Poly-America, L.P. v. GSE Limin Tech., Inc.*, 838 F.3d 1302, 1311 (Fed. cir. 2004) ("We have held that a licensee generally may not sue for damages unless it has exclusive rights under a patent, including the right to sue.").

Here, only Synthes USA, LLC maintains the necessary exclusive rights that afford standing. Synthes, Inc. is neither an owner nor an exclusive licensee of the '270 patent. Synthes argues, however, that Synthes USA Sales, LLC should be considered an implied licensee. Although Synthes USA Sales, LLC apparently has the right to sell products covered by the '270 patent, there is no evidence that Synthes USA, LLC is prevented from licensing the '270 to a third party or another related Synthes entity. *See Spine Solutions*, 620 F.3d at 1318 ("[T]he fact that Synthes Spine is currently the only entity practicing the [patent-in-suit] does not mean that SSI has promised to exclude all others from doing so. Nothing in the record shows that SSI would be prohibited from licensing the [patent-in-suit] to a third party, should it so desire."). Indeed, Synthes acknowledges that it only nominally opposes Spinal Kinetic's motion to dismiss in order to preserve the ability to challenge the standing issue on appeal. Dkt. No. 234 at 3:13-28.

The court grants Spinal Kinetics' motion to dismiss Synthes, Inc. and Synthes USA Sales, LLC for lack of standing because they neither own the '270 patent nor are they exclusive licensees.

B. Motion for Summary Adjudication Precluding Certain Damages

Spinal Kinetics also moves for summary adjudication precluding plaintiffs Synthes, Inc. and Synthes USA Sales, LLC from recovering any damages and precluding plaintiff Synthes USA, LLC from recovering any lost profit damages. Because the court has found that Synthes, Inc. and Synthes USA Sales, LLC lack standing, the court turns to whether Synthes USA, LLC can assert a viable claim for lost profits.

According to Spinal Kinetics, the '270 patent has never been commercialized. However, Synthes USA, LLC still seeks profits it claims it lost on sales of the Synthes ProDisc products as a result of Spinal Kinetics' infringement. Synthes has only accused one product (the Spinal Kinetics M6 product) of infringing the '270 patent. The vast majority of M6 products have been sold in Europe, and, in particular, Germany. Accordingly, Synthes USA, LLC's lost profit claim relies on sales of the ProDisc product it allegedly lost outside the United States. Around the time of Spinal Kinetics' 2006 entry into the cervical disc market in Germany, the ProDisc-C device was the market leader. 6/17/11 Tiu Decl., Exh. 1 at 15. Two years later (in 2008), the ProDisc-C device market share had significantly fallen, with substantial sales being diverted to Spinal Kinetics' M6-C device. *Id.*

The M6-C now leads the German cervical market, followed by the ProDisc-C device. *Id.* at 16. For Europe overall, research estimates that in 2010, the ProDisc-C device had approximately a 27% market share, while the M6-C device had about a 23% share. *Id.* Even though Synthes USA, LLC does not sell products directly to customers, it claims that it could have supplied ProDisc devices from the United States to other Synthes entities for distribution in Europe, and thus should be able to recover the "wholesale profits" it would have made under those circumstances. Synthes does not claim to have transferred substantial quantities of ProDisc products from the United States to its Swiss subsidiary for sale in Europe during the relevant time period for damages, but argues that there are no known barriers of significance that would prevent this from occurring, whether in the past or future. Dkt. No. 245 at 3.

35 U.S.C. § 284 provides that "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer." Synthes USA, LLC appears to claim that simply by satisfying the *Panduit* factors, it is entitled to lost profits from lost sales outside of the United States. *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978). The *Panduit* test requires that a patentee establish: (1) demand for the patented product; (2) absence of acceptable non-infringing substitutes; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of the profit it would have made. *Id.* at 1156. However, Synthes USA, LLC's theory ignores the supply chain that has been serving the European ProDisc market for the entire relevant time period (Synthes Hagendorf, GmbH). Instead, Synthes USA, LLC has come up with a fictional supply chain wherein ProDisc products destined for Europe could have been manufactured in the United States and then artificially funneled through Synthes USA, LLC for no other reason than to make its lost profits claim.

Synthes USA, LLC contends that under *Rite-Hite Corp. v. Kelley Co., Inc.*, it is entitled to "wholesale profits" due to sales it would have made, albeit through "wholly-owned and operated sales organizations and through independent sales organizations." 56 F.3d 1538, 1542-43 (Fed. Cir. 1995). Plaintiff's reliance is misplaced. In *Rite-Hite*, the patentee distributed all of its products through its wholly-owned and operated sales organization and through independent sales organizations (ISO's).

Id. at 1542. During the period of infringement, the patentee's sales organizations accounted for approximately 30 percent of the retail dollar sales and the ISOs accounted for the remaining 70 percent. *Id.* The patentee sued for its lost profits at the wholesale level and for the lost profits of its own sales organizations. *Id.* The distribution channels already existed and were actually used. Here, in contrast, there is no evidence to suggest that the hypothetical supply chain has ever been used. The unrebutted evidence shows that "but for" the alleged infringement, Synthes' European distribution chain would have made the lost sales, not Synthes USA, LLC. Moreover, Synthes USA, LLC does not explain why or how the transfer pricing formulas are structured so that it is guaranteed a significant profit from each hypothetical sale (for simply storing and transferring the product), while Synthes USA Sales, LLC is forced to take a significant loss on the same sale. Accordingly, Spinal Kinetics motion is granted. Synthes USA, LLC's damages, if any are awarded, must be based upon a reasonable royalty.

C. Motion for Partial Summary Judgment that Each of Claims 29-31 Is Not Entitled to the Effective Date of the PCT Application Under 35 U.S.C. § 120.

The '270 patent was first filed as a Patent Cooperation Treaty (PCT) international patent application on April 14, 2003. Dkt. No. 226 Exh. 1. "The PCT offers an alternative route to filing patent applications directly in the patent offices of those countries which are Contracting States of the PCT." Manual of Patent Examining Procedure, 8th Ed. Rev. 4, October 2005 ("MPEP") § 1801. The named inventors of the '270 patent were residents of Switzerland in 2003, and so the PCT international application was filed in Switzerland. Dkt. No. 227, Exh. 12 (WO 2004/089257). The application was assigned the PCT number PCT/CH03/00247 and was later published as WO 2004/089257. *Id.* The '270 patent application entered the national stage in the United States and was assigned Serial No. 10/553,495 on July 25, 2006. *Id.* While in the national stage of prosecution, the applicants made various amendments to the claims as originally set forth in the PCT application. In February, 2008, applicants added what later became claims 29-31. Dkt. No. 226 Exh. 4.

