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UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT TACOMA

COLOPLAST A/S,  
  
Plaintiff,  
  
v.  
  
GENERIC MEDICAL DEVICES, INC.,  
  
Defendant.

CASE NO. C10-227BHS  
  
ORDER DENYING  
DEFENDANT’S MOTION  
FOR SUMMARY JUDGMENT

This matter comes before the Court on Defendant Generic Medical Devices, Inc.’s (“Generic”) motion for summary judgment (Dkt. 105). The Court has considered the pleadings filed in support of and in opposition to the motion and the remainder of the file and hereby denies the motion for the reasons stated herein.

**I. PROCEDURAL HISTORY**

On February 8, 2010, Plaintiff Coloplast A/S (“Coloplast”) filed a complaint for patent infringement against Generic alleging that Generic is infringing United States Patent No. 6,638,211 (the “‘211 Patent”) and United States Patent No. 7,621,864 (the “‘864 Patent”) (collectively “Patents-in-Suit”). *Id.* ¶¶ 9-17. On March 1, 2010, Generic answered and asserted numerous affirmative defenses including invalidity. Dkt. 17.

On July 21, 2011, the Court issued an order construing the disputed claims of the Patents-in-Suit. Dkt. 50.

1 On December 14, 2011, Generic filed a motion for summary judgment of  
2 invalidity. Dkt. 105. On January 3, 2012, Coloplast responded. Dkt. 112. On January 6,  
3 2012, Generic replied. Dkt. 116.

## 4 II. FACTUAL BACKGROUND

5 Both the '211 Patent and the '864 Patent are entitled "Method for Treating Urinary  
6 Incontinence in Women and Implantable Device Intended to Correct Urinary  
7 Incontinence." The patents also contain the same introductory paragraph that reads as  
8 follows:

9 The invention relates to a method for treating urinary incontinence in  
10 women. It also relates to an implantable device intended to correct urinary  
11 incontinence in women. The said device is more particularly suited to the  
12 treatment of stress urinary incontinence.

13 *See, e.g.*, '211 Patent, col. 1, ll. 16-20.

14 Generic asserts that there are two surgical techniques for treating urinary  
15 incontinence by placing a sling under the urethra and through the obturator foramen, the  
16 "outside-in" approach and the "inside-out" approach. Dkt. 112 at 6. In an outside-in  
17 transobturator procedure, external incisions are made in the external skin in the region of  
18 the obturator foramen. Declaration of Aaron Wainscoat ("Wainscoat Decl."), Exh. I,  
19 Expert Report of Daniel Elliot, M.D. ("Elliott Report") at 36. An Emmet needle or trocar  
20 is then led through the external incision of the perineal skin (i.e. from outside the body to  
21 the inside of the body), through the obturator foramen and out through an internal vaginal  
22 incision. *Id.* The end of the sling is then attached to the trocar, or led through the eye of  
23 an Emmet needle, and then pulled back through the vaginal incision, through the muscle  
24 and obturator foramen, and out through the perineal incision. *Id.* These steps are  
25 performed with respect to each of the ends of the sling – i.e. each of the ends of the sling  
26 are retracted by the trocar or Emmet needle through a vaginal incision, along the path  
27 made by the trocar or Emmet needle and out through the incision in the perineal skin.

1 This is known as the “outside-in” transobturator technique, named for the path of the  
2 introducer which begins outside the patient. *Id.*

3 In an “inside-out” transobturator procedure, a vaginal incision is made and the  
4 sling is pre-attached to the end of a trocar that is shaped for use with the “inside-out”  
5 transobturator procedure. Then the trocar with attached sling is inserted into the vaginal  
6 incision and the sling is pushed through the tissue and the obturator foramen and exits  
7 through an external incision in the perineal skin. Elliott Report at 42. This is known as  
8 the “inside-out” technique based upon the path of the trocar which begins in the vaginal  
9 incision inside of the patient, and takes a different route through the body than a needle or  
10 trocar used in an “outside-in” approach.

