

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

B. Braun Melsungen AG, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 09-347-LPS
	:	
Terumo Medical Corporation, et al.,	:	
	:	
Defendants.	:	

**MEMORANDUM OPINION**

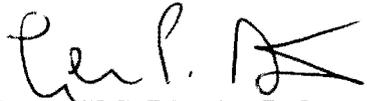
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April 21, 2011  
Wilmington, Delaware



**Stark, U.S. District Judge:**

The Court held a five-day jury trial in this patent infringement action in November 2010. On November 22, 2010, the jury returned a verdict finding infringement of three of six asserted claims of the patent-in-suit, but also finding that only one of the infringed claims (claim 17) was valid.<sup>1</sup> (D.I. 341) Now pending before the Court are both parties' motions for judgment as a matter of law (JMOL) or a new trial (D.I. 367, 368, 371), as well as their competing proposals for permanent injunctive relief and Defendants' alternative request that any such injunction be stayed pending appeal (D.I. 364, 382). For the reasons set forth below, the Court will deny both parties' JMOL motions and motions for a new trial, will enter judgment consistent with the jury verdict, and will enter the permanent injunction proposed by Defendants, effective immediately.

#### **BACKGROUND**

This action was filed by Plaintiffs, B. Braun Melsungen AG & B. Braun Medical Inc. (collectively, "Braun"), against Defendants Terumo Medical Corporation and Terumo Corporation (collectively, "Terumo") on May 13, 2009, alleging infringement of U.S. Patent No. 7,264,613 ("the '613 patent"). (D.I. 1) Specifically, Braun claimed that Terumo infringes one or more claims of the '613 patent through the manufacture, use, sale, offer for sale, and/or importation into the United States of its Surshield® Safety I.V. Catheter ("Surshield"). (*Id.* at ¶¶ 7-11)

Terumo filed an answer and counterclaims on July 9, 2009 (D.I. 13), and Braun answered

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<sup>1</sup>The jury found that Terumo infringed claims 20, 21, and 28 (D.I. 341); before trial, pursuant to the parties' stipulation, the Court had already found that Terumo infringed claims 9, 12, and 17 (D.I. 238; *see also* D.I. 221; Transcript of 11/12/10 Pretrial Conference – Part II (D.I. 351) (hereinafter "Pretrial II Tr.") at 79-81).

the counterclaims on July 29, 2009 (D.I. 19). Later, on December 29, 2009, Terumo amended its answer and counterclaims (D.I. 81), and Braun then responded to the amended counterclaims on January 15, 2010 (D.I. 109). In its amendment, Terumo raised various affirmative defenses and asserted counterclaims seeking declarations of non-infringement, invalidity, unenforceability, and that the case is exceptional. (D.I. 81) With respect to invalidity, Terumo submitted that each of the patent-in-suit's asserted claims is invalid, under 35 U.S.C. §§ 101, 102, 103, and/or 112. (*Id.* at Countercl. ¶ 17) At trial, the grounds Terumo presented for invalidity were obviousness and lack of adequate written description.

On July 8, 2009, now retired Judge Joseph J. Farnan, Jr., to whom this case was previously assigned, held a scheduling conference. (Transcript of 7/8/09 Scheduling Conference (D.I. 16) (hereinafter "Sched. Conf. Tr.")) Judge Farnan placed this case on a "fast track," setting a trial date of July 2010, and bifurcating issues of damages and willful infringement. (*Id.* at 14-16, 21, 23) At this initial scheduling conference, Plaintiffs explained that their primary motivation in filing suit was to obtain permanent injunctive relief. (*Id.* at 14, 19-20) Judge Farnan then advised the parties that if Plaintiffs were to prevail in this action, injunctive relief would almost certainly be granted. (*Id.* at 20; *see also eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006)) Following briefing and a *Markman* hearing on February 9, 2010 (D.I. 126), the Court issued its order construing the claim terms in dispute, adopting all of the proposed constructions offered by Plaintiffs.<sup>2</sup>

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<sup>2</sup>The undersigned judge, who was then a Magistrate Judge, had issued a Report and Recommendation ("R&R") regarding claim construction on June 3, 2010. (D.I. 178) Judge Farnan overruled Defendants' objections to the R&R and adopted the recommendations on July 9, 2010. (D.I. 214)

On August 5, 2010, the Court signed the parties' joint stipulation (D.I. 221) granting Braun summary judgment of infringement on claims 9, 12, and 17 of the '613 patent. (D.I. 238) Pursuant to the stipulated order, Defendants preserved their right to appeal the Court's claim construction order and, if the claim construction order is modified on appeal, Defendants may challenge infringement of claims 9, 12, and 17. (*Id.* ¶¶ 9-10, 12)

The issues of infringement and validity were tried to a jury between November 15 and 19, 2010. (Transcripts of Jury Trial 11/15/10 – 11/19/10 (D.I. 356-360) (hereinafter, collectively, "Trial Tr.")) On November 22, 2010, the jury returned a verdict finding that Terumo infringed claims 20, 21, and 28 under the doctrine of equivalents and that Terumo did not infringe any of claims 1, 2, or 8. (D.I. 341; *see also* Transcript of Jury Verdict 11/22/10 (D.I. 361)) The jury further found that none of claims 1-2, 8-15, 17-21, or 28 of the '613 patent were invalid because of lack of written description. (D.I. 341; *see also* D.I. 361) However, the jury did find that claims 9-15, 18-21, and 28 of the '613 patent were invalid on the ground of obviousness. (D.I. 341; *see also* D.I. 361) The bottom line is that the only infringed claim the jury found to be valid was dependent claim 17. (*See* D.I. 341; D.I. 361)

Pursuant to the schedule imposed by the Court, the parties filed their post-trial motions on January 7, 2011. (D.I. 354) The Court heard oral argument on the motions on February 28, 2011. (*See* Transcript of February 28, 2011 hearing (D.I. 414) (hereinafter ("2/28/11 Tr."))

## LEGAL STANDARDS

### A. Motions for Judgment as a Matter of Law<sup>3</sup>

Judgment as a matter of law is appropriate if “the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party” on an issue. Fed. R. Civ. P. 50(a)(1). “Entry of judgment as a matter of law is a sparingly invoked remedy,” one “granted only if, viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability.” *Marra v. Phila. Housing Auth.*, 497 F.3d 286, 300 (3d Cir. 2007) (internal quotation marks omitted).

To prevail on a motion for judgment as a matter of law, renewed under Fed. R. Civ. P. 50(b), following a jury trial, the moving party ““must show that the jury’s findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury’s verdict cannot in law be supported by those findings.”” *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)); accord *Price v. Delaware Dep’t of Corr.*, 40 F. Supp. 2d 544, 549 (D. Del. 1999).

