IN THE SUPERIOR COURT OF THE STATE OF DELAWARE
IN AND FOR NEW CASTLE COUNTY

MICHAEL LESH, M.D. and ERIK VAN DER BURG, acting jointly as the Shareholder Representatives for former shareholders of Appriva Medical, Inc.,	)	C.A. No. 05C-05-218 CLS
Plaintiffs,	)	
v.	)	
EV3 INC.,	)	
Defendant.	)	

Date Submitted: February 1, 2013
Date Decided: April 15, 2013

On Defendant ev3's Motion for Summary Judgment. **DENIED.**

ORDER

Jon E. Abramczyk, Esq. , Matthew R. Clark, Esq., Morris of Nichols, Arsht & Tunnell, LLP, Wilmington, Delaware and Jay Lefkowitz, Esq., Eric F. Leon, Esq., John Del Monaco, Esq., of Kirkland & Ellis, LLP, New York, New York and Robert A. Goodin, Esq., Francine T. Radford, of Goodin, MacBride, Squeri, Day & Lamprey, LLP, San Francisco, California. Attorneys for Plaintiffs.

Matt Neiderman, Esq., Benjamin A. Smyth, Esq. of Duane Morris, LLP, Wilmington, Delaware and Jeffrey J. Bouslog, Esq., Bret A. Puls, Esq., Dennis E. Hansen, Esq., Cynthia S. Wingert, Esq. of Oppenheimer, Wolff & Donnelly, LLP, Minneapolis, Minnesota and Matthew A. Taylor, Esq., James L. Beausoleil, Jr., Esq., Seth A. Goldberg, Esq. of Duane Morris, LLP, Philadelphia, Pennsylvania. Attorneys for Defendant ev3, Inc.

Scott, J.

Introduction

Before the Court is Defendant ev3's Motion for Summary Judgment. The Court has reviewed the parties' submissions and determined that ev3's motion is **DENIED** for the following reasons.

Background

The plaintiffs in this case are two former shareholders of Appriva Medical, Inc. ("Appriva"), Dr. Michael Lesh ("Lesh") and Erik van der Burg ("van der Burg") who represent the former shareholders of Appriva. Founded by Lesh and van der Burg in 1998, Appriva developed an implantable cardiac device known as the Percutaneous Left Atrial Appendage Transcatheter Occlusion ("PLAATO).[1] Defendant ev3 is a privately-held medical device company, which was founded in 2000 and owned and primarily financed by two private equity companies, Warburg Pincus and The Vertical Group. Paul Buckman ("Buckman") was the CEO of ev3 and Bruce Krattenmaker ("Krattenmaker") was ev3's Vice President of Regulatory Affairs.

Prior to being commercially marketed and sold in the United States and in Europe, PLAATO had to satisfy certain regulatory requirements. In the United States, PLAATO was required to receive approval from the Food and Drug

[1] PLAATO was designed to reduce the risk of strokes in patients suffering from atrial fibrillation by closing off the heart's left atrial appendage, which prevents blood clots from forming in the appendage and causing strokes. Pl. Opp., at p. 4.

Administration ("FDA") to conduct a "feasibility" clinical trial in the United States. Then, PLAATO was required to demonstrate by an FDA-approved clinical trial ("Pivotal Study") that PLAATO was safe and effective. There were different types of Pivotal Study designs that could be submitted to the FDA: a "non-randomized" Objective Performance Criterion control ("OPC") and a more costly and lengthy "randomized" Pivotal Study. If data obtained from the Pivotal Study showed that PLAATO met safety and efficacy requirements ("endpoints"), then an application could be submitted to the FDA for Pre-Market Approval. Once Pre-Market Approval was granted, PLAATO could be commercially marketed and sold in the United States.

In January 2002, ev3 approached Appriva to express an interest in purchasing Appriva and its PLAATO technology. On March 13, 2002, ev3 made an unsolicited offer to acquire Appriva for up to $190 million in a Letter of Intent.[2] Thereafter, on May 15, 2002, ev3 submitted to Appriva a revised Letter of Intent ("May 15, 2002 Letter of Intent") which reduced the upfront payment. The Letter of Intent also stated that "ev3 will commit funding based on the projections prepared by its management to ensure that there is sufficient capital to achieve the performance milestones detailed above."[3] In the Letter of Intent, these terms were considered part of "solely a non-binding indication of the proposal [ev3] currently

[2] Pl. Opp., Ex. 8.
[3] Pl. Opp., Ex. 18, Merger Agreement.

intend[ed] to make" and "[a]ny transaction between APPRIVA and ev3 will be subject to execution of the necessary definitive agreements between APPRIVA and ev3, containing customary representations, covenants, conditions, indemnification provisions and other terms to be agreed upon."[4]

Also on May 15, 2002, a meeting was held in which Krattenmaker discussed randomized trial options for PLAATO. After negotiations and due diligence, the parties entered into a merger agreement on July 15, 2002 ("Merger Agreement") and the merger closed on August 10, 2002. Pursuant to the Merger Agreement, the Appriva shareholders would receive an "Initial Merger Consideration" of $50 million. In addition, shareholders were entitled to contingent merger consideration based on four "Milestones."

