UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ARROW INTERNATIONAL, INC. and ARROW INTERNATIONAL INVESTMENT CORP.,	)	
Plaintiffs,	)	
v.	)	CIVIL ACTION NO. 06-cv-11564-DPW
SPIRE BIOMEDICAL, INC.	)	
Defendant.	)	

MEMORANDUM AND ORDER
July 10, 2009

Plaintiffs Arrow International, Inc. and Arrow International Investment Corp. (collectively "Arrow") bring this action against Spire Biomedical, Inc. ("Spire") for contributory infringement and inducement of infringement of U.S. Patent No. 6,872,198 (filed Aug. 30, 2002) ("the '198 patent"). Arrow alleges that Spire infringed on the patent by manufacturing and selling a particular type of catheter used for the treatment of hemodialysis, and by providing instructions to physicians for implanting that catheter in patients by a particular method. Spire has counterclaimed and now presses for summary judgment on grounds that: (A) the '198 patent is unenforceable because of inequitable conduct (Dkt. No. 32), and (B) the '198 patent is invalid (Dkt. No. 36) due to (1) anticipation and (2) obviousness.[1] Arrow opposes Spire's summary judgment motions and

[1] Spire initially also moved for summary judgment on grounds of non-infringement. (Dkt. No. 34.) On November 7, 2008, Spire filed a motion to withdraw its Motion for Partial Summary Judgment of Non-Infringement, which I will grant. (Dkt. No. 73.)

has filed a cross-motion for summary judgment on the issue of unenforceability due to inequitable conduct. (Dkt. No. 58.)[2] For the reasons discussed below, I will grant Arrow's summary judgment motion on the issue of inequitable conduct, but I will grant summary judgment to Spire on grounds that the '198 patent is invalid due to obviousness.

I. FACTUAL BACKGROUND

A. The Parties

Plaintiff Arrow International Investment Corp. is the owner of the '198 patent, entitled "Double-Y-Shaped Multi-Lumen Catheter with Selectively Attachable Hubs." Plaintiff Arrow International, Inc. is the parent corporation of Arrow International Investment Corp. and is the exclusive licensee of the '198 patent. Defendant Spire Biomedical, Inc. manufactures and sells a product called the Pourchez RetrO high flow kink resistant catheter ("Pourchez RetrO"). The plaintiffs allege that Spire's manufacture and sale of the Pourchez RetrO, coupled with the instructions Spire provides to physicians for its use,

[2] I note that this is a simplified account of the parties' respective outstanding motions. Spire's Answer and Counterclaim now includes two counterclaims for unenforceability due to inequitable conduct. Spire has filed a motion to amend (Dkt. No. 30) in order to add a third counterclaim based on additional grounds for inequitable conduct. Arrow opposes Spire's motion to amend, and has also filed a motion to dismiss the proposed new counterclaim, as well as a motion for summary judgment on all three of Spire's inequitable conduct counterclaims. (Dkt. No. 58.) These motions are discussed at greater length in Section III.A, *infra*.

constitutes infringement of the ‘198 patent.

B. Hemodialysis Catheters

A healthy kidney cleans blood by removing excess fluid, minerals and waste. When a person’s kidneys are unable to perform that function, hemodialysis is necessary. Hemodialysis is a process by which blood is extracted from a patient, filtered and purified with the aid of a hemodialysis machine, and then returned to the patient’s bloodstream. It has been the principal treatment for kidney failure and other renal diseases for at least fifty years.

Depending on a patient’s condition, there are different ways to access the patient’s bloodstream in order to conduct hemodialysis. For patients with relatively strong blood flow, blood can be accessed from an arm, through either the patient’s own blood vessels or a surgically implanted graft. For patients with insufficient blood flow, the bloodstream is instead accessed directly from the patient’s heart.

The patient’s blood is removed from and returned to the bloodstream by means of a catheter. A catheter is a hollow, flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or to distend a passageway. (‘198 Patent col.1 ll.21-23.) The end of the catheter that is placed inside the patient’s body is the “proximal” end. The end of the catheter that remains outside the body and is attached to the

hemodialysis machine is called the "distal" end.[3] (*Id.* at col.11 ll.19-31.) A single catheter may be further subdivided into two or more separate tubes, or "lumens." The "arterial" lumens carry blood away from the body to be cleaned, and the "veinal" lumens return blood to the bloodstream. (*Id.* at col.5 ll.24-46.)

C. The '198 Patent

The '198 patent claims a method of implanting a multi-lumen catheter into a patient by means of retrograde tunneling. The patent is limited to a catheter with a particular structure: a "double Y-shaped" catheter. *See Arrow Int'l* v. *Spire Biomedical, Inc.*, No. 06-11564-DPW, 2006 WL 3093228, at *6 (D. Mass. Oct. 31, 2006) ("Claim Construction Order"). This catheter consists of an "elongated, central, multi-lumen tube portion" with extension tubes protruding from both the proximal and distal ends, forming Y-shaped branches.[4] The central portion has a cylindrical outer shape and is segmented internally into separate lumens. ('198 Patent col.2 ll.64-66.) This design allows, within a single catheter unit, one lumen (the arterial lumen) to extract blood to

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[3] In other patents for hemodialysis catheters, these terms may be used in the opposite way, such that the "distal" end refers to the end inside the patient's body, and the "proximal" end refers to the end attached to the hemodialysis machine. *See, e.g.*, U.S. Patent No. 6,682,519 (filed June 1, 2000) ("the Schon patent"). For purposes of this Memorandum and Order, I will use the terms as they are defined in the '198 patent.

[4] "Y-shaped" means that the branches "intersect at a single trunk to form an inside angle of greater than zero and less than 180 degrees." *Arrow Int'l* v. *Spire Biomedical, Inc.*, No. 06-11564-DPW, 2006 WL 3093228, at *9 (D. Mass. Oct. 31, 2006) ("Claim Construction Order").

be cleaned and the other (the veinal lumen) to return blood after wastes have been removed.

The implantation method described in the '198 patent involves subcutaneous tunneling. A subcutaneous tunnel is a tunnel in a layer of fat under the patient's skin that connects the insertion access point, where the proximal end of the catheter is attached to the patient's blood vessel, with a more remote location on the patient's body, where the distal end of the catheter extends out to be attached to a hemodialysis machine. Because the insertion access point is usually in the patient's neck, this tunnel allows the catheter to protrude out from the body at a less awkward and more secure location, such as the chest. Tunneling away from the insertion access point also reduces the risk that a patient will develop a blood stream infection at the point where the catheter is inserted into the patient's blood vessel.

In the more widely used "antegrade" placement technique, the proximal end of the catheter is drawn through the tunnel *from* the remote exit point *toward* the insertion access point. After the catheter has been drawn through the tunnel, the proximal end of the catheter is inserted through the access point and attached to the patient's blood vessels. The '198 patent claims a less common "retrograde" placement technique. In this method, the proximal end of the catheter is *first* inserted into the patient's blood vessel, and then the distal end of the catheter is drawn through the subcutaneous tunnel *away* from the insertion access

point and *toward* the remote exit point. Once the distal end of the catheter is protruding from the exit point, the exposed tubes are secured to the patient with sutures or some other means and then connected to a hemodialysis machine. (*Id.* at col.5 ll.44-58.)

Arrow claims that Spire has infringed on claims 1-3 of the '198 patent. Claim 1 describes the claimed retrograde implantation method in five steps:

> (a) making an incision in the skin of the patient;
> (b) inserting the proximal tips of the proximal veinal and arterial extension tubes through the incision and placing the proximal tips in the patient;
> (c) forming a subcutaneous tunnel having a first end proximate to the incision and a second end remote from the first end of the tunnel;
> (d) guiding the distal veinal and arterial extension tubes and at least a portion of the central tube portion through the subcutaneous tunnel such that at least the distal ends of the distal veinal and arterial extension tubes extend outwardly from the tunnel through the second end of the tunnel; and
> (e) securing at least a portion of the distal end portion of the catheter to the patient.[5]

(*Id.* at col.11 ll.9-33.) Claims 2 and 3 are dependent claims that describe the means and method of attaching the catheter to

[5] "Securing" in this claim means "firmly fixing." Claim Construction Order, 2006 WL 3093228, at *9.

the hemodialysis fluid exchange machine. (*Id*. at col.11 ll.34-43.)[6]

D. Application for the '198 Patent

The named inventors of the '198 patent all worked for a company called Diatek, Inc. ("Diatek"). Diatek was formed in 2000 by Carl Fleming, Gary Fleming, Ronald Boyd, Jon Wilson and Kenneth Todd Cassidy. The Flemings and Boyd were the owners of Classic Medical, Inc. ("Classic Medical"), a medical equipment and supply distribution company. The Classic Medical owners approached Wilson and Cassidy regarding a new catheter design, which Diatek developed and manufactured as the "Cannon Catheter." Diatek received FDA approval for the Cannon Catheter on August 14, 2001; by September 14, 2001, the company had finalized agreements with distributors in several states to begin selling the product.

On August 30, 2002, the Diatek inventors filed a patent application with the United States Patent and Trademark Office ("PTO") for a catheter implantation method, which would later

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[6] Claim 2 provides: "A method according to claim 1, the method further comprising respectively connecting the distal and veinal extension tubes to arterial and veinal legs of a fluid exchange device." ('198 Patent col.11 ll.34-37.)

Claim 3 provides: "A method according to claim 2, wherein connecting the distal arterial and veinal extension tubes to arterial and veinal legs of a fluid exchange device comprises connecting the distal arterial extension tube to the arterial leg with a first connector hub, and connecting the distal veinal extension tube to the veinal leg with a second connector hub." (*Id*. at col.11 ll.38-43 (with changes from the "Certificate of Correction" attached to the '198 patent)).

become the '198 patent. The application was identified as a continuation-in-part application from U.S. Patent No. 6,638,242 (filed Feb. 28, 2002) ("the '242 patent"). The '242 patent was, in turn, a continuation application from an original patent application filed on January 24, 2001.[7] Upon filing the '198 patent application, the inventors also filed a request that the application not be published. In connection with the non-publication request, as required by statute, the inventors certified that they would not file any foreign patent applications for the invention disclosed in the '198 patent.

In 2003, Arrow purchased the assets of Diatek, including the rights to the '198 patent application. While the application was still pending, Arrow applied for a patent under the International Patent Cooperation Treaty and for several other foreign patents. Arrow did not rescind the non-publication request with the PTO before filing these foreign applications.

