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UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Court of Chancery of Delaware.

PAVEL MENN, as representative of the former shareholders of ENDODYNAMIX, INC., Plaintiff,
v.
CONMED CORPORATION and ENDODYNAMIX, INC., Defendants.

C.A. No. 2017-0137-KSJM
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POST-TRIAL MEMORANDUM OPINION

McCORMICK, C.

***1** This action arises from a stock purchase agreement by which ConMed Corporation acquired EndoDynamix, Inc., a start-up monoline company that was developing a clip applier product to be used in laparoscopic surgeries. The parties allocated the risk associated with the continued development of the clip applier through a contingent payment structure. ConMed agreed to pay the sellers $1.25 million up front, to make milestone payments of up to a total $10.25 million upon the product's achievement of four development objectives, and to make earn-out payments of $2 million upon the first sale and in the amount of 10% of the net sales generated for a period after the first sale.

Because the bulk of consideration to be paid to the sellers was contingent on the clip applier achieving development milestones and financial targets after ConMed acquired the company, the sellers obtained ConMed's agreement to use commercially best efforts to maximize the milestone and earn-out payments. The sellers further negotiated for the right to demand accelerated payment of the milestone and earn-out payments if ConMed permanently discontinued the development or sale of the clip applier products unless that determination was made for contractually specified reasons, including that the clip applier posed a risk of injury to patients.

Before the parties entered into the stock purchase agreement, ConMed identified safety issues in the clip appliers' design. As part of the stock purchase agreement, ConMed negotiated for the right to implement design changes to address those concerns. Those design changes were identified in a schedule to the agreement. After the parties closed on the agreement, ConMed devoted substantial resources to implementing those design changes and developing the clip applier in other ways. ConMed put the product through multiple animal lab studies and applied for and obtained FDA clearance. By October 2015, ConMed had made the up-front payment and three of the four milestone payments, for a total of $9 million in payments to sellers.

ConMed, however, continued to encounter problems in the product's development, including safety features identified in the schedule to the stock purchase agreement. In early 2016, ConMed tasked a newly acquired and highly experienced development team with reevaluating the product. They concluded that ConMed should scrap the product entirely in favor of developing a new clip applier. In May 2016, ConMed notified the sellers of ConMed's view that the clip applier posed a risk of injury to patients and that ConMed was seriously questioning whether to move forward with development of the product. Shortly after the report, ConMed's board determined to discontinue development of the product.

In response to the report, sellers' representative, Plaintiff Pavel Menn, demanded acceleration payments. ConMed declined to make the payments, and this lawsuit ensued.

The plaintiff claims that ConMed breached its obligation to use commercially best efforts to develop the clip applier and discontinued the product's development for reasons other than a risk of injury to patients. The parties presented extensive evidence throughout the course of a seven-day trial. Ultimately, the defendants proved that they discontinued development of the clip applier based on the determination that it posed a risk of injury to patients. And the plaintiff failed to prove that the defendants breached their commercially-best-efforts obligation prior to making the determination to discontinue development of the clip applier. This post-trial decision finds in favor of the defendants.

I. FACTUAL BACKGROUND

***2** As reflected in the Schedule of Evidence submitted by the parties, the record comprises 529 joint trial exhibits, trial testimony from five fact and five expert witnesses, deposition testimony from nineteen fact and five expert witnesses, and stipulations of fact in the pre-trial order. [1] These are the facts as the court finds them after trial.

A. EndoDynamix And The SureClip Clip Applier

In 2008, Plaintiff Pavel Menn and non-party William Bookwalter founded EndoDynamix, Inc. for the primary purpose of developing a clip applier, which they called the "SureClip Clip Applier" (the "SureClip"). [2]

Clip appliers are medical instruments used in minimally invasive surgical procedures (typically, laparoscopy) that apply clips to close off a duct, tube, or blood vessel in the body. [3] The process of closing off a duct, tube, or blood vessel is called "ligation." [4] Clips are small, titanium u-shaped objects with a rounded "shoulder" from which two straight prongs called "legs" extend. [5] A clip applier is composed of a handle and a shaft. [6] The shaft is also called the "cartridge." [7] Clips are pre-loaded into the shaft. [8] The end of the shaft features mechanical jaws that clamps the clip closed. [9] Generally, a surgeon holds the clip applier by the handle and uses its trigger to release a clip from the shaft into the jaws, which close the clip onto the vessel to be ligated. [10]

The SureClip shafts came in two sizes: a 5mm and a 10mm, designed to apply 5mm and 10mm clips, respectively. [11] Its handle was "universal" in the sense that it was compatible with both the 5mm and 10mm SureClip shafts. [12] The 5mm and 10mm shafts are collectively referred to as the "Clip Applier Products." [13] With the handle, they are referred to as the "Products." [14] None of the Products could be used with any other clip applier on the market. [15]

When EndoDynamix began developing the SureClip, the clip applier market was dominated by two disposable clip appliers sold by Ethicon and Covidien, respectively. [16] Because these existing products were designed to be thrown away after a single use, some viewed their design as "cheap" or subpar. [17]

***3** To differentiate the SureClip from other clip appliers, EndoDynamix designed the SureClip as a "reposable" clip applier, consisting of a reusable stainless-steel handle and a disposable single-use shaft. [18] The hope was that a reusable handle would capitalize on hospital initiatives to lower costs and reduce waste. [19]

Moreover, clip appliers generally had a history of patient safety-related performance issues. Menn testified during his deposition and at trial that clip appliers have been the subject of FDA Medical Device Reports ("MDRs") and recalls. [20]

Thus, to further distinguish the SureClip from other clip appliers, EndoDynamix's early marketing materials highlighted the most common reasons for the MDRs for clip appliers and stated that the SureClip had features that resolved these patient safety issues and had the following safety features and functionalities common to clip applier products:

- "Last-clip lockout," which is a visual indication of the last clip in a cartridge along with a mechanism to prevent closure of the clip applier's jaws once the final clip in the cartridge is released. [21]

- "Visualization," which refers to the surgeon's ability to visually evaluate the placement of a clip on the tissue when the clip applier's jaws are open. [22]

- "Tips-first closure," is a type of "clip closure," which occurs when the tips of the clip legs come into contact before the clip is crushed and the tissue is ligated. Tips-first closure is designed to ensure that only the tissue to be ligated is included within the clip and that no tissue escapes from the clip. [23]

- "Clip scissoring" refers to a problem in clip closure, which occurs when the clip's legs overextend beyond the center line. Clip scissoring can cause tissue damage. [24]

Other design features of the SureClip further distinguished it from products on the market. For example, clips used in clip appliers had to be designed for two purposes: first, to ligate the tissue, and second, to "feed" down the shaft. [25] Products on the market satisfied the second function by having the clips push each other, like a train, head-to-tail down the shaft. [26] The established method of feeding clips was imperfect; clips often jammed in the shafts of disposable clip appliers. [27] The established method of feeding clips also required design tradeoffs that affected the clip's performance on the tissue. [28]

***4** By contrast, the SureClip employed an "individual clip management" design, which meant that the shaft mechanics, and not the follow-on clips, advanced the clips down the shaft. [29] The SureClip's individual clip management also allowed EndoDynamix to design the clip itself with a sole focus on ligating the vessel. [30] Toward that end, EndoDynamix designed a clip with rounded "shoulders," which was intended to minimize irritation to the surrounding tissue once applied. [31] The clip also had a patented "double hard cross section" pattern on the inside of the legs intended to reduce the need for surgeons to use multiple clips to ligate a vessel. [32]

Further, the SureClip had "atraumatic jaws," which meant that they caused minimal tissue injury. [33] Disposable clip appliers on the market had narrower, sharper jaws that could damage vessels if closed when no clip was loaded in the jaws. [34] The SureClip's jaws were smooth and rounded, with broad surfaces designed to avoid tissue damage. [35]

Other terms unique to the field of clip applier development permeate this decision. The following glossary is intended to aid those unfamiliar with the vernacular:

- "Clip loading and stability" refers to the loading and stability of the clip as it enters the jaw of the device until it is implanted. [36]

- "Clip security" refers to the ability of an implanted clip to remain secure in its position. [37]

- "Device weight" refers, as the title suggests, to the weight of the device. It is relevant from a design perspective because a heavy device can slip from a surgeons hand, cause fatigue in the surgeon during prolonged use, or fall out of the trocar (defined below), causing injury to a patient.

- "Trocar" is a port or tube through which the clip applier is inserted into the body. [38]

B. ConMed Expresses An Interest In Acquiring EndoDynamix.

After forming EndoDynamix, Menn and Bookwalter raised money, assembled staff, and built facilities for designing, developing, and manufacturing the SureClip. [39] By 2010, the SureClip had piqued the interests of Defendant ConMed Corporation ("ConMed"), a publicly traded New York corporation specializing in developing and selling surgical products. [40]

In March 2010, ConMed's then-Chief Executive Officer traveled with a delegation to EndoDynamix's Massachusetts headquarters to observe the SureClip. [41] ConMed was already a market leader in reposable instruments, but it only sold one size of clip applier (a 10 mm) that accounted for a small percentage of the clip applier market, and surgeons were increasingly preferring 5 mm clip appliers. [42] The SureClip would help ConMed round out its product offerings and attract hospital-group customers that were looking for one-stop shopping for all of their instruments. [43] After the initial March 2010 meeting, ConMed kept apprised of

SureClip's development, visiting several more times in 2011 and 2012. [44]

In 2013, ConMed observed the functionality of SureClip in two labs (the "2013 Animal Labs"), testing whether SureClip had safety features and functionality common to other clip applier products. [45] In these labs, surgeons tested the SureClip on live pigs. [46] The first lab occurred in September 2013 and the second lab occurred in December 2013. [47]

***5** Through the 2013 Animal Labs, ConMed observed that the statements in EndoDynamix's marketing materials concerning the SureClip's safety features were somewhat aspirational—they did not reflect the product's actual design at the time. [48] Still, from December 2013 through April 2014, ConMed conducted extensive diligence on the SureClip design. [49] And in April 2014, ConMed sent a letter of intent to acquire the stock of EndoDynamix. [50]

C. The Stock Purchase Agreement

The parties' negotiations culminated in a Stock Purchase Agreement (the "Agreement") executed on July 30, 2014. [51] The Agreement was entered into between ConMed, on the one hand, and EndoDynamix, certain stockholders of EndoDynamix (the "Stockholder Parties"), and Menn (as representative of the Stockholder Parties) on the other. [52]

1. Payment Structure

The bulk of the consideration to be paid to the Stockholder Parties under the Agreement was contingent on the achievement of post-closing development milestones and financial thresholds.

Specifically, the Agreement required ConMed to make an upfront payment of $1.25 million (less certain expenses and other amounts) at closing as well as two categories of contingent, post-closing payments defined respectively as "Milestone Payments" and "Earn-Out Payments." [53]

Section 4.02 of the Agreement established four Milestone Payments totaling up to $10.25 million. [54] The first payment of approximately $3.75 million was due upon the successful completion of an animal lab study using the Clip Applier Products (the "Animal Lab Milestone"). [55] The next two Milestone Payments were tied to FDA 510(k) clearance, a process that allows a manufacturer to bring a new device to market by having it declared substantially equivalent to a predicate device that is already on the market. [56] ConMed would pay approximately $2.5 million upon reaching inventory levels and completing documentation sufficient to meet FDA submission standards (the "FDA Application Milestone"), and approximately $1.5 million upon receiving FDA clearance of the Clip Applier Products (the "FDA Clearance Milestone"). [57] The last payment, of approximately $2.5 million, was due upon the first commercial sale of any of the Products (the "Triggering Sale"). [58]

Section 4.03 of the Agreement established two categories of Earn-Out Payments: (i) $2 million one year after a Triggering Sale; and (ii) payments equal to nearly 10% of the net sales generated from the Products for five years after a Triggering Sale. [59]

2. Seller-Friendly Provisions

As is common in contracts involving contingent, post-closing consideration, the Stockholder Parties negotiated for a provision requiring ConMed to use its best efforts to maximize payments to them.

Section 4.03(g) of the Agreement obligated ConMed to "work in good faith" with EndoDynamix and use "commercially best efforts" to maximize the Milestone Payments and Earn-Out Payments for the benefit of the Stockholder Parties. [60]

The Stockholder Parties also negotiated for the right to accelerate payment of the unpaid amounts of Milestone Payments or Earn-Out Payments upon the occurrence of certain events (the "Acceleration Payments").