Spinal Kinetics seeks summary judgment that each of the asserted claims is not entitled to the effective filing date of the PCT application. Claims 29-31 recite "bone contacting plate(s)" that are "*substantially rigid*," a plurality of "*openings*" and a "*flexible core*" that is "*substantially cylindrical*."

Spinal Kinetics contends that these limitations did not appear in the original PCT application. In addition, Spinal Kinetics argues that claims 29-31 contained new matter under 35 U.S.C. § 132 and, therefore, cannot claim priority to the April 14, 2003 PCT application filing date. Spinal Kinetics relies on the Federal Circuit's decision in *Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010) in an attempt to shift the burden of persuasion to Synthes to establish entitlement to the PCT application filing date.

> This court first considers whether the district court misplaced the burden of showing the [ ] patent's entitlement to an earlier effective date. A patent is presumed valid and the party asserting invalidity has the burden of persuasion to show the contrary by clear and convincing evidence. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1329 (Fed.Cir.2008). The challenger has the burden of going forward with invalidating prior art. *Id.* The patentee then has the burden of going forward with evidence to the contrary, i.e., the patentee must show that the prior art does not actually invalidate the patent or that it is not prior art because the asserted claim is entitled to the benefit of an earlier filing date. *Id.*; *see also PowerOasis*, 522 F.3d at 1304-06 (holding that the patentee had the burden to come forward with evidence to prove entitlement to an earlier filing date when it was undisputed that a certain reference was invalidating prior art).

Id. According to Spinal Kinetics, the resulting loss of priority would make available "intervening" prior art references having dates earlier than July 25, 2006, but not earlier than April 14, 2005. These intervening references include Spinal Kinetics' *Instructions for Use* Manual, the pre-publication manuscript of the book *Dynamic Reconstruction of the Spine*, and the sale of the accused M6 implant on or about January 9, 2006. Spinal Kinetics contends that each of these intervening references anticipates claims 29-31. But at bottom, Spinal Kinetics seeks to avoid the burden of establishing a violation of the written description requirement by clear and convincing evidence.

The anticipation defenses raised in Spinal Kinetics' motion have never been included in its Patent Local Rule 3-3 invalidity contentions. Spinal Kinetics offers no excuse for its violations of the court's scheduling order and the Patent Local Rules. All of the information needed to support these anticipation and priority theories have been in Spinal Kinetics' possession since the case was filed. For this reason alone, Spinal Kinetics' motion is denied.

But even considering the motion on its merits, it fails. There are "three types of U.S. national applications: a national stage application under the PCT (an application which entered the national stage in the U.S. from an international application after compliance with 35 U.S.C. 371), a regular

domestic national application filed under 35 U.S.C. 111(a), and a provisional application filed under 35 U.S.C. 111(b)." MPEP § 1893. Where the national stage in the United States proceeds in accordance with 35 U.S.C. § 371, the international and national stages have the same filing date. *See* 35 U.S.C. § 363 ("An international application designating the United States shall have the effect, from its international filing date under article 11 of the treaty, of a national application for patent regularly filed in the Patent and Trademark Office . . . ."). In other words, these are two stages of the same application, not one application claiming priority to "a prior application." MPEP § 1893.03(b). Here, the USPTO issued a notice that it had determined that the '270 application "has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office." Dkt. No. 246.1.

Spinal Kinetics improperly expands the scope of *Research Corp.*. In that case, the defendant identified anticipating prior art pre-dating the filing of the patent at issue. The only way the patentee could avoid the prior art was to claim priority to an earlier filed patent. 627 F.3d at 871. But the '270 patent makes no such claim to a prior patent, nor does Synthes need to claim priority to an earlier filed and separate patent to escape Spinal Kinetics' assertion of allegedly intervening prior art. Rather, the April 14, 2003 PCT application's filing date is also the United States filing date for the national stage application that matured into the '270 patent. *See Broadcast Innovation, L.L.C. v. Charter Communications, Inc.*, 420 F.3d 1364, 1368 (Fed. Cir. 2005) (noting that "under 35 U.S.C. § 363, the international filing date of a PCT application is also the U.S. filing date for the corresponding national stage application"); *see also* MPEP § 1893.03(b) ("It should be borne in mind that the filing date of the international application is also the filing date for the national stage application."). Moreover, the *Research Corp.* decision cites to a distinguishable case, *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299 (Fed. Cir. 2008), for the proposition that a patentee has the burden to come forward with evidence to prove entitlement to an earlier filing date when it was undisputed that a certain reference was invalidating prior art. In *PowerOasis*, the court considered a continuation-in-part (CIP) application that claimed priority to an earlier filed application. *Id.* at 1304. In shifting the burden to the patentee to show entitlement to the earlier filing date, the court relied on the fact that "the PTO did not, at any point, make any determination with regard to the priority date of the various

claims of the asserted patents." *Id.* The court went on to note that "[s]ince CIPs generally add new matter, the claims may be fully supported by the parent application or they may rely on the new matter for support." *Id.* at 1305 n.4. Put differently, a CIP application is generally not examined in light of the disclosure that the applicant is claiming priority to, so there is no PTO priority determination to which to defer.[1] In the instant case, however, the February 2008 amendment introducing what are now claims 29-31 was examined in the context of the original April 14, 2003 disclosure. Because the '270 does not claim priority to an earlier filed patent application, Spinal Kinetics' reliance on *Research Corp.* is unavailing.

As Synthes points out, there is a procedure for filing regular domestic national applications pursuant to 35 U.S.C.§ 111(a), and then claiming priority to a prior PCT international application designating the United States pursuant to 35 U.S.C. §§ 120 and 365(c). *See* MPEP §§ 1895, 1895.01. This is known as a "Bypass Continuation," and there are perceived advantages and disadvantages to such a procedure. *Id.*; *see also, e.g.*, Dkt. No. 246-1 Exh. 4. However, it is undisputed that this procedure was not used in the case of the '270 patent.

Spinal Kinetics cites a variety of cases in an attempt to place a burden on Synthes to show that no new natter was added to the '270 application after the PCT application was filed in order for Synthes to claim the PCT application filing date. However, not one of them deals with the national stage of a PCT application. Rather, all of the cases cited by Spinal Kinetics deal with one or more continuation applications filed under 35 U.S.C. § 120 claiming priority to one or more earlier-filed United States applications. Moreover, Spinal Kinetics' argument that Synthes cannot rely on 35 U.S.C. § 371 because it has not complied with 37 C.F.R. § 1.78 is inapposite:

> Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America *claiming benefit of one or more prior-filed copending nonprovisional applications* or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application . . . .