In assessing the sufficiency of the evidence, the court must give the non-moving party, “as [the] verdict winner, the benefit of all logical inferences that could be drawn from the evidence presented, resolve all conflicts in the evidence in his favor, and, in general, view the record in the light most favorable to him.” *Williamson v. Consol. Rail Corp.*, 926 F.2d 1344,

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<sup>3</sup>At trial, both parties properly made, and renewed, motions for judgment as a matter of law, which were taken under advisement. (See Trial Tr. at 823:21-22, 824:21-23, 1050:6-18, 1064:11-20, 1093:7-8)

1348 (3d Cir. 1991), *reh'g en banc denied*, (3d Cir. Mar. 29, 1991); *see also Perkin-Elmer Corp.*, 732 F.2d at 893. The court may not evaluate the credibility of the witnesses, may not weigh the evidence, and may not substitute its view of the evidence for the jury's view. *See Price*, 40 F. Supp. 2d at 550. Rather, the Court must determine whether the evidence reasonably supports the jury's verdict. *See Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998); *Gomez v. Allegheny Health Servs. Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995) (describing standard as "whether there is evidence upon which a reasonable jury could properly have found its verdict"); 9B Wright & Miller, *Federal Practice & Procedure* § 2524 (3d ed. 2008) ("The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury properly could find a verdict for that party."); *see also Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1065 (Fed. Cir. 1998) ("granting a [JMOL] for the party bearing the burden of proof is reserved for extreme cases," and thus such grant of a JMOL is appropriate "only where: (1) the movant has established [its] case by evidence that the jury would not be at liberty to disbelieve and (2) the only reasonable conclusion is in [the movant's] favor") (internal quotation marks omitted).

## **B. New Trial**

Federal Rule of Civil Procedure 59(a) provides in relevant part: "The court may, on motion, grant a new trial on all or some of the issues – and to any party – as follows: (A) after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court. . . ."

Among the most common reasons for granting a new trial are: (1) the jury's verdict is against the clear weight of the evidence, and a new trial must be granted to prevent a miscarriage

of justice; (2) newly discovered evidence exists that would likely alter the outcome of the trial; (3) improper conduct by an attorney or the court unfairly influenced the verdict; or (4) the jury's verdict was facially inconsistent. *See Zarow-Smith v. New Jersey Transit Rail Operations, Inc.*, 953 F. Supp. 581, 584 (D.N.J. 1997).

The decision to grant or deny a new trial is committed to the sound discretion of the district court. *See Allied Chem. Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36 (1980); *Olefins Trading, Inc. v. Han Yang Chem. Corp.*, 9 F.3d 282, 289 (3d Cir. 1993) (reviewing district court's grant or denial of new trial motion under deferential "abuse of discretion" standard). However, where the ground for a new trial is that the jury's verdict was against the great weight of the evidence, the court should proceed cautiously, because such a ruling would necessarily substitute the court's judgment for that of the jury. *See Klein v. Hollings*, 992 F.2d 1285, 1290 (3d Cir. 1993).

Although the standard for grant of a new trial is less rigorous than the standard for grant of judgment as a matter of law – in that the court need not view the evidence in the light most favorable to the verdict winner – a new trial should only be granted where "a miscarriage of justice would result if the verdict were to stand," the verdict "cries out to be overturned," or where the verdict "shocks [the] conscience." *Williamson*, 926 F.2d at 1352-53; *see also Price*, 40 F. Supp. 2d at 550.

### **C. Permanent Injunction**

"According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *eBay*, 547 U.S. at 391. To secure a permanent injunction, a plaintiff must show: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate

to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.” *Id.* In *eBay*, the Supreme Court overruled the Federal Circuit’s prior “general rule that courts will issue permanent injunctions against patent infringement absent exceptional circumstances.” *Id.* (vacating and remanding *MercExchange, L.L.C. v. eBay, Inc.*, 401 F.3d 1323, 1339 (2005)). Under *eBay*, then, permanent injunctions in patent cases must be based on a case-by-case assessment of the traditional equitable factors governing injunctions. *See* 547 U.S. at 391. “[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that . . . discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards.” *Id.* at 394.

Furthermore, a court has broad discretion to protect a patentee’s right to exclude. “Although injunctions are tools for prospective relief designed to alleviate future harm, by its terms the first *eBay* factor looks, in part, at what has already occurred.” *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010). “Courts awarding permanent injunctions typically do so under circumstances where [the] plaintiff practices its invention and is a direct market competitor.” *Becton Dickinson & Co. v. Tyco Healthcare Group LP*, 2008 WL 4745882, at \*3 (D. Del. Oct. 29, 2008) (internal quotation marks omitted). Moreover, “permanent injunctions are typically granted in two-competitor situations where the patentee has demonstrated an unwillingness to part with the exclusive right.” *Cordance Corp. v. Amazon.com, Inc.*, 730 F. Supp. 2d 333, 341 n.35 (D. Del. 2010).

Even if a court determines that the four factors set forth in *eBay* ultimately tip in favor of

awarding injunctive relief, the timing and sequencing of such relief is still squarely within the court's discretion. Such a flexible approach may include a "sunset" provision. For example, the Federal Circuit quoted with approval a district court's conclusion that certain contemplated "sunset" provisions "balance[] the policy of protecting the patentee's rights against the desirability of avoiding immediate market disruptions." *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008). There, the court remarked: "We agree that the sunset provisions mitigate the harm to the public and that the district court did not abuse its discretion in fashioning a remedy that protects Broadcom's rights while allowing Qualcomm time to develop non-infringing substitutes." *Id.*

Other courts, however, have rejected "sunset" provisions and the creation of a so-called "soft landing" for infringers. *See, e.g., Callaway Golf Co. v. Acushnet Co.*, 585 F. Supp. 2d 600, 622 (D. Del. 2008), *rev'd on other grounds*, 576 F.3d 1331 (Fed. Cir. 2009) ("Defendant asserts that it will be severely harmed 'by requiring it to modify its normal cycle of new product introductions and introduce a new version of the [infringing product] outside of its normal product cycle.' Defendant suggests allowing it to infringe until the first quarter of 2009, when it plans to launch a new version of the [infringing product]. The court is not in the business of making defendants' infringements easier to unravel.") (internal citations and quotation marks omitted).

## DISCUSSION

### A. Terumo's Post-Trial Motions<sup>4</sup>

#### 1. Motions for judgment as a matter of law

##### a. *Obviousness of claim 17*

Terumo first argues that the Court should grant Terumo's motion for judgment as a matter of law that claim 17 would have been obvious,<sup>5</sup> because no reasonable jury could have found claim 17 valid in light of the evidence of record. (D.I. 369 at 10) The Court will deny the motion. Given multiple material factual disputes, the jury could reasonably have concluded that Terumo failed to present clear and convincing evidence of the obviousness of claim 17.

The sole element at issue relates to Claim 17's limitation requiring a crimp located "proximally" of the needle tip. Claim 17, which depends on independent claim 9, provides: "The IV catheter apparatus of claim 9, further comprising a crimp located proximally of the needle

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<sup>4</sup>Terumo's post-trial motions consist of its (i) Renewed Motion for Judgment as a Matter of Law (D.I. 367) and (ii) Motion for a New Trial on the Validity of Claim 17 and/or for Vacatur of the Court's Order Granting Summary Judgment of Infringement of Claim 17 (D.I. 368).