If Milestone #1 was achieved by January 1, 2005, Appriva shareholders would be entitled to a payment of $50 million.[5] Milestone #1 was described as "the receipt of the surviving corporation of IDE Clinical Approval and Achievement of Acceptable Clinical Outcomes at either the 75 or 100 total Patient Year Analysis Point. The cumulative cohort of trial patients must be comprised of a minimum of 80 total patients enrolled with at least 40 patients from the United

[4] *Id*.
[5] Merger Agreement, Section 4.3(a)(i).

States".[6] "IDE Clinical Approval" was defined as "authorization under FDA regulations from the FDA to commence enrollment in a Phase III clinical study designed to support Pre-market Approval".[7]

Milestone #2 was defined as "International Registry Completion." "International Registry Completion" meant "the inclusion of at least 300 patients into the International Registry,[8] provided that at least 250 of such patients shall have come from Switzerland or countries belonging to the European Union or European Economic Area".[9] Appriva shareholders would be entitled to receive $25 million so long as Milestone #2 was achieved by January 1, 2008.[10]

Appriva shareholders would be entitled to receive $50 million so long as Milestone #3 was achieved by January 1, 2008.[11] Milestone #3 consisted of the "submission to the FDA of an application seeking Pre-Market Approval which such application the surviving Corporation believes includes adequate data that

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[6] *Id.*, Art. I.
[7] *Id*.
[8] The "International Registry" is a "collection of entry, acute and follow-up data on patients who have undergone the PLAATO procedure in countries other than the United States and Canada. A patient shall be deemed entered into the International Registry on the day he or she undergoes the PLAATO procedure, irrespective of whether PLAATO device is successfully implanted in such patient. Patient data collection in this registry will be conducted in accordance with a protocol approved by all required county specific regulatory agencies and hospital ethics boards". *Id.*
[9] *Id.*
[10] *Id*. at Section 4.3(a)(ii).
[11] *Id*. at Section 4.3(a)(iii).

supports the achievement of the Phase III trial primary endpoint(s);"[12] If Milestone #4, which was the Pre-Market Approval by the FDA, was achieved by January 1, 2009, Appriva shareholders would receive $25 million.[13]

Section 9.6 of the Merger Agreement provided that ev3's "obligation to provide funding for the Surviving Corporation, including without limitation funding to pursue achievement of any of the Milestones, shall be at [ev3's] sole discretion, to be exercised in good faith." The Merger Agreement also contained an integration clause ("Integration Clause") which stated that all prior and contemporaneous agreements were superseded "other than the Letter of Intent, dated March 15, 2002, as amended."[14]

After the closing of the merger, ev3 developed a new trial design instead of the OPC trial or a randomized trial. In February 2003, ev3 submitted a pre-IDE submission which would have provided ev3 informal feedback from the FDA instead of submitting a formal IDE Application. In the Fall of 2002, Warburg and Vertical Group began seeking ways to gain additional investors; however, by March 2003, they could not secure the total amount from new outside investors as they had hoped. Thereafter, Warburg developed a new operating plan in which it considered "postponing the start of Appriva's U.S. clinical trial (***a savings of $50***

[12] *Id*. at Art. I.
[13] *Id*. at Section 4.3(a)(iv).
[14] *Id*. at Section 16.9.

million in contingent milestone payments) while realizing revenues related to PLAATO's European commercialization and HDE approval in the U.S."[15] In an April 2003 e-mail, Buckman wrote to the Board and stated that funding wasn't the issue for the PLAATO trials "because [ev3 had] 2003 for both trials budgeted. The issue is the IDE milestone payment of $50 [million] which obviously gates the U.S. trial."[16]

In May 2003, the FDA responded to the pre-IDE submission and indicated that it would require a randomized trial. Thereafter, ev3 unsuccessfully attempted to renegotiate the milestone payments with the Appriva shareholders. ev3 then decided to pursue a different type of regulatory approval known as a Humanitarian Device Exception ("HDE").

