

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF ARKANSAS  
TEXARKANA DIVISION

ST. JUDE MEDICAL, INC. and  
ST. JUDE MEDICAL PUERTO RICO LLC

PLAINTIFFS

VS.

CASE NO. 08-CV-4101

ACCESS CLOSURE, INC.

DEFENDANT

**MEMORANDUM OPINION**

Before the Court are Defendant Access Closure, Inc.’s (“ACI”) Motion for Summary Judgment, (Doc. 146), and Plaintiffs St. Jude Medical, Inc. and St. Jude Medical Puerto Rico LLC’s (collectively “St. Jude”) Motion for Summary Judgment. (Doc. 145). St. Jude has responded to ACI’s motion, (Doc. 169), and ACI has responded to St. Jude’s motion. (Doc. 167). The parties have filed their respective replies. (Doc. 179 and Doc. 181). The motions for summary judgment are ripe for consideration, and the Court addresses both in this memorandum opinion.

**BACKGROUND**

This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, et seq. St. Jude is one of the world’s leading providers of medical technology, including the vascular closure devices at issue in this case. ACI also makes and sells vascular closure devices, including a product known as the Mynx Vascular Closure Device (“the Mynx”).

The technology at issue in this case is used to close blood vessels following catheterization procedures. For example, in an angioplasty, a balloon-like device is inserted through the femoral artery and guided to the clogged artery, where it is then expanded to reduce blockage. When the device is removed, a hole is left in the femoral artery. Prior to the purported inventions at issue here,

the medical treatment applied to promote healing of these holes required manual pressure on the skin over the opening in the artery (often involving heavy sand bags) to prevent bleeding. The need for manual pressure increased the patient's discomfort, tied-up staff time, and often forced an overnight stay. The patents at issue in this case describe devices and methods intended to facilitate faster and more comfortable recovery using procedures and tools for sealing the hole in the blood vessel.

There are two distinct patent families at issue in this case. One family emanates from an inventor named Bradford Fowler and includes the '616 patent, the '602 patent, and the '375 patent (collectively, the "Fowler patents"), all entitled "Insertion Assembly and Method of Inserting a Vessel Plug into the Body of a Patient."<sup>1</sup> The Fowler patents share a common written description. St. Jude asserts claim 14 of the '616 patent; claims 38, 40, and 44 of the '602 patent; and claim 21 of the '375 patent. The Fowler patents disclose vascular closure devices and methods for positioning a plug to seal a hole in a blood vessel. Among other things, the Fowler patents describe closing or sealing the wound in a blood vessel by using a positioning element to locate a plug "adjacent to the outer surface of the blood vessel duct or lumen." In one embodiment, the positioning element is an inflatable balloon that is inserted into the hole in the blood vessel and expanded. The vessel plug is then inserted until encountering resistance from the expanded balloon. Once the plug is properly positioned, the balloon may be deflated and withdrawn.

The second patent family involved in this case originates with an inventor named Ernst Janzen. The Janzen family comprises, *inter alia*, the '498 patent and the '439 patent (collectively, the "Janzen patents"), both entitled "Device and Method for Sealing Puncture Wounds."<sup>2</sup> The

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<sup>1</sup> U.S. Patent Nos. 5,275,616 ("the '616 patent"), 5,601,602 ("the '602 patent"), and 5,716,375 ("the '375 patent").

<sup>2</sup> U.S. Patent Nos. 5,725,498 ("the '498 patent") and 7,008,439 ("the '439 patent")

Janzen patents also share a common written description. St. Jude asserts claims 7-9 of the '439 patent.<sup>3</sup> The Janzen patents also disclose vascular closure devices and methods for positioning a plug to seal the hole in a blood vessel. In one exemplary embodiment, a guide wire is used in positioning a sheath containing the plug into the tissue tract created during a catheterization procedure. The guide wire guides the plug towards the hole. Once the end of the plug "is near to or abuts" the hole in the blood vessel, the sheath is withdrawn, leaving the plug next to the hole. The plug seals the flow of blood sufficiently so that the blood can clot. It is later absorbed by the body.