Following an interview with a PTO examiner on February 2, 2004, Arrow agreed to restrict the '198 application to eight

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[7] A continuation application does not include any matters that were not disclosed in a prior application and is entitled to priority as of the filing date of the parent application. Manual of Patent Examining Procedures ("MPEP") § 201.07. A continuation-in-part application includes some matters disclosed by the parent application but also adds some new matters. MPEP § 201.08. The claims in a continuation-in-part application that are supported by the parent application are entitled to claim the parent application's filing date as a priority date. Claims based on new matters are only entitled to priority from the filing date of the continuation-in-part application. MPEP § 201.11.

claims (renumbered claims 1-8) and withdrew all other claims from consideration. None of the remaining claims had been disclosed in the '242 patent or the patent application filed January 24, 2001. The priority date for these claims was therefore August 30, 2002, the filing date of the '198 continuation-in-part application. On March 29, 2005, the PTO issued the '198 patent. Since that time, neither Arrow nor Diatek has developed or sold any products within the scope of the patent.

E. Litigation History

On April 5, 2005, approximately one week after the '198 patent was issued, Arrow commenced this action against Spire for infringement for activities related to the Pourchez RetrO. Spire moved for summary judgment, claiming that Arrow's foreign patent applications, which were in contravention of the certification filed with the non-publication request, had caused the '198 patent to be abandoned.[8] After Arrow filed a Petition for Revival of a Potentially Abandoned Patent with the PTO, I dismissed the infringement case without prejudice on grounds that Arrow had not fully exhausted administrative remedies on the issue of abandonment. *See Arrow Int'l* v. *Spire Biomedical, Inc.*, 443 F. Supp. 2d 182, 185-86 (D. Mass. 2006). Thereafter, the PTO

[8] Under 35 U.S.C. § 122(b)(2)(B)(iii), failure to notify the PTO properly of foreign patent applications after making a non-publication request "shall result in the application being regarded as abandoned, unless it is shown to the satisfaction of the Director that the delay in submitting the notice was unintentional."

granted revival of the '198 patent, and Arrow subsequently filed a second suit against Spire for indirect infringement of the '198 patent. On October 31, 2006, I issued the Claim Construction Order, 2006 WL 3093228, to resolve the meaning of disputed terms in the '198 patent. The parties meanwhile sought to resolve the case by alternative dispute resolution. They were apparently unable to do so and seek resolution on the merits in this court.

II. SUMMARY JUDGMENT STANDARD

Summary judgment is "as appropriate in a patent case as in any other." *Barmag Barmer Maschinenfabrik AG* v. *Murata Machinery, Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984). To grant summary judgment, this Court must find that the "pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A "genuine factual issue" is one that "may reasonably be resolved in favor of either party." *Anderson* v. *Liberty Lobby*, 477 U.S. 242, 250 (1986). In making this inquiry, the court must "view the evidence presented through the prism of the substantive evidentiary burden" and draw all "justifiable inferences" in favor of the nonmoving party. *Id.* at 254-55. The judge's function "is not himself to weigh the evidence and determine the truth of the matter," *id.* at 249, but rather to determine "whether the evidence presented is such that a jury applying that evidentiary standard could reasonably find

for either the plaintiff or the defendant." *Id.* at 255.

The court must grant summary judgment "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 325 (1986). Therefore, where the moving party does not have the trial burden of proof, it may satisfy its initial summary judgment burden of production by showing "that there is an absence of evidence to support the nonmoving party's case." *Id.* The burden then shifts to the nonmoving party to produce specific facts showing at a minimum that a genuine issue of material fact exists. *Anderson*, 477 U.S. at 256. This analysis is applicable to Arrow's cross motion for summary judgment on inequitable conduct, because Spire would bear the burden at trial of showing inequitable conduct by clear and convincing evidence. *See Kingsdown Med. Consultants, Ltd.* v. *Hollister Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

III. ANALYSIS

A. Inequitable Conduct

Spire's Answer and Counterclaim now includes two counterclaims based on allegations of inequitable conduct: (1) that the '198 patent applicants improperly failed to disclose their knowledge of Spire's catheter development activities to the PTO, and (2) that Arrow improperly filed foreign patent applications for the invention disclosed in the '198 patent

without first rescinding the non-publication request. Spire has also moved to add a third inequitable conduct counterclaim, based on allegations that the patentees made misleading statements to the PTO regarding the '198 patent application's priority date and subsequently withheld material information relating to the commercialization and public use of the Cannon Catheter. Spire's Motion for Summary Judgment on Unenforceability Due to Inequitable Conduct is based only on this proposed third counterclaim. Arrow opposes Spire's motion to amend, and has also filed a motion to dismiss Spire's proposed third counterclaim, as well as a motion for summary judgment on all three of Spire's inequitable conduct counterclaims. Because I find insufficient evidence to raise a genuine issue of material fact for any of Spire's inequitable conduct counterclaims, I will grant summary judgment to Arrow on the inequitable conduct issue.

1. Legal Standard

Every patent applicant owes a duty of candor and good faith to the PTO. *See M. Eagles Tool Warehouse, Inc.* v. *Fisher Tooling Co.*, 439 F.3d 1335, 1339 (Fed. Cir. 2006) (*citing* 37 C.F.R. § 1.56(a)). A breach of this duty constitutes inequitable conduct, which will invalidate a patent in its entirety. *See J.P. Stevens & Co., Inc.* v. *Lex Tex Ltd., Inc.*, 747 F.2d 1553, 1561-62 (Fed. Cir. 1984). The burden of proving inequitable conduct lies with the accused infringer, who must present evidence that the patent applicant: (1) made an affirmative misrepresentation of material

fact or failed to disclose material information, and (2) intended to deceive the PTO. *See Star Scientific, Inc.* v. *R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). "Further, at least a threshold level of each element - i.e., both materiality and intent to deceive - must be proven by clear and convincing evidence." *Id*.[9]

The Federal Circuit has explained that "[t]he need to strictly enforce the burden of proof and elevated standard of proof in the inequitable conduct context is paramount because the penalty for inequitable conduct is so severe." *Id*. Even where the party alleging inequitable conduct proves a threshold level

[9] At the summary judgment hearing and in subsequent briefing the parties disputed the scope of the "clear and convincing" evidentiary standard for proving inequitable conduct. According to Arrow, "not only must the elements of inequitable conduct be proved by 'clear and convincing evidence,' the predicate facts supporting each element must themselves be proven by 'clear and convincing' evidence." Although Arrow has cited several cases featuring language that arguably supports this interpretation - *see, e.g, Ferring B.V.* v. *Barr Labs., Inc.*, 437 F.3d 1181, 1186 (Fed. Cir. 2006) ("The predicate facts must be proven by clear and convincing evidence.") - I will apply the heightened evidentiary standard only to the essential *elements* of inequitable conduct (i.e., materiality and intent to deceive), rather than to every piece of underlying evidence. I interpret the "predicate facts" language from *Ferring* to refer to these essential elements, which are themselves questions of fact. *See Young* v. *Lumenis, Inc.*, 492 F.3d 1336, 1345 (Fed Cir. 2007) ("Both elements of a conclusion of inequitable conduct, intent and materiality, are questions of fact and must be proven by clear and convincing evidence."). This interpretation of the standard is consistent with the general principle that "individual pieces of evidence, insufficient in themselves to prove a point, may in cumulation prove it. The sum of an evidentiary presentation may well be greater than its constituent parts." *United States* v. *Ortiz*, 966 F.2d 707, 711 (1st Cir. 1992) (internal quotation omitted).

of materiality and intent to deceive by clear and convincing evidence, a court may still decline to render the patent unenforceable. At that stage, the court must balance the equities to determine whether the applicant's conduct was egregious enough to warrant loss of the entire patent. *Id*.

In the context of inequitable conduct, information is considered material "where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."[10] *Digital Control Inc.* v. *Charles Mach. Works*, 437 F.3d 1309, 1315 (Fed. Cir. 2006) (internal quotation omitted). Under this standard, "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." *Li Second Family Ltd. P'ship* v. *Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000). On the other hand, evidence that is merely cumulative of information already disclosed to the PTO examiner is not considered material. *See Star Scientific*, 537 F.3d at 1367.

With respect to the second prong of inequitable conduct, intent to deceive, the Federal Circuit has emphasized that "materiality does not presume intent, which is a separate and

[10] There are several distinct tests for defining "materiality" for purposes of inequitable conduct, and the Federal Circuit has held that information is material if it meets any one of them. *See Impax Labs., Inc.* v. *Aventis Pharms.*, 468 F.3d 1366, 1374 (Fed. Cir. 2006). The "reasonable examiner" test is the broadest formulation, and that is the standard I will apply in this case.

essential component of inequitable conduct." *Id*. at 1366 (internal quotation omitted). The alleged conduct must not amount "merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the *specific intent* to . . . mislead[] or deceiv[e] the PTO." *Id*. (emphasis and alteration in original, internal quotation omitted); *see also Kingsdown*, 863 F.2d at 876 (holding that conduct amounting to "gross negligence" does not by itself justify an inference of intent to deceive). Because direct evidence of intent is rarely available, deceptive intent "can be inferred from indirect and circumstantial evidence." *Star Scientific*, 537 F.3d at 1366. Such an inference, however, "must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." *Id*. Given the need to evaluate the facts and circumstances of a particular case carefully to draw such an inference, a finding of deceptive intent "is rarely enabled in summary judgment proceedings." *KangaROOS U.S.A., Inc.* v. *Caldor, Inc.* 778 F.2d 1571, 1577 (Fed. Cir. 1985).

2. Knowledge of Spire's Development Activities

In Spire's first inequitable conduct counterclaim, it alleges that the inventors of the '198 patent were aware of Spire's development activities for the Pourchez RetrO prior to

filing the '198 patent application, yet failed to disclose those activities to the PTO. According to Spire, the development activities must be considered material prior art in light of Arrow's claim, underlying this lawsuit, that the Pourchez RetrO and its accompanying instructions infringed on the '198 patent. Although Spire did not move for summary judgment on this ground, it has opposed Arrow's summary judgment motion by contending there are genuine issues of material fact with respect to this counterclaim.