[1] Where there is an interference proceeding, or where there is a determination of priority during prosecution incident to a rejection, the PTO might make a determination regarding the priority of certain claims in a CIP. *See PowerOasis*, 522 F.3d at 1303-04 (discussing and distinguishing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570 (Fed. Cri. 1985) where an interference proceeding clearly determined a priority date).

37 C.F.R. § 1.78(a)(2)(i) (Dkt. No. 275-1) (emphasis added). The '270 patent does not "claim the benefit of one or more prior-filed copending non provisional applications or international applications designating the United States of America." *Id.* Indeed, the '270 patent does not claim priority to any other patent–it is merely the end product of entry into the national stage of a single PCT application.

Accordingly, Spinal Kinetics' intervening prior art references cannot anticipate claims 29-31 because the '270 patent has an April 14, 2003 filing date. Moreover, the burden has not shifted to Synthes to show that claims 29-31 are entitled to an April 14, 2003 filing date. Spinal Kinetics must show by clear and convincing evidence that the asserted claims fail to comply with 35 U.S.C. § 112. *Microsoft Corp. v. i4i Ltd. Partnership et al.*, 131 S.Ct. 2238 (2011).

D. Motions to Strike and to Exclude

Synthes moves to strike or otherwise exclude the testimony of Spinal Kinetics' experts George Strong, Nicholas Koske, and Thomas Smegal on certain issues. Synthes also moves to exclude untimely evidence at trial and for all other purposes.

1. Thomas Smegal

Synthes contends that Thomas Smegal's testimony regarding prior-art-based invalidity defenses – and any testimony on technical matters – should be excluded in its entirety because Mr. Smegal is not skilled in the art of spinal implants.

Mr. Smegal is a patent law practitioner with over 45 years of experience. Mr. Smegal also provided opinion testimony in two long running patent cases in the area of spinal devices. Moreover, Mr. Smegal has consulted with Nicholas C. Koske, who Spinal Kinetics states is one of ordinary skill in the art of spinal implants.

While his legal experience is extensive, Mr. Smegal is not qualified to testify on technical issues in this case. Mr. Smegal's technical engineering degree is limited to a B.S. in Chemical Engineering. Simply "speaking" with Mr. Koske is not enough to bestow the "knowledge, skill, experience, training, or education" required to meet Fed. R. Evid. 702 standards. Even where the technology is simple, "it is an abuse of discretion to permit a witness to testify as an expert on the issues of noninfringement or invalidity unless that witness is qualified as an expert in the pertinent art." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008). Moreover,

"[a]llowing a patent law expert to testify on the issues of infringement and validity amounts to nothing more than advocacy from the witness stand. . . . A technically unqualified patent attorney can do much mischief by leading the jury to seemingly sound conclusions without ever providing a well-grounded factual basis in the pertinent art." *Id.* at 1364-65 & n.8. Therefore, the court excludes Mr. Smegal's technical testimony. The court also strikes Mr. Smegal's statements of law found at ¶¶ 19-28 of his rebuttal report relating to non-infringement. Courts have generally "condemned the practice of attempting to introduce law as evidence." *See Meyer v. Fidelity Sav.*, 944 F.2d 562, 577 (9th Cir. 1991).

The result of the above analysis is that Mr. Smegal's proffered testimony is excluded in its entirety.

2. Motions to Strike and Exclude Evidence Relating to the Powderized Tantalum Sheath Design

On June 19, 2009, Synthes' first set of interrogatories asked Spinal Kinetics to "explain in detail each non-infringing alternative that Spinal Kinetics contends was or is available to it and the basis for such contention, including without limitation the time period or periods during which such alternative was or is available" and (2) for each non-infringing alternative identified, to provide "the time, cost, and technology needed to implement the alternative." Dkt. No. 267-2 Exh. 1. Synthes also requested production of documents "describing or referring to any design alternative to the M6 intervertebral implants," the "time, cost, and technology needed to implement" the design alternative, and "acceptability in the marketplace of any design alternative to the M6." *Id.* Exh. 3.

On June 23, 2010, the court construed "elastic sheathing body" recited in claim 29 of the '270 patent, as urged by Spinal Kinetics, to require the "elastic sheathing body" to be "homogeneous." Dkt. No. 84. During the period between the court's claim construction and the close of fact discovery, Spinal Kinetics appears to have designed an alternative sheathing body for the M6 device that it now alleges to be non-infringing because tantalum powder has been added to the sheath. Spinal Kinetics claims that Nicholas Koske disclosed this design alternative to its damages expert, George Strong, on May 4, 2011.[2] According to Spinal Kinetics, the testing of the alterative sheath

[2] Spinal Kinetics claims that the March 4, 2011 date reflected in Mr. Strong's report is a typographical error. However, Mr. Strong verified the March 4, 2011 date in his deposition. Dkt. No. 267-2 Exh. 24 at 166.

design was not complete until May 3, 2011. On May 5, 2011, Spinal Kinetics provided plaintiffs with a disclosure of the alternative sheath design in the expert reports of Mr. Koske and Mr. Strong. Dkt. No. 267-2 Exhs. 6 and 7. Both Mr. Koske and Mr. Strong were subsequently deposed. However, Spinal Kinetics has not produced a single document relating to the development, manufacture, composition, or testing of its powderized tantalum sheath design.

Synthes now moves to strike and exclude all evidence related to the alternative sheath design. Synthes contends that the alternative sheath design should have been disclosed before the May 5, 2011 expert reports. The court agrees with Synthes. Spinal Kinetics has violated its obligations pursuant to Fed. R. Civ. P. 26(e)(1), which not only require supplementation of interrogatory responses, but also require that requests for production that are "incomplete or incorrect" be supplemented "in a timely manner." Spinal Kinetic's contention that it did not disclose the alternative sheath design earlier because the design and testing of it were not completed until May 3, 2001 is not well taken. Spinal Kinetics suggested at oral argument that discovery regarding the alternative design has not been produced because, as of the time of the hypothetical royalty negotiation, Spinal Kinetics would have only considered the potential success of an alternative design and not the specifics of the later successfully tested design. If this is what Spinal Kinetics actually intended to offer, any alternative design work done after the hypothetical negotiation would not be relevant to what Spinal Kinetics could have considered at the time of the hypothetical negotiation. However, Mr. Strong and Mr. Koske take into account the reported viability and cost of implementing the alternative design. Spinal Kinetics cannot reasonably assert that the success of the alternative design was so uncertain that it need not mention that design in response to discovery requests, or in supplementing those responses, but yet claim that the cost of the alternative design places an upper limit on what royalty would have been negotiated at the time of the October 2008 hypothetical negotiations.

