

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

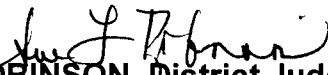
DR. QINGSHENG ZHU and DR. JULIO)	
SPINELLI, acting jointly as the)	
Stockholder Representative Committee)	
for Action Medical, Inc.,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 14-542-SLR
)	
BOSTON SCIENTIFIC CORPORATION)	
and CARDIAC PACEMAKERS, INC.,)	
)	
Defendants.)	

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MEMORANDUM OPINION

Dated: March 15, 2016
Wilmington, Delaware


ROBINSON, District Judge

I. INTRODUCTION

In 2009, defendants Boston Scientific Group and its indirect, wholly owned subsidiary Cardiac Pacemakers, Inc. (collectively, “BSC”) acquired Action Medical, Inc. (“Action Medical”) pursuant to an Agreement and Plan of Merger (the “Merger Agreement”). (D.I. 1 Ex. A) Plaintiffs Dr. Qingsheng Zhu and Dr. Julio Spinelli (collectively, “plaintiffs”) comprise the Stockholder Representative Committee of Action Medical. (*Id.* § 2.5) The Merger Agreement is governed by Delaware law and grants plaintiffs authority to enforce certain rights. (*Id.* §§ 2.5, 10.7)

On April 24, 2014, plaintiffs filed suit against BSC alleging breaches of contract and breaches of the implied covenant of good faith and fair dealing. (D.I. 1) Plaintiffs’ claims are based on BSC’s purported failure to spend a contractually required minimum amount towards the development and commercialization of Action Medical’s technology (the “Technology”), thereby depriving plaintiffs of contingent milestone payments. (*Id.* ¶¶ 1, 93-99, 111-126) Plaintiffs also claim that once BSC decided to no longer pursue the Technology, it failed to promptly return that technology as required by the Merger Agreement. (*Id.* ¶¶ 100-110)

Currently before the court are the following motions filed by BSC: (i) motion for summary judgment (D.I. 97); (ii) motion to preclude expert opinions and testimony of Dr. Julio Spinelli (D.I. 83); (iii) motion to preclude expert opinions and testimony of Stan Myrum (D.I. 86); and (iv) motion to strike the “Supplemental Sub-Analysis” opinions of Stan Myrum (D.I. 90). The court has subject matter jurisdiction over this action pursuant

to 28 U.S.C. § 1332(a), and personal jurisdiction over the defendants pursuant to Section 10.8(a) of the Merger Agreement.

II. BACKGROUND

A. Merger

In 2005, Dr. Zhu formed Action Medical as a vehicle to further develop the Technology, which he also invented. (*Id.* ¶ 17) The Technology provides a patented approach to pacing that uses a specific waveform called “Xstim” delivered at or near the “His bundle” region of the heart. (D.I. 1 ¶ 22) After performing clinical studies in 2005 and 2006, Action Medical approached BSC for an investment and/or partnership to help further develop and commercialize the Technology. (*Id.* ¶¶ 27, 31-32) BSC is in the business of developing, manufacturing, and marketing medical devices including implantable devices commonly known as “pacemakers.” (*Id.* ¶ 10) Dr. Zhu was particularly interested in a partnership with BSC because he previously worked at Guidant Corporation, which was acquired by BSC and made into its Cardiac Rhythm Management division. (D.I. 121 at 2) Thus, Dr. Zhu had a personal history with the decision makers he approached at BSC for an investment. In 2007, BSC paid \$6.5 million for an 18% stake in Action Medical. (D.I. 1, ¶ 36) In April 2009, BSC paid another \$16 million to acquire all of Action Medical. (D.I. 1, ¶ 51)

B. Relevant Contract Provisions

Section 1.6 of the Merger Agreement contains all of the provisions relevant to the parties’ litigation. Sections 1.6(a)-(d) required BSC to pay plaintiffs contingent payments if certain events occurred with respect to any products incorporating the Technology (“Contingent Payment Products”). The contingent payments were

comprised of: (i) a \$7 million milestone payment for regulatory approval in the EU; (ii) a \$16 million milestone payment for regulatory approval from the FDA; and (iii) annual payments based upon a percentage of worldwide sales of Contingent Payment Products. (*Id.* § 1.6 (a)-(d)) The parties expressly acknowledged in the Merger Agreement that it was “uncertain” whether the qualifying events to receive any contingent payments would occur and, therefore, it was “not assured” that BSC would be required to make any milestone payments. (*Id.* § 1.6(e))