<sup>5</sup>"Obviousness is a question of law based on underlying findings of fact." *In re Kubin*, 561 F.3d 1351, 1355 (Fed. Cir. 2009). A patent is invalid for obviousness "if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The relevant factual inquiries are derived from the Supreme Court's decision in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966), and include: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations of nonobviousness, such as commercial success, long felt but unresolved need, failure of others, acquiescence of others in the industry that the patent is valid, and unexpected results. The party challenging a patent's validity based on obviousness must demonstrate by clear and convincing evidence that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007).

tip.” (PTX 1, ‘613 patent (Claim 17)) Because the jury found claim 9 obvious, the question is whether it would have been obvious to add the limitation of claim 17, i.e., “further comprising a crimp located proximally of the needle tip.” (D.I. 369 at 10; *see* D.I. 341 at 4; PTX 1, ‘631 patent (Claim 17)) The Court agrees with Terumo that “[b]y process of elimination, the only possible basis for the jury’s finding of non-obviousness must read on the word ‘proximally.’” (D.I. 369 at 17)

On this point, there was a genuine factual dispute, and the record contains sufficient evidence from which a jury reasonably could find that the prior art did not disclose a crimp proximal of the needle tip. While Terumo heralds the testimony of its own invalidity expert, Dr. John C. Kulli, that the McLees prior art patent discloses a crimp located proximally of the needle tip (D.I. 369 at 21-22; *see* Trial Tr. (Kulli) at 700:12-701:3; 715:24-716:7), Braun’s validity expert, Dr. Gerald E. Miller, Ph. D., a biomedical engineer, testified that the McLees patent teaches away from putting the crimp proximal of the tip (*see* Trial Tr. (Miller) at 972:9-23). *See generally* *Applera Corp. v. Micromass UK Ltd.*, 204 F. Supp. 2d 724, 755 (D. Del. 2002) (“In considering the prior art in the field of the invention, the fact finder must also consider prior art which teaches away from the invention.”). Terumo generally faults Dr. Miller’s testimony as “artful” and “evasive.” (D.I. 369 at 1)<sup>6</sup> All that need be said about such criticisms, however, is

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<sup>6</sup>In criticizing Dr. Miller’s testimony, Terumo points out, for example, that a significant term in claim 9 was “intersect,” which the Court construed as requiring the intersecting arms to have “one or more points in common from at least one perspective.” (D.I. 369 at 1 n.1) “Despite the Court’s construction, Dr. Miller testified on direct examination that the arms in the prior art ‘241 Kulli patent didn’t intersect because the arms didn’t have at least one or more points in common when viewed from the side” – testimony Terumo contends was “clearly improper and misleading in view of the Court’s claim construction.” (*Id.*; *see* Trial Tr. (Miller) at 872:8-873:19) The Court agrees that such testimony was improper as it was inconsistent with the Court’s claim construction. However, Terumo did not object to the testimony at trial or request

that Terumo had a fair opportunity to cross-examine Dr. Miller, and did so. The Court concludes that while the overall verdict may support Terumo’s belief that the jury largely discredited Dr. Miller’s testimony, its verdict on claim 17 clearly indicates it found him sufficiently credible and persuasive on the obviousness – or non-obviousness – of claim 17. It is not for the Court to make credibility determinations. *See Price*, 40 F. Supp. 2d at 550.

The Court agrees with Braun that the “common thread between all of the claims found to be non-obvious” is that “the combination of the McLees patent and the Kulli patent does not disclose a clip stopping section or a crimp proximal of the needle tip.” (D.I. 388 at 23) “Braun’s position is, and always has been, that the accused product [Terumo’s Surshield] has a crimp located proximally of the needle tip, and that the McLees patent does not disclose a crimp located proximally of the needle tip.” (*Id.* at 6) To Braun, the crimp in McLees is *at* the needle tip, not “proximal” of the needle tip. (*Id.* at 14) (citing, *e.g.*, Trial Tr. at 419:9-423:23 (Woehr); 752:14-21 (Kulli); 892:17-22 (Miller)) The Court concludes that neither Braun nor Dr. Miller unfairly changed its position on this point.

Additionally, “other objective indicia of non-obviousness, such as commercial success of the patented product, a long-felt need for the invention, and the unexpectedness of the results, must also be considered in determining whether the prior art suggests the invention.” *Applera*, 204 F. Supp. 2d at 755. Here, Braun’s Introcan Safety® product (“Introcan”), containing a crimp, is commercially successful, and the Surshield was introduced onto the market only after

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that it be stricken from the record. Nor does the Court believe this testimony was unfairly prejudicial to Terumo, particularly given Terumo’s extensive cross-examination of Dr. Miller. (*See* Trial Tr. (Miller) at 896:3-974:15) Even if Dr. Miller’s improper testimony were stricken, the jury still reasonably could have found that Terumo failed to meet its burden to prove by clear and convincing evidence that claim 17 was invalid due to obviousness.

its designer added a crimp, while earlier safety needles lacking a crimp were not successful. (*See* D.I. 369 at 29; D.I. 388 at 27-28, 30-31; 2/28/11 Tr. at 72-74) All of these factors support the jury's finding of the non-obviousness of claim 17.

Terumo makes much of Braun's "admission" in the body of the '613 patent itself, which says: "the needle in the McLees device includes a larger diameter portion near and at the needle tip." (D.I. 369 at 7-8, 18; PTX 1, '613 patent, col. 2, lines 27-28) This language was highlighted for the jury by both sides during trial. (*See, e.g.*, Trial Tr. at 880:2-891:18) (Braun's direct examination of Dr. Miller regarding differences in McLees and '613 patents and discussing McLees' "flared tip, the enlarged tip"); *id.* at 363:16-366:4 (Terumo's counsel publishing lines 22 through 47 of the '613 patent, which contains the "admission" at issue); *id.* at 419:9-423:19 (Braun's redirect examination of patent inventor Mr. Woehr); PTX 1, '613 patent) The Court presumes, as it must, that the jury made a finding about this language consistent with its verdict. *See Price*, 40 F. Supp. 2d at 550 ("If the record contains the minimum quantum of evidence from which a jury might reasonably afford relief, then the reviewing court must deny the motion. Thus, [w]here there is sufficient conflicting evidence, or insufficient evidence to conclusively establish the movant's case, judgment as a matter of law after the verdict should not be awarded. The reviewing court should not grant judgment as a matter of law merely because its view of the evidence differs with that manifest in the jury's verdict. Such action on the part of the reviewing court would constitute a usurpation of the jury's province as factfinder.") (internal quotation marks and citations omitted).