11 During claim construction, Generic argued that the Court should add language to  
12 the claims of the Patents-in-Suit because it “is necessary to make clear that the Patents-in-  
13 Suit are limited to the ‘outside-in’” procedure. Dkt. 35 at 26. The Court rejected  
14 Generic’s argument and proposed construction. Dkt. 50 at 11-12. The Court concluded  
15 that adding the proposed language would violate the canon of claim construction not to  
16 import limitations from the specific embodiment disclosed in the specification into the  
17 claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005). For example, the  
18 specific embodiment disclosed in the ‘211 Patent describes an “outside-in” procedure  
19 wherein an Emmet needle is inserted from the outside of the body and, once the tape is  
20 placed in the eye of the needle, the needle is “pulled back” through the relevant region of  
21 the body. ‘211 Patent, col. 3, ll. 31–56. Claim 1 of the ‘211 Patent claims a method  
22 comprising the step of “extending each of the free ends of said tape in the region of two  
23 obturator foramen of the iliac wing and leading them out into the groin opposite the  
24 corresponding foramen . . . .” *Id.*, col. 4, ll. 34–37. The Court construed these terms in  
25 their ordinary and customary meanings. Dkt. 50 at 11–12.  
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1 In the instant motion, Generic requests a ruling of law on the same issue, albeit  
2 approached via different requirement for patentability.

### 3 III. DISCUSSION

4 Generic moves for summary judgment that the Patents-in-Suit are invalid because  
5 (1) they do not provide an adequate written description of the claimed invention and (2)  
6 they do not enable one of ordinary skill in the art to practice the claimed invention. Dkt.  
7 105.

#### 8 A. Summary Judgment Standard

9 Summary judgment is proper only if the pleadings, the discovery and disclosure  
10 materials on file, and any affidavits show that there is no genuine issue as to any material  
11 fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c).  
12 The moving party is entitled to judgment as a matter of law when the nonmoving party  
13 fails to make a sufficient showing on an essential element of a claim in the case on which  
14 the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323  
15 (1986). There is no genuine issue of fact for trial where the record, taken as a whole,  
16 could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec.*  
17 *Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (nonmoving party must  
18 present specific, significant probative evidence, not simply “some metaphysical doubt”).  
19 *See also* Fed. R. Civ. P. 56(e). Conversely, a genuine dispute over a material fact exists if  
20 there is sufficient evidence supporting the claimed factual dispute, requiring a judge or  
21 jury to resolve the differing versions of the truth. *Anderson v. Liberty Lobby, Inc.*, 477  
22 U.S. 242, 253 (1986); *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass’n*, 809 F.2d  
23 626, 630 (9th Cir. 1987).  
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25 The determination of the existence of a material fact is often a close question. The  
26 Court must consider the substantive evidentiary burden that the nonmoving party must  
27 meet at trial – e.g., a preponderance of the evidence in most civil cases. *Anderson*, 477  
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1 U.S. at 254; *T.W. Elec. Serv., Inc.*, 809 F.2d at 630. The Court must resolve any factual  
2 issues of controversy in favor of the nonmoving party only when the facts specifically  
3 attested by that party contradict facts specifically attested by the moving party. The  
4 nonmoving party may not merely state that it will discredit the moving party’s evidence at  
5 trial, in the hopes that evidence can be developed at trial to support the claim. *T.W. Elec.*  
6 *Serv., Inc.*, 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory,  
7 nonspecific statements in affidavits are not sufficient, and missing facts will not be  
8 presumed. *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 888-89 (1990).

9 **B. Invalidity Standard**

10 Under § 282 of the Patent Act of 1952, “[a] patent shall be presumed valid” and  
11 “[t]he burden of establishing in-validity of a patent or any claim thereof shall rest on the  
12 party asserting such invalidity.” 35 U.S.C. § 282. The section also “requires an invalidity  
13 defense to be proved by clear and convincing evidence.” *Microsoft Corp. v. i4i Ltd.*  
14 *Partnership*, 131 S. Ct. 2238, 2242 (2011).

15 **C. Written Description**

16 One requirement of a valid patent is that the patent contain an adequate written  
17 description of the invention claimed. Section 112 of Title 35 provides in part as follows:

18 The specification shall contain a written description of the invention . . . in  
19 such full, clear, concise, and exact terms as to enable any person skilled in  
20 the art to which it pertains, or with which it is most nearly connected, to  
21 make and use the [claimed invention] . . . .