ACI began producing a vascular closure device named the Mynx in May 2007. In October 2008, St. Jude filed this lawsuit, alleging that ACI has and is infringing, contributorily infringing, and inducing the infringement, both directly and indirectly, of the above described patents through its involvement with the Mynx. St. Jude sought injunctive and compensatory relief, including treble damages for willfulness under 35 U.S.C. § 284 and attorney's fees under 35 U.S.C. § 285. ACI answered, denying the allegations, raising twelve affirmative defenses, and asserting eleven counterclaims seeking declaratory judgments of invalidity, non-infringement, or unenforceability due to inequitable conduct. St. Jude later amended the complaint to request that the Court order correction of the patent(s) under 35 U.S.C. § 256 if an error were shown to exist with respect to the naming of inventors on one or more of the patents-in-suit. The Court has issued its Claim Construction Order. (Doc. 101). Discovery has closed, although some matters remain pending. Both parties have moved for summary judgment on certain aspects of the suit. This opinion addresses the issues raised by the parties in their respective motions for summary judgment.

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<sup>3</sup> St. Jude originally asserted claim 1 of the '498 patent and claim 10 of the '439 patent, but has since dropped those claims. Because claim 1 was the only asserted claim of the '498 patent, that patent is no longer at issue in this case. The remaining claims of the '439 patent are still at issue.

## SUMMARY JUDGMENT STANDARD

FED. R. CIV. P. 56(c) states that summary judgment is appropriate “if 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.” Under this standard, the inquiry is not whether the evidence favors one side or the other, but “whether a fair minded jury could return a verdict for the plaintiff on the evidence presented.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251 (1986). The court must view all facts and draw all reasonable inferences in favor of the non-moving party. *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007). “Summary judgment will not lie if the dispute about a material fact is ‘genuine,’ that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Liberty Lobby*, 477 U.S. at 248.

## DISCUSSION

Each party has moved for summary judgment on certain aspects of the suit. In the interest of efficiency, the Court addresses both motions in this memorandum opinion. Section I addresses issues raised by ACI, and Section II addresses issues raised by St. Jude.

### SECTION I

ACI moves for summary judgment on the grounds that (1) St. Jude cannot prove infringement; (2) the asserted patents are invalid as a matter of law; (3) St. Jude cannot prove willful infringement; and (4) St. Jude cannot prove that it is entitled to the lost profits damages it seeks.

#### **1. Proof of Infringement**

ACI argues that it infringes neither the Janzen nor Fowler patents. Regarding the Janzen patent, ACI contends that it does not infringe because (1) the sealant in the Mynx device is initially loaded at the distal end; (2) the Mynx device does not include a guide wire or equivalents; (3) the

Mynx device does not include an ejecting mechanism; and (4) the Mynx device does not involve the four sequenced steps required by claim 9 of the '439 patent. Regarding the Fowler patents, ACI contends that it does not infringe because (1) the Mynx device does not include the elongate positioning member described in claim 21 of the '375 patent; (2) the Mynx device does not close incisions; (3) no single actor performs the steps of claim 14 of the '616 patent; and (4) the balloon in the Mynx device is never relaxed. In addition, ACI contends that because it does not infringe directly, it also cannot indirectly infringe any of the patents.