Mr. Koske testified that the powderized tantalum sheath design "has a full design control set of documentation . . . . It's something that has gone through our design control process." Dkt. No. 236-2 Exh. 6. Without these documents, Synthes (and the court) are unable to evaluate whether the alterative sheath design is in fact an acceptable, non-infringing substitute. *See, e.g., Parker-Hannifin Corp. v. Champion Labs., Inc.*, 2008 U.S. Dist. LEXIS 3291 at *22 (N.D. Ohio 2008) (excluding

evidence of alleged non-infringing alternative not disclosed during discovery because "[p]laintiffs were denied the opportunity to conduct discovery on this point, to evaluate the availability and acceptability of the [alleged alterative] and to develop an opinion on whether they infringe").

Spinal Kinetics' motions to strike and exclude evidence relating to the powderized tantalum sheath design is granted.

3. Motion to Strike George Strong's Royalty Opinions

Synthes contends that Mr. Strong's royalty opinion should not be admitted because it is based on irrelevant and non-comparable agreements and because Mr. Strong relies upon unreasonable assumptions of profitability and value. Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the district court must exercise its "gatekeeper" function in ensuring that scientific testimony is relevant and reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 137 (1999). "To be admissible, expert testimony opining on a reasonable royalty rate must 'carefully tie proof of damages to the claimed invention's footprint in the market place.'" *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011) (internal citation omitted).

Mr. Strong relies on a Stanford License agreement that allegedly requires Spinal Kinetics to pay royalties for the M6 products. Synthes argues that the Stanford Licence agreement is not comparable because it was negotiated between non-competitors years before the hypothetical negotiation in the instant case and before the M6 product was ever commercialized. In addition, Mr. Strong relies on agreements between Synthes and its consultants relating to the development of Synthes' ProDisc devices.

The royalty agreements on which Mr. Strong relies are at least marginally relevant because they relate to the allegedly competing Synthes ProDisc products, as well as the alleged infringing product. Synthes is correct in arguing that all the agreements involve situations and circumstances different from the facts of this case. That said, a perfectly comparable agreement is rarely available. While different in many respects, these license agreements are not "radically different from the hypothetical agreement under consideration." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301,1327 (Fed. Cir. 2009). Synthes' arguments, while possessing some merit, go to the weight of the evidence and not to admissibility.

Synthes also argues that Mr. Strong's royalty determination is based on unreliable and arbitrary assumptions of profitability and value. Mr. Strong uses an 8.2% rate of return on sales of the Spinal Kinetics products and subtracts that figure from Spinal Kinetics' operating margin and uses the result as the starting upper limit for his royalty rate calculation. Synthes' criticism focuses on the 8.2% which it contends is arbitrary and not the return that companies selling artificial discs or similar products obtain. Mr. Strong identifies the figure as coming from an industry publication entitled "Annual Statement Studies, Financial Ratio Benchmarks, Risk Management Association 2009-2010," a standard resource used by financial analysts. The figure represents an average operating profit for 178 surgical and medical instrument manufacturing companies. Although the use of this figure could be criticized, it is not as arbitrary as the 25% rule that was held to be inadmissible in *Uniloc*, 632 F.3d at 1315. The 25% rule was applied across companies and industries. In the instant case, the 8.2 % figure is limited to medical and surgical devices.

Synthes also objects to Mr. Strong's assumption that the "value contribution ratio" of manufacturing know-how to design of 4:1 is arbitrary and should not be allowed as a basis for supporting Mr. Strong's reasonable royalty calculation. Mr. Strong relied on information provided by Mr. Afzal, the CEO of Spinal Kinetics. Although one can question the opinion of Mr. Afzal, he is a person who presumably has the knowledge based upon his experience at Spinal Kinetics to support such an opinion.

Although serious questions have been raised as to the accuracy of and support for Mr. Strong's royalty rate opinion, the motion to bar his testimony is denied except as it relates to the powderized
tantalum design alternative which has been excluded.

4. Motion to Strike and Exclude Testimony of Nicholas Koske

Synthes seeks to strike or exclude the testimony of Mr. Koske, Spinal Kinetics' Research and Development Manager, on the subjects of: (1) the development and history of the M6 design; (2) allegedly non-infringing modifications; and (3) Spinal Kinetics' § 112 defenses. Synthes claims that Mr. Koske was never disclosed as a fact witness and his expert opinions were not fairly or timely disclosed. Synthes does not seek to exclude his testimony regarding the testing videos which was the subject of his March 8, 2011 deposition. Dkt. No. 236 at 15.

Synthes submits that it first became aware that Mr. Koske was a potentially significant witness on February 24, 2011 when it received Spinal Kinetics listing of potential expert witnesses. Synthes promptly took Mr. Koske's deposition on March 8, 2011, which focused on his involvement in the testing of the M6 devices to show the absence of restraint of radial expansion of the core. On May 5, 2011, Mr. Koske was designated by Spinal Kinetics as a rebuttal expert witness. The subjects of his report were his background, facts pertaining to the development of the M6 products, opinions concerning Spinal Kinetics § 112 defenses, testing of the M6 devices to show the absence of restraint of radial expansion of the core, a critique of Synthes' testing of the M6 and the development of the alternative tantalum sheath design.

Fed. R. Civ. P. 37(c)(1) requires automatic exclusion of witnesses who are not identified pursuant to Fed. R. Civ. P. 26(a)(1)(A), unless the party seeking to call the witness can demonstrate that the failure was "substantially justified or harmless." Synthes contends that Mr. Koske's statements detailing the development history of the accused products is fact testimony that Mr. Koske cannot give because he was not disclosed as a fact witness. *See UniRAM Tech., Inc. v. Taiwan Semiconductor Mfg. Co.*, 2007 U.S. Dist. LEXIS 67862 (N.D. Cal. Sept. 5, 2007) (disallowing statements in expert report when individual was percipient witness who was not identified pursuant to Rule 26(a)(1)(A)).

Although Mr. Koske was not disclosed as a fact witness, Synthes has had the opportunity to depose him. Further, it appears that he is essentially substituting for his predecessor, Michael Reo, who was disclosed as a factual witness and testified to Mr. Koske's involvement in the design and development of the M6 product after Mr. Koske arrived at Spinal Kinetics. At oral argument, Spinal Kinetics' counsel claimed that there was an understanding with Synthes' counsel that Mr. Koske was being substituted for Mr. Reo. Synthes' counsel adamantly denied any agreement, and there does not appear to be any documentary support for such an agreement. Nevertheless, the court finds that the failure to list Mr. Koske as a factual witness was harmless under the circumstances.