***b. Obviousness of claims 1, 2 and 8***

Terumo next argues that the Court should grant Terumo's conditional motion for

judgment as a matter of law that claims 1, 2, and 8 would have been obvious. (D.I. 369 at 31) The motion is “conditional” because, as Terumo says, “assuming the jury’s noninfringement verdict stands, the Court need not reach [this] motion;” however, “[i]f, for any reason, the jury’s noninfringement verdict is overturned, Terumo moves for judgment as a matter of law that claims 1, 2, and 8 would have been obvious.” (*Id.*) For the reasons discussed *infra*, the jury’s verdict on non-infringement will not be disturbed. Accordingly, Terumo’s conditional request is moot.

***c. Invalidity of all asserted claims for lack of adequate written description***

Defendants further assert that the Court should determine as a matter of law that all of the asserted claims of the ‘613 patent are invalid for lack of an adequate written description as required by 35 U.S.C. § 112. (*Id.* at 32) “A determination that a patent is invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 is a question of fact, and we review a jury’s determinations of facts relating to compliance with the written description requirement for substantial evidence.” *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010) (internal quotation marks omitted). “Fact findings reviewed under the substantial evidence standard require affirmance unless appellant shows that no reasonable juror could have reached such a result.” *In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1532 (Fed. Cir. 1992). The Court concludes that there is substantial evidence to support the jury’s verdict and will deny the motion. *See Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (“Because the issue of whether the written description requirement has been satisfied is a question of fact, we must determine whether substantial evidence supports the jury’s verdict that the requirement has been met.”).

Essentially, this dispute centers around the term “unitary.” Braun points out that Terumo’s entire written description theory hinges on its assumption that the patent specification defines the term “unitary” to require that the needle guard be formed of a single piece of metal. (D.I. 388 at 41) Indeed, during claim construction, Terumo had argued that the term “unitary” means “made of a single piece of metal;” for purposes of the Court’s claim construction analysis, the Court interpreted “unitary” to mean “made of a single piece of metal.” (D.I. 178 at 29; D.I. 214) This was in the context of construction of the term “needle protector clip.” (D.I. 178 at 29) Terumo advocated that “needle protector clip” be construed as a “unitary needle guard.” The Court rejected Terumo’s position during claim construction, observing that nothing in the language of the asserted claim limits the needle protector clip (or needle guard) to being unitary. (*See id.* at 29-31)

At trial, Braun’s expert, Dr. Miller, opined that one of ordinary skill in the art would find that the inventors had a non-unitary needle guard in their possession, based on the written description. (*See* Trial Tr. at 855:13-17; 858:19-22) In light of this and other evidence, the jury was free to find that Terumo failed to prove by clear and convincing evidence that the asserted claims of the ‘613 patent are invalid for lack of an adequate written description.

Prior to trial, Braun moved for summary judgment on written description, but Terumo opposed, arguing that there were genuine factual disputes, such as “whether or not the ‘613 Patent discloses a multiple-piece needle guard and satisfies the written description requirement.” (D.I. 222 at 20) Terumo was correct, and the Court denied summary judgment. These factual disputes were later resolved against Terumo by the jury. There is substantial evidence in the record to support the jury’s determination.

Terumo points to *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1341 (Fed. Cir. 2010), *cert. denied*, 131 S. Ct. 520 (2010), as a purportedly similar case, and one in which the court used the statutory written description requirement to prevent a patentee from improperly expanding the scope of its claimed invention. *Anascape* states: “A patentee is not deemed to disclaim every variant that it does not mention. However, neither is a patentee presumed to support variants that are not described.” 601 F.3d at 1339. Terumo emphasizes that “the *Anascape* court concluded that ‘the description in the ‘525 specification was not reasonably read as describing a larger invention, of which the single input was only a preferred embodiment.’” (D.I. 369 at 41; *see also Anascape*, 601 F.3d at 1340) Instead, *Anascape* found:

[T]he only reasonable reading of the ‘525 specification is that it is directed to and describes only a controller having a single input member operable in six degrees of freedom. In contrast, the ‘700 specification and claims were enlarged to cover more than single input members operable in six degrees of freedom. The district court erred in ruling that this subject matter is adequately described in the ‘525 specification, for the statutory requirements are not met, on any reading of the ‘525 specification.

601 F.3d at 1340; *see also* 2/28/11 Tr. at 105:15-19 (Terumo stating: “Here, we . . . have some that describe it as unitary and some that are silent. That is exactly the *Anascape* case. In *Anascape*, some of the specification, some of the drawings had it as a single input and some were silent. That was not good enough.”).

As Braun points out, however, the *Anascape* court did not invalidate claims due to the written description requirements. Instead, *Anascape*

involved the question of whether a child (or later-filed) patent could claim priority to the filing date of the parent (or earlier-filed) patent. [*Anascape*, 601 F.3d at 1335]. Because the court found that the disclosure of the parent patent did not provide an adequate written description for the claims of the child patent, it held that those claims were not entitled to the effective filing date of the parent application. But it was a concession that intervening prior art anticipated the asserted claims that rendered those claims invalid, not written description. *Id.* at 1341. Even putting aside the question of priority, the so-called similarities between *Anascape* and this case are distinguishable. In *Anascape*, the later-filed application contained “extensive and substantive” changes from the parent application. *Id.* at 1338. The court relied on this “classical new matter” as an indication that the inventor was not in possession of this subject matter at the time he filed the parent application. *Id.* Here, Terumo can point to no such changes in the ‘613 disclosure over the life of its prosecution.

(D.I. 388 at 47-48) Accordingly, the Court is not persuaded by Terumo’s reliance on *Anascape*. See 601 F.3d at 1341-42 (Gajarsa, J., concurring) (“I write separately to highlight the majority’s best use of the written description requirement as a priority-policing mechanism in contradistinction to an independent basis for invalidity. . . . Here, the majority’s opinion demonstrates a good example in applying the written description in a priority policing context, while leaving invalidity in the capable hands of the enablement doctrine.”) (internal citations omitted).

***d. Non-infringement of claims 20, 21, and 28***

Defendants also argue that the Court should grant judgment as a matter of law that claims 20, 21, and 28 of the ‘613 patent do not infringe under the doctrine of equivalents because the Surshield does not “contain[] each limitation of the claim, either literally or by an equivalent.”

(D.I. 369 at 52) The Court will deny this motion as well.

Independent claim 20 requires “at least one arm attached to and extending distally of the

proximal wall.” (*Id.* at 53) Dr. Miller testified that the bottom arm satisfies the attachment limitation, because it is “indirectly attached to the proximal wall.” (*See, e.g.,* Trial Tr. at 853:16-19) Terumo says that “indirect attachment,” however, is not equivalent to attachment, and, thus, the record does not contain substantial evidence that the bottom arm is “attached” to the proximal wall. (D.I. 369 at 53) For the same reasons, Terumo argues that the verdict of infringement of claims 21 and 28, which depend on claim 20, likewise falls. (*See id.* at 55)

Braun, however, rightfully points out that the parties did not dispute, and the Court did not construe, the term “attached,” let alone limit that term in a way that would preclude indirect attachment, either literally or by equivalents. (D.I. 388 at 53) Moreover, the Court agrees with Braun that one cannot be certain which of the claim limitations the jury found was met only by the doctrine of equivalents, as opposed to literally. (*See id.* at 50)

## **2. Conditional requests for new trial**

### ***a. Validity of claim 17 and/or vacatur of summary judgment of infringement of claim 17***

Terumo argues that in the event the Court does not grant either of Terumo’s invalidity motions with respect to claim 17, it should grant a new trial on the validity of claim 17 and/or vacate its order granting summary judgment of infringement of Claim 17. (*See* D.I. 368) The Court will deny these requests.