In Section 1.6(f), BSC agreed to spend a minimum of \$15 million before April 22, 2013 “in connection with ... matters relating to” Contingent Payment Products. (*Id.* § 1.6(f)) The same section makes clear, however, that BSC had “sole discretion” over “all decisions relating to any Contingent Payment Products.” (*Id.*) BSC also had “sole discretion” in how to spend the \$15 million. (*Id.*) The Merger Agreement states that the \$15 million could be spent on, among other things, “development, manufacturing, regulatory, marketing, and/or sales,” but contains no specific commitments in this regard. (*Id.*)

Section 1.6(f) also states that BSC’s minimum spending obligation would “immediately cease” if BSC achieved FDA approval or made a “determination that further spending would not materially increase the level of feasibility of the product and/or its commercial viability.” (*Id.*) BSC was obligated to consult with plaintiffs before making any determination and to send a written notice of its determination (a “Spending Determination Notice”). (*Id.*) Delivery of the notice was at BSC’s “sole discretion.” (*Id.*)

Finally, plaintiffs’ “sole and exclusive remedy for any claim arising out of delivery ... of a Spending Determination Notice” was the “Participating Rights Holders Option.”

(*Id.* § 1.6(g)) Under that option, plaintiffs had the right to form a new company to which BSC would contribute the Technology. (*Id.*) In exchange, plaintiffs had to give BSC an 18% interest in the new company. (*Id.*)

C. Development of the Medical Technology

Shortly after it acquired Action Medical, BSC conducted animal studies to determine whether the Technology offered advantages over conventional pacing or His bundle pacing using conventional waveforms. (D.I. 98 at 5; D.I. 102 Exs. 5, 6, 8) BSC also conducted a study in humans called the High Septal Pacing for Cardiac Resynchronization Therapy Study (“HISTORY”). (D.I. 102 Ex. 14) HISTORY was designed to test His bundle pacing, using Xstim and other waveforms, as an alternative to conventional cardiac resynchronization in patients with heart failure. (*Id.*) Among other things, HISTORY was intended to provide a head-to-head comparison of Xstim to conventional unipolar and bipolar waveforms, which had not yet been studied. (D.I. 102 Exs. 4, 15)

The HISTORY trial began in Germany and expanded to additional sites in Hong Kong, Spain, and Canada. (*Id.* Exs. 11, 12) The first patient was enrolled in September 2011. (*Id.* Ex. 13) Although BSC intended to enroll at least 50 patients, BSC stopped the study in March 2012 having enrolled only 14 patients. (*Id.* 14; D.I. 127 Ex. 7 ¶ 178) BSC claims that it stopped enrollment in the study because it did not want to risk patient safety after the data from 14 patients was sufficient to detect a meaningful negative trend. (D.I. 135 at 7) The final report on HISTORY was completed in July 2012. (D.I. 102 Ex. 16) BSC concluded from the study that Xstim was not superior to other waveforms. (*Id.* Exs. 15, 16)

Plaintiffs claim that the HISTORY study was “woefully inadequate,” because the design of the study and the analysis were inconsistent with industry standards. (D.I. 121 at 5) Specifically, according to plaintiffs:

- BSC took over a year to finalize the Clinical Investigation Plan, and then took another year to enroll the first patient. (*Id.* at 5)
- BSC “engaged in meaningless preclinical testing.” (*Id.* at 15)
- BSC “decided to stop HISTORY . . . knowing it would not obtain statistically significant data,” because it enrolled only 14 of the 50 patients sought. (*Id.*)
- The results of the HISTORY study were “uninterpretable.” (D.I. 121 at 16)

BSC factually disputes each of these assertions, but resolving those factual disputes is not necessary to deciding the motion for summary judgment. It is sufficient to note that BSC did engage in testing and development of the Technology.