Synthes' motion to exclude Mr. Koske from testifying about the alternative design using a non-homogeneous sheath is granted for the reasons stated in section II.D.2 above.

Synthes' last argues that Mr. Koske's should not be allowed to express opinions about what the

'270 patent discloses, specifically whether its specification supports the claims at issue and whether the disclosure is enabling. Spinal Kinetics' expert reports on invalidity were due on April 14, 2011. No report was filed for Mr. Koske at that time. Mr. Koske filed a "rebuttal report." There is no justification for Spinal Kinetics to have Mr. Koske's opinions on invalidity submitted in a rebuttal report.

5. Motion to Exclude Michael Reo's Expert Declarations

Synthes seeks to exclude what it describes as expert testimony from Mr. Reo's first (Dkt. No. 223) and second (Dkt. No. 253) declarations. In those declarations, Mr. Reo submitted several opinions directed to Spinal Kinetics' § 112 defenses, in particular lack of enablement as to the claim term "openings," lack of written description as to the claim terms "substantially rigid," "substantially cylindrical" and "flexible core;" and indefiniteness of the term "substantially rigid." Synthes contends that because Mr. Reo never gave a written expert report or summary before June 10, 2011, he was not deposed regarding these opinions and should therefore be excluded from offering expert testimony. Spinal Kinetics, however, argues that because Mr. Reo was identified in plaintiffs' own Rule 26(a)(1) disclosures, and that because of his first-hand experience as Spinal Kinetics Senior Director of Engineering he should be allowed to offer lay opinion testimony under Fed. R. Evid. 701.

However, Fed. R. Evid. 701 expressly excludes lay opinion testimony "based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Mr. Reo's opinions relating to the scope and adequacy of the '270 patent disclosure are the very type of expert testimony contemplated by Fed. R. Evid. 702. "If the witness with specialized knowledge was a percipient witness, that does not mean that his expert testimony automatically qualifies as lay testimony." *SEC v. Sabhlok*, 2010 U.S. Dist. LEXIS 84367 (N.D. Cal. July 23, 2010). Mr. Reo's technical opinions regarding the adequacy of the '270 patent disclosure cannot be characterized as lay testimony. Because Mr. Reo never provided a written expert report or summary, his § 112 opinions are excluded.

6. Motion to Exclude Thomas Afzal's Enablement Opinion and Early Stage Development Testimony

Thomas Afzal's declarations detail Spinal Kinetics' early design and development activities between October 2003 and July 2004. Dkt. Nos. 219 and 249. Early in discovery, Synthes sought

Fed. R. Civ. P. 30(b)(6) testimony from Spinal Kinetics relating to the design and development of the accused products. However, Spinal Kinetics represented that no one at the company had this knowledge. Dkt. No. 236-3 Exh. 13 (February 19, 2010 email). Synthes argues that in view of these representations, Mr. Afzal was not questioned regarding the early design and development of the accused products during his deposition.

In response, Spinal Kinetics argues that Mr. Afzal was identified in Spinal Kinetics' initial disclosures as knowledgeable about the "development, manufacture, costs of development and manufacture, sales outside of the United States and operation of Spinal Kinetics products that are accused of allegedly infringing the '270 patent." Dkt. No. 261-3 Exh. 20. Spinal Kinetics' initial disclosure is insufficient to remedy its later failure to identify Mr Afzal to Synthes. If an entity refuses to produce a Rule 30(b)(6) witness, claiming it has no knowledge regarding an event, it then cannot call on one of its employees to testify about the event. Because neither Mr. Afzal nor any other Spinal Kinetics employee was presented as a 30(b)(6) witness with knowledge of Spinal Kinetics' early design and development activities, Mr. Afzal's testimony regarding these activities must be excluded. *See Ierardi v. Lorillard, Inc.*, 1991 U.S. Dist. LEXIS 11320, at *8-*9 (E.D. Pa. Aug. 13, 1991) ("If the designee testifies that [the entity] does not know the answer to plaintiffs' questions, [the entity] will not be allowed effectively to change its answer by introducing evidence during trial."). Moreover, Mr. Afzal's opinion on enablement is excluded because he was not designated as a potential expert and no expert report or Rule 26(a)(2)(C) summary was ever provided.[3]

E. Motion for Partial Summary Judgment Dismissing Invalidity Defenses Based on 35 U.S.C. § 112 and 35 U.S.C. § 101

Synthes moves to dismiss Spinal Kinetics' 35 U.S.C. § 112 (1) written description, (2) enablement, (3) indefiniteness (4) and best mode defenses and 35 U.S.C. § 101 (5) lack of utility defense.

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).

[3] Synthes also moves to exclude Dr. Marc Levenston's June 29, 2011 declaration found at Dkt. No. 252. Because the opinions reflected therein find some support in his original expert report, Synthes' motion to exclude Dr. Levenston's June 29, 2011 declaration is denied.

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 court may grant summary judgment "when no reasonable jury could return a verdict for the nonmoving party." *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1365 (Fed. Cir. 2009) (citations omitted). "Conclusory expert assertions cannot raise triable issues of material fact on summary judgment." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1001 (Fed. Cir. 2008). As with all invalidity defenses, Spinal Kinetics bears the final burden of proof by clear and convincing evidence as to each of its separate defenses. *Microsoft Corp.*, 2011 U.S. LEXIS 4376 (U.S. June 9, 2011).

1. Written Description

The written description requirement, as well as enablement and best mode requirements, are contained within 35 U.S.C. § 112, first paragraph, which provides:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The test for sufficiency of a written description is "whether the disclosure clearly 'allows persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (quoting *Vas-Cath. Inc. v. Mahuker*, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991)). "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis*, 522 F.3d at 1307 (citing *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1072-73 (Fed. Cir. 2005)).

a. "Flexible Core"

Spinal Kinetics asserts that the '270 patent fails to provide an adequate written description that supports the claimed "flexible core." Specifically, Spinal Kinetics contends that the '270 patent does not disclose an inelastically deformable central part, which would be included in the court's construction of "flexible core."

Synthes points out that the court has already construed "flexible core" to mean "deformable central part." Dkt. No. 84 at 7-9. The court also found that "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." *Id.* at 9. Synthes argues that the new matter objection with respect to "flexible core" has already been considered and correctly decided, and the court's claim construction raises no plausible reason to reconsider that decision. Synthes further contends that nothing in the '270 patent specification or prosecution history would preclude an "inelastically" deformable central part.