***6** Under Section 4.03(h) of the Agreement, ConMed owed Acceleration Payments if it "acquire[d] a business

that will integrate with[ ] ... the Company and following such acquisition [ConMed] permanently discontinues the development or sale of any of the Clip Applier Products" [61] or ConMed "otherwise permanently discontinue[d] the development or sale of the Clip Applier Products" other than for certain reasons defined in the Agreement. [62]

To exercise the acceleration rights, the Agreement required that Menn serve ConMed with an acceleration notice providing ConMed with an opportunity to cure the breach. [63] The Acceleration Payments would become due if, after twenty business days from service of the acceleration notice, the breach was not cured. [64]

3. Buyer-Friendly Provisions

ConMed negotiated for protections as well. For example, the Stockholder Parties agreed that ConMed "expects to be able to freely run the Company's business in its discretion following the Closing," and that ConMed would have "full control and direction over the Company's business following the Closing, including decisions regarding the [SureClip]." [65]

ConMed negotiated for exceptions to its obligation to make Acceleration Payments under Section 4.03(h). One is relevant here. ConMed was not obligated to make Acceleration Payments if the decision was based on a "commercially reasonable determination" made in ConMed's "sole discretion that the use of such Clip Applier Product(s) pose(s) a risk of injury to either patients or surgeons ...." [66]

ConMed also negotiated for the express right to make design changes to the SureClip. As discussed above, through the 2013 Animal Labs, ConMed identified design changes to the SureClip that it viewed as essential to the product's safety and success. Indeed, shortly after submitting the letter of intent, on April 4, 2014, ConMed tendered a list of required design changes that arose out of the two 2013 Animal Labs. [67] The April 4 list became Schedule 8.10 to the Stock Purchase Agreement. [68] The modifications in Schedule 8.10 addressed product safety features, including last clip lock-out, visualization, clip loading and stability, and clip closure and security. [69] Although Schedule 8.10 does not expressly reference tips-first closure as an intended design improvement, Schedule 8.10 required that the "[c]lip must not push tissue out of the [j]aws" which is an issue that tips-first closure was designed to prevent. [70] Similarly, Schedule 8.10 does not explicitly reference clip scissoring, but it does mention clip closure, and clip scissoring is a specific type of clip closure issue. [71]

***7** The parties agreed in Section 8.10 of the Stock Purchase Agreement that ConMed was empowered to implement the modifications listed on Schedule 8.10. [72]

The parties further agreed through Section 8.10 that

> nothing in this Agreement shall restrict the right of the Company or its Affiliates following the Closing to make modifications to the specifications of any Product to the extent that any such specification modifications, in the reasonable discretion of the Company or any of its Affiliates, are necessary to address (i) existing or future market conditions, (ii) compliance with any Applicable Law (including, without limitation, any rule or regulation of the FDA) .... [73]

Schedule 8.10 and Section 8.10 were included in the Agreement at ConMed's request. In negotiations over the Stock Purchase Agreement, EndoDynamix had included a provision obligating ConMed to make Acceleration Payments if ConMed made "design modifications ... without the prior written consent of [Menn]." [74] ConMed rejected that language and added Section 8.10 and Schedule 8.10. [75]

ConMed secured the Stockholder Parties' agreement that "no modification made to the specifications of any Product made in accordance with Section 8.10 shall (a) be deemed to be a breach of Section 4.03(g)" containing the best-efforts obligation. [76]

ConMed also secured the Stockholder Parties' agreement that the Acceleration Payments would serve as liquidated damages due to the "indeterminate harm anticipated" and the difficulty of proving "loss and damages." [77] Specifically, the Agreement defined Acceleration Payments as reasonable liquidated damages. [78] It further specified that ConMed had no obligation to pay liquidated damages in the event of the contractually specified exceptions to the Acceleration Payments. [79]

D. Post-Closing Events

Upon closing, EndoDynamix ceased operating as a separate entity and became a subsidiary of ConMed. [80] SureClip development was integrated into what later became known as the "Advanced Surgical Division" of ConMed. [81] At the time of the acquisition, John ("Jed") Kennedy was Vice President of the Advanced Surgical Division. [82] After the integration in January 2015, Kennedy was replaced by Bill Peters as Vice President of the division. [83]

As of August 26, 2014, ConMed had targeted a March 2016 launch date for SureClip. [84] ConMed held an official "Kick-Off Meeting" on September 3, 2014. [85] Over 50 ConMed employees from various departments, including engineering, manufacturing, compliance, and sales were invited to attend. [86]

ConMed appointed David Wu as project leader over the SureClip project. [87] Wu holds a B.S. from the University of Rochester, where he majored in biomedical engineering and has worked on numerous laparoscopic devices. [88] Two engineers were assigned to work with Wu on the project. Dennis Cook led a team of manufacturing engineers responsible for the handle, and Mike Thomas led a team of manufacturing engineers responsible for the cartridges. [89] Additional team members were focused on quality assurance and packaging issues related to the clip applier. [90]

***8** Menn and other former EndoDynamix employees including Nate Rosso, Victor Dardzinski, and Khanh Nguyen joined ConMed and worked on the project. [91]

1. The September 2014 Animal Lab

On September 12 and 13, 2014, ConMed held an animal lab to test modifications made to SureClip (the "September 2014 Animal Lab"), including those made in accordance with Schedule 8.10 of the Agreement. [92] The lab results would inform whether ConMed would pay the $3.75 million Animal Lab Milestone Payment. [93] The definition of "Animal Lab Milestone" in the SPA referenced Schedule II, which included criteria to be evaluated by surgeons, as well as several items to be "[m]easured by [a] ConMed engineer." [94] The tested devices were prototypes fabricated in EndoDynamix's Salem facility. [95]

Six surgeons participated in the lab. One of the surgeons, Dr. Deborah Nagle, was recommended by Menn. [96] Each surgeon received a survey sheet describing the criteria to be evaluated and asking to give the 5mm and 10mm devices a "pass" or a "fail" for each criterion. [97]

The SureClip received some favorable feedback. The 10mm SureClip device received all passes from five surgeons. [98] One surgeon really liked the design features, describing them as follows:

> To make a metaphor ... when you hold an iPhone ... that is a quality piece of machinery just from looking at it. And so, when you have this [SureClip] in your hand, and the way it behaves and the way it moves and the way it feels, you know there is a lot of engineering going into this. And it's made really well. [99]

Yet the feedback was not entirely favorable. [100] One of the six surgeons failed the 10mm device's last-clip lockout feature. [101] Although three of the six surgeons passed the

5mm device, [102] two of those surgeons expressed concerns and identified areas of improvement for the device. [103] The other three, including Menn's selected surgeon, failed the 5mm device. [104] The ConMed engineers also failed the devices on multiple criteria, such as last-clip lockout, tips-first closure, clip scissoring, and clip loading, among other things. [105]

In a presentation summarizing the results of the September 2014 Animal Lab, Ed Connell, ConMed's marketing manager assigned to SureClip, reported that the "[r]eposable clip applier platform and overall design was very well received by all surgeons." [106] He further reported that the 10mm clip applier cartridge "[p]erformed well with few recommendations." [107] Connell later testified that the "few recommendations" were minor and that, on the whole, the 10mm device passed the criteria tested in the September 2014 Animal Lab and was on schedule for the targeted March 2016 launch date. [108]

***9** As for the 5mm SureClip device, Connell's presentation stated that the cartridge had "[s]ome failures noted with recommendations to enhance the ongoing design efforts." [109] As Connell explained, ConMed understood that the 5mm device "was just behind because it hadn't had the focus as much as" the 10mm device. [110] The purpose of the September 2014 Animal Lab with respect to the 5mm device "was really seeing where the 5[mm] was with the work we had done on the 5[mm] and testing it." [111] Ultimately, Connell testified that while the 5mm device "had some failures noted during the device performance" at the September 2014 Animal Lab, he believed at the time that "it was close enough that we knew we were close." [112]

2. The October 2014 Animal Lab

ConMed scheduled another animal lab for October 2 and 3, 2014 (the "October 2014 Animal Lab"). [113] The narrow focus of the October 2014 Animal Lab was to re-test the 5mm device to evaluate whether the device included a last-clip lockout. [114] Menn and Kennedy agreed that the October 2014 Animal Lab would include only two of the six surgeons who participated in the September 2014 Animal Lab. [115] Both of the selected surgeons had passed the 10mm device during the September 2014 Animal Lab. [116] And both of the selected surgeons passed the 5mm device during the October 2014 Animal Lab. [117]

Although the 5mm device received a passing grade, it still had issues. At the conclusion of the lab on October 3, Kennedy emailed ConMed's CEO Curt Hartman that of the four devices tested on animals, three passed the last-clip lockout criterion and one failed. [118] Plaintiff introduced video clips from the October 2014 Animal Lab. The video shows the plastic "dummy" clip, which was intended to serve as a lockout, fell out of the jaws into the animal. [119] This issue caused one of the other four surgeons to fail the device in the September 2014 Animal Lab. [120]

Despite the recurring lockout issues, on October 3, Kennedy wrote that a group representing Quality Assurance, Research & Development, Marketing, and Sales, "agreed unanimously that the test samples demonstrated a *workable design* and that reliability of the [last-clip lockout] feature *could be addressed* during the project." [121] Kennedy recommended "that the animal lab milestone be considered successfully completed and that the associated $3.75 MM payment be released." [122]

ConMed made the $3.75 million Animal Lab Milestone payment to the Stockholder Parties in October 2014. [123]

3. ConMed Applies For FDA 510(k) Clearance.

Because the Agreement tied two Milestone Payments totaling $4 million to SureClip's FDA 510(k) clearance, the Agreement required ConMed to make an FDA 510(k) submission. [124]

Shortly after acquiring EndoDynamix, ConMed began developing its strategy for obtaining FDA 510(k) clearance. [125] ConMed's Director of Regulatory Affairs, Jessie Verna, and Anna D'Lima who reported to Verna, were assigned to work on the 510(k) application for FDA clearance. [126]

***10** Originally, the Regulatory Affairs group had intended to seek 510(k) clearance for the entire SureClip device. By November 2014, however, they had decided to seek clearance for the clip only. On November 19, 2014, D'Lima emailed Kennedy and the project team:

> Handle performance testing will not be included in the 510(k). This approach is based on the handle being regulated as a Class I device .... The 510(k) submission will be limited to include the cartridge/clip performance data. [127]

In response to her November 19 email, Kennedy asked, "[i]s there any risk with this approach?" [128] Verna explained that the reusable handle could still be subject to FDA Design Control standards and would still have been required to undergo validation testing prior to launch. [129] At trial, Verna credibly testified that the reason for this approach was that the handle required further development, and the Regulatory Affairs Group believed that seeking clearance for the clip only moved the product forward in the swiftest possible way. [130]

ConMed retained an independent laboratory operated by North American Science Associates, Inc. ("NAMSA") to evaluate the safety and efficacy of the clips for FDA 510(k) clearance. [131] NAMSA initiated its study in January 2015. During the study, clips were implanted in a pig and, 28 days later, the site was reopened and evaluated. The NAMSA report passed the subject of the study—the clips. [132]

Although the NAMSA report passed the subject of the study, the report noted the lack of tips-first closure as an "adverse event" involving the clip applier:

> 14.3.2 Adverse Events
>
> One procedure related adverse event was reported for this study.
>
> In one animal (I5P59), during multiple clip deployments it was observed that the SureClip handle piece (used to deploy the clips) was not functioning properly, *causing the tip of several clips to come together before the tissue was fully encompassed*. As a result, additional clips were required/applied in order to fully ligate the sites. This event was reported as a procedure related adverse event as it pertained to the SureClip handle accessory and was not related to the actual test article (clips). [133]

Wu testified that the "adverse event" concerning clip-loading and closure was a persistent problem and consistent with the observations made in prior labs. [134] Wu prepared a presentation dated March 22, 2015, summarizing the features of the SureClip 5mm cartridge against that of Ethicon, and illustrating the deficiencies in the SureClip based on the issues identified during the animal labs. [135] The presentation highlighted that, at the time, the SureClip still did not achieve tips-first closure; the SureClip could jam as a clip was advanced into the jaws of the SureClip leading to malformed clips; the size of the SureClip clip opening was one-half the size of the Ethicon device's opening; and the space between the jaws was reduced making placement more difficult. [136]

***11** Nevertheless, on April 8, 2015, ConMed filed its 510(k) application with the FDA. [137] ConMed paid the $2.5 million FDA Application Milestone, bringing the total consideration paid under the Agreement to $7.5 million. [138]

Although the 510(k) application sought clearance for the clip only, [139] and the lab report attached to the application identified an adverse event involving the clip applier, representations made by ConMed in the application seemed to speak to the safety of the SureClip as a whole.

