

United States District Court
District of Massachusetts

_____)	
DIOMED, INC.,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No.
)	04-10019-NMG
)	
ANGIODYNAMICS, INC.,)	
)	
Defendant.)	
_____)	CONSOLIDATED
)	
DIOMED, INC.,)	
)	
Plaintiff,)	Civil Action No.
)	04-10444-NMG
v.)	
)	
VASCULAR SOLUTIONS, INC.,)	
)	
Defendant.)	
_____)	

MEMORANDUM & ORDER

GORTON, J.

Pending before the Court in these consolidated patent cases are a motion to exclude expert testimony and several cross-motions for summary judgment.

I. Background

The plaintiff, Diomed, Inc. ("Diomed"), develops laser technology that is designed to treat varicose veins in a minimally invasive manner. It sells a product under the mark EVLT® which apparently relates to U.S. Patent No. 6,398,777

("the '777 patent"), owned by Diomed.

In January, 2004, Diomed filed a complaint alleging that AngioDynamics, Inc. ("AngioDynamics") infringed the '777 patent. The case was assigned at that time to the session of United States District Judge Richard G. Stearns. AngioDynamics is a market competitor of Diomed. It is alleged to have infringed the '777 patent (and/or to have induced or contributed to infringement by others) through its manufacture, use, marketing and sales of its so-called EVLS Procedure Kit, a system for laser treatment of varicose veins.

In its answer to plaintiff's complaint, AngioDynamics denies the allegations of infringement and asserts that the '777 patent is invalid both on its face and as applied to the actions of AngioDynamics. It filed counterclaims seeking declaratory judgments against Diomed and a third party, Endolaser Associates, LLC ("Endolaser"), that the '777 patent has not been infringed and is invalid. According to the counterclaim, Endolaser jointly owns the '777 patent with Diomed. AngioDynamics later amended its affirmative defenses and counterclaims to allege patent misuse, violation of federal antitrust law and violation of Mass. Gen. Laws ch. 93A ("Chapter 93A").

In March, 2004, Diomed filed a separate complaint against Vascular Solutions, Inc. ("VSI") alleging that it had also infringed the '777 patent through its use and marketing of a

product designed to treat varicose veins. VSI sells a laser and associated treatment kit under the name "Vari-lase". In its answer, VSI denies infringement, asserts that the '777 patent is invalid and counterclaims for declarations of invalidity and non-infringement. VSI has amended its answer twice to assert that Diomed's action is barred by inequitable conduct and to seek a declaration that the '777 patent is unenforceable.

In May, 2004, Endolaser filed a motion to dismiss the counterclaims against it on the ground that it has transferred all of its rights in the '777 patent to Diomed. After considering written and oral arguments on behalf of Endolaser and AngioDynamics, Judge Stearns allowed Endolaser's motion to dismiss in an order entered on November 12, 2004.

In February, 2005, the Diomed cases against AngioDynamics and VSI were consolidated.¹ Judge Stearns bifurcated AngioDynamics' counterclaims against Diomed for violations of antitrust law and Chapter 93A and ordered that discovery with respect to those claims would be stayed until the patent infringement and validity claims had been decided. All parties have demanded that their claims be tried to a jury.

A Markman hearing for the purpose of claim construction was

¹ Diomed has also filed claims of patent infringement against defendants Total Vein Solutions, LLC ("TVS") (Civil Action No. 04-10686) and New Star Lasers, Inc. ("New Star") (Civil Action No. 04-12157) but neither proceeding has been consolidated into this case.

held in March, 2005, and Judge Stearns entered a memorandum and order ("M&O") construing the claims soon thereafter. See Diomed, Inc. v. Angiodynamics, Inc., No. Civ.A. 04-CV-10019-RGS, 2005 WL 834875 (D. Mass. April 12, 2005). Diomed has alleged that both defendants infringe independent Claims 9 and 21, and dependent Claims 10-14 and 16-19, of the '777 patent. Id. at *1.

Judge Stearns concluded that the '777 patent comprises a "method" of treating blood vessels through the use of laser energy and that Claim 9 thereof addresses the means of inserting, positioning and emitting laser energy into a blood vessel. Id. at *1-2.

Construing the insertion and placement steps of Claim 9, Judge Stearns found that the fiber optic line used to emit laser energy required an uncoated tip and that positioning the laser necessarily required

deliberately putting the uncoated tip of the fiber optic line in physical contact with the wall of the blood vessel, which requires the drainage of blood and compression of the vein.

Id. at *5-6. Construing the third step whereby laser energy is emitted, the court declared that the fiber optic tip was to be maintained in physical contact with the interior surface of the blood vessel wall while laser energy was emitted in order to decrease the diameter of the blood vessel. Id. at *7.

The parties also sought construction of the term "emptying"

as it was used in dependent Claim 10: "[t]he method of claim 9, further comprising emptying the blood vessel prior to emitting said laser energy". Judge Stearns interpreted "emptying" to mean "the process of emptying most, but not necessarily all of the blood from the blood vessel". Id. at *8. Although the parties sought construction of additional terms, Judge Stearns concluded that the remaining disputes did not require resolution by the court because the terms were not ambiguous or material. Id. at *1 n.2.

Discovery in the consolidated cases continued during 2005 and the parties filed motions for summary judgment. Oppositions and replies to those motions were filed in January and February, 2006, and oral argument was scheduled for June 1, 2006. In May, however, Judge Stearns discovered that he was being treated by a physician who had been asked to serve as an expert witness of Diomed. After seeking and considering the parties' positions concerning recusal or disqualification, Judge Stearns entered an order recusing himself from the case on June 26, 2006. Shortly thereafter, the matter was assigned to this session.

Now pending for consideration by this Court are 1) a joint motion of defendants AngioDynamics and VSI to exclude expert evidence upon which plaintiff is expected to rely, 2) Diomed's motion for summary judgment with respect to patent validity and enforceability, 3) Diomed's motion for summary judgment on the issue of patent infringement, 4) VSI's motion for summary

judgment on infringement and 5) AngioDynamics' motion for summary judgment on infringement. After first considering the evidentiary motion, the Court will address the cross-motions for summary judgment by order of topic, beginning with the issues of patent validity and enforceability and concluding with the issue of infringement.

II. Defendants' Motion to Exclude Evidence

Defendants VSI and AngioDynamics move this Court to bar Diomed from presenting any evidence, testimony, analyses or opinions of two purported experts, Philip Green ("Mr. Green") and Dr. Luis Navarro ("Dr. Navarro"), on the grounds that certain expert opinions of those witnesses were not timely disclosed. Mr. Green is expected to provide expert testimony relating to damages whereas Dr. Navarro, one of the inventors of the '777 patent, is expected to testify both as a fact witness and as an expert witness.