D. BSC’s Spending Determination Notice

Around April 12, 2013, Dr. Douglas Daum (Vice President of Research and Development at BSC) and Dr. Zhu discussed by telephone BSC’s determination that it was no longer going to pursue development of the Technology. (D.I. 125 Ex. 21) Afterwards, Dr. Zhu sent an email summarizing his understanding of the conversation, including that BSC had spent anywhere between \$6 million to \$60 million developing the Technology, “depending on how BSC wants to attribute costs.” (*Id.*) In response, Dr. Daum elaborated that:

The amount we have spent developing the Action Medical technology depends on what we attribute to be in the scope of our spending towards technology development. This includes direct and indirect applicable technology. Examples of direct spend would include clinical trials, preclinical investigations, etc. Indirect spend could include lead evaluations that are required to implement the therapy but are also applicable to other devices....

(*Id.*) Dr. Daum also stated that the “direct spend” would not equal \$15 million or more.¹

(*Id.*) On April 16, 2013, BSC sent plaintiffs a formal written Spending Determination Notice. (D.I. 125 Ex. 22)

Around May 10, 2013, plaintiffs sent BSC written notice that they were forming a new company, called Act2 Medical, Inc. (“Act2”), into which BSC would be required to contribute the Technology. (*Id.* Ex. 23) Although the parties have exchanged drafts of the necessary transaction documents, Act2 has not yet been formed and the Technology has not yet been transferred to Act2. (*Id.* Exs. 26, 30, 37) Both sides accuse the other of causing the delay that has prevented the transaction from closing. (D.I. 98 at 10-11; D.I. 121 at 6-7)

Regardless of who contributed most to the delay, on May 10, 2015, BSC sent plaintiffs a set of transaction documents for execution. (D.I. 125 Ex. 37) Plaintiffs have not signed those documents. Instead, plaintiffs’ counsel emailed BSC that litigation has already commenced and, therefore, any transaction between the parties must account for the parties’ conflict and BSC’s breaches of the Merger Agreement. (*Id.* Ex. 38) In their opposition brief, plaintiffs requested an order of “specific performance in the form of transfer of the technology without BSC retaining an 18% interest.” (D.I. 121 at 13 n. 5)

¹ The actual amount spent is unclear. In their brief, plaintiffs claim that BSC spent \$4.5 million, but do not explain how they arrived at that number or what evidence in the record supports it. (See D.I. 121 at 5). At oral argument, BSC said it spent a little more than \$5 million, but also does not explain how it arrived at that number. (Tr. 13).

III. STANDARD OF REVIEW

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 415 U.S. 475, 586 n. 10 (1986). A party asserting that a fact cannot be—or, alternatively, is—genuinely disputed must support the assertion either by citing to “particular parts of materials in the record,” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 415 U.S. at 587 (internal quotation marks omitted). The Court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586-87; see also *Podohnik v. U.S. Postal Service*, 409 F.3d 584, 594 (3d Cir. 2005) (stating that a party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). Although the “mere existence of some alleged factual dispute between the parties will not defeat an

otherwise properly supported motion for summary judgment,” a factual dispute is genuine where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating that entry of summary judgment is mandated “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”).

IV. DISCUSSION

Plaintiffs allege four claims. In count I, plaintiffs claim that BSC breached the Merger Agreement by failing to spend a minimum of \$15 million to develop and commercialize the Technology. (D.I. 1 ¶ 97) In count II, plaintiffs claim that BSC breached the Merger Agreement by not executing the documents necessary to transfer the Technology to Act2. Count III recasts plaintiffs’ count I breach of contract claim as a breach of the implied covenant of good faith and fair dealing. Specifically, plaintiffs allege that BSC breached the implied covenant by failing to take steps to pursue the achievement of the contingent payment milestones, thereby depriving plaintiffs of the benefit of those payments. (D.I. 1 ¶¶ 116-17) In count IV, plaintiffs allege that BSC breached the implied covenant by delivering the Spending Determination Notice without making a determination in good faith that further spending would not materially increase the commercial viability of the Technology. (*Id.* ¶ 124) According to plaintiffs, this act or omission also deprived plaintiffs of the benefits of the milestone payments. (*Id.* ¶ 125)