ConMed stated that the entire SureClip device was as safe and effective as the predicate device in a number of ways. [140]

First, in the Summary of Safety and Effectiveness, ConMed certified to the FDA that the SureClip was as safe and effective as the predicate device, the Ethicon clip applier. [141]

- Because the SureClip contained some features that differed from the predicate device, ConMed certified to the FDA that the technological differences between the SureClip and the predicate device "are limited to design features considered to be 'customer preference' driven,

including the new warning clips that provide immediate, visual[ ] feedback; ... and the jaw lockout feature." [142]

- ConMed represented that "[p]roduct performance and animal testing demonstrate the safe and effective application of the new design features for the same intended use as the predicate device." [143]

- ConMed certified that "[t]he differences between the predicate and the SureClip Clip Applier do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the *SureClip Clip Applier is safe and effective for its intended use*, and is substantially equivalent to the predicate device." [144]

In the "Substantial Equivalence Discussion," ConMed certified that the solid "lockout block" that feeds into SureClip's jaws after the final clip is deployed "provides an enhanced lockout feature for the same purpose of preventing closure of empty jaws on a structure or vessel" as compared to the Ethicon clip applier. [145]

Also, in a document titled "Performance Testing – Animal," ConMed certified that the "SureClip Clip Applier devices performed safely and effectively for the same intended use and simulated use conditions as the comparably sized predicate and reference devices; therefore, the ligating clip design of the SureClip Clip Applier is substantially equivalent to Ethicon clip appliers." [146]

Similarly, in a document titled "Performance Testing – Bench," ConMed certified that the SureClip 5mm and 10mm devices received a "pass" in various categories, including "Clip Formation" and "Jaw Lockout." [147]

4. The April 2015 Animal Lab

***12** After ConMed submitted its 510(k) application, but before ConMed received 510(k) clearance, ConMed held four additional animal labs. [148] The 2015 animal labs were "Voice of the Customer" events designed to obtain feedback from surgeons. [149]

The first Voice of Customer Lab was held on April 28, 2015 (the "April 2015 Voice of Customer Lab"). Two surgeons participated, and Wu oversaw the lab. [150] During the lab, the surgeons compared the SureClip to the Ethicon device. [151] One of the surgeons was Blom, a medical doctor and surgeon who participated in an earlier animal lab in December 2013. [152] In his contemporaneous survey, Blom indicated that the SureClip was "harder to use. There are certain aspects that make it more dangerous. The jaws being so narrow ... [he] also thought the clips were loose." [153] He further observed that SureClip was "[h]arder to deploy and seemed less secure. It's harder to see." [154] Both surgeons indicated that SureClip was heavier than competitors and identified weight as a disadvantage of SureClip. [155]

ConMed called Blom as a witness at trial. During his trial testimony, Blom reviewed video clips from the April 2015 Voice of Customer Lab. While watching the video, Blom narrated his experience during the lab on key issues, like last-clip lockout, [156] visualization, [157] tips-first closure, [158] tissue being pushed out of the jaws, [159] clip stability, [160] malfunction of clips as they loaded into the jaws, [161] and device weight. [162] Blom testified that he believed the SureClip was inferior to the Ethicon device in multiple categories. [163] He testified that he would not switch to the SureClip. [164] During trial, he attributed this decision to his concerns about patient safety. [165]

5. ConMed Pauses Product Development To Evaluate SureClip Functionalities.

***13** After the April 2015 Voice of Customer Lab, ConMed memorialized the key design features, risks, and potential changes to the design in a PowerPoint presentation sent to Donaldson and Connell on May 20, 2015. [166]

The presentation had a slide for each of seven SureClip characteristics: device weight, actuation force, clip opening, jaw opening & visualization, electrical conductivity, tactile/audile indicators, and handle ergonomics. [167] Each slide included a risks section.

- Under device weight, the risks were listed as: (1) "Decreased reusability due to polymeric material (L to M)" subpoint "Material selection, FEA, and testing" and (2) "Unable to reduce handle weight by 40% (L to M)" subpoint "Will update model and perform analysis for weight." [168]

- Under actuation force, the risks were listed as: "Achieving reduction of over 10-15 lbf for device (M)" subpoint "Analysis & prototyping prior to tooling change." [169]

- Under clip opening, the risks were listed as "New design (L) – concept derived from competitors" subpoint "Iterative prototyping prior to cutting tooling." [170]

- Under jaw opening and visualization, the risks were noted instead in the clip opening section. [171]

- Under electrical conductivity, the risks were listed as: "Polymer material may not withstand forces (M)" subpoints (A) "FEA analysis will be performed on components" and (B) "Risk reduced if actuation force is reduced" and "Arcing may occur if design is insufficient (M)" subpoint "Design needs to be tested." [172]

- Under audible/tactile indicators, the risks were listed as: "Distinctness & loudness of click for indication (L)" subpoint "Design needs to be tested & validated" and "Cleaning and Sterilization validation (M)" subpoint "Validation may need to be repeated." [173]

- Under handle ergonomics, the risks were listed as: "Decreased reusability due to polymeric material (L to M)" subpoint "Material selection, FEA, and testing." [174]

ConMed identified a number of "critical deficiencies" in the SureClip design, including: the force required to fully actuate the handle; the lack of tips-first closure in the 5mm cartridge; the comparatively narrow width of the 5mm cartridge, which has the potential to push tissue out of the jaws prior to ligation; and the need for an audible or tactile indicator for full closure. [175] ConMed also identified other "less critical" deficiencies, but viewed the above list as "deal breakers" warranting immediate attention. [176]

Given these concerns, Wu recommended pausing project development to evaluate the existing design deficiencies. [177] In a May 22, 2015 email to the development team, he wrote: "[b]ased on the feedback that we have received in recent labs, there are a few factors that have presented themselves negatively. As such, we have decided to hold and evaluate the design of the SureClip." [178]

***14** ConMed followed Wu's recommendation and determined to "initiate a new project plan to redesign the product" to address the main areas of concern. [179]

Connell relayed the decision and negative feedback from the April 2015 Voice of Customer Lab to Menn on May 26, 2015. [180] This prompted Menn to email Donaldson, Wu, and others on May 27, 2015. Menn wrote:

> I have spoken with Ed yesterday and found out about some concerning feedback from doctors on Appliers that have been built in Utica and Largo. Just wanted to share with you some thoughts on possible easy improvements .... [181]

Menn's email went on to identify some design enhancements. ConMed took Menn's proposal seriously, as reflected by internal communications. [182]

6. The June 2015 Animal Labs

In June 2015, ConMed conducted three additional "Voice of Customer" labs (the "June Voice of Customer Labs") to gather information from surgeons concerning potential design changes.

The first June Voice of Customer Lab took place on June 2 and 3, 2015, and involved four surgeons. [183] Donaldson prepared a memo describing the results. [184] As he explained, one difference between this lab and "previous labs was the

fact that [ConMed] had competitive devices available for comparison throughout the procedure," including clip applier products from Ethicon, Microline, and Covidien, as well as ConMed's legacy 10mm all-disposable clip applier. [185] Overall, the feedback from this lab was positive. [186] In his memo, Donaldson concluded that "there is a segment of the population which has indicated that the design of the SureClip in its current configuration is acceptable and even preferred over currently used devices." [187] Three of the four surgeons indicated they would purchase the SureClip device. [188] The device also received eleven failures of the handle and the 5mm and 10mm cartridges, at least one failure from each of the four surgeons. [189]

The second June Voice of Customer Lab took place on June 18, 2015 and involved eight surgeons. [190] This lab again asked the surgeons to evaluate potential design changes to SureClip, and to compare SureClip against competitive devices. [191] First impressions ranged from "[c]omfortable" to "[h]eavy." [192] Six of the eight surveyed surgeons stated they would buy the device, with the caveat that price was a factor for two of the six, and the two remaining surgeons declined to answer the question. [193] The device also received 19 failures of the handle and the 5mm and 10mm cartridges from seven of the eight surgeons. [194]

***15** The third, and final, June Voice of Customer Lab took place on June 24, 2015, and involved three surgeons. [195] At this lab, the three surgeons surveyed stated they would buy the device. [196] The device also received six failures of the handle and the 5mm and 10mm cartridges, at least one failure from each of the three surgeons. [197]

7. ConMed Continues Efforts To Commercialize The SureClip.

By the conclusion of the June Voice of Customer Labs, ConMed had collected data dating back to 2014 from 29 surgeons. [198] ConMed thus stood poised to make what ConMed's Global Director of Marketing Maria Rivlin referred to as a "data driven business decision[ ]." [199] In a July 1, 2015 email to Peters, Rivlin reported: "Good news: ... We can now make data driven business decisions. Bad news: 50% of the surgeons would NOT purchase the device." [200] Rivlin then summarized the main concerns as follows:

> 52% of the time SureClip failed on "force to fire"
>
> 54% of the time SureClip failed on "trigger reach"
>
> 60% of the time SureClip failed on "visualization" with the 5mm cartridge. [201]

Shortly after, on August 3, 2015, Donaldson prepared a memo to Peters and ConMed Vice President of Research and Development Brett Poole describing the history of ConMed's efforts to develop the SureClip. [202]

On August 18, 2015, ConMed's Advanced Surgical Division gave a presentation to ConMed CEO Curt Hartman to review the state of its ongoing projects, including the SureClip. [203] The presentation reported that ConMed expected to "freeze" the SureClip design on August 20, 2015, and was 75% confident in a May 2016 product release date. [204]

ConMed also continued to pursue FDA 510(k) clearance of the SureClip. During the approval process, ConMed received a "Deficiency List" from the FDA, in which the FDA asked questions about, among other things, an "adverse event" observed during the independent animal testing of SureClip:

> The adverse event description identifies multiple device failures where in: 'multiple clip deployments it was observed that the SureClip handle piece (used to deploy the clips) was not functioning properly, causing the tip of several clips to come together before the tissue was fully encompassed.' This type of adverse event (i.e. misfire, failure to form clip, etc.) could be related to the clip and is frequently reported during clinical use of similar devices. Please provide an in-depth detailed discussion and analysis of the observed adverse event in the context of other information (e.g. bench testing, risk analysis) to address whether this type of failure does not recur will occur [sic] during clinical use. [205]

ConMed responded to this inquiry on September 22, 2015, telling the FDA that it had changed the device so that the malfunction identified during the independent animal testing could not occur again. [206]

8. ConMed Identifies Issues With SureClip's Cleanability And Reliability.

***16** Meanwhile, in August and September 2015, Wu began cleaning and sterilization trials on the SureClip. [207] Those efforts revealed further impediments to SureClip's market launch.

The original cleaning and sterilization protocol had been developed by EndoDynamix before ConMed acquired the device. [208] EndoDynamix had retained an outside lab, Toxikon, to validate the protocol. [209] Initially, EndoDynamix had Toxikon test a "manual" cleaning protocol of brushing the handle off under tap water, wiping it with a disinfectant, then rinsing and drying. [210] Toxikon failed this protocol. [211] In response, EndoDynamix modified the SureClip by adding a hole at the bottom of the handle to better drain the cleaning liquid. [212] EndoDynamix also designed a new cleaning protocol, which was no longer manual, but instead required a 10-minute presoak, a 10-minute ultrasonic bath, a warm water rinse, a second 10-minute ultrasonic bath, and a rinse and dry regimen by blowing compressed air into the handle. [213] Toxikon validated the new cleaning protocol by testing the modified handle with the drain hole and the two rounds of ultrasonic baths. [214]

During the August and September 2015 cleaning trials, Wu observed that the ultrasonic cleaning was causing pitting and corrosion of the aluminum parts of the SureClip after three to five cleaning cycles. [215] Wu further noted that the functionality of the device deteriorated with each cleaning. [216] Wu testified that turning the handle's rotating knob became difficult, and that the handle was more prone to seize up after the cleaning protocol. [217] Wu documented the deterioration he observed in the lab. [218] He testified that he did not resolve the problem and concluded that the pitting was inherent to using aluminum parts in the device. [219]

In late September 2015, ConMed retained medical device consultant Rick Granger to review the project. [220] In a report dated September 30, 2015, Granger identified issues with the cleanability of the reusable handle:

> The current design does not look like it will clean well and probably will retain cleaning fluid/debris among the internal components. I would anticipate that after only 10-20 autoclave cycles that the instrument will feel gritty from a buildup of material on the sliding components due to lack of lubrication. [221]

Granger explained the basis for this statement at trial:

> I had experience with reusable instruments at U.S. Surgical. And those were very simple instruments, where they were a metal handle that you could completely open and remove all of the mechanism and be able to rinse and wash the device very, very thoroughly before it was sterilized.
>
> This device has no way of opening it. It's not designed to be sealed in any way to keep things out. It's just a matter of time before fluids and debris are going to migrate themselves into the device. And I truly believe there's no way to get them out effectively. [222]

***17** Granger's report raised safety and reliability concerns regarding the SureClip's cleaning and sterilization protocol. The testing protocol validated by Toxikon raised marketing concerns as well. As Peters testified at trial, the time-consuming autoclave process required a "significant amount of work" by hospitals using the device. [223]

9. ConMed Reports To The Stockholder Parties That It Might Need to Redesign The SureClip.

The Agreement required ConMed to provide, beginning on October 15, 2014, and on each January 15, April 15, July 15, and October 15 thereafter until the Triggering Sale, written reports to the Stockholder Parties describing ConMed's progress toward achieving the Milestone Payments