“Only if Braun is allowed to use a different meaning of ‘proximally,’ does Terumo ask the Court to vacate its order granting summary judgment of infringement of claim 17 . . . .” (D.I. 397 at 19) The Court does not agree with Terumo that Braun altered its position on “proximal.” As Braun points out, its position is, and always has been, that the Surshield has a crimp located

proximal of the needle tip, and that the McLees patent does not disclose a crimp located proximally of the needle tip. (See D.I. 388 at 6) Braun's expert, Dr. Miller, clearly stated his position regarding the location of the crimp in the Surshield device in his infringement report. (See *id* at 6; D.I. 389, Ex. 3, Miller 4/9/10 Infringement Report (marked as PTX 220, but not admitted into evidence), at 27-29, 55-57 and 83-85) He also clearly stated his position regarding the prior art in his validity report:

[N]o combination of the Kulli 241 patent and the McLees 504 patent and either the so-called McLees Inventive Work, or the Kulli notebook discloses or renders obvious a crimp – by any party's construction – that is proximal of the needle tip.

(D.I. 388 at 6; *see* D.I. 389, Ex. 4, Miller 5/7/10 Rebuttal Expert Report re Validity (marked as PTX 363, but not admitted into evidence), at 93-94) Braun's position at trial was consistent with these opinions. (See, e.g., Trial Tr. at 892:17-22 (“Q. . . . Do either of Kulli or McLees show everything we talked about in claim 9, further comprising a crimp located proximally of the needle tip? A. No. Obviously, Kulli doesn't have that at all. And McLees is at the tip itself.”); *see also id.* at 890:8-13 (“Q. Now, Dr. Miller, do either the Kulli reference or the McLees reference disclose a clip stopping section comprising a second different dimension positioned proximally of the tip? A. No. Kulli doesn't have that at all; and McLees is actually at the tip.”) Nor does the Court find any other reason to allow Terumo to escape from a stipulation into which it knowingly and intelligently entered. Likewise, the Court does not perceive a basis for granting a new trial on the validity of claim 17. *See Becton Dickinson & Co. v. Tyco Healthcare Group LP*, 2006 WL 890995, at \*10 (D. Del. Mar. 31, 2006) (holding that, in order to receive new trial,

defendant needs to demonstrate (i) “reasonably genuine surprise,” that is (ii) “inconsistent with substantial justice,” and which (iii) “resulted in actual prejudice”) (internal quotation marks omitted). As Braun explains, “Terumo had advance notice of Braun’s positions and made no defense at trial that its crimp was not proximal of the needle tip, [and] there is no reason to disturb this stipulated judgment of infringement.” (D.I. 388 at 2)

**b. *Erroneous claim constructions***

Terumo asks for the Court to grant a new trial because of “erroneous claim constructions.” (D.I. 369 at 59) The Court will deny this request. Terumo suggests that “[i]f the Court had adopted the correct constructions, which Terumo proposed during Markman, Terumo would not infringe [claims 9, 12 and 17]. Accordingly, Terumo is entitled to a new trial using the correct claim constructions.” (*Id.*) The Court, however, adheres to its belief that it correctly construed the claims. No new trial is warranted on these grounds.

**B. Braun’s Post-Trial Motions**

**1. Motions for judgment as a matter of law**

**a. *Non-obviousness of claims 9-15, 18-21, and 28***

By its motion, Braun first seeks judgment as a matter of law that claims 9-15, 18-21, and 28 are not obvious, on the grounds that no reasonable jury could have found those claims invalid for obviousness. In support of its contention, Braun argues that Terumo failed to present evidence from the vantage point of a person of ordinary skill in the art. (*See* D.I. 371; D.I. 372 at 6-17) The Court finds, however, that the record contains clear and convincing evidence from which the jury reasonably could have concluded that the challenged claims were obvious.

Terumo’s expert on invalidity, Dr. Kulli, is the inventor on numerous patents in the field

of needle protection devices, including the Kulli '241 patent, on which Terumo's invalidity challenges were largely based. (Trial Tr. at 663:4-8) He is also a medical doctor. (*Id.* at 654:5-15) He routinely uses safety I.V. catheters. (*Id.* at 657:25-658:25) He estimates that he has used an I.V. catheter around 10,000 times. (*Id.* at 658:12-18)

Dr. Kulli testified that the combination of his '241 patent and the McLees patent rendered claims 9-15, 18-21, and 28 obvious to one of ordinary skill in the art. (*Id.* at 687:10-13; 693:7-694:8; 713:8-715:23; 716:8-722:13; 821:21-822:23; *see also id.* at 747:10-13) The jury was free to credit this testimony. By doing so, the jury reasonably could have concluded by clear and convincing evidence that these claims of the patent-in-suit were invalid due to obviousness.

Braun contends that a portion of Dr. Kulli's testimony – that relating to whether the combination of the Kulli and McLees patents discloses intersecting arms, consistent with the Court's construction – was improper because it was not disclosed in Dr. Kulli's expert report. (*See* D.I. 372 at 18-22) The Court disagrees. Dr. Kulli opined in his expert report that every needle guard with two arms meets Braun's definition of "intersect," and Braun's definition is the same definition the Court later adopted. (D.I. 387, Kulli 4/9/10 Expert Report, at ¶ 252) Subsequent to the Court's issuance of its claim construction opinion, Dr. Kulli testified further to this opinion at his deposition. (D.I. 387, Kulli Depo. Tr. 6/16/10 at 215:16-21; *see also id.* at 211:15-16; 212:13-18)

Also, the Court also required Terumo to disclose prior to trial which prior art upon which it was basing its obviousness challenge. (*See* Pretrial II Tr. at 5:6-15, 10:6-24, 41:11-42:7; 90:11-91:1) Terumo did so, and there was no unfair prejudice to Braun. Braun had a full opportunity to cross-examine Dr. Kulli at trial. (*See* Trial Tr. at 722:19-764:17, 799:5-809:14)

Terumo also presented evidence of the interest of others in licensing Dr. Kulli's invention, which was significant evidence of a motivation to combine Kulli and McLees.<sup>7</sup> Dr. Kulli testified that three large companies approached him to license his patent for use in an I.V. catheter. (See D.I. 386 at 17) Specifically, Smith's Medical licensed the Kulli patent for use in its AdvantIV product, which, like the McLees patent, is a passive safety I.V. catheter (and bears the marking of the Kulli patent). (See Trial Tr. (Kulli) at 800:20-801:2; Trial Tr. (Miller) at 933:10-937:9) In 1991, Becton Dickinson licensed the Kulli patent for use "in or as part of an I.V. insertion set or other device for use in placing a catheter." (See D.I. 387, DTX 305; Trial Tr. (Kulli) 694:9-696:1; Trial Tr. (Miller) at 921:24-924:2) Also, in 1996, Sero-Guard Corporation and Act Medical licensed the Kulli patent for use in a safety I.V. catheter needle guard. (See D.I. 387, DTX 558; Trial Tr. (Kulli) at 697:11-698:14; Trial Tr. (Miller) at 924:3-927:13)<sup>8</sup>

Braun complains that "[n]o reasonable juror could have found the prior art combination [of the Kulli and McLees patents] relied upon by Dr. Kulli rendered the claims obvious because the prior art does not disclose all of the limitations of the asserted claims and it expressly teaches away from the proposed combination." (D.I. 372 at 3; *see id.* at 12-16 (citing to various excerpts of Dr. Kulli's testimony, as well as DTX 652 (Kulli patent) [D.I. 373 Ex. 11] and DTX 660 (McLees patent) [D.I. 373 Ex. 9]) The Court disagrees. On these factual questions, the jury was

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<sup>7</sup>To the extent Braun continues to press its objection to admission of the licenses – given Kulli's assertion of privilege during portions of his deposition testimony – the Court again overrules Braun's objection, for the reasons previously given (*see* D.I. 333 at 1-3).

<sup>8</sup>It is also notable that the '613 patent itself addresses the Kulli and McLees references together, in its background discussion of prior art I.V. catheters. (PTX1, '613 patent, at 1:63-2:3) ("Safety catheters that have been developed to achieve this result are disclosed, for example, in . . . McLees U.S. Pat. No. 5,135,504 . . . Kulli U.S. Pat. No. 4,929,241 and Chamuel U.S. Pat. No. 5,053,107 disclose a protective needle guard for use with a hypodermic needle.")

free to rely on Dr. Kulli's testimony. *See generally In re Chapman*, 595 F.3d 1330, 1337 (Fed. Cir. 2010) ("Whether or not a reference teaches away from a claimed invention is a question of fact.").

A final point raised by Braun merits discussion. Braun highlights Terumo's unusual approach to the issue of the identity of one of ordinary skill in the art. (*See* D.I. 372 at 9-10; 2/28/11 Tr. at 127) According to Dr. Kulli, "someone of ordinary skill in the art, someone working in this field routinely should have a couple years of mechanical training or experience . . . and, in addition, should have a couple of years of using these needles in a medical environment, using, sticking these needles into people." (Trial Tr. (Kulli) at 665:20-666:1; *see also id.* at 666:4-12 (describing desirability of experience in a medical environment)) As Braun points out, this definition of one of ordinary skill in the art would exclude everyone who appeared at trial except Dr. Kulli. It would exclude, for instance, the inventors of the '613 patent, the developer of the accused device, Plaintiffs' expert (Dr. Miller), and even Defendants' other expert (Dr. Beaman). (*See* Trial Tr. at 430:9-11; 734:4-735:23; 911:16-912:3; *see also* 2/28/11 Tr. at 88-89) None of these individuals has years of experience inserting I.V. needles into human patients.

Nevertheless, determining the level of ordinary skill in the art was a factual question for the jury. *See Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666-67 (Fed. Cir. 2000) (describing multi-factor test to determine appropriate level of ordinary skill in the art, including considerations such as "1) the types of problems encountered in the art; 2) the prior art solutions to those problems; 3) rapidity with which innovations are made; 4) the sophistication of the technology; and 5) the educational level of active workers in the field"). The Court instructed the jury on this point. (Trial Tr. at 1088:24-1089:10) As Terumo points out: "[The jury] may [have] accepted

Dr. Kulli's definition, they may have accepted Dr. Miller's definition, or they may have come up with their own definition of one of skill in the art being [a person with an] engineering background who consults with healthcare professionals. Under any of those definitions, the verdict that the jury returned was substantially supported." (2/28/11 Tr. at 129:5-11) The Court agrees.

Finally, Braun contends that the Court erred in failing to instruct the jury that it should presume commercial success as a secondary consideration of non-obviousness. Specifically, Braun complains that the jury was not instructed to presume a nexus between the commercial success of Braun's Introcan and the claims of the '613 Patent. (D.I. 372 at 4, 25-26) The Court instructed the jury, in pertinent part, as follows:

#### **5.6 OBJECTIVE CRITERIA CONCERNING OBVIOUSNESS**

In evaluating obviousness, you should take into account any objective evidence (sometimes called "secondary considerations") that may have existed at the time of the claimed invention and afterwards that may shed light on the obviousness or not of the claimed invention.

Secondary considerations of non-obviousness are Braun's rebuttal to Terumo's claim of obviousness. They include:

(1) whether the claimed invention was commercially successful as a result of the merits of the claimed invention (rather than the result of design needs or market-pressure advertising or similar activities). In other words, Braun must demonstrate a nexus between the commercial success and the patentably distinct feature of the invention. In making this determination, you may need to consider whether a commercially successful product is covered by multiple patents;

...

There must be a connection between the evidence showing any of these factors and the claimed invention if this evidence is to be given weight by you in arriving at your conclusion on the obviousness issue. For example, if commercial success is only due to advertising, promotion, salesmanship or the like, or is due to features of the product other than those claimed in the patent-in-suit, then any commercial success may have no relation to the issue of obviousness.

(D.I. 339 at 33-34; *see also* Trial Tr. at 1084:18-1091:18 (entire Sec. 5.6 jury instructions))

On post-trial motions, challenges to jury instructions must be reviewed in the context of the overall instructions, not just a single sentence. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1331 (Fed. Cir. 2010) (“In reviewing jury instructions, the full trial record and the jury instructions in their entirety must be examined because instructions take on meaning from the context of what happened at trial, including how the parties tried the case and their arguments to the jury.”) (internal quotation marks omitted). Applying this standard, the Court concludes that the jury was properly instructed and does not find in its instructions a basis to vacate the jury verdict of obviousness.

***b. Infringement of claims 1, 2, and 8***

Braun further asserts that judgment in its favor on the infringement of claims 1, 2, and 8 is appropriate because no reasonable juror could have concluded otherwise based on the facts and the proper meaning of the claim term “resilient” – a claim term not construed by the Court. (D.I. 372 at 2, 26; D.I. 401 at 25) According to Braun, Terumo’s expert, Dr. Beaman, changed course at trial and improperly relied upon two different definitions of the term “resilient” – one for the bottom arm and a new, different one for the top arm. (D.I. 401 at 25) Braun asserts that, on cross-examination, Dr. Beaman conceded that his opinion that the accused device does not

infringe claims 1, 2, and 8 was based only on his view that the top “arm” of the accused device is not “resilient.” (D.I. 372 at 2, 27; Trial Tr. at 640:1-6)

The Court will deny Braun’s request. The jury was free to accept Dr. Beaman’s testimony that Surshield’s top arm is not “resilient.” This testimony was substantial evidence of non-infringement. (*See* D.I. 372 at 28-29; Trial Tr. at 615:1-3, 642:15-643:11) Quite simply, the jury was free to credit Dr. Beaman’s testimony.

**2. Conditional requests for new trial**

***a. Whether claims 9-15, 18-21, and 28 are invalid for obviousness***

“To preserve its rights to the extent any new trial is granted on other grounds, Braun . . . submits a new trial should be granted on the obviousness of claims 9-15 and 18-19.” (D.I. 372 at 3) Braun further contends that “a new trial” would be warranted “if Terumo is granted a new trial in response to any of its motions.” (*Id.* at 4; *see also* D.I. 371 (“[I]n the alternative, and only to the extent it would not delay entry of an injunction for infringement of claim 17, grant[] Braun a new trial on the issue of whether claims 9-15, 18-21, and 28 of the ‘613 patent are invalid for obviousness.”)) Because the Court is not granting any of Terumo’s requests for a new trial, Braun’s contingent request for a new trial is moot.

***b. Whether claims 1, 2, and 8 are infringed***

Similarly, Braun also states that “if judgment is not entered for Braun on the issue of infringement of claims 1, 2, and 8, and a new trial of any claim is ordered, Braun . . . submits a new trial on infringement of these claims is warranted.” (D.I. 372 at 30; *see* D.I. 371) This conditional request is moot.

### C. **Braun's Motion for Permanent Injunction**

Under the Patent Act, “[t]he several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable.” 35 U.S.C. § 283. The Federal Circuit has stated that “injunctive relief against an adjudged infringer is usually granted.” *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1281 (Fed. Cir. 1988). “While the right to exclude is the essence of the concept of property, district courts are, nevertheless, given broad discretion under 35 U.S.C. § 283 . . . to determine whether the facts of a case warrant the grant of an injunction and to determine the scope of the injunction.” *Joy Techs. Inc. v. Flakt, Inc.*, 6 F.3d 770, 772 (Fed. Cir. 1993); *see also generally Broadcom*, 543 F.3d at 686 (“We agree that the sunset provisions mitigate the harm to the public and that the district court did not abuse its discretion in fashioning a remedy that protects Broadcom’s rights while allowing Qualcomm time to develop non-infringing substitutes.”).

Braun seeks immediate entry of a permanent injunction that would result in the immediate, complete removal of Terumo’s Surshield device from the U.S. market. While Terumo objects to such broad, immediate relief, it does not oppose injunctive relief entirely. Instead, Terumo proposes “the Court should provide for a ‘sunset’ period of fifteen months, allowing Terumo to continue to sell the Surshield in the smaller (30%) alternative care market segment where it is presently sold. This will allow Terumo time to introduce a new, non-infringing safety I.V. catheter product prior to any injunction taking effect in the alternative care market segment. (D.I. 382 at 1) Furthermore, “[a]s part of a court-approved ‘sunset’ provision, Terumo is willing to agree to refrain from selling the Surshield in the acute care market, and also

to refrain from offering the Surshield as part of any GPO contract bids directed to existing Braun GPO contracts up for renewal.” (*Id.* at 2)

After careful consideration of the factors applicable to a request for permanent injunctive relief, the Court has concluded that Terumo’s proposed injunction is appropriate. The Court reaches this conclusion for the following reasons.

***1. Irreparable injury***

While Braun contends that it will suffer from continued irreparable injury if a permanent injunction is not immediately granted on Braun’s proposed terms, most of the claimed harm appears to be reparable, even under Defendants’ proposed terms.

Braun correctly identifies several factors that favor broad injunctive relief. First, Braun has never licensed the ‘613 technology to anyone. (*See* D.I. 365 at 1, 10; Trial Tr. at 268:22-269:1) Second, Braun’s right to exclude, and its reputation as an innovator,<sup>9</sup> are threatened without the protection of injunctive relief.

Other factors, however, favor the more limited relief proposed by Terumo. First, any fair reading of Braun’s opening brief – prepared before Braun knew of Terumo’s proposal for injunctive relief – reveals that the great bulk of irreparable harm Braun fears is from improper competition by Terumo in the acute (hospital) care market, which accounts for 70% of the market in which the companies compete. (*See* D.I. 365 at 12; Trial Tr. at 537:6-25) In particular, Braun

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<sup>9</sup>Braun further contends that without the full injunctive relief it seeks, it will be unable to continue to promote innovation, including by investing in further improvement in the Introcan. (*See* 2/28/11 Tr. at 11-12; D.I. 365 at 15, 18-20; *see, e.g.*, Trial Tr. at 343:4-20; D.I. 366 Ex. 11, C. Trauger Decl., ¶¶ 8-9) Given the limited additional harm that Braun will suffer as a result of the injunctive relief the Court is imposing, however, the Court is not persuaded by this contention.

observed in its opening brief that, without injunctive relief, Terumo's fledgling non-acute limited competition would expand to the acute market, particularly as large, GPO contracts opened up for renewal. (See D.I. 365 at 12; Trial Tr. at 272:6-16) Terumo's proposal directly addresses these legitimate concerns of Braun by agreeing to refrain from competing in the acute market with the infringing Surshield device. (See D.I. 382 at 1-2, 9, 11-13) To date, Terumo's competition with Braun has been limited to the non-acute market, and even here Braun has limited Terumo to approximately a 1% market share. (See D.I. 365 at 5 (citing Trial Tr. at 1009:24-1010:8), 11 ("Surshield, 0.0%" (citing D.I. 366 Ex. 9, PTX-431)); D.I. 382 at 2, 12) There is little reason to believe that additional cabined competition, until June 2012, by a product Terumo will be phasing out, under the auspices of a Court-imposed permanent injunction, will expand to such an extent as to impose substantial, irreparable harm to Braun.

In sum, then, the Court concludes that the more limited injunctive relief proposed by Terumo and ordered by the Court adequately addresses the irreparable harms Braun will suffer going forward.

**2. Remedies available at law are inadequate to compensate for that injury**

Braun has made it clear that will seek additional appropriate remedies, including damages, in the next phase of the case. (See D.I. 372 at 1)<sup>10</sup> This factor has largely been addressed already, in the context of the Court's analysis of the harms that Braun will suffer if it is denied the full injunctive relief it seeks. The Court is simply unpersuaded that the harm Braun has already suffered as a result of Terumo's infringement, combined with the additional limited

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<sup>10</sup>The Court is not asked at this point to determine the amount of damages Terumo will have to pay Braun for its infringing conduct.

harm Terumo will be able to impose through June 2012 under the stringent constraints being imposed by the Court, constitute significant *irreparable* harm.