Rule 26(a)(2) of the Federal Rules of Civil Procedure obligates parties to disclose the identities of potential expert witnesses in accordance with any court-imposed scheduling order. Moreover, where those witnesses are either employees whose duties include the regular provision of expert testimony or non-employees who are "retained or specially employed to provide expert testimony", the party using such a witness is to provide a written report containing, inter alia, "a complete statement

of all opinions to be expressed and the basis and reasons therefor".

In this case, the parties were directed to provide all expert reports by June 22, 2005, and to serve or notice all discovery requests by October 15, 2005. Mr. Green was timely identified as an expert witness on the issue of damages and his expert report was produced on June 22, 2005. That report was supplemented, however, in December, 2005, and defendants now seek to exclude the opinions presented therein. Dr. Navarro was identified as a potential expert witness but no expert report was produced with respect to his expected testimony. Defendants now seek to exclude from evidence certain opinions that Dr. Navarro reached on the basis of experiments he conducted after the deadline for filing expert reports.

Diomed opposes defendants' joint motion. It contends that precluding Mr. Green's evidence is unwarranted because defendants had sufficient foreknowledge of the analysis contained in his supplemental report and the delay in producing that supplement was caused by defendants' conduct.

With respect to Dr. Navarro, Diomed asserts that it had (and continues to have) no obligation to provide an expert report because Dr. Navarro is neither an employee of Diomed nor was he retained for the purpose of providing expert testimony. A license agreement between Diomed and Endolaser (a company of which Dr. Navarro is a principal and which assigned to Diomed

all its rights and interest in the '777 patent) provides that Dr. Navarro is to be paid \$3,500 per day for services performed in connection with any action to enforce the '777 patent. Regardless of whether an expert report is required for Dr. Navarro, Diomed contends that defendants have had adequate knowledge of his opinions thereby negating any argument that they have suffered prejudice.

Unless a party's failure to disclose information required by Rule 26(a) is "substantially justified or harmless", the noncompliant party is forbidden from using such information as evidence at trial or in support of a motion for summary judgment. Poulis-Minott v. Smith, 388 F.3d 354, 358 (1st Cir. 2004) (quoting Lohnes v. Level 3 Commc'ns, Inc., 272 F.3d 49, 60 (1st Cir. 2001)). See also Fed. Rule Civ. P. 37(c)(1).

In ruling upon a motion to exclude expert testimony, the trial court must bear in mind the intent of the disclosure rules "to facilitate a fair contest with the basic issues and facts disclosed to the fullest practical extent". Poulis-Minott, 388 F.3d at 358 (quoting Lohnes, 272 F.3d at 60) (internal quotation marks omitted). Appellate court review of such rulings concentrates upon factors such as the

history of the litigation, the proponent's need for the challenged evidence, the justification (if any) for the late disclosure, and the opponent's ability to overcome its adverse effects.

Macaulay v. Anas, 321 F.3d 45, 51 (1st Cir. 2003) (citations

omitted). Surprise and prejudice are also factors to be considered as is the effect of late disclosure upon the trial court's docket. Id. (citations omitted).

In Mr. Green's initial expert report, he apparently focused upon a "reasonable royalty" theory of damages. His supplemental report, however, contains an additional theory based upon lost profits. Defendants contend that they were unaware of plaintiff's intent to rely upon a lost-profits theory until Mr. Green made reference to it at his deposition in September, 2005. Diomed responds that the omission of a lost-profits analysis in Mr. Green's initial report resulted from defendants' failure to provide full disclosure of customer information. Furthermore, plaintiff suggests that any prejudice suffered by defendants is not so significant as to warrant exclusion of the expert opinion.

At this stage of the litigation (with no trial date having been set), the Court finds Diomed's position more persuasive than defendants'. It appears that the present dispute may have resulted from a misunderstanding with respect to discovery requests made by Diomed. While Diomed contends that it persisted in requesting information pertinent to its lost-profits theory, defendants maintain that the discovery requests lacked sufficient specificity to encompass customer-specific information upon which plaintiff's lost-profits theory depends.

In any event, despite Diomed's failure to comply with the

letter of Rule 26(a), defendants have not shown sufficient prejudice to merit wholesale exclusion of Mr. Green's opinion on lost profits. Defendants were alerted to plaintiff's potential reliance upon a lost-profits theory when they received Mr. Green's initial report in June, 2005, and were again apprised of that theory at Mr. Green's deposition in September, 2005. The supplemental report was produced in December, 2005, and the issue of damages is not pertinent to the pending motions for summary judgment.

Nevertheless, because of Diomed's failure to comply fully with its discovery obligations, Diomed will make Mr. Green available for a short supplemental deposition, solely on the issue of the lost-profits theory, with all costs (except defendants' legal fees) to be borne by Diomed. Defendants will then be given leave to identify a rebuttal expert, if desired, and to produce a rebuttal report.

Defendants also contend that Diomed should be foreclosed from presenting evidence relating to experiments that Dr. Navarro conducted after the June 22, 2005, deadline for expert reports. Although Dr. Navarro was identified as a potential expert witness, Diomed produced no expert report concerning his opinion (either before or after the deadline) on the ground that it had no obligation to do so.

Defendants dispute the proposition that Dr. Navarro is not subject to the full spectrum of expert disclosure rules because

1) fact witnesses are subject to such rules where their testimony is a product of specialized knowledge and exceeds purely percipient observations and 2) opinions derived from Dr. Navarro's experiments fall squarely within the expert disclosure requirements because they were performed for the purpose of supporting plaintiff's case. Although some of the experiments were conducted in connection with a presentation that Dr. Navarro was to make at a medical conference, defendants assert that those experiments were also designed to benefit plaintiff's litigation.

Finally, defendants contend that, even if Diomed mistakenly believed that Dr. Navarro's opinions were not subject to the expert disclosure rules, it is fair that the consequences of that mistake be borne by Diomed rather than defendants. They assert that allowing plaintiff to rely on those opinions prejudices them because of the additional time, effort and costs they must now expend to rebut such evidence.

Diomed maintains that 1) Dr. Navarro need not prepare an expert report because he was not retained for the purpose of providing an expert opinion and 2) in any event, excluding Dr. Navarro's opinion is unwarranted because defendants have suffered no prejudice. Diomed contends that defendants were fully aware of Dr. Navarro's experiments and that they deposed him at least once since Diomed expressed its intention to rely upon those experiments. Plaintiff suggests that defendants'

knowledge about the content of and bases for Dr. Navarro's opinion qualifies as a sufficient substitute for an expert report.

Whether Dr. Navarro was "retained" as an expert witness by Diomed is debatable. Diomed is compensating him pursuant to a license agreement that was apparently made when Endolaser assigned its interest in the '777 patent to Diomed. While the terms of Dr. Navarro's services under that agreement do not, in themselves, establish him as a retained expert, there is a sustainable argument that Dr. Navarro qualifies as a retained expert under the circumstances of this case.