While pursuing the pivotal trial design and as of December 2002, ev3 was planning to conduct a 300-patient clinical trial in Europe, but its plan was to split the 300 patients into two 150-patient phases. ev3 then decided to pursue a "controlled commercialization vs. a more complex and large registry" which would have resulted in " a complete European trial, as planned, but with fewer patients and maybe taking longer".[17] In an e-mail, Buckman stated "Looks like we may be

[15] Pl. Opp., Ex. 24.
[16] *Id*., Ex. 29.
[17] *Id*., Ex. 52.

in a position to not have any milestone exposure based upon current data, IDE schedule, and EU registry plan."[18]

In late 2004 and early 2005, ev3 began preparations for an initial public offering and made representations about its pursuit of PLAATO in connection with the IPO. In early March 2005, ev3 submitted a pivotal trial application to the FDA for a randomized trial. In September 2005, ev3 ceased development and commercialization of PLAATO based on several considerations.

Standard of Review

Summary judgment is to be granted when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."[19] When considering a motion for summary judgment, the Court must view the evidence in the light most favorable to the nonmoving party.[20] Where there is a material fact in dispute or if it seems desirable to inquire more thoroughly into the facts in order to clarify the application of the law, summary judgment is inappropriate.[21] If a motion for

[18] Pl. Opp., Ex. 53.
[19] Superior Court Rule 56; *Moore v. Sizemore*, 405 A.2d 679, 680 (Del. 1979).
[20] *Bailey v. City of Wilmington*, 766 A.2d 477, 479 (Del. 2001).
[21] *Tew v. Sun Oil Co.*, 407 A.2d 240,242 (Del. Super. 1979).

summary judgment is properly supported, the burden shifts to the non-moving party to show that there are material issues of fact.[22]

Discussion

I. Milestones #1, #3, and #4

Defendant ev3 moves for summary judgment on Counts I through VI of Plaintiffs' eight-count complaint. In Count I, Plaintiffs alleged that ev3 breached its obligations under the Merger Agreement by failing to make good faith efforts to pursue the achievement of Milestone #1 and by repudiating their obligation to pursue the achievement of Milestones #3 and #4 and to make the corresponding payments.

ev3 asserts that Plaintiffs fail to show specific evidence of bad faith and that ev3's actions were based not only on the Merger Agreement's standard giving ev3 "sole discretion, to be exercised in good faith", but on reasonable business decisions. ev3 also argues that the implied covenant of good faith and fair dealing cannot apply where the parties have expressly provided for the standard governing the conduct of the parties.

The purpose of the implied covenant of good faith and fair dealing is to "enforce the parties' contractual bargain by implying only those terms that the parties would have agreed to during their original negotiations if they had thought

[22] *State v. Regency Group, Inc.*, 598 A.2d 1123, 1129 (Del. Super. 1991).

to address them."[23] The express agreement must clearly show that the parties "would have agreed to proscribe the act later complained of as a breach of the implied covenant of good faith—had they thought to negotiate with respect to that matter."[24] The implied covenant also applies to a party's discretionary rights. However, if the agreement expressly provides a standard for evaluating a decision, then that "[e]xpress contractual provision[] always supersede[s] the implied covenant…"[25]

Section 9.6 expressly provided that ev3's "obligation to provide funding for the Surviving Corporation, including without limitation funding to pursue achievement of any of the Milestones, shall be [ev3's] sole discretion, to be exercised in good faith." Based on this language, the Court finds that the standard governing ev3's conduct in funding and pursuing the milestones is this "sole discretion, to be exercised in good faith" standard expressly set forth; therefore, the implied covenant of good faith does not apply because the covenant is superseded by this express standard.

Issues of fact exist as to whether ev3 exercised its discretion in good faith with regard to the achievement and funding of Milestone #1. ev3 has offered evidence

[23] *ASB Allegiance Real Estate Fund v. Scion Breckenridge Managing Member, LLC*, 50 A.3d 434, 440 (Del. Ch. 2012).
[24] *Ibid*.
[25] *ASB Allegiance,* 50 A.3d at 441.

that it put a considerable amount of effort into designing the pivotal study in order to submit the IDE Application, to include retaining clinical and regulatory experts, in order to achieve Milestone #1. In addition, ev3 has submitted facts showing that, when it the proposed study was rejected on May 28, 2003 and the FDA indicated that it would require a randomized study, ev3 made significant efforts to pursue alternative designs and pursued HDE approval based on its discussion with the FDA. Plaintiffs have presented the statements and the revised Warburg operating plan which suggest that the decision was made not to finance or pursue Milestone #1 prior to the FDA's rejection of the pivotal study. Based on these facts, an issue of fact exists as to whether ev3 acted in good faith in the pursuit and funding of Milestone #1.

Milestones #3 and #4 were directly dependent upon the achievement of the FDA's IDE clinical approval. If the FDA did not grant IDE clinical approval, then ev3 could not submit an application for and the FDA could not grant Pre-Market Approval. Although the facts do not show with certainty that the FDA would have approved a randomized trial design if it had been immediately submitted by ev3 or that it would have granted Pre-Market Approval, Plaintiffs have presented facts showing that there was a likelihood of approval had a randomized trial design been submitted earlier. Nevertheless, ev3 also presented evidence that the FDA had denied Pre-Market Approval on a similar device despite the device's randomized

trial design. Since the Court finds that an issue of fact exits as to whether ev3 acted in bad faith with regard to Milestone #1, the Court also finds that an issue of fact exists as to whether ev3's actions, relating to the IDE application, materially contributed to the nonoccurrence of Milestones #3 and #4.[26] Therefore, summary judgment is also denied as to Plaintiffs' claims relating to Milestones #3 and #4.