**3. *Considering balance of hardships, remedy in equity is warranted***

The Court finds that this factor weighs heavily in favor of Terumo's proposed injunctive relief, as opposed to Braun's much more expansive proposal. If the Court were to immediately and entirely exclude Terumo's Surshield from the market, medical professionals who are currently using Terumo's device would be required to stop doing so. In at least some instances, this would result in medical professionals being abruptly deprived of a device for which they have expressed a preference, and have been specifically trained to use. (*See, e.g.*, D.I. 385, Omiecinski Decl., ¶¶ 10-11) Terumo's reputation would also be harmed to a degree disproportionate to the infringement found by the jury. What would appear to many to be an urgent, "recall-like" decree from this Court is simply not warranted under the circumstances presented here. (*See id.* ¶ 14)

Additionally, it must be noted that nearly every aspect of this case has presented what can only fairly be described as close calls. The jury's "split" verdict, in the Court's view, reflects the close nature of this case. This factor, too, cautions against imposing the broad, immediate injunction that Braun seeks, which would clearly impose substantial harm on Terumo.<sup>11</sup>

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<sup>11</sup>Another way of addressing these concerns would be to stay any injunction pending appeal, which Terumo has also proposed. (*See* D.I. 382 at 19-20) Granting such a stay is within the discretion of the Court. *See Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) ("In deciding whether to grant this motion, we must apply the four factors that always guide our discretion to issue a stay pending appeal: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.") (internal quotation marks omitted). However, requiring Braun to wait the

**4. *The public interest would not be disserved by a permanent injunction***

The Court concludes that the public interest likewise favors entry of the more limited injunctive relief proposed by Terumo, as opposed to the injunction sought by Braun. The Court reaches this conclusion largely for the reasons already described, primarily the impact of Braun's requested relief on medical professionals currently using Terumo's Surshield. Again, the Court does not minimize the importance of the competing considerations relied on by Braun – including, especially, the public interest in strong and consistent enforcement of patent rights. *See Callaway*, 585 F. Supp. 2d at 622 (finding insufficient evidence “to counter the strong public policy favoring the enforcement of patent rights recognized by the courts.”) (internal quotation marks omitted). However, in the overall circumstances presented here, particularly the public interest in access to competing alternatives to safe<sup>12</sup> medical devices, *see, e.g., Cordis Corp. v. Boston Scientific Corp.*, 2003 WL 22843072, at \*6 (D. Del. Nov. 21, 2003) (denying preliminary

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additional year or more that appellate proceedings are likely to take would unduly prejudice Braun and be too generous to Terumo (which is, as cannot be overlooked, an adjudged infringer of a valid patent). This is especially so given that Terumo has well understood from the inception of this case that imposition of injunctive relief was almost certain to follow from a verdict for Braun. *See supra*. Nor does the Court find that Terumo has shown a likelihood of success on the merits of any appeal, only that the issues presented are close calls.

<sup>12</sup>The Court was surprised to be invited to make a determination, in the context of post-trial motions, as to whether Braun's Introcan or Terumo's Surshield is the safer, and indeed better, product. (*See, e.g.*, D.I. 382 at 1 (“The Surshield employs a better, safer design than Braun's Introcan, thereby providing medical professionals – particularly those who have been using the design and are trained in using the Surshield – with a more effective safety IV catheter option.”); *id.* at 18 (“The evidence shows that Terumo's new, state of the art Surshield safety IV catheter is a safer product because it has a more technically sophisticated design.”)) Terumo especially emphasized its belief “that based on this record, there is sufficient evidence for [the Court] to find that the Surshield has a safer design than the Intr[o]can.” (2/28/11 Tr. at 42:8-11) It is not necessary for the Court to decide which product is safer (or even if one actually is safer than the other).

injunction in part due to “the obvious concern of depriving the public of the best and safest medical devices by limiting competition”), the public interest favors the more limited injunction proposed by Terumo.

### **CONCLUSION**

For the reasons discussed, the Court will deny Terumo’s Renewed Motion For Judgment As A Matter Of Law (D.I. 367) and Motion For A New Trial On The Validity Of Claim 17 And/Or For Vacatur Of The Court’s Order Granting Summary Judgment Of Infringement Of Claim 17 (D.I. 368), as well as Braun’s Motion For Judgment As A Matter Of Law And/Or A New Trial On Certain Limited Claims And Defenses Presented At Trial (D.I. 371). The Court will direct the Clerk of Court to enter judgment consistent with the jury’s verdict. (D.I. 341) Finally, the Court will grant Braun’s Motion For Permanent Injunction (D.I. 364), but only to the extent of entering an injunction on the terms proposed by Terumo. An appropriate Order will be entered.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

B. Braun Melsungen AG, et al.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 09-347-LPS
	:	
Terumo Medical Corporation, et al.,	:	
	:	
Defendants.	:	

**ORDER**

At Wilmington, this 21st day of April 2011, for the reasons set forth in the Memorandum Opinion issued this date;

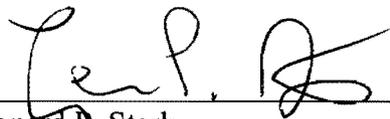
IT IS HEREBY ORDERED that:

1. The Renewed Motion For Judgment As A Matter Of Law filed by Defendants Terumo Medical Corporation and Terumo Corporation (D.I. 367) is **DENIED**.
  
2. The Motion For A New Trial On The Validity Of Claim 17 And/Or For Vacatur Of The Court's Order Granting Summary Judgment Of Infringement Of Claim 17 filed by Defendants Terumo Medical Corporation and Terumo Corporation (D.I. 368) is **DENIED**.
  
3. The Motion For Judgment As A Matter Of Law And/Or A New Trial On Certain Limited Claims And Defenses Presented At Trial filed by Plaintiffs B. Braun Melsungen AG & B. Braun Medical Inc. (D.I. 371) is **DENIED**.
  
4. The Clerk of Court is directed to enter judgment consistent with the verdict (D.I. 341) reached by the jury.

5. The Motion For Permanent Injunction filed by Plaintiffs B. Braun Melsungen AG & B. Braun Medical Inc. (D.I. 364) is **GRANTED**, on the conditions as proposed by Defendants, that is:

Pursuant to 35 U.S.C. § 283, and effective immediately, Terumo Medical Corporation and Terumo Corporation (collectively “Terumo”), are hereby permanently enjoined from infringing U.S. Patent No. 7,264,613 until expiration of that patent, by making, using, selling or offering to sell in the United States the Terumo Surshield® Safety I.V. Catheter (“Surshield”), including any colorable imitation thereof, on the following terms:

- (A) Terumo is hereby enjoined from selling or offering to sell the Surshield (i) into the acute care market; or (ii) from offering the Surshield as part of any bid process for an expiring Braun Group Purchasing Organization contract;
- (B) Terumo will be permitted to continue selling the Surshield into the alternative care market until June 1, 2012; and
- (C) After June 1, 2012, Terumo is hereby enjoined from making, using, selling or offering to sell the Surshield in the United States.

  
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Leonard P. Stark  
UNITED STATES DISTRICT JUDGE