Balancing the reasonableness of Diomed's proposition that Dr. Navarro need not provide an expert report against its contention that defendants have suffered no prejudice in the absence of such a report, the Court will deny defendants' motion to exclude expert opinions of Dr. Navarro but will require Diomed to produce an expert report concerning those opinions that complies with Fed. R. Civ. P. 26(a)(2). Furthermore, Diomed will henceforth treat Dr. Navarro as an expert witness subject to Rule 26(a)(2).

III. Plaintiff's Motion for Summary Judgment with Respect to Patent Validity and Enforceability

In their respective answers, defendants AngioDynamics and VSI seek declarations, and assert affirmative defenses, that the '777 patent is invalid and unenforceable. Plaintiff now moves

for summary judgment with respect to both issues.

To be protected under the patent laws, an invention must be novel, useful and not obvious. See Graham v. John Deere Co., 383 U.S. 1, 3, 12 (1966). The validity of existing patents is presumed, 35 U.S.C. § 282, and can be overcome only by clear and convincing evidence. Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1372 (Fed. Cir. 2005) (citation omitted). Because a judge tasked with ruling upon a motion for summary judgment "must view the evidence presented through the prism of the substantive evidentiary burden", Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986), a patentee is entitled to summary judgment with respect to the patent's validity where a reasonable jury could not find clear and convincing evidence of the patent's invalidity.

A. Validity

Defendants allege in their counterclaims that the '777 patent is invalid because it 1) was anticipated or rendered obvious by prior art, 35 U.S.C. §§ 102-03, and 2) was not sufficiently described in the patent application, id., § 112.²

Defendants' current position with respect to § 112, which

² Of the two defendants, only AngioDynamics filed a memorandum of law opposing plaintiff's motion for summary judgment with respect to patent validity and enforceability. VSI joins and relies upon its co-defendant's memorandum in all respects, however. Thus, with respect to the issues of validity and enforceability, the Court ascribes all assertions of AngioDynamics to both defendants.

pertains to the written specification of patents, is unclear. In their opposition to Diomed's motion for summary judgment on the issue of patent validity, defendants declare their intent to withdraw their § 112 counterclaim. In their memoranda relating to the issue of patent infringement, however, defendants press the § 112 counterclaim/defense, contending that ambiguity of claim construction persists despite the Markman ruling and that, if the elements of compression and drainage are interpreted as Diomed contends, the '777 patent is subject to challenge under § 112.

Thus, the Court declines to address the § 112 issue with respect to validity because defendants have withdrawn their § 112 counterclaim in that regard. On the other hand, the Court will assess the merits of the § 112 counterclaim/defense when it attends to the matter of infringement because defendants rely upon that statute in support of their arguments of non-infringement.

1. Anticipation - Legal Principles

In accordance with the prerequisite of novelty, an invention may not be patented where it was anticipated and is, consequently, not new. See 35 U.S.C. § 102. Whether anticipation renders an invention unpatentable is a question of fact, Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1315 (Fed. Cir. 2002) (citation omitted), but the burden of proof by

clear and convincing evidence continues to be borne by the challenger. Id.

As a general matter, the patentability of an invention is subject to an anticipation challenge where the invention was, prior to the patent application date, 1) known by others, 2) used by others or the public, 3) already patented, 4) sold, 5) described in a printed publication, 6) abandoned or 7) invented by someone other than the applicant. 35 U.S.C. § 102.

Anticipation of an invention by prior art will not invalidate a patent unless the prior art reference "disclose[s] all the elements of the claimed invention or their equivalents functioning in essentially the same way". Carter-Wallace, Inc. v. Gillette Co., 675 F.2d 10, 15 (1st Cir. 1982) (quoting Shanklin Corp. v. Springfield Photo Mount Co., 521 F.2d 609, 616 (1st Cir. 1975)) (internal quotation marks omitted). Thus, "each and every limitation [must be] found either expressly or inherently in a single prior art reference". Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339 (Fed. Cir. 2003) (quoting Celeritas Techs. Inc. v. Rockwell Int'l Corp., 150 F.3d 1354, 1360 (Fed. Cir. 1998)). An element is "inherent" if it is "necessarily present". SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005) (citations omitted). See also Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1269 (Fed. Cir. 1991) ("Inherency ... may not be established by probabilities or possibilities"). In addition, an anticipatory

prior art reference must "enable one of skill in the art to make and use the claimed invention". Id. (quoting Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1374 (Fed. Cir. 2001)).

To determine whether an invention was anticipated by prior art, the court must first ascertain the scope and content of applicable prior art. Next, each element of the pertinent claim must be compared against the prior art reference. See Schumer, 308 F.3d at 1315 (stating that proof of anticipation generally requires "testimony from one skilled in the art" which "explains in detail how each claim is disclosed in the prior art reference") (citations omitted). Consideration of extrinsic evidence is permitted to support a contention that an element of the claimed invention was inherently taught by a prior art reference. See In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999); Biogen, Inc. v. Amgen, Inc., 973 F. Supp. 39, 42 (D. Mass. 1997) ("Extrinsic evidence may be considered to explain, but not to expand on, the meaning of an anticipatory reference.") (quoting Ciba-Geigy Corp. v. Alza Corp., 864 F. Supp. 429, 436 (D.N.J. 1994)).

2. Obviousness - Legal Principles

Where a patent has not been anticipated by a single prior art reference, it may be deemed invalid, nevertheless, if

the differences between the subject matter sought to be patented and the prior art [viewed in total] 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). Cf. Velandier v. Garner, 348 F.3d 1359, 1362-63 (Fed Cir. 2003) (reasoning that, "[b]ecause [the defendant] did not identify a single reference that anticipated all of the limitations of any of the claims at issue", he was understood to have brought a challenge based on obviousness).

Although the validity of a patent is ultimately a question of law, the determination of "non-obviousness" requires a case-by-case, factual assessment. Graham, 383 U.S. at 17-18. In considering whether a patent is obvious owing to the state of the art at the time of the alleged invention,

the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. ... Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Id. (citation omitted). See also Omegaflex, Inc. v. Parker Hannifin Corp., 425 F. Supp. 2d 171, 180-81 & nn. 16-19 (D. Mass. 2006) (elaborating on the factors listed above).

Where prior art manifests all elements of a challenged invention, the court must also consider:

- (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and
- (2) whether the prior art would also have revealed that in

so making or carrying out, those of ordinary skill would have a reasonable expectation of success.

Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1164 (Fed. Cir. 2006) (quoting Velander v. Garner, 348 F.3d 1359, 1363 (Fed. Cir. 2003)). Those two additional factors have been designated as the requirement of "motivation", that is, that "some teaching or suggestion within the prior art" provided motivation to combine those elements as did the claimed inventor. Crown Operations Int'l, Ltd. v. Solutia Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002) (citations omitted). Notably, the "motivation to combine need not be found [exclusively] in prior art references, but equally can be found in the knowledge generally available to one of ordinary skill in the art". Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293, 1322 (Fed. Cir. 2005) (quoted cases and internal quotation marks omitted).