A determination of infringement, both literal and under the doctrine of equivalents, is a question of fact. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 229 F.3d 1313, 1323 (Fed. Cir. 2002). “The issue of infringement is amenable to summary judgment only when there is no genuine issue of material fact as to whether correctly interpreted claims read upon the accused device or method, literally or under the doctrine of equivalents.” *Lifescan, Inc. v. Home Diagnostics, Inc.*, 76 F.3d 358, 359 (Fed. Cir. 1996). Viewing the evidence and drawing all reasonable inferences in St. Jude’s favor, the Court concludes that summary judgment is inappropriate on any of the infringement claims. Although ACI’s arguments may ultimately prevail at trial, the Court would have to resolve numerous factual ambiguities in ACI’s favor in order to grant summary judgment of non-infringement. Just as an example, there is considerable evidence indicating that the wire in the Mynx balloon catheter shaft plays some role in guiding the plug, and thus could be considered the equivalent of the Janzen guide wire. The Court would have to ignore or discount this evidence, which Rule 56 of course prohibits, in order to grant ACI’s motion. Similarly, with regard to the Fowler patents, the Court has little doubt that a fair minded jury could conclude that the Mynx balloon is “relaxed” despite the presence of the core wire. In conclusion, St. Jude has proffered substantial evidence of infringement, and a reasonable jury could return a verdict in its favor.

## 2. Validity of Patents

ACI argues that several of the asserted claims are invalid. ACI contends that the Fowler '616, '602, and '375 patents are invalid because the inventor filed the patents before advancing his ideas to a point where they were reducible to a working device by one of ordinary skill in the art without undue experimentation. ACI also argues that claims 7, 8, and 9 of the '439 patent are anticipated and thus invalid because the Fowler '421 patent discloses each and every limitation of these claims. Lastly, ACI contends that claims 7, 8, and 9 of the '439 patent are insufficiently distinct from claim 7 of the '498 patent, and thus invalid for obviousness-type double patenting.

Patents are presumed to be valid, see 35 U.S.C. § 282, and a party alleging invalidity must overcome this presumption with clear and convincing evidence. *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chem. Co.*, 204 F.3d 1360, 1367 (Fed. Cir. 2000).

Regarding enablement, the Court concludes that issues of material fact preclude summary judgment. ACI has presented evidence that Fowler and Quinton Instrument Company, Inc., his employer, were unable to produce a working device in the years following the filing of the original patent in 1990. St. Jude counters that only minimal experimentation took place before Quinton decided to pursue the development of a different device. St. Jude argues that this minimal experimentation was successful and that even if it was not, the issue is not experimentation per se, but rather undue experimentation. *See Chiron Corp. v. Genentech*, 363 F.3d 1247, 1253 (Fed. Cir. 2004). Although the failure to reduce the patent to a commercialized device supports a conclusion that the patent specification lacks enablement, see *Ormco Corp. v. Align Technology, Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007), it is not the only reasonable conclusion that can be drawn from the evidence. As St. Jude contends, Quinton may simply have chosen not to pursue the Fowler specification. Because the failure to develop a commercial device is not determinative, the

enablement question turns on whether it would have taken undue experimentation for a person of ordinary skill in the art to make and use the claimed inventions based on the Fowler specification in 1990. *See* 35 U.S.C. § 112. Aside from minimal discussion about the state of vascular closure in 1990, ACI does not address the many factors that courts typically consider in addressing this issue. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Because factual questions exist with respect to, *inter alia*, whether the experimentation was undue and what constitutes a person of ordinary skill in the art in 1990, summary judgment is inappropriate.

Material issues of fact also remain with regard to whether the Fowler ‘421 patent anticipates and thus invalidates the Janzen ‘439 patent. Initially, the parties dispute whether the Fowler ‘421 patent predates the Janzen ‘439 patent. St. Jude argues that the inventions claimed in the ‘439 patent were conceived before the October 1, 1990 filing date of the ‘421 patent and that the Janzen inventors were diligent in reducing the ‘439 patent to practice. Accordingly, argues St. Jude, Janzen predates Fowler and thus Fowler cannot be prior art. ACI attacks the documentary evidence supporting St. Jude’s contention that Janzen conceived of the idea before the Fowler patent was filed. The Court does not find that the documentary evidence definitively establishes either party’s position. Thus, the jury will need to evaluate the conflicting evidence and draw its own conclusions regarding the date of conception. Even assuming Fowler ‘421 was prior art, material issues of fact exist as to whether the ‘421 patent anticipates the ‘439 patent. Specifically, it is not clear that the ‘421 patent envisions inserting the plug over the guide wire (*i.e.*, that the plug has a hole through which the wire passes). Although the jury might accept ACI’s argument, it is not as obvious as ACI contends that the “along or over” language refers to the plug rather than the insertion assembly more generally and thus that the guide wire necessarily passes through the vessel plug.