(the "Quarterly Reports"). [224] ConMed delivered a Quarterly Report to the Stockholder Parties on October 19, 2015, stating that there was a possible need to redesign SureClip "because the original product design may pose a risk of injury to patients[.]" [225]

10. ConMed Obtains FDA Clearance.

On October 21, 2015, ConMed submitted a revised "Summary of Safety and Effectiveness" to the FDA. [226] ConMed did not inform the FDA of any safety risks to patients posed by the SureClip. [227] Instead, ConMed again certified that "[t]he differences between the predicate and the SureClip Clip Applier do not raise any new risks of safety or efficacy. Supporting information per this premarket [510(k)] submission confirms that the SureClip Clip applier is safe and effective for its intended use and is substantially equivalent to the predicate device." [228] Based on the revised summary, on October 23, 2015, the FDA provided 510(k) clearance. [229]

ConMed paid the second FDA-related milestone payment, bringing the total paid to the Stockholder Parties to $9 million. [230]

11. ConMed Agrees To Acquire SurgiQuest.

On November 16, 2015, ConMed announced that it had entered into a definitive agreement to acquire SurgiQuest, Inc. [231] Headquartered in Milford, Connecticut, SurgiQuest developed medical devices for use in minimally invasive surgery and laparoscopic procedures. [232] SurgiQuest made access instruments, through which other medical devices —like clip appliers—can be inserted into the abdominal cavity. [233]

SurgiQuest did not develop, sell, or market clip appliers. [234] But many SurgiQuest employees had worked for a company called US Surgical, which became Covidien, which was one of the leaders in the clip applier market. [235] Thus, SurgiQuest engineers had experience and core competencies in developing clip appliers. [236] Peters testified that the SurgiQuest team's clip applier experience was important to ConMed. [237]

12. ConMed Assigns A New Team To The SureClip Project.

***18** In the Fall of 2015, ConMed transferred the SureClip project to its facility in Centennial, Colorado and assigned a new team to the project. [238] Colorado-based Mason Williams, a senior mechanical engineer in ConMed's Advanced Surgical Division, took over project management responsibilities from Wu. [239] Williams was credentialed and experienced. [240] Peters held Williams in high regard and assigned him to high-priority projects. [241] Williams understood that his job was to "finish the project and commercialize the device." [242]

To get up to speed, Williams had several phone calls with Wu and conducted key stakeholder interviews. [243] He also received and reviewed the Granger report. [244]

By November 2015, Williams had concluded that the actual cost of the SureClip was significantly higher than the target cost. [245] He summarized these concerns in a presentation emailed to his immediate supervisor, Mike Lontine, on November 11, 2015. [246] These presentations were prepared in the ordinary course of business to inform the ConMed steering committee of the status of projects. [247] The presentation reflected that the project was moving forward, albeit slightly behind the original schedule. [248]

After reviewing the materials, Lontine sent an email attaching Granger's recommendations and a presentation to two members of the marketing department reflecting a pessimistic view of the project. In the cover email, Lontine wrote: "As you know, we are getting up to speed on the project. However, you may not fully understand the present limitations we have" and that "we may not really have design resources until January." [249] In the presentation, Lontine identified open issues on the project, including last-clip lockout, clip closure, clip loading, and cleaning; highlighted multiple risks and concerns related to the design, marketing, and manufacturing; outlined a revised schedule; and requested three additional

engineers and experts in cleanability, clip delivery, and mechanisms. [250]

Although the record does not reveal a precise reason, it appears that Lontine did not receive the additional resources right away, and the project stagnated for a period. A "New Product Leadership" meeting was held on December 3, 2015, to review the status of SureClip. [251] The Colorado team reported that "SureClip is the lowest Advanced Surgical priority." [252] On December 4, 2015, D'Lima observed in an email to Kennedy that SureClip had received 510(k) clearance "but no [one] seems to have acknowledged this news. I remember that the team worked very hard to get this accomplished." [253]

On December 8, 2015, Paul Mulville, a senior manufacturing engineer at ConMed, reported that "[t]he SureClip project has been side-lined for a while." [254] On December 9, 2015, Williams expressed his frustration with the project to Jason Roberts, ConMed's Principal Engineer. [255] Roberts responded with a meme captioned: "Warning. Indecisive." [256] To that, Williams responded: "True story." [257]

13. ConMed Finalizes The Acquisition Of SurgiQuest, And The SurgiQuest Team Assists In A Design Review Of The SureClip.

***19** ConMed onboarded the SurgiQuest team before devoting additional human resources to developing the SureClip. ConMed closed the $265 million acquisition of SurgiQuest on January 5, 2016. [258] After the acquisition, SurgiQuest's operations were integrated with ConMed as part of the Advanced Surgical Division, [259] and Peters requested that the former SurgiQuest employees review the SureClip project. [260]

On January 26, 2016, Wu presented to the former SurgiQuest team a summary of the SureClip and its status. [261] The presentation included a description of the SureClip's components, design features, and design changes that ConMed had made to the EndoDynamix model. [262] The presentation referenced a few additional "minor changes" that ConMed expected to complete by May 2016. [263]

Defendants have argued that their intention, in early 2016, was to continue developing the SureClip, and Wu's presentation reflected that intent. Wu noted that ConMed expected a product release date of December 2016 and a product launch date of February 2017. [264] ConMed's 2015 Form 10-K Annual Report, filed on February 22, 2016, similarly reflected that ConMed "expect[ed] the remaining [SureClip Agreement] milestones to be achieved, and royalty payments to be made [to the Stockholder Parties], between 2016 and 2021." [265]

ConMed's plan for the SureClip shifted shortly after. With the benefit of fresh eyes, the SurgiQuest team evaluated the SureClip project and presented three recommendations to the Advanced Surgical Division on February 18, 2016. [266]

The team recommended that ConMed: (i) "stop developing the re-posable [clip applier] devices," and instead develop a fully disposable clip applier product; (ii) "[d]evelop an all-disposable 5mm clip applier by reverse engineering existing technology" of a competitor device; and (iii) use its legacy 10 mm all-disposable clip applier (the Reflex ELC) and "give it a face lifted handle." [267]

As SurgiQuest's former CEO and then-ConMed Chief Technology Officer, Kurt Azarbarzin, confirmed, in essence, SurgiQuest was recommending that ConMed develop a completely different clip applier product. [268]

14. ConMed Discontinues The SureClip Project.

Less than a week after SurgiQuest presented their recommendation to abandon the SureClip, on February 23, Trutza told the SureClip team "to stop work on the 10mm. We are not going to market (at least in the US) with a stainless steel handle." [269]

***20** Although the determination to discontinue the SureClip had not yet been made at the board level, Trutza's February 23 email effectively halted all development of the SureClip at the operations level.

From that point forward, the management team responsible for developing the SureClip transitioned from planning the product's development to analyzing how ConMed could minimize the financial impact and legal risk of discontinuing the SureClip project. On March 5, 2016, Trutza emailed Peters proposing the following options for ConMed: (i) take EndoDynamix's clip applier technology and refuse to pay the Stockholder Parties anything more than the Milestone Payments ConMed had already paid; (ii) try to give EndoDynamix their intellectual property back and refuse to pay the Stockholder Parties anything more than the Milestone Payments ConMed had already paid; or (iii) go to "Def Con 4" and "go after [the Stockholder Parties] for selling us something that that [sic] 'they knew' was inferior, etc." [270] The last part of Trutza's email was redacted as privileged. [271]

On March 6, 2016, the senior management team was told that the SureClip project was "stopped." [272] An email circulated to ConMed's CEO and other senior management reported that the SureClip "[p]roject is stopped due to concerns about re-usable clip applier not being the right product for the market." [273]

By the end of March 2016, ConMed personnel had halted all work on the SureClip. On March 25, 2016, ConMed R&D Engineer Patrick Olsen wrote: "We (R&D) have been told that the SureClip project is over and to not work on it anymore. R&D responsibilities for Clip Appliers has been transferred to SurgiQuest where, if anything, they will design a *new disposable Clip Applier from scratch*." [274] On March 28, 2016, a ConMed engineer asked Williams about the status of the SureClip and a design change she had been working on. [275] Williams asked Wu if the design change was "killed with SureClip." [276] Wu responded that "we should just kill this idea for now." [277] The next day, Williams confirmed that the SureClip project had "been formerly [sic] '86'd.' " [278] Thomas testified that his best recollection is that he did not do any further work on SureClip after March 29, 2016. [279]

Consistent with these internal emails, ConMed's expense records reflect that there were no expenses incurred on the SureClip project after March 23, 2016. [280] Before that time, ConMed had invested approximately $10 million and nearly 15,000 engineering hours into SureClip. [281]

***21** By March 30, 2016, the SurgiQuest team had started work on the new, all-disposable clip applier. A "Weekly Project Meeting" on March 30, 2016, describes a "5mm and 10mm Clip Applier" project and lists its "Status" as "Start Project." [282] ConMed removed the name "SureClip" from the all-disposable clip applier project. [283]

By mid-April 2016, ConMed had created conceptual mockups of the new 5mm clip applier. [284] It did not resemble the SureClip device and was labeled "ConMed 5mm Clip Applier." [285] Also by mid-April 2016, ConMed had mockups of the "face lift" it gave to ConMed's legacy 10mm clip applier. [286]

The Advanced Surgical Division made a presentation to the ConMed Board of Directors during a May 25, 2016 meeting concerning the status of the SureClip device. Their PowerPoint presentation stated: "Conclusion and Action: Discontinue the commercialization of the SureClip Device." [287] The meeting minutes reflect that "[f]ollowing some discussion" concerning the status of the EndoDynamix acquisition, "the consensus was that management should proceed to renegotiate terms." [288] This directive suggests that the Board determined to halt development of the SureClip during the May 25, 2016 meeting.

15. Menn Demands Acceleration Payments.

Meanwhile, on May 3, 2016, ConMed sent a Quarterly Report to the Stockholder Parties stating that it believed that SureClip posed a risk of injury to patients and thus failed to comply with "Applicable Law." [289] The report stated that "[i]n the interests of candor, however, we are at a point where we seriously question whether we will move forward at all with the SureClip clip applier, as opposed to the design of a completely new and different clip applier." [290]

Although the report's language suggested that ConMed had not yet made the determination, and perhaps that was technically true as to a Board-level decision, the reality

was that ConMed had already discontinued the SureClip project. ConMed's general counsel, Daniel Jonas, authored the report.[291] He testified at his deposition that, as of the date of the report, he knew that ConMed had already, effectively, "made the decision to move toward a disposable [clip applier]."[292]

In response to the Quarterly Report, Menn faxed a letter on May 16, 2016, disputing ConMed's statements and exercising the acceleration rights under Section 4.03(h) of the Agreement.[293]

ConMed and Menn, along with certain other former directors of EndoDynamix, met in June 2016 to discuss the status of the SureClip project. At that meeting, ConMed stated that the project had been "paused," as opposed to discontinued.[294] A month later, on August 9, 2016, ConMed submitted a term sheet to Menn for the proposed sale of the business back to the Stockholder Parties.[295]

***22** On January 17, 2017, Menn sent a demand letter to ConMed seeking Acceleration Payments because ConMed breached the Agreement by discontinuing SureClip.[296]

E. This Litigation

Menn filed this suit on February 22, 2017.[297] The Verified Complaint asserts four direct claims against ConMed and EndoDynamix ("Defendants"). Counts I and II assert breach of contract claims against ConMed for failing to use its commercially best efforts to maximize SureClip sales; failing to send Quarterly Reports and other written reports describing ConMed's progress with SureClip; and failing to make the required Acceleration Payments.[298] Count III asserts a claim for breach of the implied covenant of good faith and fair dealing against ConMed for failing to reasonably exercise its discretion in determining if the SureClip poses a safety risk to customers and patients.[299] Count IV asserts a claim for breach of contract against EndoDynamix for failing to use commercially best efforts to maximize sales of SureClip.[300]

The parties engaged in discovery in 2017 and 2018. On December 3, 2018, Defendants moved to amend their answer based on ConMed's decision to officially discontinue SureClip development, the need to convert prior admissions into qualified denials based on information obtained through discovery, and in order to assert an arbitration clause as an affirmative defense.[301] The court granted the motion for leave to amend as to the first two issues, but denied on grounds of waiver Defendants' request to raise the arbitration clause as an affirmative defense.[302] Defendants filed an amended answer on March 6, 2019, and discovery continued.[303]

The court held trial from March 18, 2021 through April 7, 2021.[304] Post-trial briefing concluded on July 9, 2021, and post-trial oral argument was heard on September 16, 2021.[305] After reviewing the post-trial briefs, the court requested supplemental briefing, which concluded on March 14, 2022.[306]