3. Analysis

Defendants contend that the '777 patent is invalid because it was anticipated or rendered obvious by means of the following prior art references: 1) an article and video presentation by Dr. Brunello Puglisi ("Puglisi"), 2) an article by Dr. Gerald O'Reilly ("O'Reilly") and others, 3) inventions by Brian Farley ("Farley") and others which were patented under U.S. Patent Nos. 6,638,273 and 6,033,398, 4) an article and video presentation by

A. Mazza ("Mazza") and/or 5) an article by Ken Biegeleisen ("Biegeleisen").

As construed by Judge Stearns, Claim 9 of the '777 patent involves 1) inserting a fiber optic line with an uncoated tip into a blood vessel, 2) deliberately placing that tip against the blood vessel wall and 3) maintaining physical contact between the tip and the vessel wall as laser energy is emitted thereby decreasing the diameter of the blood vessel.

Dependent upon Claim 9 are claims comprising, inter alia, 1) the emptying of most, but not necessarily all, of the blood within the vessel prior to laser emission (Claim 10), 2) use of a fiber optic line that is approximately 200 microns to 600 microns in diameter (Claims 12 and 13), 3) the manual application of external compression prior to laser emission to ensure contact between the tip of the fiber optic line and the blood vessel wall (Claim 17) and 4) emission by bursts of laser energy in an approximate range of 500 nanometers to 1100 nanometers (Claims 18 and 19).

For Diomed to prevail on its motion for summary judgment, it must show that the elements of Claim 9, as further delineated by the claim construction and dependent claims, 1) were not contained in a single prior art reference thereby anticipating the '777 patent and 2) were not rendered obvious by the existence of one or more prior art references. The Court will discuss the prior art references seriatim in order to determine,

first, whether any particular reference anticipated the '777 patent and then, whether the prior art, as a whole, rendered plaintiff's invention obvious.

a. Puglisi Article and Video

As an initial matter, Diomed contends that a five-minute video of Puglisi performing surgery does not constitute "prior art" because it is not a "printed publication". See 35 U.S.C. § 102. Defendants challenge that characterization by focusing on the term "publication". They assert that a video may qualify as prior art where it was sufficiently disseminated to the public.

The Court is unpersuaded by defendants' proposition. The definition of "printed" cannot be stretched to include a presentation which does not include a paper component or, at minimum, a substitute for paper such as the static presentation of slides. Cf. In re Klopfenstein, 380 F.3d 1345 (Fed. Cir. 2004). In the Klopfenstein case, upon which all parties rely, the circuit court held that a printed slide presentation that was pasted onto poster boards and displayed at a conference for two and a half days constituted a printed publication. The court contrasted that reference with purely oral presentations that included neither slides nor paper copies of the presentation. Id. at 1349 n.4.

In this case, defendants liken the Puglisi video to the

presentation in the Klopfenstein case by reason of the video's dissemination to a large number of people over several years. That fact alone, however, does not cure the absence of any "print" component to the video, an element that was met by the print-out of slides described in the Klopfenstein case. Consequently, the video is not a "printed publication" under 35 U.S.C. § 102.

Nor do defendants demonstrate, or even argue, that the Puglisi video anticipated the '777 patent by establishing a state of knowledge or use by others in the United States. See Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1369 (Fed. Cir. 2000); 35 U.S.C. § 102(a). Defendants offer evidence that Puglisi showed his video at conferences in Austria, Belgium, France and Italy, and that he made oral presentations in accompaniment therewith, speaking in French or Italian. The inventors of the '777 patent were apparently unaware of the video and of Puglisi's work. In view of those facts, defendants cannot demonstrate "clear and convincing" proof that the information presented in the video was "known or used by others in this country" as is required under § 102(a).

With respect to a 1989 article by Puglisi entitled "Application of the ND-YAG laser in the treatment of varicose syndrome", Diomed asserts that no anticipation is evident because the method described in the article does not entail placing an uncoated fiber optic tip directly against a blood

vessel wall. In addition, the article purportedly fails to include any reference to drainage or compression.

Defendants respond that the procedure described in the article promotes physical contact with the vein wall, teaches drainage and compression and is not inconsistent with the use of an uncoated fiber optic tip. Indeed, defendants rely upon the Puglisi video as evidence that the procedure in fact employed an uncoated tip.

After considering the Puglisi article, the Court resolves the matter in Diomed's favor. To start, the four-page article makes no explicit reference to the nature of the fiber optic tip, its placement against the vein wall, the employment of compression prior to the procedure or drainage of the vein. The article's ambiguity on those issues compels defendants to rely upon extrinsic evidence to prove that the claims of the '777 patent are inherently encompassed within Puglisi's procedure.

That extrinsic evidence, namely Puglisi's video and deposition testimony, falls short of establishing a genuine dispute of material fact concerning the anticipation of the '777 patent by Puglisi's article. First, because Puglisi testified at his deposition that there were differences between the procedures depicted in the video and his article, the value of the video as extrinsic evidence is suspect. Second, Puglisi also testified that the procedure discussed in his article employed a laser with a covered tip. That fact alone forecloses

anticipation of the '777 patent. Finally, although Puglisi's deposition testimony implied that physical contact between the fiber optic tip and blood vessel wall may have occurred during his procedure, there is insufficient evidence that such contact was an inherently necessary component thereof.

b. O'Reilly Article

Diomed asserts that an article published by O'Reilly and others in 1982 entitled "Transcatheter Fiberoptic Laser Coagulation of Blood Vessels" did not anticipate the '777 patent because it did not disclose 1) contact between the laser tip and blood vessel wall, 2) compression and 3) drainage of blood. The four-page article describes a potential method of isolating intracranial aneurysms by means of transmitting laser energy intra-arterially. To describe the procedure, O'Reilly and his co-authors document experiments they performed on the central auricular arteries of rabbits.

Defendants make an effective argument that the procedure taught in the O'Reilly article employed a bare-tipped fiber. They are unable, however, to show evidence of deliberate and persistent contact between that fiber optic tip and the blood vessel wall. That the veins involved in the experiment were narrow and that blistering occurred as a result of the procedure is insufficient proof that deliberate physical contact was an inherently necessary component of O'Reilly's method.

Consequently, the Court concludes that the O'Reilly article did not anticipate the '777 patent.

c. Farley '398 Patent

U.S. Patent No. 6,033,398 ("the '398 patent"), granted to Farley and others in 2000, addresses a "method and apparatus for treating venous insufficiency using directionally applied energy". Diomed contends that the '398 patent does not support defendants' counterclaims because the fiber optic laser described therein was not bare-tipped and in fact, because of its particular construction, was incapable of making contact with a blood vessel wall. In addition, Diomed asserts that the patent fails to refer to the use of compression or drainage in conjunction with the laser.

Defendants dispute the contentions of Diomed, asserting that the '398 patent discloses use of an uncoated fiber tip, external manual compression, drainage and direct contact between the tip and vein wall. In response to plaintiff's assertion that the apparatus described in the '398 patent is incapable of achieving direct contact, defendants point out that the patent encompasses numerous forms of energy emission not all of which foreclose the possibility of direct contact.