Lastly, the Court declines to grant summary judgment that the asserted claims of the Janzen

'439 patent are invalid for obviousness-type double patenting over claim 7 of the '498 patent. The parties agree that the '498 patent discloses the use of hemostatic material to seal the vessel. St. Jude has raised an issue of material fact with respect to whether the '439 patent's use of a plug that physically (as opposed to biochemically) impedes the passage of materials through the vessel precludes a finding that the asserted claims of the '439 patent are obvious in light of the '498 patent.

### **3. Willful Infringement**

ACI argues that St. Jude has failed to provide clear and convincing evidence that ACI produced the Mynx despite an objectively high likelihood that its actions constituted infringement of a valid and enforceable patent.<sup>4</sup> ACI contends the numerous substantive defenses it has raised demonstrate that its actions were not objectively reckless. ACI also argues that St. Jude's ongoing efforts to correct errors in the patent undercut any finding of recklessness. ACI points out that St. Jude never mentioned its alleged reckless infringement during two years of interaction prior to the filing of this suit. Lastly, ACI challenges the legal sufficiency of the evidence produced by St. Jude.

ACI's arguments are insufficient for the Court to find that the alleged infringement was not willful as a matter of law. As ACI acknowledges, St. Jude has presented evidence that ACI knew of the patents, that ACI did not have a reasonable belief regarding non-infringement, and that third parties indicated infringement concerns to ACI. Additionally, St. Jude has identified an expert witness to testify that the infringement was willful. Based on the Court's evaluation of ACI's arguments as presented thus far, it would be inappropriate to conclude as a matter of law that the asserted defenses are so substantial and meritorious as to mandate a finding of objective

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<sup>4</sup> The determination of willfulness involves both an objective and subjective element. *In re Seagate*, 497 F.3d 1360, 1371 (Fed Cir. 2007). ACI's motion focuses solely on the objective test.

reasonableness. This, of course, is not to say that ACI's defenses are necessarily lacking. Rather, the Court concludes that it is appropriate to revisit the question of willfulness following the jury trial, with the benefit of the jury's view as to the merits of ACI's defenses and the willfulness of any infringement. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 858-60 (Fed. Cir. 2010).

#### **4. Lost Profit Damages**

Lastly, ACI argues that St. Jude cannot collect lost profit damages because the owner of the '439 patent (St. Jude Medical, Inc.) does not manufacture or sell any products with which the allegedly infringing products compete. Rather, the devices for which sales have been lost are manufactured and sold by three separate, wholly-owned corporate subsidiaries of St. Jude Medical, Inc. According to ACI, under *Mars, Inc. et al v. Coin Acceptors, Inc.*, 527 F. 3d 1359 (Fed. Cir. 2008), a patent holder cannot collect the lost profits of a wholly owned subsidiary without showing that profits flow inexorably from subsidiary to parent.

St. Jude responds that it is not seeking to recover lost profit damages, but rather the decrease in its own market value due to the lost sales of its wholly-owned subsidiaries. Put differently, St. Jude seeks to recover for the economic harm that ACI's infringement caused to the value of its ownership interest in its subsidiaries as a result of ACI's infringement. Accordingly, contends St. Jude, the very premise of ACI's motion is flawed.

Because St. Jude disclaims any potential recovery under a lost profits theory, ACI's arguments regarding the unavailability of lost profits damages are moot. St. Jude cannot recover damages for the '439 patent on a lost profits theory.