As a threshold matter, it is not apparent from the summary judgment record what Spire's "development activities" actually involved or what the Diatek patentees could have learned about them. Mark Little, the Chief Executive Officer and President of Spire, testified at his deposition that Jon Wilson of Diatek called him after learning that Spire had acquired the patent for a particular type of catheter.[11] According to Little, Wilson spoke to him primarily about *Diatek's* catheter development and expressed interest in working out a deal with Spire. Little testified that he did not describe Spire's own development activities to Wilson "in any detail," and he was unsure whether he discussed them at all. Paramjith Anand, another Spire representative, testified at his deposition that he told Kenneth

[11] The patent in question was U.S. Patent No. 6,001,079 (filed Sept. 4, 1996) ("the Pourchez patent"). It is undisputed that the Pourchez patent itself was before the PTO examiner during the prosecution of the '198 patent.

Todd Cassidy of Diatek that Spire "ha[d] their own catheters in development"; however, Anand declined to disclose any specifics to Cassidy about Spire's development efforts. Lastly, Spire contends that Dr. John Ross, who worked with Diatek on the development and marketing of the Cannon Catheter, was consulted by Spire in June 2002 regarding the development of the Pourchez RetrO. Spire has not, however, provided any evidence as to what Dr. Ross actually knew about the development of the Pourchez RetrO or what he may have told anyone at Diatek.[12]

Given this dearth of evidence regarding Spire's Pourchez RetrO development activities and what the '198 patent applicants could have known about them, Spire cannot meet its evidentiary burden for proving inequitable conduct on this ground. No reasonable factfinder could conclude that there is clear and convincing evidence that the development activities were material, or that the Diatek patentees withheld information about them from the PTO with deceptive intent. I will accordingly grant summary judgment to Arrow on this counterclaim.

3. Foreign Patent Applications

Spire's second inequitable conduct counterclaim is based on Arrow's foreign patent applications for the invention disclosed by the '198 patent. In its summary judgment briefing, Spire

[12] The only evidence cited by Spire to support this contention regarding Dr. Ross is a letter indicating that Dr. Ross was sent two free samples of the Pourchez RetrO.

acknowledged, with reference to these foreign filings, that "[a]lthough such conduct may not in and of itself rise to the level of inequitable conduct, it provides context and additional evidence of the patentees' indifference for the rules governing patent prosecution." It is unclear whether Spire intended this statement as a withdrawal of this counterclaim or simply as an alternative argument. For purposes of this Memorandum and Order, I will assume that the counterclaim has not been withdrawn.

I find that Spire has satisfied the "materiality" prong of inequitable conduct on this counterclaim. When the Diatek inventors filed a non-publication request with the '198 patent application, they also submitted a certification, required by statute, that expressly agreed they would not file any foreign patent applications without first rescinding the non-publication request. It is undisputed that after purchasing the rights to the '198 patent application, Arrow applied for several foreign patents without notifying the PTO. The statutory penalty for violating the certification is abandonment of the underlying patent. *See* 35 U.S.C. § 122(b)(2)(B)(iii). On this basis, I conclude that there is clear and convincing evidence that Arrow's failure to notify the PTO constituted a material breach of its duty of candor.

I find, however, that Spire has presented insufficient evidence to raise a genuine issue of material fact as to whether Arrow intended to deceive the PTO. There are several indications

from the record that Arrow's violation of the certification was inadvertent. First, it was Diatek, not Arrow, that had filed the non-publication request and certification several years before Arrow filed for the foreign patents. This makes it more plausible that Arrow's failure to rescind the non-publication request was the result of an oversight, rather than an intentional deception. Second, the application for the '198 patent *was* eventually published on March 11, 2004; yet Arrow still did not rescind the non-publication request with the PTO until two years later. If Arrow's intent was to keep the patent application improperly hidden, as Spire alleges, it is unclear why Arrow would continue this tactic well after the patent application was in fact published. Lastly, when the PTO revived the '198 patent in August 2006, it expressly held that it accepted Arrow's assertion that the failure to rescind the non-publication request had been unintentional. In the face of this circumstantial evidence suggesting inadvertence, Spire has presented *no* evidence which would indicate that Arrow's failure to notify the PTO was based on deceptive intent. Because no reasonable factfinder could conclude that there is clear and convincing evidence of Arrow's intent to deceive the PTO regarding the foreign patent applications, I will grant Arrow's summary judgment motion on this counterclaim.

4. '198 Priority Date and the Cannon Catheter

Spire's third counterclaim for inequitable conduct alleges

that the patentees repeatedly misled the PTO examiner about the proper priority date for the '198 patent application, thereby enabling them to withhold material prior art concerning offers for sale and public uses of the Cannon Catheter.

a. Motion to Amend

Because this third inequitable conduct counterclaim does not appear in Spire's original Answer and Counterclaim, I must resolve Spire's motion to amend its pleadings (Dkt. No. 30) before addressing the merits.[13] Under Fed. R. Civ. P. 15(a)(2), a court should freely give leave for a party to amend its pleadings "when justice so requires." The court may, however, deny a motion to amend for an adequate reason, such as undue delay, bad faith or prejudice. *See Carmona* v. *Toledo*, 215 F.3d 124, 136 (1st Cir. 2000). When a party moves to amend after the close of discovery, and after motions for summary judgment have been docketed, "the proposed amendment must be not only theoretically viable but also solidly grounded in the record [and] . . . supported by substantial evidence." *Hutchins* v. *Zoll Med. Corp.*, 430 F. Supp. 2d 24, 37 (D. Mass. 2006) (alteration in original) (*quoting Watson* v. *Deaconess Waltham Hosp.*, 298 F.3d 102, 109 (1st Cir. 2002)).

According to Spire, this counterclaim was not filed earlier primarily because the pertinent evidence concerning the Cannon

[13] I note that I will grant Spire's motion to file a reply brief (Dkt. No. 47) in support of its motion to amend.

Catheter was difficult to locate among the unordered and unindexed documents produced by Arrow. It may be true that with greater diligence Spire could have discovered the basis for this counterclaim earlier in the proceedings and filed a more timely motion to amend. Nevertheless, I find that Spire's proposed counterclaim has sufficient evidentiary support to warrant a finding on the merits, and in the interests of justice and the absence of any significant prejudice to Arrow, I will grant the motion to amend.[14]

b. Alleged Misrepresentations and Omissions

According to Spire's third counterclaim, the patentees breached their duty of candor to the PTO in two related ways. First, Spire alleges that the patentees misled the PTO examiner regarding the proper priority date for the '198 patent application. As a general rule, the filing date of an application will determine the scope of the prior art that an examiner will consider in evaluating whether an application should be rejected on grounds of anticipation or obviousness. Of

[14] In addition, I reject Arrow's contention that Spire's proposed counterclaim fails to satisfy Fed. R. Civ. P. 9(b). Arrow objects that Spire refers to the '198 patent inventors as "the patentees" in its proposed counterclaim, rather than identifying them by name. Given that there is no dispute as to the identify of the '198 patent applicants, I find no merit to this objection. *See MedImmune, Inc.* v. *Centocor, Inc.*, 271 F. Supp. 2d 762, 772 (D. Md. 2003) (holding that specifying the persons responsible for inequitable conduct as "the applicants" satisfied the particularity pleading requirements of Fed. R. Civ. P. 9(b)), *vacated on other grounds*, 549 U.S. 1163 (2007).

particular relevance to this case, the prior art includes any invention that was offered for sale or in public use more than one year before the application's filing date. *See* 35 U.S.C. § 102(b); *see also In re Kaslow*, 707 F.2d 1366, 1374 (Fed. Cir. 1983). There are, however, circumstances where patent applicants may take advantage of the filing date from an earlier application. *See* 35 U.S.C. § 120. A "continuation" application, which includes only matters already disclosed by an earlier application, is entitled to claim the filing date of its parent application. Manual of Patent Examining Procedure ("MPEP") § 201.07. A "continuation-in-part" application, which includes some matters disclosed by an earlier application and some new matters, will have different priority dates for different claims. Claims supported by the parent application are entitled to use the parent application's filing date; claims based on new matters must use the filing date of the continuation-in-part application. MPEP § 201.11.

When the Diatek inventors filed the '198 patent application on August 30, 2002, they claimed the priority date of an application filed on January 24, 2001. The '198 application was filed as a "continuation-in-part" application; it included some matters that had been disclosed by the January 24, 2001 application and some new matters. On February 2, 2004, at the suggestion of the PTO examiner, the patentees amended the '198 application to remove all but eight claims. As Arrow now

acknowledges, the remaining claims *all* contained matter that had not been disclosed by the parent application, meaning that none of them were entitled to the January 24, 2001 priority date. At the time the patentees made the amendment, however, they did not inform the examiner that the remaining claims were not entitled to the earlier date. Furthermore, in subsequent filings to the examiner, the patentees continued to indicate that January 24, 2001 was the proper priority date. For example, on February 13, 2004, the patentees filed an amendment to correct typographical and grammatical errors which retained a reference to the earlier filing date. On March 3, 2004, the patentees filed an Information Disclosure Statement that notified the examiner of prior art from "before Jan. 2000," once again implicitly reinforcing their assertion of the January 24, 2001 priority date.

The second aspect of the patentees' alleged breach of their duty of candor was their failure to inform the PTO examiner of certain activities related to the Cannon Catheter, a product that Diatek itself had developed. During the summer of 2001, Diatek representatives communicated with several distributors of medical devices to discuss potential contracts for selling the Cannon Catheter. In mid-August 2001, two doctors working with Diatek - Drs. John Ross and Sanford Altman - performed implantations of the Cannon Catheter in hospital patients. Both of these

activities occurred more than one year before August 30, 2002, the date the '198 patent application was filed. According to Spire, these activities qualified the Cannon Catheter as prior art which was potentially invalidating to the '198 application. Spire alleges that by claiming an improper early priority date, the patentees were able to avoid disclosing these activities to the PTO.

c. Materiality

I first consider whether the evidence presented by Spire concerning these allegations meets the "materiality" prong of the inequitable conduct test. With respect to false or misleading statements about a patent application's priority date, the Federal Circuit has held:

> It is not necessary for a holding of inequitable conduct that an examiner rely on a claim for priority or that entitlement to an earlier priority be expressly argued in order to overcome prior art. . . . A claim for priority is inherently material to patentability because a priority date may determine validity, whether an issue arises in prosecution or later in court challenges to validity.

Nilssen v. *Osram Sylvania, Inc.*, 504 F.3d 1223, 1233 (Fed. Cir. 2007); *see also Li*, 231 F.3d at 1380 ("[I]nformation regarding the effective filing date is of the utmost importance to an examiner. Consequently, an applicant's misrepresentation that he is entitled to the benefit of an earlier filing date is highly material.").