Because material issues of disputed fact remain as to whether the '270 patent disclosure clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed, Synthes' motion dismissing Spinal Kinetics' written description defense with respect to "flexible core" is denied.

b. "Substantially Cylindrical"

Spinal Kinetics contends that because the phrase "substantially cylindrical" does not appear in the '270 patent specification, it fails to meet the written description requirement. In response, Synthes contends that Spinal Kinetics' experts fail to address several figures in the '270 patent that depict cores in the shape of a cylinder. *See* '270 Patent, Figs. 4, 5, and 6. Synthes points out that drawings alone may suffice to meet the written description requirement (*see, e.g., Cooper Cameron Corp. v. Kvaerner Oilfield Prods.*, 291 F.3d 1317, 1322 (Fed. Cir. 2002)).

Because material issues of disputed fact remain as to whether the '270 patent disclosure clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed, Synthes' motion dismissing Spinal Kinetics' written description defense with respect to "substantially cylindrical" is denied.

c. "Substantially Rigid"

Spinal Kinetics argues that the term "substantially rigid" lacks written description support because the terms "rigid" and "substantially rigid" were never used in the specification or in the originally filed claims of the '270 patent.

The specification does, however, disclose the use of titanium or titanium alloy. '270 patent col.6 ll.4-5. Synthes points out that in his earlier report, Dr. Levenston noted that "the term 'rigid,' as a term in mechanics, means that an object is incapable of undergoing deformation under any circumstances (and is therefore an idealization that never truly exists)." Dkt. Not. 227 Exh. 17 at 16.

Synthes contends that while titanium may be more flexible than an identical plate made of stainless steel, titanium is still substantially rigid for purposes of fixation, especially where the plates are thick as shown in figures 3, 4, and 7 of the '270 patent.

Because material issues of disputed fact remain as to whether the '270 patent disclosure clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed, Synthes' motion dismissing Spinal Kinetics' written description defense with respect to "substantially rigid" is denied.

d. "Plurality of Openings"

Spinal Kinetics' contends that the '270 patent describes only one embodiment with grooves on the periphery of the cover plates for anchoring the fiber system; not an all-encompassing and generic "openings" as recited broadly in claim 29.

Synthes points out that at the *Markman* hearing, Spinal Kinetics' acknowledged that the term "openings" was suitable as a claim construction – so long as such "openings" were restricted in location. *See* Dkt. No. 84 at 6. But the court rejected such a restriction, noting that "there is no limitation in Claim 29 or disclosure in the specification that restricts the manner in which [anchoring of the fiber system] may be accomplished. The specification indicates that 'the anchoring of the fiber system is possible by various means.'" *Id.* (citing '270 patent col.2 ll.4-5). Synthes also contends that Spinal Kinetics' argument improperly seeks to focus attention on whether the specific openings of the accused device are disclosed, and away from the proper inquiry as to whether the applicants were in possession of the concept of "openings" as claimed.

Because material issues of disputed fact remain as to whether the '270 patent disclosure clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed, Synthes' motion dismissing Spinal Kinetics' written description defense with respect to "plurality of openings" is denied.

2. Enablement

The enablement requirement of 35 U.S.C. § 112, first paragraph, requires that the patent application enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" *See, e.g.*, *Invitrogen*, 429 F.3d at 1070 (Fed. Cir. 2005). The

enablement inquiry is treated as a question of law. *Id.* Spinal Kinetics relies heavily on Mr. Smegal's opinion to support its argument that the claims at issue in the '270 patent are not enabled. Mr. Smegal is not one skilled in the art and, therefore, as discussed above, his opinions are not admissible.

Spinal Kinetics' experts Mr. Reo and Dr. Levenston contend that the '270 patent fails to enable a person skilled in the art to make and use the claimed "substantially rigid" bone contacting plate. Dkt. No. 223 at ¶ 24; Dkt. No. 252 at ¶ 22. According to Mr. Reo and Dr. Levenston, spinal implants must undergo fatigue tests for 10 million cycles of combined motion before commencing clinical trials. Dkt. No. 223 at ¶ 28; Dkt. No. 252 at ¶ 26. Mr. Reo and Dr. Levenston claim that '270 patent gives no direction or guidance on how to make or use "substantially rigid" bone contacting plates capable of withstanding fatigue testing and, therefore, a person skilled in the art would be required to undertake undue experimentation to determine the appropriate rigidity for the bone contacting plates. Dkt. No. 223 at ¶ 31; Dkt. No. 252 at ¶ 29.

Mr. Reo was not disclosed as an expert and thus his opinion on enablement cannot be considered. He is limited to testimony as a percipient witness to the development of the M6 product. Even so, claim 29 of the '270 patent does not claim the performance requirements identified by Mr. Reo and Dr. Levenston. As a matter of law, "Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. YieldUp Int'l Corp.*, 349 F.ed 1333, 1338 (Fed. Cir. 2003). Mr. Reo and Dr. Levenston fail to put forth any evidence suggesting that a skilled engineer could not construct a "substantially rigid" plate from titanium. In sum, the term "substantially rigid" satisfies the enablement requirement.

Mr. Reo and Mr. Afzal also claim that the term "plurality of openings" in not enabled by the '270 patent specification. *See* Dkt. No 223 at ¶ 7; Dkt. No. 249 at ¶ 3. Since neither Mr. Reo nor Mr. Afzal was disclosed as an expert, they cannot offer opinions as to what the '270 patent discloses. But even considering the merits, their declarations are insufficient to show a lack of enablement. Spinal Kinetics' position is based on the notion that it apparently took Spinal Kinetics some eight months to "evaluate, in order, various designs of 'peripheral grooves,' 'holes' and 'slots' in cover plates, and determine an acceptable design comprising slots with rounded edges that (a) does not wear or break

fibers during fatigue testing, and (b) allows for winding of fibers using winding machines." Dkt. No. 248 at 10-11. As already explained, the specification need not enable a commercially-finalized design unless specifically claimed. Moreover, Spinal Kinetics seems to miss that § 112 requires that the specification enable the claimed invention, not a specific product. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) (noting that "the law makes clear that the specification need teach only one mode of making and using a claimed composition"(citation omitted)).

Synthes' motion to dismiss Spinal Kinetics' enablement defenses is granted.

3. Indefiniteness

Spinal Kinetics contends that the terms "substantially cylindrical" and "substantially rigid" are indefinite. The Federal Circuit set forth and "exacting standard" for proving indefiniteness:

> [B]ecause claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet "an exacting standard." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). "Only claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." *Id.* at 1250 (quoting *Datamize*, 417 F.3d at 1347). A claim is not indefinite merely because parties disagree concerning its construction. An accused infringer must thus demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art. *Id.* at 1249-50.