The more difficult question is whether St. Jude can recover the lost profits of its subsidiaries under a reduction in income theory. In its response, ACI notes that the mechanics of the "lost

profits” calculation are essentially identical to the “reduction in income” calculations and argues that St. Jude’s proposed theory is nothing more than a relabeling of the unavailable lost profits damages. ACI also highlights the dearth of precedent supporting St. Jude’s reduction in income theory. In its opposition, St. Jude responds that the Supreme Court and Federal Circuit have both embraced an expansive view of 35 U.S.C. § 284. *See General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654-55 (1983); *Rite-Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1544 (Fed. Cir. 1995). St. Jude also notes that *Mars* specifically states that patent damages are not limited to reasonable royalties and lost profits and could embrace alternate theories:

We have previously recognized that patentees may be entitled to damages above a reasonable royalty on theories entirely distinct from lost profits . . . [but because Mars seeks only lost profits and reasonable royalties] . . . we need not determine whether Mars would have been entitled to recover under any other damages theory for the economic injury that it suffered as a result of [its subsidiary’s] lost sales.

527 F.3d at 1366.

The Court concludes, in line with *Rite-Hite*, *Mars*, and *SEB, S.A. v. Montgomery Ward & Co., Inc.*, 412 F. Supp. 2d 336, 345-48 (S.D.N.Y. 2006), that St. Jude may be able to recover on its proposed theory if it can show what damages *it* sustained from ACI’s actions. The case law interpreting § 284 envisions a flexible approach to patent damages, and the Court will permit St. Jude to present its theory to the jury.

## **SECTION II**

St. Jude moves for summary judgment on ACI’s affirmative defense of unenforceability due to inequitable conduct, arguing primarily that ACI cannot rely solely on the materiality of the withheld references to establish inequitable conduct because both materiality and intent to deceive are required. St. Jude cites to several Federal Circuit cases for the proposition that intent cannot

be inferred from a high degree of materiality, but must be proven separately. *See, e.g., Astrazeneca Pharm. LP v. Teva Pharm. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009).

ACI alleges that inequitable conduct occurred during the prosecution of every patent-in-suit. Regarding the Fowler patents, ACI contends that the failure to disclose the earlier work of Drs. Rienks and Van de Moer, the Takayasu article, and various Janzen patents constituted inequitable conduct. ACI also alleges inequitable conduct during the prosecution of the Janzen '439 patent, contending that the '439 patent is unenforceable for failure to disclose to the United States Patent Office ("PTO") the allowance of the '498 patent and the fact that the examiner of the '498 patent rejected some claims pending in the '498 application in light of the Kensey '301 patent.

The Federal Circuit discussed the requirements for a finding of inequitable conduct in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*:

The burden of proving inequitable conduct lies with the accused infringer. To successfully prove inequitable conduct, the accused infringer must present evidence that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the PTO. 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. And even if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable. Thus, even if a threshold level of both materiality and intent to deceive are proven by clear and convincing evidence, the court may still decline to render the patent unenforceable.

537 F.3d 1357, 1365 (Fed. Cir. 2008) (citations and quotations omitted). Thus, in order to avoid summary judgment, ACI must put forward, at a minimum, sufficient evidence to establish a threshold level of both materiality and intent under the clear and convincing standard.

The parties spend little time discussing the legal standard for materiality, presumably because there is general agreement as to its content. The Court will follow *Leviton Mfg. Co., Inc. v.*

*Universal Sec. Instruments, Inc.*, which defines materiality as follows:

Under our scattered precedents, information may be considered material if 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. Information concealed from the PTO may be material even though it would not invalidate the patent. However, a withheld otherwise material reference is not material if it is merely cumulative to, or less relevant than, information already considered by the examiner.