22 35 U.S.C. § 112; *see also Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353–54  
23 (Fed. Cir. 2010) (en banc) (“[A] separate requirement to describe one’s invention is basic  
24 to patent law. Every patent must describe an invention. It is part of the quid pro quo of a  
25 patent; one describes an invention, and, if the law’s other requirements are met, one  
26 obtains a patent.”).

1            “[T]he purpose of the written description requirement is to ‘ensure that the scope  
2 of the right to exclude, as set forth in the claims, does not overreach the scope of the  
3 inventor’s contribution to the field of art as described in the patent specification.’” *Id.*  
4 The requirement “serves both to satisfy the inventor’s obligation to disclose the  
5 technologic knowledge upon which the patent is based and to demonstrate that the  
6 patentee was in possession of the invention that is claimed.” *Capon v. Eshhar*, 418 F.3d  
7 1349, 1357 (Fed. Cir. 2005).

8            As stated by the Federal Circuit, “[t]he test for sufficiency of a written description  
9 is whether the disclosure clearly allow[s] persons of ordinary skill in the art to recognize  
10 that [the inventor] invented what is claimed.” *Crown Packaging Technology, Inc. v. Ball*  
11 *Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011) (internal  
12 quotations omitted, alterations in original). The “hallmark of written description is  
13 disclosure,” and a court examining the sufficiency of a written description must make “an  
14 objective inquiry into the four corners of the specification from the perspective of a  
15 person of ordinary skill in the art.” *Ariad*, 598 F.3d at 1351. “The disclosure must  
16 reasonably convey[ ] to those skilled in the art that the inventor had possession of the  
17 claimed subject matter as of the filing date.” *Crown*, 635 F.3d at 1380 (internal  
18 quotations omitted, alteration in original). In other words, “the specification must  
19 describe an invention understandable to that skilled artisan and show that the inventor  
20 actually invented the invention claimed.” *Ariad*, 598 F.3d at 1351.

21            The inquiry into the written description requirement is a question of fact and is  
22 “amenable to summary judgment in cases where no reasonable fact finder could return a  
23 verdict for the non-moving party.” *Boston Scientific Corp. v. Johnson & Johnson*, 647  
24 F.3d 1353, 1361 (Fed. Cir. 2011) (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522  
25 F.3d 1299, 1307 (Fed. Cir. 2008)). To prevail, a challenger to validity must provide clear  
26 and convincing evidence that persons skilled in the art would not recognize in the  
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1 disclosure a description of the claimed invention. *Centocor Ortho Biotech, Inc. v. Abbott*  
2 *Laboratories*, 636 F.3d 1341, 1347 (Fed. Cir. 2011).

3 In this case, Generic argues that the Patents-in-Suit are invalid because the written  
4 descriptions do not disclose the “inside-out” procedure. Generic’s current argument is  
5 similar to the argument it advanced during claim construction and is based on the premise  
6 that the patents only cover the disclosed specific embodiment, the “outside-in” procedure.  
7 The Court again rejects this argument, and, with respect to the current burden, the Court  
8 finds that Generic has not only failed to provide clear and convincing evidence in support  
9 of its position, but also has failed to show that no reasonable juror could find for  
10 Coloplast.

11 Coloplast argues that the claimed inventions relate to the transobturator procedure  
12 itself regardless of whether the tape is pushed (inside-out) or pulled (outside-in) through  
13 the patient’s body. Dkt. 112 at 13-18. The Court finds that the record contains  
14 admissible evidence that a reasonable juror could return a verdict for Coloplast on this  
15 issue. First, the ‘211 Patent discloses a technique that is “contrary to the surgical  
16 techniques employed in the state of the art” wherein the tape was “led up alongside the  
17 bladder to form a U and thus be situated in close proximity to vital organs . . . .” ‘211  
18 Patent, col. 2, ll. 19–22. Instead, in practicing the claimed invention, the tape is “diverted  
19 from the bladder to form a V” such that “no risk of damaging the bladder, the iliac artery  
20 or the small intestine is run.” *Id.* at ll. 23–25. This is accomplished by “extending” and  
21 “leading” the tape from the vaginal incision out into the groin. *Id.* at 13–15. The Court  
22 finds that a reasonable juror could find that “extending” and “leading” encompasses both  
23 pushing (inside-out) or pulling (outside-in) the tape sling.  
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25 Second, Coloplast’s expert has testified that a person of ordinary skill in the art  
26 would understand the claimed invention to encompass both techniques. Specifically, Dr.  
27 Elliot stated that “both the outside-in and inside-out transobturator approaches involve  
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1 ‘extending each of the free ends of the tape’ in the region of the two obturator foramen  
2 and leading them out into the groin opposite the corresponding foramen.” Elliot Report at  
3 50. A genuine dispute over a material fact exists if there is sufficient evidence supporting  
4 the claimed factual dispute, requiring a judge or jury to resolve the differing versions of  
5 the truth. *Anderson*, 477 U.S. at 253. At the very least, Dr. Elliot’s testimony is  
6 sufficient evidence supporting Coloplast’s version of the factual dispute requiring a jury  
7 to resolve the issue.