Haemonetics Corp. v. Baxter Healthcare Corp., 607 F.3d 776 (2010).

Spinal Kinetics has failed to meet that exacting standard. This court has already explained that terms of degree need not be perfectly defined. *See* Dkt. No. 137 at 4 ("The Federal Circuit has also held that the term 'substantial' is a meaningful modifier implying 'approximate,' rather than 'perfect.'" (citations and quotations omitted)). Considering the function of the claims in light of the specification, the terms "substantially cylindrical" and "substantially rigid" are not insolubly ambiguous. *See Seattle Box. Co. v. Indus. Crating & Packing, Inc.*, 731 F.3d 818, 826 (Fed. Cir. 1984) ("The trial court must decide, that is, whether one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification."). Indeed, the Federal Circuit has repeatedly warned that terms of degree frequently do not warrant a more precise construction. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998) ("Claims are often drafted using terminology that is not a precise or specific as it might be . . . . That does not mean, however,

that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product."). In such cases, it is often more appropriate to pass an imprecise term to the jury in its role as a fact finder. Accordingly, Synthes' motion to dismiss Spinal Kinetics' indefiniteness defense is granted.

4. Best Mode

On February 11, 2011, the court denied Spinal Kinetics' motion for summary judgment on the issue of best mode. Dkt. No. 153. Synthes now argues that because Spinal Kinetics has failed to put forth any additional evidence on the existence of a best mode, the defense should be dismissed.

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). 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).

Although Spinal Kinetics has failed to produce additional evidence regarding the existence of a best mode, the court finds that the February 2002 Thesis submitted by inventors Adrian Burri ("Mr. Burri") and Daniel Baumgartner ("Dr. Baumgartner") raises a question of fact as to whether the inventors had a "best mode" for "bone contacting plate" or "fiber system." Synthes' motion to dismiss Spinal Kinetics' best mode defense is denied.

5. Utility

Spinal Kinetics' lack of utility defense is based on the expert report of Casey K. Lee, M. D. Dkt. No. 251. Specifically, Dr. Lee asserts that the implant disclosed in the '270 patent "has no utility" because the fibers, elastic sheathing body and form-locking arrangement for coupling the cover plates to the closing plates would fail due to wear and tear, and as such, will not work. *Id.* at ¶¶ 10-13. Mr. Smegal makes similar criticisms. Dkt. No. 227 Exh. 18 at 81-82.

35 U.S.C. § 101 provides that "[w]hoever invents or discovers any new and useful process,

machine, manufacture, or composition of matter, or any new and useful improvement thereof," may obtain a patent on the invention or discovery. "The threshold of utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999). Dr. Lee's and Mr. Smegal's criticisms are directed to long-term "wear and tear" failure and, moreover, only address one potential embodiment described in the specification. These criticisms are insufficient to show that the device claimed in the '270 patent is "totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir.1992). Accordingly, the court dismisses Spinal Kinetics' utility defense.

F. Motion for Partial Summary Judgment Dismissing Spinal Kinetics' Anticipation and Obviousness Defenses

1. The Baumgartner/Burri Thesis

The subject matter of the '270 patent originated primarily from the work of two Swiss citizens, Daniel Baumgartner and Adrian Burri. Both were students at the Swiss Federal Institute of Technology in Zurich ("ETH"). The inventors worked jointly on a "Diploma Thesis" ("the Thesis") from the middle of 2001 through February of 2002 under the supervision of Dr. Markus Meier, a professor at ETH. The inventors eventually partnered with the medical device company Mathys Medical AG ("Mathys") and its spin off, the RMS Foundation. In 2001, Dr. Beat Gasser was the head of basic research at the RMS Foundation and provided some support for the Thesis work. Additional support was provided by Mathys directly. Beat Lechmann was the head of the Mathys business unit responsible for spine products. One of the engineers who worked for Mr. Lechmann, Ulrich Reinbold, was an advisor regarding the students' work.

Near the beginning of the Thesis work, Dr. Meier appears to have raised the question of whether the Thesis work would be published or kept confidential. Specifically, Dr. Meier sent an email to Mr. Reinbold and copied Mr. Lechmann and the two students. Dkt. No. 227 Exh. 9 and Exh. 4 at 68-69, 74-75. Mr. Reinbold responded that the work must be kept confidential.

On February 21, 2002, Dr. Baumgartner and Mr. Burri presented their Thesis in a lecture hall at the RMS Foundation. Dr. Gasser prepared and posted an invitation and invited RMS Foundation employees to the February 21, 2002 presentation of the Thesis work. Dkt No. 224-1 at ¶ 8. The

invitation also stated that those who are interested are welcome. *Id.* According to Dr. Gasser, this statement did not mean that the presentation was open to the public, but rather, the named invitees were welcome to invite others who worked for Mathys or RMS Foundation. *Id.* Approximately 10-12, maybe more, people attended. *Id.* at ¶ 9. The presentation was made using PowerPoint slides and lasted approximately half an hour. *Id.* Dr. Baumgartner and Mr. Burri also presented their Thesis on February 25, 2002 in a classroom at ETH. *Id.* at ¶ 10. The only people who attended that presentation were Dr. Meier, the two students, Mr. Lechmann, Mr. Reinbold and Dr. Gasser. *Id.*

As part of their work, the students prepared a written Thesis in their native German. Dkt. No. 227 Exh. 6. There is no evidence that this written Thesis was ever placed in a public library, including the ETH library. Two copies of the Thesis were placed in the RMS Foundation's internal technical library which is not open or accessible to the public. Dkt. No. 224-1 at ¶ 5. After the Thesis was complete, Dr. Baumgartner began working with a Swiss patent firm, Dr. Lusuardi AG, to have several patent applications prepared directed to several inventions conceived during the Thesis work. Dkt. No. 227 Exh. 2. The '270 PCT application was subsequently filed on April 14, 2004.

Both Synthes and Spinal Kinetics move for summary judgment on whether the Baumgartner/Burri Thesis is an anticipating publication under 35 U.S.C. § 102(b). Synthes argues that the Baumgartner/Burri Thesis document and presentations are not printed publications. In contrast, Spinal Kinetics asserts that the Thesis presentations were made openly without any restrictions on confidentiality. Spinal Kinetics also asserts that the written Thesis was freely available from the RMS technical library.