II. Milestone #2

An issue of fact exists as to whether ev3 exercised its discretion in good faith with regard to Milestone #2. ev3 has proffered evidence showing that its decision to conduct the International Registry in two phases was based on several legitimate factors. However, Plaintiffs suggests that Buckman's March 2003 e-mail in which he stated, "Looks like we may be in a position to not have any milestone exposure based upon current data, IDE schedule and EU registry plan", [27] suggests that ev3 could have decided to divert patients from the European Registry and implant the patients with PLAATO in a commercial setting to ensure that it would not meet the 300-patient milestone. Construing the facts in favor of the Plaintiffs, the Court finds that an issue of fact exists as to whether ev3 acted in good faith with respect to Milestone #2. Further, Plaintiffs argue that Milestone #2 was actually achieved

[26] *See WaveDivision Holdings, LLC v. Millennium Digital Media Sys., L.L.C.*, 2010 WL 3706624, at*14 (Del. Ch. Sept. 17, 2010)(quoting Restatement (Second) of Contracts § 245)("It is an established principle of contract law that '[w]here a party's breach by nonperformance contributes materially to the non-occurrence of a condition of one of his duties, the non-occurrence is excused'").
[27] *E.g,* Pl. Ex. 53.

and that ev3 has breached the Merger Agreement by failing to make the corresponding payment. Plaintiffs support this argument with an e-mail from a European PLAATO investigator that 340 European patients had been implanted with PLAATO. Based on this, an issue exists as to whether ev3 actually reached the Milestone #2 payment and, consequently breached the Merger Agreement by failing to make the corresponding payment.

III. Fraud Claims

Whether there has been fraud is a question of fact for the jury to consider.[28] However, in order for Plaintiffs fraud claims to survive summary judgment, genuine questions of fact must exist that a "false representation of a material fact [was] knowingly made with intent to be believed to one who, ignorant of its falsity, relies thereon and is thereby deceived."[29] In addition, the reliance alleged must be justifiable.[30] Plaintiffs have submitted evidence that Krattenmaker informed the Appriva shareholders that a randomized trial design would be "[m]ost supportable to FDA".[31] Plaintiffs also present bullet points from the "Operating Plan and International Strategy" portion of the May 15, 2002 presentation in which certain

[28] *Johnson v. Messick*, 11 Del. Ch. 454, 106 A. 58, 59 (1919); *Clayton v. Cavender*, 15 Del. 191, 40 A. 956 (Super. Ct. 1893).
[29] *Harman v. Masoneilan Int'l, Inc.*, 442 A.2d 487, 499 (Del. 1982)(citing *Twin Coach Company v. Chance Vought Aircraft, Inc.*, 163 A.2d 278 (Del. Super. 1960); *See also In re Brandywine Volkswagen, Ltd.*, 306 A.2d 24, 28 (Del. Super. 1973).
[30] *H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 142 (Del. Ch. 2003).
[31] Pls. Ex. 13.

representations were made, such as a representation that the Appriva operating plan would remain generally intact. Plaintiffs characterize the statements made as a series of promises on which ev3 failed to deliver. To show that ev3 failed to disclose that it had no plans to actually pursue the randomized trial option, Plaintiffs offer the statements obtained in discovery by Krattenmaker that he never told Appriva that there was no way ev3 would pursue a randomized trial option[32] and that he would have wanted to know, had he been in Appriva's position, about the problems associated with the randomized trial option and about ev3's views about the feasibility of pursing a randomized trial option.[33] However, in this same deposition, Krattenmaker also stated that, in his view, "[ev3] had not abandoned or necessarily discounted [the randomized trial] as an option."[34] Furthermore, ev3 presented evidence that Buckman did not believe that the statements made during the presentation were false at the time they were made.[35] Therefore, the Court finds that the issue of fraud is a question of fact properly reserved for the jury and summary judgment is denied for the fraud claims against ev3.

[32] Pl. Ex. 15, Krattenmaker Dep. Tr. 65:7-14).
[33] *Id*. at 70:3-18.
[34] *Id.* at 65:20-23
[35] Def. Mot. Exs. 14, 28.

Conclusion

Based on the foregoing reasons, Defendant ev3's Motion for Summary Judgment is **DENIED**.

IT IS SO ORDERED.

/S/CALVIN L. SCOTT
Judge Calvin L. Scott, Jr.