Arrow has relied heavily on *Purdue Pharma L.P.* v. *Boehringer Ingelheim GmbH*, 237 F.3d 1359 (Fed. Cir. 2001), to argue that there was nothing improper about the patentees' asserted priority date. According to Arrow, *Purde Pharma* stands for the principle that so long as the *specifications* of a later filed patent application substantially incorporate the *specifications* of an earlier filed application, a claim of priority to the earlier application is "properly founded," even if the later patent's *claims* are not entitled to that priority date. I do not read *Purdue Pharma* to endorse such a broad principle. The court in *Purdue Pharma* noted expressly that the examiner in that case had "himself recognized that the claims of the [later] patent were based on additional disclosure not presented in the [earlier patent], which suggests that the examiner did not assume that the claims are entitled to the priority date of the [earlier patent]." *Id*. at 1367 (internal quotation omitted). In this case, there was no similar indication that the PTO examiner recognized the remaining claims in the '198 patent were not entitled to the earlier priority date. In fact, the examiner's failure to correct the patentees when they made subsequent filings referring to the January 24, 2001 priority date is evidence that the examiner did *not* realize the error. Furthermore, in *Purdue Pharma,* the court found the improper priority date did not ultimately limit the prior art considered

by the examiner. In this respect, the court distinguished another Federal Circuit case by noting, "[W]e are not faced with a situation like that . . . where the applicant made an invalid priority claim to overcome an intervening reference." *Id*. That situation is precisely what has been alleged in this case with respect to the Cannon Catheter activities.

Arrow has also contended that even if the January 24, 2001 priority date was improper, the patentees' failure to clarify the issue was not a material misrepresentation. According to Arrow, the patentees had no affirmative obligation to inform the examiner that the remaining '198 patent claims were not entitled to the earlier filing date because the MPEP instructs *examiners* to inform *applicants* when "the claims in the later-filed application are not entitled to the benefit of an earlier filing date." MPEP § 201.11. In other words, because the examiner had an independent duty to verify the priority date, the patentees' failure affirmatively to raise the issue was immaterial. The Federal Circuit has considered and rejected a similar argument. In *KangaROOS*, the court explained:

> If the claim for priority met the elements of fraud . . . lapse on the part of the examiner does not excuse the applicant. . . . There is no reprieve from the duty of square dealing and full disclosure that rests on the patent practitioner in dealings with the PTO. We agree with the district court that this duty is not done by one who knowingly takes advantage of an error by the PTO.

778 F.2d at 1576.

Finally, Arrow has argued that any misrepresentations regarding the priority date were immaterial because the Cannon Catheter activities the patentees failed to disclose would not, in any event, have constituted invalidating prior art. According to Arrow, this is because: (1) the patentees' discussions with potential distributors did not constitute "offers for sale," and the doctors' implantations of the Cannon Catheter did not constitute "public use"; and (2) the Cannon Catheter was cumulative of Diatek's '242 patent, which *was* before the examiner during the prosecution of the '198 patent.

I find that both these arguments fail. First, regardless of whether the Cannon Catheter activities were actually invalidating, it is clear that a reasonable examiner would have considered evidence pertaining to them pertinent in evaluating the '198 patent application.[15] *See Li*, 231 F.3d at 1380 ("[T]he test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability."). Second, disclosure of the Cannon Catheter activities would not have been cumulative of the '242 patent because the '242 patent could not

[15] In any event, as discussed at greater length in Section III.B.2.c, *infra*, in the context of obviousness, I find that the hospital procedures by Drs. Ross and Altman *did* constitute "public use" of the Cannon Catheter.

itself have been invalidating prior art for the '198 patent application. Under 35 U.S.C. § 102(e), a patent or patent application will only constitute prior art if it was filed "by another"; in this case, the '242 patent and the '198 patent were filed by the same inventors. Finally, the patentees' misrepresentations concerning the proper priority date were *themselves* inherently material, whether or not any pertinent prior art was withheld or excluded in reliance on them. *See Nilssen*, 504 F.3d at 1233. For these reasons, I find that any reasonable factfinder must conclude that there is clear and convincing evidence the patentees made material misrepresentations and omissions to the examiner.

d. Intent to Deceive

Spire contends that the patentees' intent to deceive the PTO can be inferred from the totality of the patentees' conduct. According to Spire, this conduct includes:

> (1) the choice of secret examination when they were not entitled it, (2) the assertion (and maintenance throughout prosecution) of a false priority claim, (3) the submission of information disclosure statements that suggested the criticality of an earlier date for 102(b) purposes, and (4) the failure to disclose the commercialization of the Cannon Catheter during the '198 patent prosecution despite disclosure of this information in several related co-pending applications.

I find, however, that the evidence presented by Spire, even taken together, fails to raise a genuine issue of material fact as to

the patentees' intent to deceive.

First, I note that there is no evidence the patentees were not entitled to file a non-publication request with the '198 patent application - what Spire refers to as a "secret examination." The problem with the non-publication request arose only later when Arrow, after purchasing rights to the '198 patent application, filed for foreign patents without first notifying the PTO. As discussed above, there is no evidence to indicate that Arrow's failure to rescind the non-publication request prior to filing these foreign applications involved deceptive intent.

Second, there is no evidence in the record to suggest that the patentees' misrepresentations concerning the priority date involved deceptive intent. It is undisputed that when the '198 patent was initially filed as a continuation-in-part patent, it was entirely proper for the patentees to cite the January 24, 2001 filing date of the parent application. It was only after the application was amended, at the examiner's request, that the earlier priority date ceased to be applicable. This does not excuse the patentees' failure to clarify the issue with the examiner, nor does it diminish the materiality of their subsequent misrepresentation. Standing alone, however, the mere failure to disclose material information does not provide clear and convincing evidence of an intent to deceive. *See Star Scientific*, 537 F.3d at 1366 ("[M]ateriality does not presume

intent.") (internal quotation omitted).

In cases where the Federal Circuit has upheld findings of inequitable conduct for misrepresenting priority dates, there has been at least some other circumstantial evidence of deceptive intent. *See, e.g., Nilssen*, 504 F.3d at 1233 (patentees' contemporaneous letters supported finding deceptive intent); *Li*, 231 F.3d at 1381 (additional misleading statements during prosecution of the patent supported a finding of deceptive intent). Spire argues that the patentees' failure to disclose the Cannon Catheter activities provides such evidence in this case. It is true that the patentees could not properly have withheld these activities from the examiner merely because they did not believe them to constitute prior art under 35 U.S.C. § 102(b). *See LaBounty Mfg., Inc.* v. *U.S. Int'l Trade Commission*, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("Close cases should be resolved by disclosure, not unilaterally by the applicant."). However, the Cannon Catheter evidence does not provide evidence of deception *independent* of the incorrect priority date. After all, if January 24, 2001 had remained the proper priority date, the patentees would have had no reason to submit evidence of activities that occurred half a year later. If anything, the fact that Diatek submitted evidence of Cannon Catheter activities to the PTO for *other* patent prosecutions where the priority date was more clearly established - including for a continuation

application based on the ‘198 patent - suggests that the failure to submit it in this case did not involve deceptive intent.

In order to meet the “clear and convincing” evidence standard with regard to deceptive intent, the party alleging inequitable conduct must show that an inference of deceptive intent is “the single most reasonable inference able to be drawn from the evidence.” *Star Scientific*, 537 F.3d at 1366. I find that no reasonable factfinder could conclude that the evidence in this case meets that standard. I will therefore grant summary judgment to Arrow as to Spire’s third counterclaim.

B. Invalidity

Spire also moves for summary judgment on grounds that the ‘198 patent is invalid under the Patent Act. Under 35 U.S.C. § 282, the Patent Act presumes validity and places the burden on a challenging party to show by clear and convincing evidence that a patent is invalid. *See Mas-Hamilton Group* v. *LaGard, Inc.,* 156 F.3d 1206, 1216 (Fed. Cir. 1998). Once the challenging party has offered a *prima facie* case of invalidity, the party supporting validity has the burden to present contrary evidence, but the ultimate burden of persuasion remains on the challenging party. *Id.* Spire argues that the ‘198 patent is invalid because: (1) it is fully anticipated by a single prior art reference, and (2) it is rendered obvious by a combination of several prior art references.

1. Anticipation

a. Legal Standard

It is a fundamental principle of patent law, codified at 35 U.S.C. § 102, that patent claims must be novel. *See In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1377 (Fed. Cir. 2007). Although § 102 refers to "the invention" as a whole, the novelty inquiry generally proceeds on a claim-by-claim basis. *See Finisar Corp.* v. *DirectTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). A claim is "anticipated," and therefore lacking in novelty, only if "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *SRI Int'l, Inc.* v. *Internet Sec. Sys.*, 511 F.3d 1186, 1192 (Fed. Cir. 2008) (*quoting Verdegaal Bros., Inc.* v. *Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

A prior art reference may anticipate a claim even when the relevant properties of the subject matter disclosed in the reference were not appreciated at the time. *See Abbott Labs.* v. *Baxter Pharm. Prods., Inc.*, 471 F.3d 1363, 1367 (Fed. Cir. 2006). Anticipation does require, however, that the prior reference "be sufficiently enabling to place the information in the possession of the public." *Omeprazole,* 483 F.3d at 1378. This means that the reference "must teach one of ordinary skill in the art to make or carry out the claimed invention without undue

expiramentation." *Elan Pharms., Inc.* v. *Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003) (internal quotation omitted).[16]

Anticipation of a patent claim is a question of fact, but it may properly be decided on summary judgment if the record reveals no genuine issues of material fact. *See Golden Bridge Tech., Inc.* v. *Nokia, Inc.*, 527 F.3d 1318, 1321 (Fed. Cir. 2008). The party challenging the validity of the claim must prove anticipation by clear and convincing evidence. *See Scripps Clinic & Research Found.* v. *Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). The question of what is disclosed by a prior art reference is also a question a fact. *See Golden Bridge,* 527 F.3d at 1323. A court may rely on extrinsic sources to explain

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[16] Spire, relying on *Kalman* v. *Kimberly-Clark Corp*., 713 F.2d 760 (Fed. Cir. 1983), argues that a prior art reference may anticipate patent claims for purposes of 35 U.S.C. § 102 even if the reference does not "teach" the content of those claims. In fact, *Kalman* held that "[t]he law of anticipation does not require that the reference 'teach' what the subject patent *teaches*." *Id*. at 772 (emphasis added). Contrary to what Spire contends, the *Kalman* court was emphasizing that a prior art reference will anticipate patent claims under § 102 - even if it does not disclose everything that the subject patent *teaches* - so long as it discloses everything the subject patent *claims*. *Cf. MEHL/Biophile Int'l Corp.* v. *Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999) ("[The prior art] cannot anticipate because it does not *teach* all the limitations of the *claimed* invention.") (emphasis added).