Whether the '398 patent anticipated the '777 patent presents a closer question than the previously discussed examples of prior art. First, the '398 patent describes a

procedure for treating varicose veins that is substantially similar, on its face, to the method encapsulated in the '777 patent. Farley's invention is described as follows:

A method for venous repair comprises the steps of introducing a catheter having a working end and means for applying energy located at the working end to a treatment site in the vein lumen; positioning the means for heating adjacent the treatment site in the vein lumen; directionally emitting energy from the means for heating to selectively heat the treatment site and cause shrinkage of venous tissue at the treatment site; and terminating the emission of energy from the means for heating after sufficient shrinkage to restore vein competency. ... In [one of several] aspect[s] of the invention, an optical energy source may be used to impart directional energy to selectively heat venous tissue.

Comparing the two patents more specifically, defendants make a cogent argument that external manual compression was disclosed in the '398 patent where it states that a "physician may palpate the vein into apposition with the electrodes to achieve good contact between the electrodes and the vein wall".

Defendants rest on weaker footing in other respects, however. Although some descriptions in the '398 patent support an inference that an uncoated laser tip could be used, that contention is undermined by the invention's deployment of a light-diffusing device and its pictorial representation of an apparatus with an uncoated section below a covered tip.

Furthermore, defendants fail to adduce sufficient evidence that the '398 patent teaches direct contact. Indeed, the description of the method reported in the '398 patent strongly suggests that no direct contact is to occur. The most pertinent

paragraph of the '398 patent teaches a "directional" application of energy "toward" a blood vessel wall. Furthermore, one of the principal independent claims of the '398 patent speaks of placing the energy-emitting apparatus "adjacent the treatment site" in order to "directionally emit[] energy". Those descriptive terms, while not invariably inconsistent with a teaching of direct contact, imply the absence of such contact. Likewise, although the patent at one point refers to placement of the laser tip "in apposition with the vein wall", that statement does not approximate clear and convincing evidence of contact.

d. Farley '273 Patent

Defendants also argue that U.S. Patent No. 6,638,273 ("the '273 patent") which was granted to Farley and others anticipated the '777 patent of Diomed. While conceding that the '273 patent does not expressly refer to direct physical contact between an uncoated laser tip and vein wall, defendants contend, nevertheless, that the patent inherently teaches that method. Furthermore, they assert that the '273 patent explicitly discloses external compression for the purpose of draining blood.

Diomed responds in a reply brief that defendants failed to disclose their reliance upon the '273 patent in various

discovery materials including interrogatory answers, depositions and their expert report. Thus, notwithstanding the merits of defendants' position, Diomed asserts that they should be foreclosed from relying upon the '273 patent. Diomed further disputes the merits of defendants' contentions, noting that the '273 patent does not disclose the use of any fiber optic line, let alone one with an uncoated tip. The Court, once again, is persuaded by Diomed's contention, especially in light of its independent observation that the '273 patent was applied for after the application date of plaintiff's patent.

e. Mazza Video and Article

Similar to its argument with respect to the Puglisi video, Diomed first contends that a video by Mazza should not be considered "prior art". The Court concurs for the reasons set forth above. There is no evidence that the Mazza video was reduced to print form in any fashion. Nor have defendants shown that the Mazza video represented knowledge and use of its contents by others in the United States.

Diomed contends that a 1993 article by Mazza and others entitled "The Use of Argon Laser in the Treatment of Idiopathic Varices in the Lower Limbs" did not anticipate or render obvious the '777 patent because it failed to disclose the use of a bare fiber optic tip which physically contacts a venous wall. Diomed asserts, in fact, that the article plainly depicts the use of a

metal-covered tip and makes no mention of compression or drainage.

In response, defendants do not suggest that the Mazza article anticipated the '777 patent. They contend, however, that its contents, in combination with other prior art, rendered Diomed's invention obvious. In support of that argument, they aver that the laser apparatus depicted in the Mazza article necessarily incorporates an uncoated section close to its tip and that, furthermore, the elements of contact, compression and drainage are all inherent in Mazza's procedure. With respect to the latter contention, defendants rely upon extrinsic evidence including the Mazza video and alleged similarities between the procedures of Mazza and Puglisi. For reasons that are set forth in more detail below, the Court concludes that the Mazza article did not render the '777 patent obvious.

f. Biegeleisen Article

Finally, Diomed avers that a 1989 article by Biegeleisen entitled "Use of the venoscope for the treatment of varicose veins" did not anticipate the '777 patent because Biegeleisen's process entails use of an angioscope with a crystal tip rather than a laser. Furthermore, plaintiff contends that the article fails to disclose direct contact with the vessel wall, compression, drainage or any decrease in vessel diameter.

Defendants apparently concede that the Biegeleisen article

did not anticipate the '777 patent but contend that the article is relevant to an analysis of obviousness. Asserting that the procedure described in the article inherently encompasses direct contact between a physical probe and the vessel wall, defendants maintain that it, in combination with other prior art references, rendered the '777 patent obvious.

The Court concludes that the Biegeleisen article provides scant support for defendants' argument. The only link between the Biegeleisen article and the '777 patent is one paragraph in the article which speculates that lasers might eventually be used "as a cauterizing agent" or "perhaps to restore the lumen of an obstructed vein". Those references do not demonstrate physical contact between a fiber optic line and a vessel wall as defendants contend.

g. Obviousness

Notwithstanding the fact that the individual prior art references do not anticipate the '777 patent, defendants argue, in the alternative, that those references, in combination, rendered Diomed's invention obvious thereby precluding patentability under 35 U.S.C. § 103. Plaintiff challenges that claim in its motion for summary judgment, asserting that the subject matter of the '777 patent was not obvious because the prior art did not teach a number of claim limitations including direct contact between an uncoated fiber tip and blood vessel

wall, compression and drainage. Furthermore, Diomed asserts that defendants have failed to identify any motivation for combining the various teachings presented in the prior art references.

The Court declines to accept Diomed's argument that none of the elements of the '777 patent were disclosed in prior art references. For example, the laser described in the O'Reilly article is apparently uncoated at its tip and the laser apparatuses described in other prior art references depict an uncoated section near the tip which arguably could encourage the development and/or use of an uncoated tip. In addition, Farley's '398 patent refers to the possibility of manual external compression and a number of prior art references imply drainage of a vein at some point during the procedure.

Ultimately, however, the Court concludes that defendants are unable to carry their burden of proof on the issue of obviousness. None of the prior art references disclosed, expressly or inherently, direct physical contact between the laser apparatus and vein wall. Furthermore, defendants do not offer sufficient evidence of motivation to combine the prior references. No evidence is proffered, whether through the prior references themselves or otherwise, indicating that one skilled in the art would be inspired to develop Diomed's patented method in response to the then-current state of varicose vein treatment. A "hindsight combination of components selectively

culled from the prior art" is not enough. Crown Operations Int'l, 289 F.3d at 1376 (quoting ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998)) (internal quotation marks omitted).