II. LEGAL ANALYSIS

By the time of trial, Plaintiff's four separate causes of action had crystalized into three claims, which this analysis addresses in the following order. First, ConMed breached its obligations under Section 4.03(h) of the Agreement to make Acceleration Payments to the Stockholder Parties. Second, ConMed breached its obligation under Section 4.03(g) of the Agreement to use "commercially best efforts" to develop and then sell the Clip Applier Products.[307] Third, ConMed violated the implied covenant of good faith and fair dealing when exercising its discretion under the Agreement.[308]

A. The Acceleration Payments

***23** Section 4.03(h) of the Agreement provides in relevant part, that

> In the event that after the Closing Date, ... (iii) Buyer acquires a business that it will integrate with, or which is competitive with, the Company and following such acquisition Buyer permanently discontinues the development or sale of any of the Clip Applier Products, (iv) Buyer otherwise permanently discontinues

> the development or sale of any of the Clip Applier Products (other than ... (z) based on a commercially reasonable determination by the Company or the Buyer in their sole discretion that the use of such Clip Applier Product(s) pose(s) a risk of injury to either patients or surgeons ... [)] the Representative may, in any case in his sole discretion, upon 20 Business Days prior written notice to Buyer, and the expiration of a 20 Business Day opportunity to cure following such notice, ... elect to have paid in full by Buyer the sum of (A) all amounts described in Section 4.02 that remain unpaid, which amounts shall be paid on the First Acceleration Payment Date, plus (B) subject to Section 4.03(m), the amounts set forth on Schedule 4.03(h) on the dates set forth on Schedule 4.03(h)[ ] .... [309]

Plaintiff advances two arguments for why the Stockholder Parties are entitled to Acceleration Payments under this provision. Plaintiff first argues under Section 4.03(h)(iii) that SurgiQuest was "integrated" with EndoDynamix, SurgiQuest was a "competitive" business, and that ConMed permanently discontinued the development of SureClip after it acquired SurgiQuest. [310] Plaintiff next argues that ConMed otherwise permanently discontinued the development or sale of the SureClip under Section 4.03(h)(iv). [311] Defendants deny that they either integrated SurgiQuest or made a determination to discontinue the sale of the SureClip as required by Sections 4.03(h)(iii) and (iv) respectively. They further argue that they are relieved from making Acceleration Payments under Section 4.03(h)(iv) because they have proven the existence of exceptions to that provision.

The parties' arguments concerning the Acceleration Payments collectively present three issues, which the court addresses in the following order: Did ConMed integrate EndoDynamix with a competitor under Section 4.03(h)(iii)? Did ConMed determine to discontinue the development of the SureClip under Section 4.03(h)(iv)? Did ConMed prove the existence of any exception to Section 4.03(h)(iv)?

1. Did ConMed Integrate EndoDynamix With A Competitor?

Plaintiff's first argument can be disposed of with some ease. EndoDynamix and SurgiQuest were not competitors. EndoDynamix was a startup, which never sold a product, and which was developing a single device—a clip applier. SurgiQuest had one product, an insufflator, and did not sell clip appliers or any other surgical instruments. [312] While it is true that SurgiQuest's staff was populated by many former U.S. Surgical (later Covidien) personnel who had substantial experience developing and selling clip appliers, that fact alone does not render SurgiQuest a competitor of EndoDynamix. Because SurgiQuest and EndoDynamix were not competitors, Defendants do not owe Acceleration Payments by operation of Section 4.03(h)(iii).

2. Did ConMed Permanently Discontinue The Development Of The SureClip?

***24** Plaintiff argues that the Stockholder Parties are entitled to Acceleration Payments under Section 4.03(h)(iv) because ConMed "permanently discontinue[d] the development or sale of any of the Clip Applier Products." [313] This argument has legs.

Plaintiff has proven that ConMed permanently discontinued the SureClip. To recap the key facts on this issue:

- On February 18, 2016, SurgiQuest recommended that ConMed "stop developing" the SureClip and develop an all-disposable 5mm clip applier "by reverse engineering the existing technology" of a competitor device. [314] In essence, SurgiQuest was recommending that ConMed develop "a completely different clip applier product." [315]

- Trutza adopted this recommendation, telling the SureClip team around February 23 "to stop work" because "[w]e are not going to market (at least in the US) with a stainless steel handle." [316]

- An internal email to ConMed executive management on March 4, 2016, reported that the SureClip "[p]roject is stopped." [317]

- ConMed's expense records reflect that there were no expenses incurred on the SureClip project after March 23, 2016. [318]

- On March 25, 2016, a ConMed R&D engineer wrote that "[w]e (R&D) have been told that the SureClip project is over and to not work on it anymore," that responsibilities had been "transferred to SurgiQuest where, if anything, they will design a new disposable Clip Applier from scratch." [319]

- On March 29, 2016, Williams confirmed that the SureClip project had been "86'd." [320]

- By mid-April 2016, ConMed had created conceptual mockups of the new, all-disposable 5mm clip applier, which did not resemble the SureClip device and was labeled "ConMed 5mm Clip Applier." [321]

- On May 25, 2016, the Advanced Surgical Division made a presentation to the Board of Directors on the status of its project: "Conclusion and Action: Discontinue the commercialization of the SureClip Device." [322] The minutes of that meeting support a finding that the Board determined to discontinue development of the SureClip during the meeting. [323]

Although contemporaneous communications make clear that ConMed had discontinued the project by May 2016 at the latest, ConMed took the position in litigation it did not permanently discontinue SureClip because it "went forward with a disposable clip applier that incorporated IP from EndoDynamix." [324] But ConMed admits that the only aspect of SureClip that it incorporated into the all-disposable clip applier recommended by SurgiQuest was the pattern on the inside of the clip. [325] And, under the Agreement, ConMed is liable for the Acceleration Payments if it "permanently discontinues the development or sale of *any* of the Clip Applier Products," where "Clip Applier Products" defined to include the 5mm and 10mm cartridges. [326] ConMed did not use SureClip cartridges for the new, all-disposable device being reversed engineered by the former SurgiQuest employees. [327] ConMed's admitted discontinuation of the SureClip cartridges, alone, triggers its obligation to make the Acceleration Payments.

3. Has ConMed Proven The Existence Of Exceptions?

***25** Section 4.03(h)(iv) contains numerous exceptions that, if present, relieve ConMed of its payment obligations despite its decision to permanently discontinue the SureClip. ConMed has demonstrated the existence of one of the exceptions—that it discontinued the development of the Clip Applier Product "based on a commercially reasonable determination by the Company ... in their sole discretion that the use of such Clip Applier Product(s) pose[d] a risk of injury to ... patients." [328]

The parties agree that ConMed bears the burden of proving the existence of the exception. [329] The parties further agree that the relevant time-period for assessing whether this determination complied with the exception is around the time the determination was made, in May 2016. [330]

The parties dispute whether the contractual standard calls for an inquiry into objective or subjective facts. Plaintiff argues that the language "commercially reasonable determination" calls for an objective inquiry into whether the risk-of-injury determination was commercially reasonable. [331] ConMed contends that the risk-of-injury determination was left up to ConMed's "sole discretion" under the Agreement, and thus the standard asks whether the decision was made in good faith. [332] For the sake of analysis, the court looks both to whether, as of May 2016, ConMed actually determined in good faith that the SureClip posed a risk of injury to patients and also whether such a determination was commercially reasonable. The evidence overwhelmingly supports ConMed's position under both interpretations.

ConMed based its determination to discontinue development of the SureClip on the good faith belief that the SureClip posed a risk of injury to patients. Recall that the impetus leading to the board determination to discontinue the product was the SurgiQuest team's February 18, 2016 email recommendation. That, in turn, caused Trutza to instruct the

team to stop working on the project. Shortly after, senior management was informed the project was on hold. In May 2016, Peters recommended stopping development of SureClip to ConMed's board.

The February 18 recommendation by the SurgiQuest team was not out of the blue. Rather, it was based on the history of the SureClip project at ConMed. That history reflects a persistent concern by ConMed personnel that SureClip posed a risk of injury to patients. After acknowledging that they bear the burden of proof on this issue, Defendants engaged in a first-class fact-vomit concerning this history. [333] Most of this testimony is covered in the factual background. At the risk of duplication, what follows is a brief version of Defendants' points made in chronological order.

***26** During the September 2014 Animal Lab overseen by Wu, six surgeons noted several failures, and even the surgeons who passed the devices had concerns and cited a need for improvement. [334] At trial, Wu testified that based on the performance in this lab, in his view, the SureClip was not ready to be launched for use in human beings, and that there were issues with respect to "clip scissoring," "clip loading," "clip closure," and "clip security." [335] He further testified that these issues are unequivocally related to patient safety. [336] Indeed, all of these issues were identified as safety issues during the pre-acquisition labs and memorialized in Schedule 8.10. [337] Donaldson's testimony was to the same effect. [338]

The October 2014 Animal Lab, which was limited to testing the viability of the last-clip lockout, [339] did not resolve concerns surfaced during the September 2014 Animal Lab. Wu testified that concerns over "clip loading instability, the clip closure instability, [and] last clip lockout" necessitated additional design work after the September 2014 Animal Lab, and that following the October 2014 Animal Lab, "there were still a lot of actions that needed to be completed before the product could be launched and sold." [340] Donaldson similarly testified that the October 2014 Animal Lab did not resolve the safety concerns identified in the September 2014 Animal Lab regarding tips-first closure, clip scissoring, and damage to the trocar seal. [341]

As of March 2015, Wu had concerns about visualization through SureClip's small clip opening, an issue exacerbated by the lack of tips-first closure, and clip loading issues that caused the SureClip to jam on tissue as it was loaded. [342] Wu confirmed that, at that time, the device was pushing tissue out of the jaws during loading of the clip, rendering the clip applier incapable of performing the surgical function it was designed to accomplish—clipping a vessel. [343]

Donaldson and Peters reviewed Wu's March 2015 presentation in the Spring of 2015. [344] Peters became concerned about the safety of the SureClip when he saw the differential in the clip opening in the presentation. [345] At Wu and Donaldson's recommendation, Peters determined to initiate a redesign of the SureClip to address the main areas of concern, and later moved the project to Denver and assigned it to Williams for that purpose. [346]

***27** Meanwhile, during the April 2015 Voice of Customer Lab, two surgeons tested the SureClip and the Ethicon device in order to compare them. [347] One of the surgeons, Dr. Blom, testified at trial. During his trial testimony, Blom narrated his experience during the April 2015 Animal Lab on key safety issues identified in Section 8.10, such as last-clip lockout, [348] visualization, [349] tips-first closure, [350] tissue being pushed out of the jaws, [351] clip loading malfunctions, [352] clip stability, [353] and device weight. [354] Blom testified that he would not switch to the SureClip due to concerns about patient safety. [355] Contemporaneous evidence related to Blom's concerns are consistent with his trial testimony. [356]

***28** During the June 2015 Animal Labs, 14 surgeons reported 36 different failures of the handle and the 5mm and 10mm cartridges. [357] Wu testified that following the Colorado lab, the device was still not ready to launch [358] and that he would not have been "comfortable putting the design as it existed in June of 2015 on the market" and that the design "posed a risk to patients." [359]

By August 2015, Donaldson remained concerned that, based on the animal lab results, the SureClip was not safe or effective. He summarized his concerns in his August 3, 2015 memorandum discussed in the factual background. [360]

In September 2015, ConMed retained Granger to review the project. Peters retained Granger because first EndoDynamix and then ConMed had spent years developing the device without success. [361] In his report, Granger identified issues with respect to clip closure based on the EndoDynamix design:

> The jaw closure mechanism on both devices is not central to the clip which will cause an uneven closure. The clip closure is paramount. Parallel closure with minimum gaps at the eye, middle and tip must be equivalent to your competitors. Clip design is key to maintaining placement and clip retention. [362]

Granger testified that the animal labs confirmed the deficiencies he had noted in the design, and that the labs demonstrated safety concerns with respect to visualization, tips-first closure, and clip loading. [363]

By October 2015, the SureClip project had been reassigned to Williams' team in Denver. Thereafter, Williams and his team continued to work on the device, attempting to address the issues with the handle, clip closure and last-clip lockout. [364] When the device transitioned out of his responsibilities, the clip closure issues had not been fully resolved, and the 5mm device had no last-clip lockout. [365]

The SurgiQuest team conducted its fresh-eyes review in early 2016 at Peters' request. [366] Their review raised the same concerns about clip formation and closure as identified by Wu, Donaldson, Williams, and Granger. [367] That review was presented on or about February 26, 2016. [368] Peters testified that the review confirmed concerns about the safety of the device. [369] Those concerns were consistent with the concerns Wu and Donaldson had identified about the safety and effectiveness of the device. [370] They were highlighted in the presentation about the SureClip made to the ConMed board in May 2016. [371]

In sum, from the first post-closing animal lab through early 2016, multiple ConMed employees identified serious safety concerns with SureClip's design features. Some of the concerns raised post-closing were identified as patient-safety issues in EndoDynamix's pre-acquisition marketing materials (indeed, safety issues that EndoDynamix represented it had resolved in those marketing materials). [372] The issues were of enough concern to ConMed that ConMed memorialized the need to address them in Section 8.10 and Schedule 8.10 of the Agreement. The issues persisted throughout the post-closing animal labs. They were contemporaneously documented by ConMed's project manager, Vice President of R&D, the outside surgeon who tested the device, and the outside medical device expert who evaluated the device in 2015.

***29** This evidence reflects that ConMed's belief that the SureClip posed a safety risk to patients was made in good faith.

The analysis thus turns to the question forced by Plaintiff: Was ConMed's determination commercially reasonable? Under the Agreement, the relevant determination is "that the use of such [SureClip] pose[s] a risk of injury to either patients or surgeons." [373]

Plaintiff does not define what "commercially reasonable determination" means in this context. Legal dictionaries define "commercially reasonable" as "in accordance with commonly accepted commercial practice." [374] In other contexts, this court has held that "commercially reasonable" requires a showing that the determination was "in keeping with prevailing trade practice among reputable and responsible business and commercial enterprises engaged in the same or similar businesses." [375] When interpreting a "commercially reasonable period" requirement, Vice Chancellor Slights instructed that, "[l]ike most matters of law that exist in the realm of 'reasonableness,' " the determination of what is a commercially reasonable decision "is contextual and necessarily fact intensive." [376] Applying these broad concepts here, this court asks whether ConMed's determination that the SureClip posed a risk of injury to patients was a determination made in accordance with commonly accepted commercial practices.

The fact that NAMSA identified an "Adverse Event" regarding the SureClip supports a finding that ConMed's determination that the product posed a risk of injury to patients was commercially reasonable. NAMSA, an independent laboratory, evaluated the safety and efficacy of the clips for FDA 510(k) clearance in January 2015. NAMSA reported an "Adverse Event" regarding the SureClip directly related to clip closure. [377] The failure that NAMSA identified as an Adverse Event is the same type of safety defect that led to the safety recall of an Ethicon clip applier in 2013. [378] The fact that a similar design flaw resulted in a safety recall of a competitive product supports a conclusion that the determination was commercially reasonable.

***30** The testimony of ConMed's expert witness further supports a finding that the determination was commercially reasonable. ConMed tendered Blom as an expert on this point. Blom received his medical degree, completed his residency, and then completed a two-year fellowship specializing in stomach and esophagus surgery where roughly 75% of the procedures were laparoscopic. [379] Blom has been a board certified surgeon since 2000, he has taught laparoscopic surgery at three medical schools throughout his career, and was deployed overseas as a surgeon for the U.S. Army where he conducted laparoscopic procedures among others. [380] In 2008, Blom entered private practice in New York where he performed procedures utilizing clip appliers, completing anywhere from two to twelve such procedures per week. [381] Blom's extensive experience makes his testimony a valuable proxy for commonly accepted commercial practices.

Blom testified that he experienced the following design flaws when using the SureClip: last-clip lockout, visualization, tips-first closure, clip loading malfunctions, clip stability, clip closure, and device weight. He further testified that these issues "posed an increased risk for the use of the SureClip ... on human beings during surgery, as they could result in harm to patients. Several of the issues I raised .... could cause surgical procedures to last longer, which also increases the risk to patients." [382] Blom's testimony persuades the court that ConMed's determination that the SureClip posed a risk of injury to patients was commercially reasonable.

Moreover, the evidence from ConMed employees supporting the finding that ConMed actually made the relevant determination in good faith also supports a finding that the determination was commercially reasonable. The ConMed witnesses—Wu, Donaldson, Williams, and Peters—represent a diverse array of backgrounds and professional experience. [383] They each, independently, reached the conclusion that the SureClip posed a risk of injury to patients. These concerns were then confirmed by the SurgiQuest team, who had extensive experience developing clip appliers. [384] It is not reasonable to conclude that each witness was being commercially unreasonable in their determination and recommendation. Neither ConMed nor any of these witnesses were economically incentivized to scrap the SureClip project, for which ConMed had paid $9 million and in which ConMed invested significant development resources, to develop a totally new product. The only logical conclusion from this testimony is that there were well-recognized business risks of continuing development. This corroborates a finding that the determination was commercially reasonable.

***31** For these reasons, ConMed has carried its burden in establishing that it permanently discontinued the development of the SureClip based on a commercially reasonable determination that the use of the SureClip posed a risk of injury to patients. [385]

Plaintiff makes a series of arguments as to why ConMed has failed to establish the applicability of a contractual exception, but none are persuasive.

First, Plaintiff argues that the October 2014 Animal Lab was a success, that ConMed employees determined that SureClip was "acceptable" and "workable," and that the testimony of Wu was not reflective of SureClip's positive test results. [386] This argument, however, ignores the overwhelming weight of evidence reflecting that ConMed personnel simultaneously harbored concerns about safety features of the SureClip.

Second, Plaintiff argues that the lack of a last-clip lockout and tips-first closure is not a safety issue for SureClip. Regarding last-clip lockout, Plaintiff maintains that a lockout block was an equivalent safety feature to a last-clip lockout, and that SureClip featured atraumatic jaws which lessened any safety risk to patients. [387] Regarding tips-first closure, Plaintiff

contends that surgeons approved of SureClip's performance in testing, that tip-first closure is unnecessary, and that modified instruction for use can ameliorate any safety issue.[388] Plaintiff's argument, however, ignores the pre-Agreement marketing materials prepared by EndoDynamix identifying such features as safety features. It further runs contrary to expert reports from Blom and Granger.[389] Moreover, by advancing this argument, Plaintiff ignores the other safety issues identified through the record, such as visualization,[390] clip loading,[391] clip stability,[392] device weight,[393] and cleaning and sterilization.[394]

***32** Third, Plaintiff argues that ConMed initially intended to use SureClip as the predicate device for FDA 510(k) clearance of the new all-disposable clip applier, and that such an intention is evidence that ConMed thought SureClip was a safe device.[395] But Plaintiff acknowledges that ConMed did not ultimately use SureClip as the predicate device.[396] That ConMed considered using SureClip as a predicate device in the early part of its regulatory strategy for the device that succeeded it is not surprising and does not provide strong evidence that ConMed considered SureClip to not pose a risk to patient safety.

Fourth, Plaintiff argues that ConMed should be estopped from contending that it made a commercially reasonable determination that the SureClip posed a risk of injury to patients due to ConMed's representations in its 510(k) application.[397] According to Plaintiff, by submitting the 510(k) application for clearance to market SureClip, ConMed certified that SureClip was safe and effective for its intended use.[398] That certification was made twice: once when it submitted the 510(k) application in April 2015[399] and again in October 2015.[400] Plaintiff argues that ConMed is now barred under theories of judicial estoppel or quasi-estopped from claiming otherwise.[401]

Judicial estoppel is an equitable doctrine designed "to protect the integrity of the judicial process."[402] Judicial estoppel requires a showing that "the litigant[ ] contradict[ed] another position that the litigant previously took *and* that the Court was successfully induced to adopt in a judicial ruling."[403]

Even assuming that statements made to administrative agencies can supply a basis for estoppel, which appears to be an open issue under Delaware law,[404] Plaintiff's judicial estoppel argument fails because Plaintiff has not proved that ConMed gave an inconsistent position to the FDA or that the FDA adopted an inconsistent, prior position.[405] ConMed's representations to the FDA in its two 510(k) applications concerned whether SureClip was "substantially equivalent to the predicate device [Ethicon's 5mm and 10mm clip applier]."[406] ConMed represented to the FDA that SureClip was substantially equivalent to the predicate device and the FDA adopted that representation when it gave the device 510(k) clearance. Here, ConMed argues that SureClip poses a risk of injury to either patients or surgeons, which is distinguishable from the position that it took before the FDA regarding substantial equivalence to a predicate device. Further, ConMed's representations to the FDA only concerned the implantable clips and not the handle, which was also a source of safety concerns based on the weight and cleaning protocol.

***33** Quasi-estoppel applies when "[i]t would be unconscionable to allow a [party] to maintain a position inconsistent with one to which [it] acquiesced, or from which [it] accepted a benefit."[407] To establish quasi-estoppel, a plaintiff must show that a party "gained some advantage for [itself] or produced some disadvantage to another" through inconsistent representations.[408] Quasi-estoppel is an equitable doctrine that applies only "when it would be *unconscionable* to allow a person to maintain" an inconsistent position.[409]

Plaintiff argues that ConMed received a benefit—clearance to legally market and sell SureClip—from its representation to the FDA that SureClip was safe and effective for its intended use.[410] Now, for purposes of this litigation, ConMed seeks to reverse course to circumvent its payment obligations under the Agreement, to the disadvantage of Menn and the Stockholder Parties.[411]

Plaintiff's argument ignores that ConMed was contractually required to apply for FDA clearance. Plaintiff's argument further ignores that Plaintiff was not disadvantaged by that representation. Rather, the Plaintiff received an advantage from ConMed making the FDA 510(k) representations,

which triggered the FDA Application Milestone payment and eventually the FDA Clearance Milestone payment. Given that Plaintiff directly benefited from this representation, it is not unconscionable to allow ConMed to pursue its position in this litigation.

Having established that ConMed discontinued the development of SureClip based on a commercially reasonable determination that the use of SureClip posed a risk of injury to patients, ConMed faces no liability for canceling SureClip under the Acceleration Payments Provision.

B. The Obligation To Use Commercially Best Efforts

Section 4.03(g) of the Agreement provides:

> Buyer and the Company shall work in good faith and use commercially best efforts to maximize payouts for the benefit of the Shareholder Parties pursuant to Section 4.02 and Section 4.03 hereto, including the maximization of net sales of Products. [412]

***34** The "commercially best efforts" provision is what is known as an "efforts" clause. Efforts clauses generally replace "the rule of strict liability for contractual non-performance that otherwise governs" [413] with "obligations to take all reasonable steps to solve problems and consummate the" contractual promise. [414] Efforts clauses "define the level of effort that the party must deploy to attempt to achieve the outcome." [415]

Often, transactional designers will define benchmarks for the "commercially reasonable" standard relevant to the efforts clause within the governing agreement. For example, in two recent decisions, this court interpreted provisions requiring a buyer to use "commercially reasonable efforts" to maximize milestone and earn-out payments post-closing—*Himawan v. Cephalon, Inc.* [416] and *Neurvana Medical, LLC v. Balt USA, LLC*. [417] In each case, unlike here, the agreement contained a contractual definition—a "yardstick"—by which the court was to measure "commercially reasonable" efforts. In each case, the court's decision centered on the adequacy of the plaintiff's allegations relative to the specific contractual yardstick. While the efforts provision and context of *Himawan* and *Neurvana* are similar to that at issue here, the Agreement lacks any express contractual standard by which to gauge ConMed efforts. [418] These cases are thus of little help. The court thus turns to other inputs in search of guidance on the meaning of "commercially best efforts."

Deal practitioners who draft efforts clauses "have a general sense of [the] hierarchy" of such clauses. [419] One commonly cited version of this hierarchy places "best efforts" as the highest standard with "reasonable best efforts," "reasonable efforts," "commercially reasonable efforts," and "good faith efforts" following in descending order. "Commercially best efforts" provisions are not found on the standard hierarchy. [420] Logically, such provisions would fall between "best efforts" and "commercially reasonable efforts."

***35** Although deal practitioners have some sense of the hierarchy among efforts clauses, courts applying the standards have struggled to discern daylight between them. This court, for example, has interpreted "best efforts" obligations as on par with "commercially reasonable efforts." [421]

Because this court has consistently interpreted "best efforts" obligations as on par with "commercially reasonable efforts," it follows that there is even less daylight between "best efforts" and "commercially best efforts" provisions. Indeed, the parties make no distinction in briefing. [422] This decision, therefore, interprets "commercially best efforts" as imparting the same meaning as "best efforts."

"When assessing whether a party has breached an efforts clause in a transaction agreement, 'this court has looked to whether the party subject to the clause (i) had reasonable grounds to take the action it did and (ii) sought to address problems with its counterparty.' " [423] "This standard applies with equal force to 'reasonable best efforts' and 'commercially reasonable efforts' language." [424] In that context, this court has interpreted "best efforts" to require "a party to do essentially everything in its power to fulfill its

obligation (for example, by expending significant amounts or management time to obtain consents)."[425]

***36** In briefing, the parties based their respective arguments on decisions of this court interpreting efforts provisions in the merger context. In those cases, this court has found a breach of a best-efforts obligation where a party failed to work with its counterpart to jointly solve problems, failed to keep the deal on track, or submitted false data to and refused to cooperate with regulators.[426] Other decisions of this court have found that a party breached an efforts provision when utilizing a sales force that was too small to achieve the revenue target, expending energy and resources on stimulating an alternative to the deal, or making no effort to sell or market the product.[427]

None of those scenarios are present in this case. ConMed has proven that, after it acquired EndoDynamix, it was assigned to the SureClip team of development engineers, manufacturing engineers, regulatory experts, and marketing professionals. It incurred substantial development expenses in connection with the SureClip. It did not stop development efforts a few days or even months after signing the Agreement; rather, it continued its development efforts for years. It ultimately made three of the four Milestone Payments, totaling $9 million to Plaintiff.[428]

In the face of these facts, Plaintiff does not and cannot allege that ConMed failed to work with its counterparts to jointly solve problems, submitted false data to regulators, stimulated alternatives to SureClip, or made no effort to develop SureClip.