I note that *Kalman* did not expressly analyze the degree of disclosure in the prior art necessary to constitute "teaching" the subject patent's claims. There is ample authority, however, that anticipation requires the prior art reference, at a minimum, to "teach" the claimed subject matter sufficiently to enable one skilled in the art to make or carry out the invention. *See, e.g., Elan Pharms., Inc.* v. *Mayo Found.*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

the meaning of the disclosures in a potentially anticipatory reference. *See In re Baxter Travenol Labs*, 952 F.2d 388, 390 (Fed. Cir. 1991). Such evidence, however, should be used only "to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill gaps in the reference." *See Scripps*, 927 F.2d at 1576.

b. The Schon Patent

Spire contends that claims 1-3 of the '198 patent are invalid because they were fully anticipated by U.S. Patent No. 6,682,519 (filed June 1, 2000) ("the Schon Patent"). The Schon patent claims a method for implanting a double catheter assembly into a patient for the purpose of conducting hemodialysis. In one embodiment of the Schon patent, the method is conducted with a "self-retaining" catheter assembly, where two individual catheters are "permanently or adjustably linked in one location along their length by a retaining sleeve." (Schon Patent col.2 ll.50-53.) The Schon patent indicates that the preferred catheter assembly of this type is the SchonCath, which is described in U.S. Patent No. 5,718,692.[17] The Schon patent also

[17] Spire submitted an exhibit of an AngioDynamics trade brochure from November 1998 that depicts the SchonCath. To the extent that this document was, as Arrow argues, insufficiently authenticated initially for consideration on summary judgment - *see* Fed. R. Civ. P. 56(e) - I find that the Nimkar Declaration filed with Spire's Reply Brief has adequately eliminated these concerns. *See McIntosh* v. *Partridge*, 540 F.3d 315, 322 n.6 (5th Cir. 2008). Furthermore, I find that the SchonCath is incorporated-by-reference in the Schon patent such that the

explains, however, that "the invention can be performed using substantially any known multiple catheter assembly." (Schon Patent col.6 ll.12-15.)

The method of implantation described in the Schon patent includes many of the same elements present in the challenged claims of the '198 patent. Like the '198 patent, the Schon patent discloses a retrograde catheter placement method, in which the proximal[18] end of the catheter is first inserted in a patient's blood vessel, and then the distal end is guided through one or more subcutaneous tunnels to a remote exit point, where it is secured to the patient and connected to a hemodialysis machine. In order to show that the Schon patent is an anticipatory reference, however, Spire must present clear and convincing evidence that it teaches each and every limiting element of the challenged '198 patent claims, including both

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patent and the device may be viewed as a single source for purposes of anticipation. *See Advanced Display Sys., Inc.* v. *Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000) ("Incorporation by reference provides a method for integrating material from various documents into a host document - a patent or printed publication in an anticipation determination - by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein.").

[18] The Schon patent refers to the end of the catheter assembly inside the patient as the "distal" end and the end connected to the hemodialysis machine as the "proximal" end. For the purpose of consistency in this Memorandum and Order, however, I have used these terms as they are defined in the '198 patent. *See* note 3, *supra.*

structural elements and steps of the implantation method. *See SRI,* 511 F.3d at 1192. I find that Spire has provided insufficient evidence of anticipation for at least three elements of the challenged '198 patent claims.

First, Spire has not sufficiently shown that the Schon patent teaches a *single tunnel* retrograde placement technique, as is claimed in the '198 patent claims 1(c) and 1(d). ('198 Patent col.11 ll.23-31.) It is true that claim 7 of the Schon patent describes guiding the distal end of the catheter assembly through "at least one subcutaneous tunnel." (Schon Patent col.16 ll.32.) By its plain language this claim clearly *contemplates* the use of a single tunnel. There is, however, a genuine issue of material fact as to whether the Schon patent would adequately enable a person of ordinary skill in the field to perform a single tunnel placement method with a multiple catheter assembly. The Schon patent's preferred implantation method uses two separate tunnels, and that is the only method described in the patent's specifications or illustrated in the accompanying diagrams. According to Arrow's expert, Dr. Karim Valji, inserting two catheters in the same tunnel is more difficult than using a two tunnel method, and it poses the additional risk that the second catheter to be placed will damage the first catheter.

A prior art reference lacking in specificity may nonetheless be enabling, and therefore anticipatory, if an ordinary skilled

artisan in the relevant field would have been aware of the missing information. *See In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995) ("A reference anticipates a claim if it discloses the claimed invention 'such that a skilled artisan could take its teachings in *combination with his own knowledge of the particular art and be in possession of the invention*.'") (*quoting In re LeGrice*, 301 F.2d 929, 936 (C.C.P.A. 1962) (emphasis in original)). The Schon patent could therefore be anticipatory if an ordinary skilled artisan in the field of catheter implantation would have known how to overcome the peculiar difficulties of single tunnel implantation. Spire points to a 1998 article ("the Canaud Article") published two years prior to the Schon patent application, where Dr. Canaud of the Lapeyronie University Hospital in France reports that he successfully implanted patients with multiple catheter assemblies 738 times using a single tunnel method. The Canaud Article does not, however, describe the method used by Dr. Canaud in any detail,[19] nor does it offer any guidance as to how Dr. Canaud overcame the difficulties of single tunnel implantation identified by Dr. Valji. The Canaud Article cannot, therefore, serve as an extrinsic source for interpreting claim 7 of the Schon Patent. *See Baxter,* 952 F.2d at 390 ("[E]xtrinsic evidence may be

[19] The article indicates that the method of insertion is "described in detail elsewhere," but it does not provide a reference for any such description.

considered when it is used to explain, but not expand, the meaning of a reference."). Furthermore, the large number of placements performed by Dr. Canaud is not, in and of itself, sufficient evidence to show clearly and convincingly that an ordinary skilled artisan in the field would have known how to perform the method. A genuine issue of material fact therefore remains as to whether the Schon patent is enabling with respect to the single tunnel implantation method.

Second, Spire has not sufficiently shown that the Schon patent teaches a method for implanting a "multi-lumen catheter including an elongated, central, multi-lumen tube portion," as claimed in the preamble of the '198 patent claim 1.[20] ('198 Patent col.11 ll.9-17.) There is an identifiable difference between a "multiple catheter assembly," as claimed in the Schon patent, and a "multi-lumen catheter," as claimed in the '198 patent. The former term describes two or more distinct catheter tubes that are used in conjunction with one another. The latter term describes a single catheter tube that is further subdivided into multiple chambers, or "lumens." The prior art in this case suggests that the terms are not interchangeable, as other patents consistently use each term to refer to a particular type of

[20] The preamble of the '198 patent claim 1 is limiting with respect to the catheter structure it describes. Claim Construction Order, 2006 WL 3093228, at *6.

catheter device.[21] Thus, the assertion by one of the '198 patent inventors that "[i]n the catheter business . . . [t]wo or more single lumen catheters would not be considered to be a multilumen catheter," appears to be accurate.

The catheter assembly described in the Schon patent is essentially two catheters bonded together by use of a retaining sleeve. In the preferred method, these catheters are permanently linked, preferably so that they are "touching." (Schon Patent col.9 ll.29-30.) Unlike the '198 patent, the Schon patent does not disclose a catheter with multiple lumens that are both physically part of the same tube. The Schon patent does make a passing reference to "multi-lumen catheters," indicating that in some embodiments of the invention "they could also be positioned within the retaining sleeve . . . [and] drawn out of the body through two or more subcutaneous areas." (Schon Patent col.6 ll.60-63.) This passage, however, refers to affixing two or more multi-lumen catheters together with a sleeve, rather than to the use of a single catheter with a central multi-lumen portion. Although Spire minimizes the "multiple catheter" versus "multi-

[21] For references that describe "multiple catheter assemblies," see U.S. Patent No. 5,624,413 col.1 ll.1-2 (the Markel patent); U.S. Patent No. 5,776,111 col.1 l.1 (the Tesio patent); U.S. Patent No. 6,682,519 col.1 ll.1-2 (the Schon patent). For references that describe "multi-lumen catheters," see U.S. Patent No. 6,001,079 col.1 l.1 (the Pourchez patent); U.S. Patent No. 6,638,242 col.1 l.1 (the Cannon Catheter patent); U.S. Patent No. 6,872,198 col.1 ll.1-2 (the '198 patent).

lumen catheter" distinction as a mere manufacturing technicality, it has not shown by clear and convincing evidence that the catheter claimed in the '198 patent would be covered by the catheter assembly disclosed in the Schon patent, and a genuine issue of fact therefore remains as to anticipation on this element.

Third, even if the "retaining sleeve" used in the Schon patent could accurately be described as an "elongated, central, multi-lumen tube portion," Spire has not sufficiently shown that the Schon patent teaches "guiding" at least a portion of the sleeve "through" the subcutaneous tunnel, as is claimed in the '198 patent claim 1(d). ('198 Patent col.11 ll.26-28.) In the '198 patent, the central elongated portion of the catheter is designed to move freely through the tunnel in order to complete the retrograde placement method. (*Id.*) In the Schon patent method, by contrast, the sleeve portion is designed to be wide enough that it acts as a "plug" that "prevent[s] the retaining sleeve from passing into the vein or other area to be catheterized." (Schon Patent col.9 ll.41-43.) Spire has argued that it is inherent to the Schon patent method that at least a portion of the retaining sleeve will actually move into the subcutaneous tunnel. Both Dr. Valji, Arrow's expert, and Dr. Romano, Spire's expert, agree that this is true. The illustrative diagram in the Schon patent, however, shows the

sleeve is intended to remain primarily *outside* the subcutaneous tunnel in a "recessed area." (Schon Patent Fig. 5.) Spire has failed to demonstrate clearly and convincingly that the possibility that a portion of the sleeve will move into the entrance of the subcutaneous tunnel to "plug" the tunnel is anticipatory of the '198 patent claim of "guiding" the central portion of the catheter "through" the tunnel. ('198 Patent col.11 ll.26-28.)