B. Enforceability

Defendants also contend that Diomed is foreclosed from enforcing the '777 patent on account of its inequitable conduct. They allege in their counterclaims that plaintiff purposefully refrained from disclosing to the U.S. Patent & Trademark Office ("PTO") three prior art references that bore upon the PTO's patentability decision, namely, the articles by Puglisi, O'Reilly and Biegeleisen discussed above.

1. Legal Principles

PTO regulations impose a duty upon patent applicants to disclose "all information known ... to be material to patentability". 37 C.F.R. § 1.56. The PTO will not grant a patent where "fraud on the [PTO] was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct". Id.

Material information is that which is, in pertinent respect to this case,

not cumulative to information already of record or being made of record in the application, and ... establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim

Id. A prima facie case is established when the information

"compels a conclusion that a claim is unpatentable" under a preponderance of the evidence standard where each term in the claim is construed as broadly as the specification permits and no consideration is given to any evidence in support of a contrary conclusion of patentability. Id. Although assessments of validity and enforceability may entail overlapping issues, a determination of validity does not foreclose the possibility of unenforceability. See Agfa Corp. v. Creo Products Inc., 451 F.3d 1366, 1372 (Fed. Cir. 2006).

The definition of materiality set forth in § 1.56 is not exclusive. The Federal Circuit Court of Appeals recently held that the subject PTO regulation did not supplant other definitions of materiality including:

- 1) the "reasonable examiner" standard, i.e., whether "a reasonable examiner would have considered such prior art important in deciding whether to allow the patent application";
- 2) the objective "but for" standard under which no patent would have been issued had the misrepresentation not been made;
- 3) the subjective "but for" standard under which the particular examiner approved the application where he or she would otherwise have denied it had an accurate disclosure been made; and
- 4) the "but it may have" standard under which the patent examiner may have been influenced by the misrepresentation when considering the application.

Digital Control Inc. v. Charles Mach. Works, 437 F.3d 1309, 1314-15 (Fed. Cir. 2006) (quoted cases, citations and internal quotation marks omitted). To prevail on a claim of inequitable

conduct, the claimant must prove by clear and convincing evidence that the applicant intentionally withheld, or affirmatively misrepresented, material information with the purpose of misleading or deceiving the patent examiner. Id. at 1313 (citations omitted). Once the claimant has proved "a threshold level of materiality and intent", the court is to balance those elements against each other, "with a greater showing of one factor allowing a lesser showing of the other". Id. (quoting Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001)) (internal quotation marks omitted).

Although a claim of patent unenforceability due to inequitable conduct is not entitled to be tried to a jury, the elements of intent and materiality are oftentimes too fact-intensive to merit a decision on summary judgment. Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1146 (Fed. Cir. 2003) (citation omitted). Nevertheless, summary judgment is warranted where the movant fails to offer evidence from which a reasonable fact-finder, indulging all inferences in the movant's favor, could find materiality and intent by clear and convincing evidence. Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1379 (Fed. Cir. 2002) (citation omitted).

2. Analysis

Although defendants initially alleged that the inventors of

the '777 patent unlawfully misled the PTO by failing to disclose the Biegeleisen and Puglisi papers discussed above, defendants have declined to press those allegations in the absence of evidence that the inventors of the '777 patent were aware of the Biegeleisen and Puglisi references. Consequently, the strength of defendants' inequitable conduct counterclaim rests solely upon plaintiff's failure to disclose the O'Reilly article. While the issue presents a close question in some respects, the Court finds that the weakness of defendants' contentions precludes a decision in their favor. Considering defendants' meager evidence of both intent and materiality, a reasonable fact-finder could not deduce clear and convincing proof of inequitable conduct.

As indicated above, the O'Reilly article addressed experiments performed on the auricular arteries of rabbits which offered a potential treatment for brain aneurysms in humans. The authors of the article transmitted laser energy intra-arterially by means of a fiber optic line threaded through a catheter. By emitting a particular range of energy, the researchers caused coagulation in the targeted blood vessels.

It is undisputed that Dr. Min, one of the inventors of the '777 patent, knew of the O'Reilly article. Diomed contends that the nondisclosure of that article to the PTO, despite Dr. Min's knowledge of it, is insufficient to imply an intent to deceive. Plaintiff asserts, moreover, that the O'Reilly article is

immaterial because it was cumulative of the prior art of record and failed to include three principal claim limitations (i.e., contact, compression and drainage) present in the '777 patent.

Relying upon the report and declaration of an expert, defendants dispute the contentions of Diomed. They assert, first, that Dr. Min's intent to mislead the PTO may be inferred but they fail to adduce a supportable factual basis for that contention apart from the simple fact that Dr. Min knew of the reference and did not disclose it. Defendants contend, nevertheless, that the scant evidence of intent to mislead is counterbalanced by a strong showing of materiality.

Even though the O'Reilly article did not anticipate the '777 patent, defendants allege that it disclosed significant teachings which were not encompassed by prior art references of record. They correctly point out that, under the broad standard of materiality, a reference may be material even where it would not bar patentability. Here, they assert that the procedure described by O'Reilly contained elements which were not present in two references disclosed to the PTO, namely the "Trelles" and "Goldman" patents.

A chart created by AngioDynamics' expert compares the teachings of the Trelles, Goldman and O'Reilly references. That chart indicates that the significant teaching of O'Reilly was present in either Trelles or Goldman with the exception of one issue, that is, the location of the laser-emitting section of

the treating apparatus. There is strong evidence that the O'Reilly procedure transmitted energy through an uncoated fiber-optic tip. In contrast, the Goldman procedure transmitted energy through a needle and the Trelles procedure apparently transmitted energy through a "side firing probe".

The Court determines that the single discrepancy between the O'Reilly, Goldman and Trelles references is not enough to sustain defendants' argument. Defendants analogize the present case to one in which a circuit court upheld a lower court's finding of materiality where the nondisclosed reference 1) included a combination of elements that were encompassed by separate references of record, 2) contained pertinent features that exceeded the prior art of record, 3) had been considered by the applicant, in a foreign patent application, to be the most relevant piece of prior art in existence and 4) was considered to be material by patent examiners in other countries. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 (Fed. Cir. 1995). Although this case is not entirely dissimilar to the Molins case, the nondisclosure of the O'Reilly article is clearly distinguishable from the situation in Molins and does not warrant a determination of materiality.

IV. Cross-Motions for Summary Judgment with Respect to Infringement

Diomed asserts that it is entitled to summary judgment against both AngioDynamics and VSI on the grounds that each has

actively induced and contributed to infringing conduct in violation of 35 U.S.C. §§ 271(b) and (c). Defendants contest those claims and contend that the evidence, in fact, entitles each to a declaration of non-infringement. Because the record discloses numerous disputes of material fact concerning whether defendants' products infringe the '777 patent and defendants' intent with respect to the use of those products, the Court will deny all of the parties' motions with respect to infringement.

