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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

MEDTRONIC SOFAMOR DANEK USA,
INC., et al.,

Plaintiff and Counterclaim Defendants,

vs.

NUVASIVE, INC.,

Defendant and Counterclaimant

CASE NO. 08 CV 1512 MMA (MDD)

**MEMORANDUM OF DECISION
FOLLOWING BENCH TRIAL ON
INEQUITABLE CONDUCT**

[FED. R. CIV. P. 52(a)(1)]

On December 16, 2011, the Court held a one-day bench trial on NuVasive’s allegations that United States Patent number 5,860,973 (“’973 patent”) is unenforceable due to inequitable conduct. NuVasive argues inventor Dr. Gary Karlin Michelson, and his agents, including Amedeo Ferraro, Lewis Anten, and Thomas Martin, (collectively, “applicants”), engaged in three discrete acts of misconduct during the prosecution of the ‘973 patent before the United States Patent and Trademark Office (“PTO”). First, the applicants allegedly withheld a relevant 1982 article authored by Dr. Henry V. Crock. Second, the applicants allegedly misrepresented the state of the prior art by stating that, “[i]n the past, spinal fusion implants have been inserted only from either an anterior or posterior direction, from the front or back of the patient.” [PX0326, col. 1:21-23.] Third, the applicants purportedly changed the priority date of the ‘973 patent from 1988 to 1995, after prosecution of the patent on the merits had closed.

1 At trial,¹ attorneys Luke Dauchot, Alex MacKinnon, and Nimalka Wickramasekera
2 represented Warsaw, and attorneys Frank Scherkenbach, Todd Miller, and Keeley Vega
3 represented NuVasive. Witnesses were sworn and called to testify; documents and other exhibits
4 were offered and received into evidence; and written closing arguments and proposed findings of
5 fact and conclusions of law were submitted by both parties on December 23, 2010. Having
6 weighed the evidence presented in this case, for the reasons set forth below, the Court concludes
7 NuVasive did not carry its burden to prove the existence of inequitable conduct during the
8 prosecution of the '973 patent.

9 LEGAL STANDARD

10 Patent applicants and their agents owe a duty of candor, good faith, and honesty to the
11 PTO. *Bristol-Myers Squibb Co. v. Phone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1233 (Fed. Cir.
12 2003). If the applicant breaches this duty, his inequitable conduct may render his patent
13 unenforceable. *Warner-Lambert Co. v. Schwarz Pharma, Inc.*, 418 F.3d 1326, 1342 (Fed. Cir.
14 2005). In 2011, the Federal Circuit recognized “the problems created by the expansion and
15 overuse of the inequitable conduct doctrine” and tightened the standard for establishing that a
16 patentee engaged in misconduct before the PTO. *Therasense, Inc. v. Becton, Dickinson & Co.*,
17 649 F.3d 1276, 1285 (Fed. Cir. 2011). In *Therasense*, the Federal Circuit noted that the judge-
18 made inequitable conduct doctrine emerged from a line of infringement cases that “dealt with
19 particularly egregious misconduct, including perjury, the manufacture of false evidence, and
20 suppression of evidence,” but over time it grew to encompass a much broader scope of
21 misconduct. *Id.* at 1287. The appellate court therefore sought to redirect the overused doctrine
22 that has come to “plague[] not only the courts but also the entire patent system.” *Id.* at 1289, 1290.
23 Accordingly, after *Therasense*, “[t]o prove inequitable conduct, the accused infringer must provide
24 evidence that the applicant (1) misrepresented or omitted material information, and (2) did so with
25 specific intent to deceive the PTO.” *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318,
26 1334 (Fed. Cir. 2011) (citing *Therasense*, 649 F.3d at 1287).

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¹ Unless noted otherwise, “trial” refers to the bench trial on December 16, 2011.

1 **I. MATERIALITY**

2 In cases such as this, where the patentee allegedly failed to disclose prior art to the PTO,
3 the party alleging inequitable conduct must establish that the undisclosed reference is “but-for”
4 material. *Therasense*, 649 F.3d at 1291. Stated another way, the court must determine “whether
5 the PTO would have allowed the claim if it had been aware of the undisclosed reference.” *Id.* In
6 making this determination, the court must give claims their broadest reasonable construction. *Id.*
7 A party alleging inequitable conduct need not prove but-for materiality, however, when the
8 patentee engages in affirmative egregious misconduct “such as the filing of an unmistakably false
9 affidavit . . . After all, a patentee is unlikely to go to great lengths to deceive the PTO with a
10 falsehood unless it believes that the falsehood will affect issuance of the patent.” *Id.* at 1292
11 (citations omitted).

12 **II. INTENT**

13 With respect to intent, the “accused infringer must prove that the patentee acted with the
14 specific intent to deceive the PTO.” *Id.* at 1290 (citation omitted). Where, as here, the alleged
15 inequitable conduct involves non-disclosure of information, “clear and convincing evidence must
16 show that the applicant *made a deliberate decision* to withhold a *known* material reference.” *Id.*
17 (emphasis in original) (citation omitted). “While deceptive intent can be inferred from indirect
18 and circumstantial evidence, that inference must not only be based on sufficient evidence and be
19 reasonable in light of that evidence, but it must also be the single most reasonable inference able to
20 be drawn from the evidence to meet the clear and convincing standard.” *Am. Calcar, Inc.*, 651
21 F.3d at 1334 (internal marks omitted) (citing *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*,
22 537 F.3d 1357, 1366 (Fed. Cir. 2008)). *Therasense* also made clear that intent and materiality are
23 separate requirements, and courts can no longer use a “‘sliding scale,’ where a weak showing of
24 intent may be found sufficient based on a strong showing of materiality, or vice versa.” *Am.*
25 *Calcar, Inc.*, 651 F.3d at 1334 (citation omitted).

26 With the aforementioned principles in mind, the Court issues the following findings of fact
27 and conclusions of law with respect to NuVasive’s allegations of inequitable conduct, as required
28 by Federal Rule of Civil Procedure 52(a)(1).

FINDINGS OF FACT

I. '973 PATENT²

1. The 5,860,973 (“973 patent”) issued on January 19, 2009 from U.S. Patent Application No. 741,301 (“301 application”), which was filed on October 30, 1996. [PX0326 at 01-02.]

2. The ‘973 patent teaches “a spinal fusion implant that is inserted from the side of the patient . . . referred to as the translateral approach to the spine.” [PX0326 at col.3:1-3.]

3. The ‘973 patent states that, “all prior implants have been inserted from either the front or the back of the patient.” [PX0326 at col.1:65-66.]

4. Claim 1 of the ‘973 patent recites: “A translateral spinal implant for insertion from the lateral aspect of the spine in the disc space between two adjacent vertebrae, said implant having a length that is greater than one half the transverse width of the vertebrae, said length being substantially greater than the depth of the vertebrae, and a height for contacting each of the two adjacent vertebrae.” [PX0326 at col.11:21-27.]

5. Dr. Michelson appointed Lewis Anten and Amedeo Ferraro to prosecute his application for the ‘973 patent, and transact business with the PTO in connection with the application. [PX0325 at 34.]

6. On July 25, 1997, Lewis Anten submitted an Associate Power of Attorney appointing Thomas H. Martin as his associate attorney to assist in prosecuting the ‘973 patent. [PX0325 at 142-143.]

II. CROCK PUBLICATIONS

7. In 1982, Dr. Crock published an article entitled “Anterior Lumbar Interbody Fusion—Indications for its Use and Notes on Surgical Technique,” which appeared in the peer reviewed journal, *Clinical Orthopaedics and Related Research*, volume 165 at pages 157 through 163 (“Crock Article”). [DX5885; Tr. 9:25-10:10.]

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² The headings used herein are solely for ease of reference and should not be read to limit the Court’s findings of fact and conclusions of law to any particular allegation, argument, or discussion.

1 8. In 1983, Dr. Crock published a book entitled, “Practice of Spinal Surgery,” which
2 contains a section entitled, “Technique of Anterior Lumbar Interbody Fusion” (“Crock Book”).
3 [DX5091.]

4 9. NuVasive alleges the applicants failed to disclose the Crock publications during the
5 prosecution of the ’973 patent, with the specific intent to deceive the PTO.

6 10. The applicants did not provide copies of the 1982 Crock Article or the 1983 Crock
7 Book to the patent examiners in connection with prosecution of the ’973 patent.

8 11. Dr. Crock, however, is mentioned by name in the ’973 patent. In the “Background
9 of the Invention” section, under the heading “Description of the Related Art,” the patent states: “In
10 the past, spinal fusion implants have been inserted only from either an anterior or posterior
11 direction, from the front or the back of the patient. Such implants are well known in the art and
12 may have cylindrical, rectangular and other shapes. In the past, Cloward, Wilterberger, *Crock*,
13 Viche, Bagby, Brantigan, and others have taught various methods involving the drilling of holes
14 across the disc space between two adjacent vertebrae of the spine for the purpose of causing an
15 interbody fusion.” [PX0326 at col.1:21-29 (emphasis added).]

16 12. The applicants cited Dr. Crock’s 1982 article in materials that they incorporated by
17 reference into the application that eventually issued as the ’973 patent.

18 13. James Carmichael testified at trial as an expert in PTO practice and procedure,
19 including the duty of candor and good faith. [Tr. 202:22-206:15.]

20 14. Carmichael provided credible testimony that PTO examiners are supposed to
21 consider applications incorporated by reference and treat them as if fully set forth in the pending
22 application. [Tr. 211:7-14.] The examiner is also supposed to review the incorporated patents for
23 prior art. [Tr. 210:22-211:2.]

24 15. The ’301 application (which issued as the ’973 patent) is a continuation of U.S.
25 Patent Application No. 479,596 (“’596 application”), filed on June 7, 1995. [PX0326 at col.1:4-
26 5.]

27 16. When the ’596 application was originally filed it stated: “This is a continuation in
28 part of co-pending Application Serial No. 08/074,781 entitled THREADED SPINAL IMPLANT

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