606 F.3d 1353, 1358-59 (Fed. Cir. 2010) (quotations and citations omitted).

Intent, however, is more hotly disputed. According to *St. Jude*, ACI impermissibly seeks to have the Court infer intent solely from materiality. ACI responds that *St. Jude* is incorrect that ACI is relying solely on materiality to establish intent and avers that ACI has substantial actual evidence from which intent can be drawn. ACI cites to Federal Circuit cases recognizing that direct evidence of intent is rarely available, see *McKesson Information Soln's. v. Bridge Medical, Inc.*, 487 F.3d 897, 901-02 (Fed. Cir. 2007), and that indirect or circumstantial evidence can be sufficient to support a finding of intent to deceive. See *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005). ACI seeks to have the Court apply *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1313-14 (Fed. Cir. 2008), which purports to establish a three-part test for when a court can appropriately draw an inference of intent to deceive.

The Federal Circuit has recently issued an opinion addressing the relationship between materiality and intent as pertains to inequitable conduct. See *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313 (Fed. Cir. 2010). While the majority opinion discusses much of the case law, including *Praxair*, the Court finds Judge Prost's special concurrence particularly helpful. In her concurrence, Judge Prost clarifies that materiality, while not sufficient evidence of intent, is also not wholly irrelevant to intent. Rather, materiality is simply one type of circumstantial evidence, which, when coupled with *other* evidence, can allow a court to draw a justifiable inference of deceptive intent.

Because Rule 56 only requires the court to draw justifiable inferences in favor of the non-movant, summary judgment can be appropriate despite some evidence (*i.e.*, high materiality) of intent. *See ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir.1998). At the same time, a high degree of materiality decreases the quantum of evidence necessary to infer intent. *Optium*, 603 F.3d at 1325.

With these lessons in mind, the Court turns to the specific allegations of this case and asks (1) whether the undisclosed information was material and (2) whether ACI has provided sufficient evidence, in addition to materiality, from which intent can reasonably be inferred.

### **1. Fowler Patents**

With regard to the Fowler patents, ACI's inequitable conduct allegations involve the failure to disclose the earlier work of Drs. Rienks and Van de Moer, the Takayasu article, and various Janzen patents. The Court addresses each in turn, concluding that ACI has provided insufficient evidence from which a reasonable fact finder could infer an intent to deceive.

#### **A. Work of Drs. Rienks and Van de Moer**

In the late eighties, Bradford Fowler worked for Quinton Instrument Company as a biomedical engineer. In December of 1989, Drs. Rienks and Van de Moer approached Quinton to discuss the development of their vascular technology. Fowler, who was already studying how blood interacts with various materials to achieve hemostasis, met with Dr. Rienks in December of 1989. They discussed Rienks and Van de Moer's idea for using an intravascular anchor to place and retain the vascular plug. Fowler rejected the intravascular anchor and developed an alternate solution involving the use of an expandable member to ensure proper placement of an extravascular plug. Fowler filed a patent application based on his idea that did not mention Rienks or Van de Moer.

In its motion for summary judgment, St. Jude contends that the Rienks and Van de Moer idea was not material because Fowler involved an extravascular plug rather than an intravascular anchor.

St. Jude also argues that even if the information was material, there is no evidence that Fowler or Allison, who prosecuted the Fowler patents, intended to deceive the PTO. St. Jude points to the deposition testimony of Andrew Dillon, ACI's expert, in which Dillon states that the materiality of the Rienks and Van de Moer idea was of such a serious nature that intent can be inferred. Dillon acknowledged that he had no additional evidence of intent or evidence indicating that Allison knew of Rienks and Van de Moer's earlier work or of the discussions between Fowler and Rienks.