Instead, Plaintiff advances three arguments. Plaintiff first argues that ConMed failed to meet the commercially best efforts standard by beginning an aggressive redesign of the SureClip in 2015. Plaintiff next argues that ConMed breached its commercially best efforts obligation by failing to devote sufficient resources to the project while finalizing its acquisition of SurgiQuest. Plaintiff last argues that the determination to permanently discontinue development of the SureClip in May 2016 constituted a breach of the commercial-best-efforts obligation, regardless of whether that determination was based on an exception to the Acceleration Payments provision.

***37** Plaintiff's first argument fails, in the first instance, based on the language of the Agreement. As discussed above, the bulk of ConMed's redesign efforts sought to implement safety features memorialized in Schedule 8.10. Under the Agreement, ConMed expressly reserved the right to undertake a redesign of the SureClip according to Section 8.10. And ConMed secured the Stockholder Parties' agreement that "no modification made to the specifications of any Product made in accordance with Section 8.10 shall (a) be deemed to be a breach of Section 4.03(g)" containing the commercially best efforts obligation. Thus, ConMed's decision to undertake a redesign to add features mandated by Section 8.10 was fully within its discretion under the Agreement and cannot be deemed a breach of Section 4.03(g).

Independent of this contractual defense, ConMed's efforts to improve the design of SureClip in 2015 did not breach the commercially best efforts clause. As discussed extensively above, ConMed's decision to redesign the SureClip in mid-2015 was related to safety issues. As of March 22, 2015, ConMed's engineering developers assigned to the SureClip viewed the product as less safe than its market competitors. This fact is memorialized in Wu's detailed management presentation of that date, reflecting his view that specific to the SureClip 5mm Cartridge, it was "unable to move tips together" and for a large vessel "SureClip [was] unable to obtain tip first closure through [the] entire range of closure."[429] Additionally, Wu's presentation highlighted that there was"[n]o tip first closure on clip nor jaw," which "[m]ay result in clip forming only partially around structure."[430] Moreover, Wu presented that when the "[c]lip is advanced into jaws" the "clip has the possibility of being jammed by tissue if caught," and "[r]esults in malformed clip and potential further clip jamming."[431] Donaldson concurred with Wu's recommendation. After, ConMed decided to redesign the SureClip to eliminate those flaws.

The redesign does not evidence ConMed's failure to use commercially best efforts, but rather, the opposite. Put another way, having come to the belief that the SureClip's design posed safety concerns, ConMed was contractually obligated to use commercially best efforts to eliminate those flaws, which it did.

The evidence on which Plaintiff relies does not support Plaintiff's position. At trial, Plaintiff called Paul Hermes as

a product development expert. Hermes acknowledges that ConMed "did a nice job" in the first few months of the SureClip project, but he also testified that ConMed went off track beginning in April 2015 when it began to consider design changes for the device.[432] Hermes concluded that the decision violated ConMed's commercially best efforts obligation because SureClip was "good enough" prior to that time.[433] Plaintiff also relies on Menn's testimony, which was to the same effect.[434] Plaintiff further introduced the testimony as a device expert, David Stefanchik.[435] But Hermes had no expertise as to the devices itself and Menn's testimony was self-serving. And Stefanchik testified that the device could not have been launched based on the October 2014 Animal Lab, i.e., the approval of two surgeons, despite Plaintiff's argument to the contrary.[436]

Plaintiff's next argument is similarly unavailing. ConMed's staffing decisions in late 2015 did not constitute a breach of its commercially best efforts obligation. Peters decided to move SureClip to Colorado during the time period when ConMed was acquiring SurgiQuest. Peters testified that he moved the project to Denver because ConMed "had some really strong engineers that could put some fresh eyes on [the project] [ ] the work that had been done by Tim and David was thorough, but [Peters] thought it was time for a fresh look."[437] One of these engineers was Williams, whom Peters testified was "our best."[438] Peters further testified that "putting him on a project is as high a priority as [he] can make it."[439] It is true that the project stagnated for a brief period in December 2015, but ConMed staffed the SurgiQuest team on the project in January 2016. This brief delay in development does not rise to the level of breach of a commercially best efforts provision.[440]

***38** Plaintiff's last argument raises a nettlesome issue concerning the nature of the parties' contractual scheme and specifically the relationship between Defendants' obligations under Section 4.03(h) and Section 4.03(g).

It is true, as Plaintiff argues, that the commercially best efforts obligation of Section 4.03(g) and the Acceleration Payments obligation of Section 4.03(h) are independent. Yet, it is also true, as Defendants argue, that Section 4.03(i) defines the Acceleration Payments of Section 4.03(h) to be liquidated damages for breach of the commercially best efforts obligation of Section 4.03(g) given the "substantial but indeterminate harm anticipated to be caused by the occurrence of an event described in Section 4.03(h), the difficulty of proof of loss and damages, and the value of the transactions to be consummated hereunder."[441] Further, Section 4.03(i) repeats in full and thus adopts the risk-of-injury exception to Section 4.03(h).[442]

Given the repetition of the exceptions to the Acceleration Payments provision in the Liquidated Damages provision, it would not make sense to hold that ConMed breached the commercially reasonable efforts provision by making a commercially reasonable determination to discontinue development of the SureClip in accordance with one of the contractually specified exceptions. This cannot be what the parties intended when executing the Agreement.[443] It cannot be that the Agreement permits ConMed to discontinue development of the SureClip upon a determination that it posed a risk of injury to patients, but simultaneously requires ConMed to continue to use commercial best efforts to develop the product after making that determination. Such an interpretation would run afoul of the principle of contract interpretation that requires this court to interpret the various provisions of a contract harmoniously.[444]

***39** For these reasons, Plaintiff has not proven that Defendants breached their obligation to use commercially best efforts to maximize payouts for the benefit of the Stockholder Parties.

C. Implied Covenant

The implied covenant of good faith and fair dealing requires in part that a party vested with discretion under a contract exercise its discretion reasonably, in good faith, and not in an unreasonable or arbitrary way that would destroy the counterparty's right to receive the fruits and benefits which they reasonably expected to receive under the contract.[445] The implied covenant cannot be invoked to override the express terms of the contract.[446] Moreover, rather than constituting a free floating duty imposed on a contracting party, the implied covenant can only be used conservatively "to ensure the parties' 'reasonable expectations' are fulfilled."[447] The implied

covenant is a limited remedy.[448] Its application is a "cautious enterprise."[449]

Sections 4.03(h) and (i) of the Agreement provide that ConMed has "sole discretion" to determine whether the Clip Applier Products pose a "risk of injury to either patients or surgeons" (a determination that would excuse ConMed from its obligation to pay the Acceleration Payments). Plaintiff claims that ConMed breached the implied covenant of good faith and fair dealing by failing to exercise its discretion reasonably and in good faith in two ways: (i) by deciding that SureClip posed a safety risk to doctors and patients and (ii) by failing to use commercially best efforts to maximize payments to the Stockholder Parties.

Plaintiff's arguments for breach of the implied covenant, however, duplicate its claims denied above for breach of express contractual provisions to make Acceleration Payments and use commercially best efforts. The implied covenant cannot be used to override express contractual provisions.[450]

For that reason, Plaintiff's claim for breach of the implied covenant fails.

III. CONCLUSION

For the foregoing reasons, judgment is entered in ConMed's favor as to all claims. ConMed established that one of the exceptions to the Acceleration Payments obligation applied, ConMed did not breach its obligation to use commercially best efforts, and ConMed did not breach the implied covenant of good faith and fair dealing. The parties shall confer on a form of order implementing this decision.

All Citations

Not Reported in Atl. Rptr., 2022 WL 2387802

Footnotes

1 C.A. No. 2017-0137-KSJM, Docket ("Dkt.") 152, Joint Schedule of Evid.; Dkt. 119, Pre-Trial Stipulation and Order ("PTO"). This decision also cites to: trial exhibits (by "JX" number); the trial transcript, Dkts. 132–38 (by "Trial Tr." page, line, and witness), the post-trial oral argument, Dkt. 153 (by "Post-Trial Oral Arg. Tr." page, line, and witness), and the deposition transcripts of Kurt Azarbarzin, Dennis Blom, Terence Bergé, William Bookwalter, Edward Connell, Dennis Cook, Victor Dardzinski, Timothy Donaldson, Richard Granger, Paul Hermes, Daniel Jonas, John "Jed" Kennedy, Stephen McColgan, Pavel Menn, Robert Menn, Bill Peters, Wilfredo Ruiz-Caban, Robert Sheridan, David Stefanchik, Michael Thomas, George Trutza, Jessie Verna, Mason Williams, David Wu, William Zimmerli, and Khanh Nguyen (by the deponent's last name and "Dep. Tr." page and line).

2 *See* PTO ¶ 6; Trial Tr. at 22:8–10, 32:7–14, 82:21–84:1 (Menn).

3 PTO ¶ 7.

4 *Id.*

5 Trial Tr. at 36:9–13 (Menn); *id.* at 476:4–5 (Connell).

6 PTO ¶ 8.

7 *Id.*

8 JX-441 at 1.

9 Trial Tr. at 585:4–6 (Connell).

10 JX-122 at 8; Trial Tr. at 734:21–735:1; PTO ¶¶ 7–8.

11 PTO ¶ 11.

12 *Id.* ¶ 14; Trial Tr. at 473:19–23 (Connell).

13 *See* PTO ¶¶ 11–12.

14 *Id.* ¶ 15.

15 Trial Tr. at 37:2–17 (Menn).

16 *Id.* at 18:4–8 (Menn).

17 Dr. Stephen McCologan, a member of the EndoDynamix Medical Advisory Board, and a highly credentialled surgeon and medical consultant, testified to this effect at trial. *See* Trial Tr. at 240:19–22 (McColgan) (testifying that the disposable clip appliers "were cheap, ... were poorly made[ ] [and] were designed for profit margin, not really caring about the quality at the end").

18 PTO ¶ 10; *see also* Trial Tr. at 18:2–3, 32:7–33:4 (Menn).

19 *See* JX-124 at 32.

20 JX-504 ("Menn Dep. Tr.") at 22:22–26:23; Trial Tr. at 88:12–15 (Menn).

21 Trial Tr. at 481:20–483:1 (Connell) (describing last-clip lockout); JX-9 at 10, 17, 30, 31, 32 (2012 marketing materials reflecting that the SureClip had last-clip lockout features).

22 Trial Tr. at 1347:5–9 (Donaldson) (describing visualization); *id.* 1472:3–6 (Granger) (same); JX-9 at 16–17 (2012 marketing materials reflecting that the SureClip permitted visualization).

23 Trial Tr. at 1616:9–16 (Blom) (describing tips-first closure); JX-9 at 16–17 (2012 marketing materials reflecting that the SureClip achieved tips-first lockout features).

24 Trial Tr. at 242:4–243:2 (McCologan) (describing clip scissoring); JX-9 at 16–17 (2012 marketing materials reflecting that the SureClip minimized clip scissoring).

25 *Id.* at 1106:6–12 (Stefanchik).

26 *Id.* at 1106:16–18 (Stefanchik).

27 *Id.* at 33:11–14 (Menn); *id.* at 34:24–35:13 (Menn); *id.* at 1108:1–5 (Stefanchik).

28 *Id.* at 1106:13–20 (Stefanchik).

29 *Id.* at 33:11–34:17 (Menn).

30 *Id.* at 1175:1–6 (Stefanchik).

31 *Id.* at 36:10–15 (Menn).

32 *Id.* at 36:15–37:1 (Menn).

33 *Id.* at 39:16–19 (Menn).

34 *Id.* at 39:1–12 (Menn); *id.* at 1170:14–1171:5 (Stefanchik).

35 *Id.* at 36:8–16 (Menn), *id.* at 1146:16–24 (Stefanchik).

36 *Id.* at 1549:24–1550:3, 1588:12–20 (Blom); *id.* at 1724:20–1725:1 (Peters).

37 *Id.* at 515:23–516:3 (Connell).

38 *Id.* at 313:11–22 (Kennedy); *id.* at 1555:15–1556:2, 1594:2–6 (Blom); *id.* at 1344:5–20 (Donaldson).

39 *See* PTO ¶¶ 4–5; Trial Tr. at 20:5–10, 21:1–6, 30:22–32:6 (Menn).