A. Count I - Breach of Contract

The parties do not agree on the exact amount BSC spent towards its minimum spending obligation, but do agree that it was less than \$15 million. Regardless of the actual amount spent, plaintiffs have not shown that BSC breached an express obligation of the Merger Agreement by spending less than \$15 million before it sent the Spending Determination Notice. Per the terms of the Merger Agreement, BSC had sole discretion in how to develop the Technology and how to spend the \$15 million. (See D.I. 1 Ex. A, § 1.6(f)) BSC had no contractual obligation, as plaintiffs argue, to “incrementally spend money over the course of four years until it spent the entire \$15 million.” (D.I. 121 at 9) Moreover, per the terms of the Merger Agreement, BSC’s spending obligation “immediately ceased” on April 16, 2013 when it determined that “further spending would not materially increase the level of feasibility of the product and/or its commercial viability” and sent plaintiffs a written notice to that effect. (See D.I. 1 Ex. A, § 1.6(f)) The fact that, at the time BSC sent the notice, it had 6 days left to spend approximately \$10 million does not affect the analysis.²

Ultimately, plaintiffs cannot sustain a breach of contract claim where there is no contractual underpinning for BSC’s alleged obligations. See *Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 145 (Del. Ch. 2009) (finding no breach of contract where the contract provisions do not obligate the defendant to take the particular actions plaintiffs sought); *Riverside Fund V, L.P. v. Shyamsundar*, 2015 WL 5004924, at *3

² It would not be reasonable to infer in plaintiffs’ favor that it was theoretically impossible for a company reporting \$5.631 billion in operating expenses to spend 0.18% of that amount in 6 days on a project requiring an estimated \$100 million or more to develop. (See SEC Form 10-K dated Dec. 31, 2015 at p. 34; D.I. Ex. 3 (estimating a future R&D investment of \$100-150 million to get the product to market))

(Del. Super. Aug. 17, 2015) (holding that where the contract did not require defendant to perform the specific act, plaintiff cannot sustain a breach of contract claim based on its nonoccurrence).

B. Count II - Breach of Contract

BSC argues in support of its motion for summary judgment on count II that plaintiffs failed to produce any evidence that they suffered damages from a delay in returning the Technology. (D.I. 98 at 12-13) Plaintiffs do not dispute that they presented no evidence on damages from the delay. Instead, they argue that count II survives BSC's motion because plaintiffs also sought specific performance. (D.I. 121 at 12-13) Because plaintiffs have not shown that there is any dispute as to a material fact regarding the lack of damages from the delay, summary judgment is awarded in BSC's favor on that aspect of count II.

As for specific performance, the court cannot resolve that part of the parties' dispute at this stage of the proceedings. Plaintiffs have crafted a request for specific performance that they believe would fairly address the parties' conflict and compensate them for BSC's purported breaches of the Merger Agreement. Specifically, plaintiffs have asked that the court order a transfer of the Technology without BSC retaining an 18% interest. (D.I. 121 at 13 n. 5) Although the court recognizes that the parties are in conflict, it has not found BSC in breach of the Merger Agreement. Moreover, "the Court is required to limit the remedy of specific performance to the rights created by the contract." *Del. State Troopers' Lodge Fraternal Order of Police v. State*, 1984 WL 8217, at *6 (Del. Ch. June 13, 1984). Plaintiffs may have the right to some form of specific

performance, but it is not clear at this time that the court is empowered to grant specific performance in the form requested.