A. Motion of Diomed

To prove that one has "actively induce[d] infringement of a patent" under § 271(b),

the patentee must show, first that there has been direct infringement, and second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.

Cross Med. Prods., 424 F.3d at 1312 (quoting MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005)) (internal quotation marks omitted).

Persons may be liable for contributory infringement under § 271(c), as pertinent in this case, where they sell an

apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use.

35 U.S.C. § 271(c). To prevail on a claim of contributory

infringement, the plaintiff must prove direct infringement, that the defendant knew of the patent and of the infringing use of its own product and that the defendant's product lacks a substantial non-infringing use. Cross Med. Prods., 424 F.3d at 1312 (citing Golden Blount, Inc. v. Robert H. Peterson Co., 365 F.3d 1054, 1061 (Fed. Cir. 2004)).

Because defendants' alleged liability depends upon a finding of direct infringement, the Court's analysis begins there. Determining whether a patent has been directly infringed entails two steps: first, construction of the claim, and second, comparison of that claim with the accused process or device. Applied Med. Res. Corp. v. U.S. Surgical Corp., 448 F.3d 1324, 1332 (Fed. Cir. 2006) (citation omitted). As related above, Judge Stearns construed Claim 9 in the '777 patent as encompassing 1) insertion of a fiber optic line, uncoated at its tip, into a vein, 2) deliberate contact between that fiber optic tip and the blood vessel wall and 3) maintenance of such physical contact during the emission of laser energy in order to decrease the vessel's diameter.³ With claim construction complete, the Court turns to comparing that claim with the challenged procedures of defendants.

³ Because independent Claim 9 is the broadest claim for which Diomed alleges infringement, if defendants are found not to have infringed that claim, they cannot be found to have infringed narrower and dependent claims. See Wolverine World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1199 (Fed. Cir. 1994) (citation omitted).

Diomed's case relies heavily on circumstantial evidence which may be used to support a claim of infringement. Golden Blount, Inc. v. Robert H. Peterson Co., 438 F.3d 1354, 1362 (Fed. Cir. 2006) (citation omitted). Its position can be summarized as follows. First, Diomed asserts that various written assertions and videos relating to defendants' products demonstrate that those products rely upon the very teachings set forth in the '777 patent, especially the critical elements of compression and direct contact between the laser tip and blood vessel wall. Second, Diomed avers that compression and contact inevitably result from the procedures taught by defendants. Plaintiff argues that it is irrelevant, therefore, whether defendants instruct their doctor-customers to avoid contact because performance of the accused procedures invariably results in such contact. Third, Diomed contends that endovenous laser treatment of varicose veins is effective only if contact is established between the laser and the vessel wall thereby implying that contact is an element of defendants' products. Diomed points to histological studies in support of that contention.

After setting forth its case for direct infringement, Diomed argues that defendants' marketing, post-sale support, "instructions for use" and design of their products render them liable for actively inducing and contributing to infringement of the '777 patent. Furthermore, based upon its contention that

contact is the sine qua non of effective endovenous laser treatment, Diomed asserts that defendants' products lack substantial non-infringing uses.

Defendants' responses raise genuine issues of material fact that preclude an award of summary judgment to Diomed. First, both defendants offer evidence that their products rely not upon direct contact, as Diomed alleges, but rather upon "circumferential heating". AngioDynamics argues that much of Diomed's evidence is speculative or taken out of context and both defendants dispute the contention that direct contact is the only effective means of treating varicose veins intravenously by laser. Similarly, they challenge Diomed's proposition that compression and contact inevitably result from the use of their products.

Second, defendants contest plaintiff's proof of infringement with respect to the third step of Claim 9, i.e., that physical contact between the laser tip and vessel wall be "maintained" during laser emission. The Court is persuaded that the evidence of infringement relating to the maintenance of contact is subject to varying interpretations that preclude summary judgment for Diomed.

On the one hand, plaintiff suggests that persistent contact between the laser tip and the vein wall can be inferred from the proper use of defendants' products. As discussed above with respect to the initial physical contact between the laser and

venous wall, defendants dispute that contention. On the other hand, Diomed also asserts that Judge Stearns' construction of Claim 9, in which he determined that the claim requires "maintaining ... physical contact with the vessel wall", is consistent with a claim of infringement "even if there [are] moments when the fiber tip [is] not in contact with the vein wall". In that same vein (pun intended), Diomed argues that, even if defendants' products do not obligate persistent contact between the laser tip and the vessel wall, the functional equivalent occurs when the material which clads the lasers used by defendants' customers degrades from the high temperature of the laser source thereby "uncoating" the side of the laser and causing contact to be "maintained" between the laser and the vessel wall.

Defendants disagree with plaintiff's interpretation of the "maintaining contact" requirement and dispute the conclusions that Diomed draws. Their responses raise genuine factual disputes that undermine the contentions espoused in Diomed's principal memorandum and reply brief. Consequently, genuine issues of material fact remain as to whether 1) defendants promote contact as an essential component of the treatment encompassed by their products, 2) the use of tumescent anesthesia, as recommended by those products, invariably results in contact, 3) the third step of Claim 9 may be infringed even though contact between the laser tip and vessel wall is

momentarily lost and 4) the coated section of lasers used with defendants' products decomposes so as to facilitate a larger area of contact. Because the foregoing disputes involve Diomed's proof of direct infringement, the Court need not address issues specifically relating to inducement and contributory infringement.

B. Motions of AngioDynamics and VSI

AngioDynamics and VSI have each filed cross-motions for partial summary judgment against Diomed, claiming to be entitled to declarations of non-infringement. Each avers that the undisputed facts show no evidence of direct infringement or of inducement to infringe.

As discussed in the preceding section, defendants dispute plaintiff's proposition that the mere use of tumescent anesthesia inevitably causes contact between the laser tip and blood vessel wall. Both defendants report that the physicians who follow Diomed's procedure, in contrast to their own customers, employ techniques such as manual compression in addition to tumescent anesthesia in order to ensure contact between the laser tip and the blood vessel wall. Defendants suggest that contact is, therefore, neither easily nor necessarily established by the use of tumescent anesthesia alone.

Defendants further suggest that the use of tumescent

anesthesia may be beyond the scope of Diomed's patent. They assert that, in this case, Judge Stearns did not construe the elements of "compression" and "drainage" which are embodied in the '777 patent. Defendants argue that those terms should be limited to the methods of compression and drainage specifically set forth in the patent (i.e., elevation of the leg, manual compression and application of a compression bandage). If their products are deemed to infringe the '777 patent owing to the use of tumescent anesthesia, defendants contend that the patent should be deemed to violate the specification requirements of 35 U.S.C. § 112.

Both defendants further assert that the strength of plaintiff's proof of direct infringement is enfeebled by the lack of evidence demonstrating specific acts of infringement by defendants' customers. VSI separately argues that the absence of such evidence renders Diomed's claim for damages unsustainable.

With respect to inducement to infringe, defendants propose that Diomed cannot maintain claims against them because there is no evidence that defendants specifically intended their customers to infringe the '777 patent. As factual support for their position, both defendants offer evidence that they explicitly instruct the users of their products to avoid direct contact between the laser tip and vessel wall. In legal support, defendants cite cases holding that mere awareness of

infringing conduct, by itself, is insufficient to establish liability for inducing infringement.

Diomed's response overcomes the factual and legal contentions of defendants in a number of significant respects. Although its contentions include puffery and rely substantially upon circumstantial evidence, Diomed provides adequate factual support for inferences of infringement and inducement to infringe. Consequently, the Court will deny defendants' motions.

First, plaintiff offers evidence that defendants were concerned about infringing the '777 patent. AngioDynamics at one point sought to license the '777 patent from its inventors and both defendants considered, but declined to employ, a device which would have prevented contact and, consequently, would have avoided infringement.

Second, Diomed asserts that videotaped procedures and statements made by physicians associated with defendants demonstrate that contact is an essential ingredient of the procedure facilitated by their products. Likewise, its contentions that contact invariably results from the use of tumescent anesthesia and that such contact is necessary for successful endovenous laser treatment are not without justification. For example, in response to defendants' contention that tumescent anesthesia alone does not cause contact, Diomed asserts that additional procedures such as

compression are intended as redundancies to guarantee and maximize contact rather than techniques necessary to establish contact in the first instance. The evidence offered by plaintiff and defendants with respect to the inevitability and necessity of contact (or lack thereof) is dependent upon the testimony of expert witnesses and persons skilled in the art whose credibility and weight cannot be conclusively determined on summary judgment.

Third, Diomed argues persuasively that its claims should not be foreclosed for lack of explicit evidence documenting infringement by defendants' customers. Diomed notes correctly that circumstantial evidence may be employed in support of an infringement claim. Because the challenged products are treatment kits accompanied by "instructions for use", evidence that infringement occurs when one uses those products in accordance with their instructions is relevant and probative to Diomed's claims.

On a related question, the Court agrees with Diomed that VSI's contention about damages is misplaced. Plaintiff's failure to connect its monetary damages to particular acts of infringement does not negate a damages claim under the theory that defendants' customers as a class infringe the '777 patent. See Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1274 (Fed. Cir. 2004) (citations omitted). Diomed's ability to prove those damages with reasonable certainty depends

upon issues of fact which cannot be resolved as a matter of summary judgment in this case.

With respect to the inducement claim, Diomed asserts that defendants' instructions to avoid direct contact should not shield them from liability under the circumstances. Diomed suggests that those "disclaimers" are meaningless absent any instruction on how to avoid contact and in light of the contact which inevitably occurs when defendants' products are used as directed. Furthermore, Diomed quarrels with defendants' definition of specific intent, averring that the requisite intent is shown so long as the accused intended to cause the acts which constitute infringement. Here, Diomed argues, there is evidence that defendants intended contact to occur notwithstanding their avowals to the contrary.

Diomed's contentions have enough substance to overcome defendants' motions for summary judgment. A recent circuit court decision notes that "there is a lack of clarity concerning whether the required intent must be merely to induce the specific acts [of infringement] or additionally to cause an infringement". Golden Blount, 438 F.3d at 1365 n.4 (quoting MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1332 (Fed. Cir. 2005)) (internal quotation marks omitted). Although Diomed's proof of inducement is tenuous and circumstantial, when all inferences are indulged in its favor, a reasonable fact-finder could conclude that defendants intended contact to be employed

in the use of their products regardless of their assertions to the contrary.

Defendants are also not entitled to summary judgment on plaintiff's claim of contributory infringement. Although both defendants have proffered evidence that their products do not infringe and can be used in a non-infringing manner, that evidence is counterbalanced by facts implying infringement. Given the genuine dispute concerning the extent to which defendants' products rely upon physical contact between a laser tip and blood vessel wall, summary judgment on the issue of contributory infringement would be premature.

Finally, defendants' motions are not availed by their contention that the '777 patent does not teach the use of tumescent anesthesia and would be invalid under § 112 if it were deemed to embody that application. Defendants rely upon the recent case of Lizardtech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005), for the proposition that a patented claim must be limited to the particular method disclosed in the patent. A closer look at that case, however, reveals distinctions from the case at bar. As Diomed points out, and as the Lizardtech case affirms,

a claim will not be invalidated on § 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before.

Id. (citations omitted). Here, evidence in the record suggests that a practitioner skilled in the art at the time of Diomed's patent would have known about the use of tumescent anesthesia for compression purposes. Consequently, the Court rejects defendants' argument that the use of tumescent anesthesia in conjunction with their products invariably places them outside the scope of the '777 patent.

ORDER

In accordance with the foregoing memorandum:

- 1) Defendants' Motion to Exclude Untimely Expert Opinions (Docket No. 75) is **DENIED**, provided however that:
 - a) Diomed shall make Mr. Green available for a short supplemental deposition, limited to the issue of the lost-profits theory, with all costs (except defendants' legal fees) to be borne by Diomed, and defendants are granted leave to identify a rebuttal expert, if desired, and to produce a rebuttal report, and
 - b) Diomed shall produce an expert report with respect to the opinions of Dr. Navarro that complies with Fed. R. Civ. P. 26(a)(2) and shall, henceforth, treat Dr. Navarro as an expert witness subject to that rule;
- 2) Diomed's Motion for Summary Judgment on Validity and Enforceability of U.S. Patent No. 6,398,777 (Docket No. 89) is **ALLOWED**;
- 3) Diomed's Motion for Summary Judgment on Patent Infringement (Docket No. 87) is **DENIED**;
- 4) VSI's Motion for Summary Judgment (Docket No. 79) is **DENIED**; and

5) AngioDynamics' Motion for Summary Judgment (Docket No. 100) is **DENIED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated: August 30, 2006

Publisher Information

**Note* This page is not part of the opinion as entered by the court.
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of publishers of these opinions.**

1:04-cv-10019-NMG Diomed, Incorporated v. Angiodynamics, Incorporated
Nathaniel M. Gorton, presiding
Date filed: 01/06/2004 Date of last filing: 08/30/2006

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representing

Total Vein Solutions, LLC (Defendant)

representing

Vascular Solutions, Inc. Ruberto, Israel & Weiner, P.C. 100 North Washington Street Boston, MA 02114-2128 (617) 742-4200 (617) 742-2355 (fax) steve_feldman@riw.com (Defendant)

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representing

Angiodynamics, Incorporated (Defendant)

representing

Angiodynamics, Incorporated (Counter Claimant) New Star Lasers, Inc. (Defendant)