ACI responds that the work of Rienks and Van de Moer is inherently material because it relates to inventorship. ACI implies that Fowler could not have independently developed his ideas in the few months between his meeting with Rienks and his initial memo circulating his idea.<sup>5</sup> ACI also notes that Rienks and Van De Moer's European patent was cited as prior art during the prosecution of a patent filed by Allison that was "substantially identical" to the Fowler patents, which were pending before a different examiner. ACI contends that this citation put Allison on notice that the work of Rienks and Van De Moer was material to the Fowler patents. As evidence of intent, ACI argues that Fowler and Allison both knew or should have known about the withheld references. ACI also notes that neither Fowler nor Allison have provided any justification for their repeated failure to disclose the Rienks and Van de Moer information to the PTO.

Even assuming that the Rienks and Van de Moer information, either in the form of disclosures during the 1989 meeting with Fowler or the European patent, was material, an inference of deceptive intent would be unreasonable on the facts presented. First, the evidence supports at most a low level of materiality. There are significant differences between an intravascular anchor solution and an extravascular plug as described in the Fowler patents. Moreover, regarding the

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<sup>5</sup> ACI did not assert an invalidity defense based on the inventorship of the Fowler patents.

citation to the Rienks and Van de Moer application in the prosecution of the Allison's application, the rejection was under the Kensey Nash patent with the Rienks and Van de Moer application identified as "prior art made of record and not relied upon." The cumulative nature of the reference undermines its materiality. *See Larson Mfg. Co. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009). Given the low materiality of the information, ACI has further to go to satisfy the threshold evidentiary burden for an inference of intent. *See Optium*, 603 F.3d at 1325. The evidence it has provided, essentially nothing more than that Fowler and Allison knew or should have known about the withheld material, is inadequate, particularly because St. Jude has presented a good faith reason for not citing the work of Rienks and Van de Moer (*i.e.*, that it was cumulative of Kensey Nash). In short, ACI has failed to offer evidence that could succeed in proving deceptive intent with regard to Rienks and Van de Moer by clear and convincing evidence.

**B. Takayasu article**

During previous litigation between Quinton and Datascope, Datascope submitted a 35 U.S.C. § 282 pleading that listed an article by Kenichi Takaysu, et al. entitled "A New Hemostatic Procedure for Percutaneous Transhepatic Portal Vein Catherization" as invalidating art. Allison, who was prosecuting the Fowler patents, was also Quinton's counsel of record in the *Quinton v. Datascope* litigation. ACI alleges that Allison's failure to disclose the article despite learning of Datascope's position that it invalidated the Fowler patents constitutes inequitable conduct that should invalidate the Fowler patents.

St. Jude argues that this reference is not material to the Fowler patents because Takayasu is directed at stopping bleeding in a hole in a liver using a stick-like gelfoam sponge and does not disclose the use of a balloon or expandable member. Furthermore, argues St. Jude, even if Takayasu were material, ACI lacks any evidence of intent to deceive. According to St. Jude, there is no

evidence that Allison knew of the reference or what it disclosed, and ACI's expert again improperly seeks to infer intent solely from the alleged materiality of the reference.

ACI's response contains scant mention of Takayasu. Regarding materiality, ACI states that "[w]ith respect to the Takayasu article, there is no genuine issue of material fact that this reference is prior art. Additionally, this article was cited by Datascope, SJM's predecessor, in a Notice pursuant to 35 U.S.C. § 282, as invalidating prior art." Doc. 167 at 12-13. Regarding intent, ACI states only that "[t]he pleadings from the Datascope litigation also demonstrate that the Takayasu [sic] reference was brought to Allison's attention, and in fact, that Takayasu was identified as prior art which invalidated the Fowler patents." *Id.* at 14.

Even assuming that Takayasu was material, the mere fact that Takayasu was cited (with no further elaboration) in litigation between Quinton and Datascope and that Allison was involved in that litigation falls woefully short of establishing inequitable conduct by clear and convincing evidence. As St. Jude notes, it is not even clear that Allison was aware of Takayasu. In support of its assertion that he was, ACI's cites to Allison's 1996 deposition. However, that deposition contains no reference to Takayasu; it simply states that Allison was involved in the *Quinton v. Datascope* litigation to the degree that he had trouble separating what he knew in 1990 from what he had learned during the litigation. ACI's allegations of inequitable conduct based on Takayasu cannot survive St. Jude's motion for summary judgment.