8 Therefore, the Court denies Generic’s motion for summary judgment because  
9 material questions of fact exist whether the Patents-in-Suit contain an adequate written  
10 description.

#### 11 **D. Enablement**

12 Section 112 of Title 35 also provides that the patent specification must also  
13 describe the “the manner and process of making and using [the claimed invention]” in  
14 adequate terms to “enable any person skilled in the art to which it pertains, or with which  
15 it is most nearly connected, to make and use the [claimed invention] . . . .” 35 U.S.C. §  
16 112. This provision is commonly known as the enablement requirement. “To be  
17 enabling, the specification of a patent must teach those skilled in the art how to make and  
18 use the full scope of the claimed invention without ‘undue experimentation.’” *ALZA*  
19 *Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting  
20 *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)).  
21 “Enablement is not precluded where a ‘reasonable’ amount of routine experimentation is  
22 required to practice a claimed invention, however, such experimentation must not be  
23 ‘undue.’” *Id.* In *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988), the Federal Circuit set  
24 forth the following factors that a court may consider when determining if a disclosure  
25 requires undue experimentation:  
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1 (1) the quantity of experimentation necessary, (2) the amount of direction or  
2 guidance presented, (3) the presence or absence of working examples, (4)  
3 the nature of the invention, (5) the state of the prior art, (6) the relative skill  
of those in the art, (7) the predictability or unpredictability of the art, and  
(8) the breadth of the claims.

4 858 F.2d at 737. A court need not consider all of the *Wands* factors in its analysis, but  
5 rather, a court is only required to consider those factors relevant to the facts of the case.  
6 *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

7 Whether the enablement requirement has been satisfied is a question of law based  
8 upon underlying facts, and is determined as of the patent's effective filing date. *Sitrick v.*  
9 *Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

10 In this case, there is at least a question of fact on the issue of enablement. For  
11 example, Dr. Elliot has asserted that one of ordinary skill could practice the full scope of  
12 the claimed invention, including the “inside-out” procedure, without undue  
13 experimentation. Elliot Report at 37–39 & 60–62.

14 Generic’s arguments to the contrary are based on the premise that the specification  
15 must provide the “inside-out” specific embodiment in order for this procedure to be  
16 encompassed by the claim language. *See* Dkt. 116 at 3-6. This is simply not the law as  
17 there is no requirement that the specification disclose every embodiment of the claimed  
18 invention. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en  
19 banc), *aff’d*, 517 U.S. 370 (1996) (“The written description part of the specification itself  
20 does not delimit the right to exclude. That is the function and purpose of claims.”). With  
21 regard to Generic’s burden on the instant motion, Generic has failed to provide clear and  
22 convincing evidence that one of ordinary skill in the art must engage in undue  
23 experimentation in order to practice the claimed invention by pushing the tape instead of  
24 pulling the tape. Therefore, the Court denies Generic’s motion for summary judgment on  
25 the issue of enablement.  
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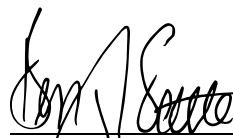
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**IV. ORDER**

Therefore, it is hereby

**ORDERED** that Generic's motion for summary judgment (Dkt. 105) is **DENIED**.

DATED this 6th day of February, 2012.



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BENJAMIN H. SETTLE  
United States District Judge