For these three basic reasons, I find that genuine issues of material fact remain as to whether the Schon patent anticipates the '198 patent.[22]

2. Obviousness

a. Legal Standard

Even if an invention has not been fully anticipated by a

[22] Arrow also claims that the Schon patent fails to anticipate the '198 patent claim that the central portion of the catheter be "elongated." Construction of this term was not raised in the hearing that led to the Claim Construction Order, 2006 WL 3093228. To the extent that construction of this term is necessary, I would be inclined to find that the "ordinary and customary meaning" of the term "elongated" in the context of describing a physical object is "stretched out" or "having a form notably long in comparison to its width." *See Webster's Third New International Dictionary* at 737 (second definition). Under this definition, I would find that the Schon patent does cover multiple catheter assemblies with "retaining sleeves" that are "elongated." The SchonCath, for example, has a retaining sleeve that is proportionally much longer than it is wide. Because Spire has provided insufficient evidence of anticipation for several other elements of the '198 patent, however, I decline to make a formal finding with regard to the claim construction of "elongated."

single prior reference, a patent will be invalid if the claimed invention is otherwise "obvious" in light of the prior art. Under 35 U.S.C. § 103(a), an invention is obvious "if the differences 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." *See DyStar Textilfarben GmbH & Co.* v. *C.H. Patrick Co.,* 464 F.3d 1356, 1360 (Fed. Cir. 2006). As with anticipation, the party challenging the validity of the patent bears the burden of establishing obviousness by clear and convincing evidence. *Pharmastem Therapeutics, Inc.* v. *Viacell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

Obviousness is a question of law based on underlying questions of fact. *Daiichi Sankyo Co., Ltd.* v. *Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). The testimony of experts in the relevant field will often be of assistance to a judge, but the decision must ultimately be made by the court, and there is no categorical rule requiring the input of experts. *See Petersen Mfg. Co.* v. *Central Purchasing, Inc.*, 740 F.2d 1541, 1548 (Fed. Cir. 1984) (holding that summary judgment on grounds of obviousness did not require a supporting expert's opinion); *Seattle Box Co., Inc.* v. *Indus. Crating & Packing, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984) ("A trial judge has sole discretion to

decide whether or not he needs, or even just desires, an expert's assistance to understand a patent.").

In *Graham* v. *John Deere Co.,* 383 U.S. 1 (1966), the Supreme Court set out a framework for determining whether a patent should be invalidated on the basis of obviousness. The Court identified three factors that must be considered: (1) "the scope and content of the prior art," (2) "differences between the prior art and the claims at issue," and (3) "the level of ordinary skill in the pertinent art." *Id.* at 17.[23] The Court further added that certain objective indicia of obviousness or nonobviousness such 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.* at 17-18. The Court recently reaffirmed the *Graham* framework in *KSR International Co.* v. *Teleflex Inc.*, 550 U.S. 398 (2007), emphasizing that the inquiry should reflect "an expansive and flexible approach." *Id.* at 415.[24]

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[23] The Supreme Court has indicated that "the sequence of these questions might be reordered in any particular case." *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 407 (2007).

[24] The Supreme Court in *KSR* criticized the Federal Circuit for applying the so-called "teaching, suggestion, or motivation" test ("TSM test") too rigidly. The TSM test permitted a finding of obviousness only where the challenging party could prove that some motivation or suggestion to combine the prior art teachings could be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art. *KSR*, 550 U.S. at 407.

The Court in *KSR* further observed that a principal reason for the rule of obviousness was to prevent the issuance of patents for "combination[s] of familiar elements according to known methods" which "do[] no more than yield predictable results." *Id.* at 416. The Court explained that "a patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." *Id.* at 415-16 (alteration in original) (*quoting Great Atlantic & Pacific Tea Co.* v. *Supermarket Equipment Corp.*, 340 U.S. 147, 152 (1950)). The Court warned, however, that in evaluating patents that combine diverse elements a factfinder "should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning." *Id.* at 421.

b. The Level of Ordinary Skill

Spire has presented no evidence directly addressing the level of ordinary skill in the pertinent art, other than to assert conclusorily that "[a] person of ordinary skill in this art is one who understands catheter structures, the methods of implanting such catheters, and the demands of hemodialysis." Arrow objects that this conclusory assertion is insufficient in the absence of expert testimony. In some circumstances, however, the prior art itself provides sufficient guidance as to the

appropriate level of ordinary skill in the art, so that an expert's testimony on the issue is unnecessary for a *Graham* inquiry. *See Chore-Time Equipment, Inc.* v. *Cumberland Corp.*, 713 F.2d 774, 779 n.2 (Fed. Cir. 1983) ("[A]n invention may be held to have been either obvious (or nonobvious) without a specific finding of a particular level of skill or the reception of expert testimony on the level of skill where, as here, the prior art itself reflects an appropriate level and a need for such expert testimony has not been shown."). I find that in this case, the prior art relating to hemodialysis catheters and their methods of implantation sufficiently reveals the appropriate level of skill, and there is therefore no need for expert testimony to define an appropriate level.

c. Whether the Cannon Catheter is Prior Art

Before examining the full scope and content of the prior art in this case, I must first address the parties' dispute over whether the Cannon Catheter is properly included among the prior art for the '198 patent.[25] The Cannon Catheter is a multi-lumen catheter developed by Diatek in 2001. Its instructions disclose

[25] At the November 12, 2008 summary judgment hearing, I re-opened discovery with respect to the issue of whether the Cannon Catheter constituted prior art for the '198 patent. Since that time, the parties have conducted discovery and submitted supplemental briefs addressing this issue. I note that there is no dispute as to whether the other materials submitted by the parties as prior art in this case may properly be considered for purposes of an obviousness analysis.

a retrograde implantation technique that is substantially identical to the method disclosed in the '198 patent. The Cannon Catheter's physical structure, however, differs slightly from the catheter structure disclosed in the '198 patent. Unlike the '198 patent catheter, the Cannon Catheter consists of two pieces: first, a single Y-shaped catheter with a split-tipped proximal end, and second, a hub assembly with two connector tubes, which is attached to the catheter's distal end after the tunneling process is complete.

An invention that is on sale or in public use more than one year prior to the filing of a patent application, under 35 U.S.C. § 102(b), constitutes "prior art" that may support an obviousness rejection under 35 U.S.C. § 103. *Kaslow*, 707 F.2d at 1374. A single offer for sale or a single public use is sufficient to qualify as being "on sale" or "in public use" for purposes of the Patent Act. *See Spalding & Evenflo Cos., Inc.* v. *Acushnet Co.*, 718 F. Supp. 1023, 1038 (D. Mass. 1989); *Sys. Mgmt. Arts Inc.* v. *Avesta Techs., Inc.*, 87 F. Supp. 2d 258, 268 (S.D.N.Y. 2000). Spire contends that prior to August 30, 2001, the critical date for the '198 patent, the Cannon Catheter was both on sale and in public use.

i. Was the Cannon Catheter on sale?[26]

According to Spire, Diatek's dealings with several medical device distributors prior to the critical date were sufficient to place the Cannon Catheter "on sale" within the meaning of § 102(b). For a product to be "on sale" under the statute: (1) it must be ready for patenting and (2) it must be the subject of a commercial offer for sale. *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). There is no dispute as to the first prong; by February 2001, the design for the Cannon Catheter was sufficiently complete that Diatek filed for FDA approval. With respect to the second prong, a commercial offer for sale is "one which the other party could make into a binding contract by simple acceptance (assuming consideration)." *Group One, Ltd.* v. *Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001). The Federal Circuit has explained that "[t]o determine if the offer is sufficiently definite, one must examine the language of the proposal in accordance with the principles of general contract law." *Scaltech, Inc.* v. *Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001). A sale to a distributor will satisfy § 102(b)

[26] At the summary judgment hearing and in earlier briefing, Spire contended that Diatek had completed a sale for the Cannon Catheter on September 4, 2001, several days after the critical date of August 30, 2001. In light of additional discovery undertaken by the parties after the hearing, it is now undisputed that the Diatek sales invoice from September 4, 2001, was for a sale of biological test data, and there was no sale of the Cannon Catheter on that date.

just as would a sale to a consumer of the product. *See Brasseler U.S.A. I, L.P.* v. *Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985).

Spire first contends that Diatek's agreement that Classic Medical would be the primary distributor of the Cannon Catheter constituted a commercial offer for sale. Classic Medical was owned by Carl Fleming, Gary Fleming, and Ronald Boyd, who were also three of the five co-founders of Diatek.[27] According to Jon Wilson of Diatek, there was an understanding from "day one" that Classic Medical would act as a distributor for the Cannon Catheter. Wilson testified at his deposition that the terms of this arrangement were resolved at least in principal "early in the process" and that by June 2001, Diatek had established a special favorable discount rate for Classic Medical.[28]

There is very little evidence, however, regarding what

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[27] Although Arrow argues that the Diatek inventors merely made a distribution agreement "amongst themselves," the overlapping roles of the Flemings and Boyd do not prevent dealings between Diatek and Classic Medical from constituting commercial sales. *See Brasseler U.S.A. I, L.P.* v. *Stryker Sales Corp.*, 182 F.3d 888, 890-91 (Fed. Cir. 1999) (finding a commercial sale where the buyer and seller were "separate in a corporate sense," even though they had been joint developers of the product in question and had kept the sales activity secret from the public); *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985) (finding a sale to be "between two separate entities," even where those entities shared a common owner).

[28] Spire has also filed several pages of handwritten notes by Kenneth Todd Cassidy from early 2001, which refer vaguely to a "sales plan" involving Classic Medical. I find the precise significance of these notes to be unclear.

specific terms were defined with respect to this agreement. For example, there is no indication that either party agreed to buy or sell a particular quantity of catheters; nor was there any agreed-upon process by which the quantity would be determined. Furthermore, there is no direct evidence of any particular price that Diatek identified for Classic Medical's purchase of the Cannon Catheters. I find Diatek's general agreement to offer a favorable discount rate to Classic Medical, without more, to be insufficient to provide clear and convincing evidence that Diatek intended to be bound to a commercial sale.

Spire also contends that Diatek's dealings with several other medical device distributors during the summer of 2001 constituted commercial offers for sale. By September 14, 2001, two weeks *after* the critical date, Diatek and four distributors had signed sales agreements with specific terms for pricing, territory, and initial stocking orders. Spire argues that for these contracts reasonably to have been completed by that time, Diatek must have begun discussing terms with the distributors prior to August 30, 2001. Arrow acknowledges that Diatek representatives were in fact in contact with the distributors several months before the critical date.

Similar to the situation with Classic Medical, however, there is very little evidence regarding the specific terms of Diatek's discussions with these distributors. Nor is there any

indication that Diatek intended to be bound by any particular offer prior to finalizing the contracts on September 14, 2001. Jon Wilson, who engaged in talks with potential distributors during the summer of 2001, characterized those talks as "preliminary discussion[s]." He summarized his message to the distributors as: "We have a new dialysis catheter. We are looking for distribution. It is going to be pretty much a standard deal." The Federal Circuit has distinguished between language that suggests a legal offer - such as "I offer" or "I promise" - and language that merely suggests preliminary negotiations - such as "I quote" or "are you interested." *Group One*, 254 F.3d at 1048; *see also Linear Tech. Corp.* v. *Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (holding that speaking to potential customers to determine an appropriate price does not constitute an offer for sale). Wilson's characterization places his talks with distributors into the latter category.

The only evidence suggesting that Diatek's dealings with distributors prior to the critical date involved more than preliminary inquiries is from Dennis Mills, owner of the Minnesota-based distributor Central Medical, Inc. Mills testified that he believed he discussed the specific terms of his distributorship agreement with Diatek "thirty to ninety days" before finalizing the agreement on September 14, 2001. Mills acknowledged, however, that he did not actually recall the

content of any specific conversations with Diatek; he was simply making an estimate based on his normal business practices. This is clearly an inadequate basis for Spire to meet its evidentiary burden for proving that there was an offer for sale.

For these reasons, I find that a reasonable factfinder would not be compelled to conclude that there is clear and convincing evidence the Cannon Catheter was "on sale" prior to the critical date.[29]

ii. Was the Cannon Catheter in public use?

Spire also contends that a series of Cannon Catheter implantations conducted by Drs. John Ross and Sanford Altman in mid-August 2001 constituted "public use" for purposes of § 102(b). On August 14, 2001, Diatek received FDA approval for the Cannon Catheter, permitting Diatek legally to market and sell the product. Two days later, on August 16, 2001, Dr. Ross performed the first implantation of the Cannon Catheter in a hospital patient. This procedure was attended by Kenneth Todd Cassidy,

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[29] Spire also argues the Cannon Catheter was "on sale" in August 2001 because Dr. Ross billed Medicare for the implantations he conducted on hospital patients. The only evidence Spire cites to support this contention are unauthenticated hospital records, which are inadmissible as hearsay on summary judgment. *See Hoffman* v. *Applicators Sales & Serv., Inc.*, 439 F.3d 9, 15 (1st Cir. 2006) (emphasizing "the crucial point that [unauthenticated] documents do not automatically become a part of the record simply because they are the products of discovery"). I therefore do not consider the hospital records in connection with the merits of the obviousness issue.

one of the Diatek inventors. The following day, August 17, 2001, Dr. Ross performed two more implantations; although Cassidy was not present, he later spoke with Ross about these procedures. On August 20, 2001, Dr. Altman placed three Cannon Catheters in patients, with Cassidy again in attendance. According to Cassidy, who had taken notes regarding these first six implantations, Diatek "had the answers that we wanted after doing the first cases." Dr. Ross subsequently performed nine more implantations prior to August 30, 2001. There were no Diatek representatives in attendance for any of these procedures. According to Ross, he made "regular" phone calls to Cassidy and Ron Boyd of Diatek to keep them "informed of [the] testing."

As a general matter, "[p]ublic use includes any use of [the claimed] invention by a

person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." *Netscape Commc'ns Corp.* v. *Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002) (internal quotation omitted). The Federal Circuit has held that the *Pfaff* test for determining whether an invention has been on sale applies equally to the question of public use. *See Invitrogen Corp.* v. *Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005). In the public use context, the two prongs of the inquiry are: (1) whether the invention was ready for patenting, and (2) whether the invention was accessible to the

public or commercially exploited. *Id*. at 1379-80. As noted above, there is no dispute in this case as to the first prong. In evaluating the second prong, the Federal Circuit has held that a court should consider: (1) "evidence relevant to experimentation," (2) "the nature of the activity that occurred in public," (3) "public access to the use," (4) "confidentiality obligations imposed on members of the public who observed the use," and (5) "commercial exploitation." *Id*. at 1380.

First, I consider evidence related to experimentation.[30] Arrow contends that Drs. Ross and Altman performed the Cannon Catheter implantations for the purpose of limited "experimental testing." In *Clock Spring, L.P.* v. *Wrapmaster, Inc.*, 560 F.3d 1317 (Fed. Cir. 2009), the Federal Circuit recently reiterated the longstanding principle that "something that would otherwise be a public use may not be invalidating [under § 102(b)] if it qualifies as an experimental use." *Id*. at 1326. *Clock Spring* recited an extensive list of thirteen factors that a court might consider in determining whether a particular use was "experimental." *Id*. at 1327. More fundamentally, the Federal Circuit emphasized that "[a] use may be experimental only if it

[30] The Federal Circuit has explained that evidence of experimental use may serve to negate *either* the "ready for patenting" or "public use" prong of the two-part *Pfaff* test. *Invitrogen Corp.* v. *Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379-80 (Fed. Cir. 2005). As noted above, I am concerned here only with the "public use" prong of that test.

is designed to (1) test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose." *Id*. The court added, "In other words . . . there is no experimental use unless claimed features or overall workability are being tested for purposes of the filing of a patent application." *Id*.

I find that the Cannon Catheter implantations in this case cannot be considered "experimental" for purposes of § 102(b). As an initial matter, by the time these procedures took place the invention had been reduced to practice in what was essentially its final form. According to Jon Wilson, one of the Diatek inventors, the Cannon Catheters used by Drs. Ross and Altman in August 2001 "had all of the components totally refined." As noted above, by August 14, 2001, the FDA had already approved the Cannon Catheter as being ready to be sold in the marketplace.[31] This alone does not mean that evidence of continuing experimentation would be irrelevant to the question of public use. For example, evidence that the Diatek inventors sought to make additional alterations to their prototypes during these

[31] Arrow has argued that even after receiving FDA approval, additional human testing was necessary to determine whether the product and method would be clinically viable. This overlooks the fact that in filing for FDA approval, Diatek asserted - and the FDA agreed - that the device could proceed directly to the market because it was "substantially equivalent . . . to legally marketed predicate devices." Cassidy himself acknowledged at his deposition that "[i]t was not a requirement for us to do any of that by any outside governing body, FDA, or anything like that."

early implantations could indicate that the use was not intended to be commercial or accessible to the public. *See Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, 516 F.3d 1361, 1369 (Fed. Cir. 2008) (Prost, J., concurring).

The evidence in the record, however, demonstrates that the use was not primarily experimental in nature. Diatek internally referred to the procedures as their "limited market release" of the Cannon Catheter. According to Cassidy, "[T]he whole purpose of them putting in these catheters was to just give us a comfort level. You know, to be there with the first catheters that were implanted and make sure there wasn't anything that we missed throughout the process of development. . . . It was our decision to do it internally, and it was our decision internally to say, 'The results are satisfactory. We can release the product and go forward with marketing.'" Cassidy noted that after the first six implantations, the inventors were satisfied. No one from Diatek witnessed any of the remaining nine implantations performed by Dr. Ross prior to August 30, 2001, and there is no evidence that the inventors received notes or formal reports about these procedures. Although Dr. Ross regularly called Cassidy and Boyd with updates of his work, it is clear that most of the implantations were performed without any meaningful control or supervision by the inventors.

Next, I consider the nature of the activity, the public

access to the use, and any confidentiality obligations imposed on those who witnessed the use. The nature of the activity in this case was a series of medical procedures performed on hospital patients. The individuals present included: the patient, the doctor, other necessary medical personnel, and, in a few cases, Kenneth Todd Cassidy of Diatek. The Federal Circuit has noted that medical procedures at a doctor's office or a hospital are to some extent inherently non-public. *See TP Labs, Inc.* v. *Prof'l Positioners, Inc.*, 724 F.2d 965, 972 (Fed. Cir. 1984) ("[I]t is beyond reasonable probability that a patient would show the device to others who would understand the function of the [invention] or would want to duplicate the device."). For this reason, the absence of strict confidentiality agreements in this setting is not alone determinative of public use. *Id*.

It is, nonetheless, significant that these procedures were conducted no differently than any other hospital procedure. Even if, as Arrow argues, Drs. Ross and Altman had a corporate fiduciary duty of confidentiality to Diatek, there is no evidence that any of the other medical personnel were informed that the catheters used for the procedures were still experimental and not publicly available. Nor were any of the patients asked to sign consent forms or otherwise informed that they were participating in experimental use of a medical product. As Dr. Ross explained, "Because the Cannon Catheter had been approved by the FDA before

I first used it, there were no special consent forms needed from the patients." In other words, the Cannon Catheter was used precisely as any other medical device of its type would be used on patients in a hospital. The fact that this use occurred in an inherently non-public environment does not by itself render the use non-public under § 102(b). *Cf. Egbert* v. *Lippmann*, 104 U.S. 333 (1881) (holding that the use of a corset spring device was "public" although the use was, by its nature, not visible to the general public).

Finally, I consider the evidence of commercial exploitation. In some respects, this factor leans against a finding of public use. Drs. Ross and Altman received the Cannon Catheters for free and did not charge their patients for them.[32] On the other hand, there is evidence that these early implantations served a valuable marketing purpose for Diatek. Jon Wilson acknowledged that in addition to their roles in developing the Cannon Catheter, Drs. Ross and Altman were "brought onboard" because their reputations would help draw public attention to the Cannon Catheter as a commercial product. In initial discussions with at least one potential distributor for the device, Carl Fleming of Diatek mentioned that Dr. Ross was of Diatek's "big

[32] Spire contends that Dr. Ross billed Medicare for some of the implantations. There is, however, no admissible evidence to support this contention. *See* note 29, *supra*.

implanters."[33] The Stock Purchase Agreement that formalized Dr. Altman's affiliation with Diatek specifically indicated that Altman would "act as a public spokesperson in connection with the advertising, promotion and sale" of Diatek products, including the Cannon Catheter. In June 2002, Dr. Altman co-authored an article published in a trade journal, in which he described his early implantations of the Cannon Catheter, including those prior to August 30, 2001. The article, titled "A New Tunneled Catheter For Vascular Access Placement is Introduced," described the success of these implantations and touted the benefits of the Cannon Catheter as a new product for hemodialysis. There is no indication from the article that the purpose of the implantations was experimental; rather, Dr. Altman characterizes the procedures as tests to evaluate the new product's advantages and disadvantages. *Cf. In re Smith*, 714 F.2d 1127, 1135 (Fed. Cir. 1983) ("The experimental use exception . . . does not include market testing where the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation.").

Considering all of these factors together, I find that Spire clearly has demonstrated a prima facie case of public use, and

[33] It is not clear from the record whether Fleming was referring specifically to Dr. Ross's implantations during the "limited market release" in August 2001, or more generally referring to Ross's ongoing role with Diatek's development and marketing of the Cannon Catheter.

that Arrow has failed to present contrary evidence sufficient to raise a genuine issue of fact. *See Mas-Hamilton Group*, 156 F.3d at 1216. Because I find that any reasonable factfinder must conclude there is clear and convincing evidence that the Cannon Catheter was in public use prior to August 30, 2001, I will consider the Cannon Catheter as prior art for the '198 patent for purposes of summary judgment.

d. Prior Art for Retrograde Tunneling

I turn now to the other relevant prior art in this case. This includes references that relate to the method of implantation claimed in the '198 patent (i.e., retrograde tunneling), as well as references that relate to the physical structure of the catheter (i.e., a double Y-shaped multi-lumen catheter with an elongated, central, multi-lumen tube portion).

Retrograde tunneling is one of only two methods by which physicians generally place catheters in a patient. The method has been known in the art of catheter implantation for almost thirty years. One of the earliest disclosures is U.S. Patent No. 4,327,722 (filed Aug. 20, 1979) ("the Groshong patent"), which claims a method of retrograde tunneling with steps substantially identical to those in the '198 patent: (1) making an incision in the skin of the patient (Groshong Patent col.7 l.68), (2) inserting the proximal end of the catheter into the patient (*id.* col.8 ll.6-12), (3) forming a subcutaneous tunnel (*id.* col.8

ll.24-29), (4) guiding the distal end of the catheter through the tunnel (*id.*), and (5) securing the catheter to the patient (*id*. col.8 ll.46-48). The primary difference from the '198 patent is that the Groshong patent only discloses a method for implanting a single lumen catheter, not a multi-lumen catheter. The Groshong patent also does not address the possibility of using a single tunnel method for two or more catheter tubes.

Other references, however, have disclosed retrograde tunneling methods for use with multiple catheter assemblies. For example, U.S. Patent No. 5,624,413 (filed Feb. 23, 1996) ("the Markel patent") claims a retrograde method that involves using two separate tunnels for two separate catheters. The Markel patent also describes attachable connection hubs that can be affixed to the catheter tubes after the tunneling procedure is complete, so as not to interfere with the process of guiding the catheter through the tunnel. (Markel Patent col.10 ll.9-12, 35-42.)

The Schon patent and the Canaud Article[34] each disclose a retrograde tunneling method for a multiple catheter assembly, where the two catheters are linked or joined to one another. The

[34] The Canaud Article was not before the patent examiner of the '198 patent. When the court considers material that was not considered by the examiner, the presumption of a patent's validity remains unchanged, but the challenging party may be able to overcome its burden of proof more easily. *See Kahn* v. *Gen. Motors Corp.*, 135 F.3d 1472, 1480 (Fed. Cir. 1998).

Schon patent discloses, but does not teach, the possibility of placing both catheter tubes in a single tunnel. The Canaud Article revealed that Dr. Canaud had, in fact, successfully performed such a procedure over seven hundred times, but it, too, does not "teach" the method.[35]

e. Prior Art for Multi-lumen Catheters

U.S. Patent No. 6,001,079 (filed Mar. 9, 1998) ("the Pourchez patent") discloses a double Y-shaped multi-lumen catheter. The Pourchez patent catheter, like the '198 patent catheter, has a single central catheter tube with at least "two inner lumens." (Pourchez patent col.1 ll.14-16.) Furthermore, like the '198 patent catheter, both the proximal end and the distal end of the Pourchez catheter are Y-shaped, with two lumens splitting off from the central tube. (*Id*. col.2 ll.30-51; Fig. 1.)

The Pourchez patent, however, discloses only the physical structure of the catheter and does not disclose any particular method of implantation. The parties are in dispute as to whether the catheter described in the Pourchez patent would be compatible with a retrograde tunneling method. Arrow's expert, Dr. Valji, contends that the connector hubs on the Pourchez catheter would - based on the state of the art at the time - have been permanently

[35] Both the Schon patent and the Canaud Article are discussed in more depth in connection with the issue of anticipation. *See* Section III.B.1.b, *supra*.

attached to the device, therefore precluding retrograde tunneling. Spire's expert, Dr. Romano, counters that the Pourchez patent does not describe any element that would prohibit its placement by a retrograde tunneling method. Reading the record in the light most favorable to Arrow, I will assume for purposes of this motion that the Pourchez patent catheter was not compatible with retrograde tunneling.

f. Other Objective Indicia

There has been effectively no evidence presented by either party regarding what the Supreme Court has called objective indicia of obviousness or nonobviousness: "commercial success, long felt but unsolved needs, [and] failure of others." *Graham,* 383 U.S. at 17. Spire has asserted simply that "[t]here exists no objective evidence indicative of nonobviousness here." Arrow has offered nothing to the contrary. Although the Supreme Court noted that these factors "might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented," *id.* at 17-18, it did not indicate that affirmative evidence regarding them was required before making a finding of obviousness or nonobviousness.

g. Conclusion

Based on the foregoing evidence, I find that Spire has shown by clear and convincing evidence as a matter of law that the '198 patent was obvious under 35 U.S.C. § 103. The '198 patent is "a

combination which only unites old elements with no change in their respective functions." *KSR,* 550 U.S. at 415-16 (internal quotation omitted); *see also Sakraida* v. *AG Pro, Inc.*, 425 U.S. 273, 282 (1976) (invalidating a patent that "simply arrange[d] old elements with each performing the same function it had been known to perform"). The motivation to make such a combination was implicit from the advantages of each individual element, which were already evident in the prior art.[36]

With the Cannon Catheter, Diatek had already developed a multi-lumen catheter to be placed by means of a retrograde implantation method. The instructions accompanying the Cannon Catheter described an implantation method that is substantially identical to the method described in the '198 patent. The only difference between the Cannon Catheter and the invention disclosed by the '198 patent is the physical structure of the catheter to be used. Whereas the Cannon Catheter has a hub assembly with connector tubes that is attached to the distal end of the catheter after tunneling, the '198 patent discloses a

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[36] The Federal Circuit has held that it is sufficient for an obviousness analysis if the motivation for an improvement is implicit in the prior art. *See Alza Corp.* v. *Mylan Labs., Inc.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006). Arrow incorrectly cites *KSR* for the proposition that the motivation must be explicit. In fact, *KSR* merely indicates that a *court's analysis* of the prior art should be explicit "[t]o facilitate review." *KSR*, 550 U.S. at 418. The Supreme Court in *KSR* expressly declined to endorse or disapprove of the Federal Circuit's decision in *Alza*. *See id.* at 421-22.

catheter with extension tubes permanently attached to a split-tipped distal end.[37] The advantage to the '198 patent design is that there are fewer steps to perform once the tunneling is completed; i.e., there is no need to attach a separate hub assembly because the distal extension tubes can be attached directly to the hemodialysis machine. I find that combining the Cannon Catheter method with a double split-tipped catheter would have been obvious to one skilled in the art of catheter implantation. The advantages to the double Y-shaped catheter design had been disclosed as far back as 1999, when the Pourchez patent was issued.

Arrow argues that the combination of the Cannon Catheter and the Pourchez patent would have required a further addition to the prior art: the use of a single tunnel method for placing multiple catheter tubes or lumens. Because the extension tubes of the '198 patent catheter are permanently attached to the elongated central portion of the catheter, they both must be guided through the same tunnel. At least two references in the prior art disclosed the idea of placing more than one catheter tube in a

[37] Arrow argues that the Cannon Catheter and '198 patent methods were different because the '198 patent claim 1(d) describes guiding distal "extension tubes" (plural) through the tunnel. Given that the distal end of the Cannon Catheter was not split-tipped, it would have had only one distal "tube" to be guided through the tunnel. I find this is not truly a difference in the implantation method, but simply indicative of the physical structural differences between the catheters.

single tunnel: the Schon patent and the Canaud Article. In fact, Dr. Canaud indicated that he had already successfully done so over seven hundred times. These sources are not sufficiently detailed to "teach" the single tunnel method, but they do emphasize that it was an obvious step for one skilled in the art to take for a multiple catheter assembly or, as with the '198 patent, a multi-lumen catheter. *See Nordberg, Inc.* v. *Telsmith, Inc.*, 881 F.Supp 1252, 1296 (E.D. Wis. 1995) ("It is well-established that contemporaneous and independent development of the claims-in-suit by another inventor strongly suggests that the invention of the patent was obvious.") (*citing In re Merck & Co.*, 800 F.2d 1091, 1098 (Fed. Cir. 1986)). In fact, Kenneth Todd Cassidy, one of the '198 patent inventors, acknowledged that for him, figuring out how to pull two distal lumens through a single tunnel was a straightforward deviation off the Cannon Catheter. For these reasons, I find that the '198 patent is an obvious combination of known elements, and I will grant Spire's summary judgment motion for invalidity on grounds of obviousness.[38]

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[38] I note further that even if the Cannon Catheter were *not* included among the prior art, I would still find that the '198 patent is an obvious combination of existing elements. As far back as the Groshong patent, it was clear that retrograde tunneling allowed for more accurate placement of the proximal end of a catheter, because insertion into the blood vessel could be made before any tunneling was done. The Pourchez patent showed the efficiency advantages of a double Y-shaped multi-lumen catheter design. Implanting a Pourchez-like catheter using a retrograde tunneling method was therefore an obvious next step, especially as there are only two general methods for implanting

IV. CONCLUSION

For the reasons set forth more fully above, I GRANT Arrow's summary judgment motion (Dkt. No. 58) and DENY Spire's summary judgment motion (Dkt. No. 32) for unenforceability on grounds of inequitable conduct. However, I GRANT Spire's summary judgment motion for invalidity (Dkt. No. 36) on grounds of obviousness.[39]

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE

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hemodialysis catheters. *See KSR,* 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.").

[39] I will also deny as moot Spire's motion to file an additional brief regarding the PTO's recent rejection of a patent application Spire contends is similar to the '198 patent. (Dkt. No. 77.) I find there is nothing in the PTO's analysis of that application that was not already addressed by the parties' briefing in this case and the pertinent case law.