C. Counts III and IV - Implied Covenant of Good Faith and Fair Dealing

In count III, plaintiffs allege that BSC breached the implied covenant of good faith and fair dealing by failing to develop the Technology in a manner that would allow plaintiffs to receive the benefit of the contingent payment milestones. (D.I. 1 ¶¶ 116-17) In count IV, plaintiffs allege that BSC breached the implied covenant by deciding in bad faith to deliver the Spending Determination Notice, thereby depriving plaintiffs of the benefits of the milestone payments. (*Id.* ¶ 124-25)

For several reasons, plaintiffs' claims do not fit within the rubric of the implied covenant of good faith and fair dealing. To begin with, the implied covenant of good faith and fair dealing is a "cautious enterprise" whereby the court will infer contractual terms to address "unanticipated developments or to fill gaps in the contract's provisions." *Nemec v. Shrader*, 991 A.2d 1120, 1125 (Del. 2010). When conducting this analysis, the court "must assess the parties' reasonable expectations at the time of contracting." *Id.*

Here, the Merger Agreement expressly addresses the relief plaintiffs seek through their implied covenant claims. Plaintiffs agreed that whether the regulatory approvals and sales of Contingent Payment Products would occur was "uncertain," and the receipt of any milestone payments was "not assured." (D.I. 1, § 1.6(e)) Moreover, the exclusive remedy for any claims arising out of delivery of the Spending Determination Notice is a return of the Technology. (D.I. 1, § 1.6(f)) This excludes damages as a form of relief. The implied covenant cannot be used to rewrite these

reasonable expectations. *Winshall v. Viacom Int'l, Inc.*, 76 A.3d 808, 816 (Del. 2013) (stating that plaintiffs cannot rely on the implied covenant to give them contractual protections they failed to secure at the bargaining table).

In addition, as the Delaware Supreme Court explained in *Winshall*, the implied covenant does not obligate a buyer in a merger transaction to “conduct their businesses, post-merger, so as to ensure or maximize the earn-out payments.” 76 A.3d at 811. In fact, the Merger Agreement expressly committed to BSC’s sole discretion all decisions on how to develop the Technology and how to spend the \$15 million. It also committed to BSC’s sole discretion the decision on whether to deliver the Spending Determination Notice. Delaware courts have repeatedly emphasized that “one generally cannot base a claim for breach of the implied covenant on conduct authorized by the terms of the agreement.” *Nemec v. Shrader*, 991 A.2d 1120, 1125-26 (Del. 2010)); *Dunlap v. State Farm Fire & Cas. Co.*, 878 A.2d 434, 441 (Del. 2005) (explaining that “[e]xisting contract terms control” such that the implied covenant “cannot be used to circumvent the parties’ bargain”). Thus, the court cannot find that BSC breached the implied covenant by exercising its contractual rights to develop the Technology how it chose to deliver a Spending Determination Notice.

Admittedly, “[w]hen a contract confers discretion on one party, the implied covenant requires that the discretion be used reasonably and in good faith.” *Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 146-47 (Del. Ch. 2009); *Winshall*, 76 A.3d at 816. But Delaware courts have explained that it is not bad faith for a buyer to conduct its business in a commercially reasonable manner. *Winshall v. Viacom Int'l, Inc.*, 55 A.3d 629, 638 (Del. Ch. 2011); *see also ev3, Inc. v. Lesh*, 114 A.3d 527, 540-41

(Del. 2015) (discussing *Winshall* with approval). It could be bad faith for a buyer to “purposefully” take some action to reduce the earn-out payments so as to shift additional profits its way at the expense of the seller’s former shareholders. *Winshall v. Viacom Int’l, Inc.*, 55 A.3d at 638. By that standard, plaintiffs have pointed to no conduct by BSC that suggests bad faith. Plaintiffs have simply disagreed with how BSC chose to develop the Technology. A dispute over BSC’s exercise of its commercially reasonable judgment does not amount to a breach of the implied covenant of good faith and fair dealing. For these reasons, BSC’s motion for summary judgment is granted as to counts III and IV.

V. CONCLUSION

For the foregoing reasons, BSC’s motion for summary judgment is granted in part and denied in part. Summary judgment is granted with respect to counts I, III, IV, and that portion of count II addressing damages. Summary judgment is denied with respect to that portion of count II addressing specific performance. BSC’s motions to preclude or strike the opinions and testimony of plaintiffs’ experts are moot. An appropriate order shall issue.