### **C. Janzen Patents (as relates to Fowler)**

ACI also alleges that Allison failed to disclose the work of Janzen, et al. during the prosecution of the Fowler patents. ACI contends that a summary judgment motion and settlement agreement in the same *Quinton v. Datascope* litigation informed Allison of Datascope's allegations

that the work of Janzen, et al. predates Folwer's work. According to ACI, Allison's failure to inform the PTO of this information constitutes inequitable conduct that should void the Fowler patents.

St. Jude argues the Janzen references are not material because they are cumulative of other references already before the PTO. St. Jude also contends that even if the references were material, ACI has no evidence that Allison intended to deceive the PTO.

In the argument section of its opposition, ACI does not mention any documents from the *Quinton v. Datascope* litigation other than Takasayu. To the degree that the failure to brief is not a concession of these allegations, they are without merit. ACI has simply failed to provide any evidence, much less clear and convincing evidence, that the supposedly material information was withheld with the intent to deceive the patent office. *See Optium*, 603 F.3d at 1322.

## **2. Janzen Patent**

ACI alleges inequitable conduct in seeking to extend the coverage of the Janzen patents by pursuing overlapping claims in different applications before different examiners. ACI alleges that Datascope, who prosecuted the Janzen applications through its attorney Krumholz, filed multiple interrelated claims in order to "game" the system. According to ACI, Datascope failed to disclose material information from related, co-pending applications. Specifically, ACI alleges that Datascope failed to disclose the allowance of the '498 patent and the fact that the examiner of the '498 patent rejected some claims pending in the '498 application in light of the Kensey '301 patent.

St. Jude argues that a rejection based on the Kensey '301 reference in the '498 application was not material to the '439 application because the claims of the '498 and '439 patent are distinct and directed to separate inventions. Because the rejection of a claim in one application is irrelevant to the claims of a distinct application, St. Jude argues that the only potentially material information

was the Kensey '301 patent itself, which was disclosed. St. Jude also contends that Krumholz was unaware of any materiality of the rejection. Lastly, St. Jude contends that no intent to deceive can be inferred from the circumstances, particularly because the file history of the '498 patent shows that the examiner of the '498 patent consulted with the examiner of the '439 on the same day that the examiner of the '498 patent issued his office action addressing the Kensey '301 application. St. Jude argues that a theory that Krumholz sought to hide the work of one examiner from another makes no sense when the examiners were in communication.

Although it is a close question, the Court declines to grant summary judgment on ACI's inequitable conduct defenses as related to the '439 patent. The jury will be evaluating ACI's contention that the '439 patent is obvious in light of the '498 patent. The resolution of that fact issue will in large part determine the materiality to the '439 application of the examiner's actions in regard to the '498 application. Additionally, the Court finds the theory that Krumholz, as prosecutor of both the '498 and '439 applications, would be aware of the materiality of a rejection of certain claims between co-pending applications from the same patent family to be considerably more plausible than ACI's theory regarding Allison's awareness of the impact of the *Quinton v. Datascope* litigation on the prosecution of the Fowler patents. Because the Court concludes that a justifiable inference of intent could be drawn from the evidence ACI has presented, summary judgment as to inequitable conduct in the '439 prosecution must be denied.

### **CONCLUSION**

Upon consideration, the Court finds that ACI's Motion for Summary Judgment should be and hereby is **DENIED** and that St. Jude's Motion for Summary Judgment should be and hereby is **GRANTED IN PART AND DENIED IN PART**. ACI's allegations of inequitable conduct in the

prosecution of the Fowler patents are hereby **DISMISSED**.

IT IS SO ORDERED, this 1st day of December, 2010.

/s/ Harry F. Barnes  
Hon. Harry F. Barnes  
United States District Judge