35 U.S.C. § 102(b) provides a bar to patentability if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." "In order to qualify as a printed publication within the meaning of § 102, a reference 'must have been sufficiently accessible to the public interested in the art.'" *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009). "A reference is considered publicly accessible if it was 'disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.'" *Id.* (citations omitted). Whether a thesis or dissertation qualifies as a printed

publication typically turns on whether the written thesis is "indexed, catalogued and shelved" in a library such that it can be found and accessed by the interested public before the relevant point in time. *Id*. at 1311-12. The public display of a slide presentation has been held to constitute a printed publication under certain circumstances. *See In re Klopfenstein*, 380 F.3d 1345 (Fed. Cir. 2004) (holding that 14 slides pasted on a poster board, displayed at two public industry meetings for more than two days and with no restrictions on copying constituted a printed publication). Where no facts are in dispute, the question of whether a reference represents a "printed publication" is a question of law. *In re Cronyn*, 890 F.2d 1158, 1159 (Fed. Cir. 1989).

Whether the Thesis presentations or the written Thesis were printed publications within the meaning of § 102(b) presents a material issue of disputed fact. Whether anyone from outside Mathys or RMS Foundation either attended or was invited to attend the Thesis presentations is not entirely clear. The email exchange between Mathys, Dr. Meier and the students suggest that the inventors had a reasonable expectation that the material would be treated as confidential. Dr. Gasser also makes claims that he and the RMS Foundation shared this understanding. Dkt. No. 224-1 at ¶¶ 4, 7. It is not clear that those with access to the Thesis work considered it to be confidential. It is also not clear whether RMS Foundation employees could have publicly distributed the copies of the Thesis in the RMS Foundation library. In light of the lack of clarity of the evidence and the different inferences that could be drawn from the evidence, the court denies Synthes' Motion to summarily adjudicate the anticipation defense in its favor.

2. Stubstad Patent

Synthes argues that Spinal Kinetics has failed to establish by clear and convincing evidence that the Stubstad et al. patent (U.S. Patent No. 3,867,728) anticipates the asserted claims. Specifically, Synthes contends that Dr. Lee's analysis of the Stubstad '728 patent is inconsistent and fails to identify claim limitations.

Considering the arguments of both parties, it appears that there is a fundamental disagreement as to what the Stubstad '728 patent teaches. The inconsistencies identified by Synthes do not completely discredit Dr. Lee's opinion, but rather, go to the weight that his opinion should be afforded. Where, as here, conflicting expert testimony raises genuine issues of material fact that are

appropriate for consideration by a jury, summary judgment is inappropriate. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1578 (Fed. Cir. 1991) ("To the extent that apparent inconsistencies among the [expert's] three declarations raise questions of credibility and weight . . . they were improperly resolved on summary judgment.").

3. Obviousness

Synthes contends that Dr. Paul Ducheyne's rebuttal report identifies deficiencies in each of Dr. Lee's obviousness combinations. Moreover, Synthes argues that Dr. Lee fails to consider the *Graham* factors while also failing to providing a basis for combining references. But the Supreme Court has held that "[t]he obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). Here, inconsistencies among expert reports raise questions of credibility and weight. Therefore, issues of material fact remain with respect to obviousness.

4. Coppes, Eberlein and Kim Patents

Synthes argues that Coppes et al. (U.S. Patent No. 7,563,284), Eberlein et al. (U.S. Patent No. 6,626,943) and Kim et al. (U.S. Patent No. 7,153,325) do not qualify as prior art because the subject matter of claims 29-31 of the '270 patent was conceived by no later than February 2002, as corroborated by the Baumgartner/Burri Thesis. Indeed, by arguing that claims 29-31 of the '270 patent are anticipated by both the written Thesis and the Thesis presentations, Spinal Kinetics necessarily admits that each limitation of the claims is disclosed therein. By claiming priority to a February, 2002 conception date, Synthes seeks to avoid the Coppes, Eberlein, and Kim patents. Coppes, the earliest of the three references, was filed on August 15, 2002. Therefore, Synthes is required to show diligence from August 15 to April 2003. *Monsanto Co. v. Mycogen Plant Science, Inc.*, 261 F.3d 1356, 1363 (Fed. Cir. 2001). Spinal Kinetics argues that Synthes has failed to show diligence from January to April 2003.

A material issue of fact remains as to whether the inventors can show diligence during the relevant time period. To be sure, Synthes does offer its privilege logs to show diligence. But here, the existence of privileged communications alone is not enough to show diligence. Moreover,

Synthes' reliance on its privilege log while refusing to waive privilege implies that Synthes is attempting to assert privilege as both a sword and shield. Without the substance of the communications, the evidence is insufficient to carry Synthes' burden on summary judgment.

III. ORDER

For the foregoing reasons, the court rules as follows:

1. Grants Spinal Kinetics' motion to dismiss Synthes, Inc. and Synthes USA Sales, LLC for lack of standing;

2. Grants Spinal Kinetics' motion for summary adjudication precluding plaintiffs Synthes, Inc. and Synthes USA Sales, LLC from recovering any damages and precluding plaintiff Synthes USA, LLC from recovering any lost profit damages;

3. Denies Spinal Kinetics' motion for partial summary judgment that each of claims 29-31 of U.S. Patent No. 7,429,270 ("the '270 patent") is not entitled to the effective filing date of the PCT application under 35 U.S.C. § 120;

4. Grants in part and denies in part Synthes' motion for partial summary judgment dismissing invalidity defenses based on 35 U.S.C. § 112 and 35 U.S.C. § 101 as follows:

   a) Denies the motion to dismiss written description and best mode defenses;

   b) Grants the motion to dismiss enablement, indefiniteness, and lack of utility defenses;

5. Denies Synthes' motion for partial summary judgment dismissing anticipation and obviousness defenses;

6. Grants in part and denies in part Synthes' motion to strike or otherwise exclude the testimony of Spinal Kinetics' experts George Strong, Nicholas Koske, and Thomas Smegal on certain issues as follows:

   a) Grants the motion to strike or otherwise exclude the testimony of Thomas Smegal in its entirety;

   b) Denies the motion to strike or otherwise exclude the testimony of George Strong except that he is precluded from basing his opinion as to a reasonable royalty on the availability of the powderized tantalum design alternative;

   c) Grants the motion to exclude opinion testimony from Nicholas Koske and any testimony on the availability of the powderized tantalum design alternative. The motion is otherwise denied;

7. Grants in part and denies in part Synthes' motion to exclude untimely evidence at trial and for all other purposes as follows:

   a) Grants the motion to exclude expert testimony from Mr. Reo and Mr. Afzal;

b) Grants the motion to bar Mr. Koske from testifying about the early stage development (pre-April 2004) of the '270 patent;

c) Denies the motion to exclude the June 29, 2011 declaration of Dr. Levenston.

DATED: 08/19/2011

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge