

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

BECTON DICKINSON AND COMPANY )  
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 Plaintiff, )  
 )  
 v. ) Civil Action No. 02-1694 GMS  
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 TYCO HEALTHCARE GROUP LP, )  
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 )  
 Defendant. )

**OPINION**

**I. INTRODUCTION**

The court tried the issue of inequitable conduct in a bench trial on October 25, 2004. The court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201(a). Having considered the testimony and documentary evidence, the court makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

**II. FINDINGS OF FACT**

**A. Procedural History**

1. On December 23, 2002, Becton Dickinson and Company (“BD”) filed the above-captioned action against Tyco Healthcare Group LP (“Tyco”), alleging infringement of certain claims of U.S. Patent No. 5,348,544 (the “544 patent”). Tyco asserted the defenses of invalidity for anticipation, failure to satisfy the written description requirement under 35 U.S.C. § 112, and inequitable conduct. The case was tried to a jury, and on October 26,

2004, the jury returned a unanimous verdict finding that Tyco infringed the claims of the ‘544 patent, and that its infringement of the patent was willful. The jury also upheld the validity of the ‘544 patent, and awarded BD lost profits and royalty damages.

2. Following the jury trial, the court held a bench trial regarding Tyco’s inequitable conduct defense.

**B. The ‘544 Patent and Technology at Issue**

3. The invention of the ‘544 patent is a “safety needle shield” to prevent accidental needle sticks to health care workers. A safety needle shield is a device that covers the needle cannula (*i.e.* needle tube) after the needle is used.

4. The asserted claims of the patent-in-suit describe a safety needle device which comprises a needle cannula, a hinged arm with proximal (*e.g.*, situated close to the technician’s body) and distal (*e.g.*, situated away from the technician’s body) segments of such a length so as to prevent the guard from moving beyond the tip of the needle, a slidably movable guard for shielding the needle tip, and a spring that moves the guard along the cannula toward the needle tip.

5. The inequitable conduct issue does not involve any of the asserted claims of the patent. Rather, it involves a “clip” element, which is found in independent claim 17 of the ‘544 patent.<sup>1</sup>

6. Tyco produces and sells the Monoject Magellan™ safety devices, including the Monoject safety needle device and the Monoject safety blood collector (“SBC”) device. The Monoject safety needle device consists of a needle hub, a hinged arm, and a guard, with

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<sup>1</sup> See Section II.D. below, discussing Tyco’s inequitable conduct defense.

living hinges located between the proximal and distal arm segments of the hinged arm, between the hinged arm and the guard, and between the hinged arm and needle hub. The Monoject SBC device also consists of a hinged arm with proximal and distal segments. The Monoject SBC device has living hinges that are located between the proximal and distal arm segments of the hinged arm and between the hinged arm and blood collection barrel.

**C. The Allegedly Withheld Prior Art References**

7. Tyco asserts two prior art references against the '544 patent: the Saf-T-Cath clip; and the MBO Laboratories, Inc. ("MBO") Angel Wing device, which is an embodiment of U.S. Patent No. 5,176,655 (the "'655 patent), assigned to MBO.

8. The Saf-T-Cath is a safety catheter device, which consists of a needle shield and steel clip for shielding the needle tip after use. The Saf-T-Cath is another medical device developed by BD.

9. The MBO device is an embodiment of the '655 patent, which was filed on November 8, 1990 and issued on January 5, 1993. The '655 patent discloses a "disposable medical needle assembly" consisting of a metal needle cannula with a beveled and sharpened tip, a guard device, a clip attached to the guard body, and tethers. (See DTX 54, at Description of Preferred Embodiments.)

**D. Tyco's Inequitable Conduct Defense**

10. As previously mentioned, Tyco's inequitable conduct defense involves a "clip" element, included as a limitation in independent claim 17, which was not asserted by BD in its infringement case.

11. Claim 17 of the '544 patent discloses:

A shieldable needle assembly comprising:

a needle cannula having a proximal end and a sharply pointed distal tip,

a guard having a proximal end, an opposed distal end and a side wall extending therebetween, said guard being slidably movable along said needle cannula from a first position substantially adjacent said proximal end of said needle cannula to a second position where said distal tip of said needle cannula is intermediate said opposed proximal and distal ends of said guard, said guard including a clip retained between said side wall and said needle cannula, said clip being configured to cover said tip when said guard is in said second position on said needle cannula; and

a hinged arm having proximal and distal segments articulated to one another for movement between a first position where said segments are substantially collapsed onto one another and a second position where said segments are extended from one another, said proximal segment of said hinged arm being articulated to a portion of said needle assembly adjacent said proximal end of said needle cannula, said distal segment of said hinged arm being articulated to said guard, said proximal and distal segments of said hinged arm having respective lengths for permitting said guard to move from said first position to said second position on said needle cannula, and for preventing said guard from moving distally beyond said second position.

'544 patent, col. 8, ll. 34-63.

12. Tyco accuses Mr. Richard Caizza ("Caizza"), one of the inventors of the '544 patent, the other inventors, and Mr. John Voellmicke, Esq. ("Voellmicke"), BD's in-house patent attorney, of committing inequitable conduct during the prosecution of the '544 patent. Specifically, Tyco accuses Caizza of intentionally withholding the Saf-T-Cath device from the patent examiner and Voellmicke. Tyco also accuses all of the '544 patent inventors and Voellmicke of intentionally withholding the MBO device from the patent examiner during the prosecution of the '544 patent.

13. During the '544 patent prosecution, the inventors disclosed to the PTO U.S. Patent No. 4,790,828 ("the Dombrowski patent") as prior art. During the infringement proceedings, one of Tyco's contentions was that the Dombrowski patent anticipates claim 1<sup>2</sup> of the '544 patent. In response to Tyco's contention, BD pointed only to the spring means limitation as distinguishing the Dombrowski patent from claim 1 of the '544 patent. Tyco claims that BD's failure to point to any of the common elements of claims 1 and 17 as distinguishing the Dombrowski patent is an effective concession that the Dombrowski patent discloses all of the common elements of claim 1 and 17. As a result, Tyco alleges that the Dombrowski patent discloses every limitation of claim 17 of the '544 patent except the "clip" limitation.

14. Additionally, Tyco alleges that while Caizza took credit for the invention of the clip, he actually copied the clip from an earlier BD product, called the Saf-T-Cath. Tyco alleges that the inventors of the '544 patent, in signing their oath, improperly represented to the PTO that they were the original inventors of each and every element of the invention. Specifically, Tyco points to Caizza's testimony, where he admitted to coming up with the idea of the clip from observing the Saf-T-Cath device. Thus, Tyco claims that Caizza made a false representation to the PTO by claiming to be the original inventor. Tyco further alleges that Caizza concealed this information from Voellmicke, as well as the PTO. Tyco asserts that, even though Caizza knew of the duty of disclosure when signing the inventor's declaration, he failed to disclose the Saf-T-Cath product and its clip.

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<sup>2</sup> Claim 1 of the '544 patent includes all of the elements of claim 17 but the clip element. Claim 1 also includes a spring means element, which is absent from claim 17.

15. Tyco further alleges that the inventors and Voellmicke were aware of the MBO device, which contained a clip similar to that disclosed in the '544 patent. Tyco asserts that the '655 patent, and corresponding embodiment called the Angel Wing, disclose a safety device consisting of a needle, a guard, and a clip that covers the needle after use. Tyco maintains that BD had prototypes of the MBO device for weeks before deciding not to license the technology from MBO. Tyco further asserts that Voellmicke participated in several telephone discussions with Dr. William McCormick ("McCormick"), the founder of MBO, during which they discussed obtaining an overseas patent for the MBO technology and the issuance of the '655 patent. Therefore, Tyco asserts that the inventors and Voellmicke had a duty to disclose the MBO device to the PTO, which they failed to uphold.

16. According to Tyco, one skilled in the art would have had the motivation to combine the Saf-T-Cath or the MBO device with the Dombrowski patent in order to solve the mechanical problems associated with the Dombrowski device. Additionally, Tyco argues that the combination of either the Saf-T-Cath or the MBO device with the Dombrowski patent meets every element of claim 17 of the '544 patent. Thus, Tyco claims, BD's failure to disclose the highly material Saf-T-Cath clip and MBO device constitutes inequitable conduct.

17. In response, BD argues that Tyco's inequitable conduct defense lacks any substance, as Tyco cannot show any proof of intent to deceive. Moreover, BD maintains that Tyco's assertion ignores the actual language of claim 17, which requires that the "clip" element be retained between the sidewall of the guard and the needle cannula. According to BD, the MBO clip is wrapped around the outside of the guard, and the Saf-T-Cath clip is retained

only by the needle and makes no contact with the sidewalls of the device. Furthermore, BD argues that it properly disclosed the far more pertinent and material Dombrowski patent, and that the additional disclosure of the MBO and Saf-T-Cath prior art would have been cumulative at best.

### **III. LEGAL STANDARDS**

18. A determination of inequitable conduct is committed to the discretion of the district court. *Kingsdown Med. Consultants v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (*en banc*), *cert. denied*, 490 U.S. 1067 (1989). As a general matter, patent applicants and their attorneys have a duty of candor, good faith, and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a). The duty of candor and honesty includes the duty to disclose to the PTO material information known to the patent applicants, or their patent attorneys. *Elk Corp. of Dallas v. GAF Bldg. Materials Corp.*, 168 F.3d 28, 30 (Fed. Cir. 1999). The court may find inequitable conduct where there has been a breach of the duty of candor, good faith, and honesty. *Id.* Upon a finding of inequitable conduct, the entire patent is rendered unenforceable. *Kingsdown*, 863 F.2d at 877.

19. To establish unenforceability based on inequitable conduct, the party raising the issue must prove by clear and convincing evidence that (1) the undisclosed prior art or information is material; (2) the knowledge of this information and its materiality is chargeable to the patent applicant; and (3) the applicant's failure to disclose the information resulted from an intent to mislead the PTO. *FMC Corp. v. Manitowoc Co. Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987).

20. Information is considered material if there is a “substantial likelihood that a reasonable examiner would have considered it important in deciding whether to allow the application to issue as a patent.” 37 C.F.R. § 1.56; *Elk Corp.*, 168 F.3d at 31. However, “an otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed.” *Id.* Intent to deceive may be inferred from the circumstances surrounding the applicant’s conduct. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995). “Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for finding a deceptive intent.” *Herbert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996). The Federal Circuit has stated that the alleged “conduct must be sufficient to require a finding of deceitful intent in light of all the circumstances.” *Kingsdown*, 863 F.2d at 873.

21. Proof of inequitable conduct may be rebutted by showing that (1) the undisclosed prior art was not material (e.g., it is merely cumulative or less pertinent than cited prior art); (2) the applicant had no knowledge of the prior art; (3) the applicant was unaware of the prior art’s materiality; or (4) the failure to disclose did not result from an intent to mislead the PTO. *FMC Corp.*, 835 F.2d at 1415.

22. Once materiality and intent have been established, the court must conduct a balancing test to determine whether the balance tips in favor of a conclusion of inequitable conduct. *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997). Generally, the more material the undisclosed information, the less the degree of intent that must be shown to reach a determination of inequitable conduct. *Elk Corp.*, 168 F.3d at 32.



#### IV. CONCLUSIONS OF LAW

##### A. Materiality

23. The court finds that the Saf-T-Cath prior art is cumulative. As previously mentioned, claim 17 of the '544 patent requires that the clip be retained between the sidewall of the guard and the needle cannula. ('544 patent col. 8, ll. 44-48.) During the trial, however, testimony was adduced that the clip of the Saf-T-Cath is not in contact with the sidewall of the needle guard but, rather, is retained by the proximal end of the needle. (D.I. 292, at 1567:10-15.)

24. Furthermore, while it may be true that Caizza took the idea of using a clip from the Saf-T-Cath device, he was the inventor of the claim as a whole, and the Federal Circuit has recognized that all inventions are combinations of known elements, and that it is the claim as a whole, rather than a single element, that is analyzed. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983).

25. Moreover, even assuming that the Saf-T-Cath device contains a metal clip similar to that disclosed in the '544 patent, the Dombrowski patent that was cited to the PTO includes flanges retained between the sidewalls of the guard and the needle. (D.I. 292, at 1521:18-24.) These flanges shield and contain the needle tip ('828 patent, col. 4, ll. 8-11), much in the same way that the clip of the '544 patent protects the needle tip. (D.I. 292, 1547:2-5.) Thus, the court concludes that a reasonable examiner reviewing the Dombrowski patent would have considered the Saf-T-Cath device cumulative. *See Elk Corp.*, 168 F.3d at 31 (“an otherwise material reference need not be disclosed if it is merely cumulative of or less material than other references already disclosed.”)

26. The court also concludes that the MBO device is cumulative and, therefore, not material. Unlike the clip of the ‘544 patent, the clip in the MBO device is external to the guard, attached by two arms that wrap around the guard body. (D.I. 292, at 1498:18-1499:24; 1506:10-20; 1507:8-20, DTX 54, col. 5, ll. 46-53 (describing the guard device of the invention as comprising “a curved leaf spring of steel . . . having an axially extending leg 52, a generally right-angled blocking plate 54, and a pair of clip legs 56”)).

27. Additionally, for the same reasons as discussed in the analysis of the Saf-T-Cath’s materiality above, the court concludes that a reasonable examiner reviewing the disclosed Dombrowski patent would have considered the MBO device cumulative. This is so because the flanges disclosed in the Dombrowski patent serve the same purpose as the MBO clip, but are more similar to the clip disclosed in the ‘544 patent, due to the fact that they are retained between the sidewalls of the guard and the needle.

#### **B. Intent to Deceive**

28. The court further concludes that, even if it assumes the allegedly undisclosed prior art references were material to patentability, the inventors and their attorney did not possess the requisite intent to deceive the PTO regarding the Saf-T-Cath and the MBO references. In order to find deceptive intent, “there must be evidence sufficient to show, clearly and convincingly, the intent to withhold material information in order to deceive or mislead the examiner.” *Jazz Photo Corp. v. United States Int’l Trade Comm’n*, 264 F.3d 1094, 1110 (Fed. Cir. 2001).

29. Here, with respect to the Saf-T-Cath, the evidence adduced during trial, at most, demonstrates the following: Caizza thought of using a clip in the ‘544 patent because he saw

a similar clip on the Saf-T-Cath (D.I. 292, at 1550:11-14); the clip was one of many important parts of the invention, particularly in those embodiments describing the clip (Id. at 1547:9-15); the '544 patent does not disclose the first use of a clip in a medical safety device (Id. at 1548:14-16); and Caizza could not recall whether he disclosed the Saf-T-Cath clip or device to the PTO, or his patent attorney (Id. at 1558:13-1559:14.)

30. The evidence presented by Tyco is a far cry from the high threshold that must be met in order to show intent to deceive. Indeed, on the present record, it is not even clear to the court that the Saf-T-Cath clip was withheld from the PTO, as neither Caizza nor Voellmicke could recall that fact. (See Id. at 1536, at 5-8.; 1558:13-1559:14.) Accordingly, the court concludes that the inventors and prosecuting attorney did not intend to mislead or deceive the PTO with respect to the Saf-T-Cath.

31. The court reaches the same conclusion with respect to the MBO device, because Tyco failed to adduce any evidence of intent to deceive the PTO. In fact, the only witness who testified at trial regarding the MBO device was McCormick, one of the inventors of the device. Tyco wishes the court to infer intent based on the following facts: (1) BD met with MBO in January 1991, prior to the issuance of MBO's patent and received prototypes of the MBO device, which they kept for some period of time before deciding not to license the product (D.I. 291, at 1433:11-16; 1436:19-1437:9); (2) McCormick called Voellmicke to ask for his advice on filing an overseas counterpart to the '655 patent application (Id. at 1446:15-1447:2); and (3) McCormick called Voellmicke to inform him that the '655 patent had issued, and that MBO had acquired the rights to the patent (Id. at 1448:13-1449:15). The court is not convinced, however, that the above facts demonstrate any intent to deceive the

PTO on the part of the inventors or Voellmicke, much less the clear and convincing intent that is required for a finding of unenforceability. To conclude otherwise would require the court to make too many assumptions, including the assumption that the inventors actually saw or were aware of the MBO device. Absent testimony from which it could infer that the inventors knew about the MBO device and failed to disclose it, the court is not willing to reach that conclusion.

**V. CONCLUSION**

31. For the aforementioned reasons, the court concludes that Tyco has not established by clear and convincing evidence that Caizza, BD, or Voellmicke committed inequitable conduct during the prosecution of the '544 patent. Accordingly, the court concludes that the '544 patent remains an enforceable patent.

Dated: September 25, 2006

/s/ Gregory M. Sleet  
UNITED STATES DISTRICT JUDGE

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**ORDER**

For the reasons stated in the court's Opinion of this same date, IT IS HEREBY  
ORDERED that:

1. The clerk shall enter judgment in favor of the plaintiff, Becton Dickinson and Company and against the defendant, Tyco Healthcare Group LP, on Tyco's inequitable conduct defense.

Dated: September 25, 2006

/s/ Gregory M. Sleet \_\_\_\_\_  
UNITED STATES DISTRICT JUDGE