40 PTO ¶ 3.

41 JX-4 at 1.

42 *See* JXs-494–95 ("Connell Dep. Tr.") at 35:16–37:4.

43 *See* Connell Dep. Tr. at 35:25–36:23.

44 Trial Tr. at 461:17–463:22, 465:22–468:19 (Connell); JX-4 at 1–2.

45 PTO ¶ 16.

46 *Id.* ¶¶ 16–17; Trial Tr. at 311:4–11 (Kennedy).

47 PTO ¶ 17.

48 *See* JX-20 at 1–4.

49 Trial Tr. at 352:7–354:17 (Kennedy).

50 JX-59 at 1.

51 JX-108 ("SPA"). ConMed purchased only 98.7368% of the stock of EndoDynamix because one stockholder could not participate in the Agreement.

52 *Id.*

53 *Id.* §§ 4.02–4.03; JX-338 at 7 (describing payment structure).

54 SPA § 4.02.

55 *Id.* § 4.02(a).

56 Trial Tr. at 1401:2–23 (Sheridan).

57 SPA §§ 4.02(b), (c).

58 *Id.* § 4.02(d).

59 *Id.* § 4.03.

60 *Id.* § 4.03(g).

61 *Id.* § 4.03(h)(iii).

62 *Id.* § 4.03(h)(iv).

63 *Id.* § 4.03(h).

64 *Id.*

65 *Id.* § 4.03(g).

66 *Id.* §§ 4.03(h)(iv)(y)–(z).

67 JX-63 at 3.

68 JX-97 at 1–3.

69 SPA Schedule 8.10; *see also* Trial Tr. at 1316:4–16, 1318:2–1320:23 (Donaldson) (testifying that the pre-acquisition animal labs identified patient safety issues related to the design changes listed on Schedule 8.10).

70 SPA Schedule 8.10; *see also* JX-473 at 1 (noting that although Schedule 8.10 did not expressly mention tips-first closure, it did require that tissue not be pushed out of the clips, and "if the tips of the clip do not close first, then it is very possible for the tissue to 'squirt' out beyond the tips of the clip during closure of the clip"); Trial Tr. at 1320:3–20 (Donaldson) (noting that tips-first closure is related to subsection 2a of Schedule 8.10, which stated that "Clip must not push tissue out of the Jaws during load," because tips-first closure can prevent this issue).

71 Trial Tr. 692:8–11 (Wu) ("Question: And what were the issues in the [December 2013] animal lab with regard to clip closure? Answer: So Dr. Otabi noted that there were some issues of scissoring, clip scissoring.").

72 SPA § 8.10.

73 *Id.*

74 JX-86 § 4.03(h).

75 SPA § 8.10; *id.* at Schedule 8.10.

76 *Id.* § 4.03(i).

77 *Id.*

78 *Id.*

79 *Id.*

80 PTO ¶ 43.

81 *See id.* ¶¶ 44, 53.

82 *Id.* ¶ 44.

83 *Id.* ¶ 53.

84 JX-118 at 3.

85 JX-124 at 4.

86 *Id.*

87 JXs-514–15 ("Wu Dep. Tr.") at 180:20–24.

88 *Id.* at 7:24–8:9, 9:23–15:10.

89 *Id.* at 46:5–25; JX-496 (Cook Dep. Tr.) at 95:5–13; JX-510 ("Thomas Dep. Tr.") at 81:8–21.

90 JX-123 at 3–5.

91 Wu Dep. Tr. at 43:11–44:16; JX-517 ("Nguyen Dep. Tr.") at 119:10–20.

92 JX-132 at 5.

93 *See* JX-130.

94 SPA at Schedule II.

95 Trial Tr. at 147:9–14 (Menn).

96 *Id.* at 159:8–160:6 (Menn).

97 JX-131.

98 *Id.*

99 JX-136 at 16.

100 Trial Tr. at 149:8–164:18 (Menn).

101 JX-131 at 16.

102 JX-133 at 12–14, 21–23, 18–20 (DelPino, Williams, and Cutry passed both devices).

103 JX-134 at 3 (Williams "[c]ommented that the opening between the 5mm jaws is small" and found it "hard to see the clip coming in"); *id.* at 4 (Cutry "[a]rgued that 5mm needs tips-first closure").

104 JX-133 at 15–17 (Nagle); *id.* at 24–26 (Kondrup); JX-134 at 3 (Kondrup "[c]ommented that the handle takes a good amount of force to squeeze; could be tough for female surgeons"); JX-133 at 27–29 (Khaitan).

105 JX-133 at 31, 34–41.

106 JX-132 at 5.

107 *Id.*

108 *See* Connell Dep. Tr. at 129:6–131:3.

109 JX-132 at 5.

110 Connell Dep. Tr. at 131:15–132:6.

111 *Id.* at 132:15–17.

112 *Id.* at 132:18–20.

113 *See* JX-146.

114 JX-144; Trial Tr. at 323:11–24 (Kennedy); JX-149.

115 JX-146; Connell Dep. Tr. at 149:24–150:18; JX-226 at 3–4.

116 JX-131 at 8–13.

117 JX-146.

118 JX-144 ("We tested 6 units, 4 in animals and 2 on the bench. 3 out of 4 functioned as expected in the animal, one failed."); Trial Tr. at 326:14–22 (Kennedy); *id.* at 1336:8–11 (Donaldson).

119 Trial Tr. at 1567:18–1568:21 (Blom).

120 JX-134 at 4 ("LCL fails because it fell out of jaws."); *see also* Wu Dep. Tr. at 56:24–57:25.

121 JX-149 (emphasis added).

122 *Id.*

123 PTO ¶ 52.

124 SPA § 4.02.

125 *See, e.g.*, JX-109 at 3–5; JX-111 at 2–5.

126 Trial Tr. at 600:12–602:13 (Verna); *id.* at 334:1–5 (Kennedy).

127 JX-159 at 3.

128 *Id.*

129 *Id.* at 2 ("In fact, it will reduce our risk if the FDA does not review handle data. Our submittal will present the handle and cartridge as two distinct things. But, it is important that we continue with handle activity as currently scheduled. – e.g. cleaning, sterilization for claimed number of uses. I say that because we will need to submit handle data to the FDA if they do not accept this approach.").

130 Trial Tr. at 608:6–611:11 (Verna); JX-152 at 1; *see also* Trial Tr. at 603:14–19 (Verna) (testifying that "the handle was removed following consideration of where we were in terms of development of the product, and as we improved our understanding of the product, ... it made sense that the handle was a Class 1 device").

131 JX-234 at 1, 5–6, 9.

132 *Id.* at 23.

133 *Id.* at 20 (emphasis added).

134 Wu Dep. Tr. at 61:15–24.

135 JX-185; Wu Dep. Tr. at 75:18–85:24.

136 JX-185.

137 JX-187.

138 *See* Post-Trial Oral Arg. Tr. at 117:11–16.

139 JX-713 at 1–2 (citing 21 C.F.R. § 878.4300 ("An implantable clip is a clip-like device intended to connect internal tissues to aid in healing.")); *id.* at 1 (stating that "[t]he SureClip Clip Applier is intended to apply implantable, medium/large titanium clips").

140 JX-438 at 1 (certifying, in a "Premarket Notification Truthful and Accuracy Statement," that all data and information submitted in connection with the 510(k) application was "truthful and accurate and that no material fact has been omitted").

141 JX-188 at 1–2.

142 *Id.* at 2.

143 *Id.*

144 *Id.* (emphasis added).

145 JX-442 at 6.

146 JX-190 at 2.

147 JX-191 at 1–2.

148 PTO ¶¶ 58–60.

149 Trial Tr. at 498:17–21, 502:18–24 (Connell).

150 Wu Dep. Tr. at 87:19–88:11.

151 *Id.* at 89:8–90:3.

152 Trial Tr. at 1538:12–1538:22, 1545:12–1546:19 (Blom).

153 JX-210 at 9.

154 *Id.*

155 *Id.* at 5, 9, 11, 15.

156 Trial Tr. at 1593:14–22 (Blom) ("Well, I just had concerns that there really isn't a last clip lockout. There is a last clip color change, that a clip comes out that's a different color. ... I had concerns about it pushing tissue or traumatizing tissue. So I was concerned about the lack of a last clip lockout actually locking the user out from using the instrument.").

157 *Id.* at 1588:2–1588:8 (Blom) ("Again, this is the concept I spoke of earlier where you're trying to visualize the structure you're ligating with the clip. So a smaller opening allows you less ability to see and to place the clip exactly where you want it. So I was having more difficulty visualizing what I was doing with the SureClip device than the Ethicon device.").

158 *Id.* at 1597:12–16 (Blom) ("Q. And you used the term 'tip-first closure' during that video clip. Were you able to achieve tip-first closure using the SureClip 5-millimeter during this animal lab? A. I was not.").

159 *Id.* at 1591:3–1591:8 (Blom) ("And it allows -- I was concerned that the tissue could go out the front, either from being pushed out or actually squeezed out as you're closing the jaws. And, actually, we demonstrated that in using the instrument. It happened during placement of the clips.").

160 *Id.* at 1587:19–22 (Blom) ("It was my opinion that the SureClip device clips were less secure than the LIGAMAX clips, even when I used a 10-millimeter SureClip and a 5-millimeter LIGAMAX.").

161 *Id.* at 1588:14–16 (Blom) ("At the very beginning of the video, we had two malfunctions of the instrument with the clips not loading correctly.").

162 *Id.* at 1594:2–6 (Blom) ("I had concerns that the handle being so much heavier being made of metal as opposed to plastic, I was concerned that it would be easier to drop. And then, if it was dropped, it could cause more trauma or damage inside a patient.").

163 *Id.* at 1602:7–14 (Blom).

164 *Id.* at 1604:15–18 (Blom) ("Q. And after you completed the April 2015 animal lab, would you have switched from the LIGAMAX device to the SureClip? A. No. I made that clear I would not.").

165 *Id.* at 1604:19–1605:4 (Blom) ("Q. And does your opinion regarding that relate in any way to patient safety? A. It basically only relates to patient safety. The reason you change to new devices is because they may bring down costs, but not at the expense of safety. Or they improve safety, even if their cost is more. So my determination was you're asking me to switch to an instrument that's harder to use, makes me more uncomfortable, makes the operation harder and, therefore, makes it less safe.").

166 JX-202 at 1–2 (May 20, 2015 email from Wu to Donaldson and Connell).

167 *Id.* at 3.

168 *Id.* at 4–5.

169 *Id.* at 6–7.

170 *Id.* at 8–9.

171 *Id.* at 10–11 ("See 'Clip Opening' changes & risks").

172 *Id.* at 12–13.

173 *Id.* at 14–15.

174 *Id.* at 16–17.

175 JX-226 at 5 (August 3, 2015 memo from Donaldson to Peters et al. summarizing history of product development).

176 *Id.*

177 JX-205 at 1 (May 22, 2015 email from Wu to Dennis Cook).

178 *Id.* (forwarding Wu email to development team); *see also* JX-226 at 5 (August 3, 2015 memo from Donaldson to Peters et al. detailing history of product development) (observing that on "[a]pproximately May 17, 2015, Product Management made a tough recommendation to pause the project to evaluate significant deficiencies regarding the basic functionality of the SureClip design").

179 JX-226 at 5.

180 *See* JX-207 at 1.

181 *Id.*

182 *See* JX-209 at 1.

183 JX-216 at 3.

184 JX-212 at 2–6 (draft memo); JX-216 at 3–7 (final memo).

185 JX-216 at 3.

186 *Id.* at 5 ("I like the feel of this SureClip one better. It just feels better, like apple [iPhone] to something else"); *id.* at 6 ("[Surgeon] did not see any disadvantage of SureClip. 'I don't see a disadvantage. I don't like my 5mm (Ethicon) and I use it every day.' .... [Surgeon] would switch to SureClip if cost were the same.") (emphasis omitted); *id.* ("Two of the[ ] [surgeons] described their current devices (Ethicon) as 'toys' when comparing to the SureClip device.").

187 *Id.* at 7 (emphasis added).

188 JX-215 at 2.

189 JX-224.

190 JX-220 at 2.

191 *Id.*

192 *Id.*

193 *Id.* at 3.

194 JX-224.

195 JX-215 at 2.

196 *Id.*

197 JX-224.

198 JX-217 at 1; JX-223 at 1.

199 JX-223 at 1.

200 *Id.*

201 *Id.*

202 JX-226 at 2–8.

203 JX-232.

204 *Id.* at 73.

205 JX-238 at 7.

206 *Id.* ("[A]n improvement has been made to the handle by replacing the c-clip with an axially assembled shaft ring. This shaft ring fully encompasses the shaft groove diameter compared to the c-clip which did not fully enclose the shaft groove diameter. With the shaft groove fully encompassed force cannot be applied to the clip until it is fully advanced in the cartridge. *Thus, this type of malfunction can no longer occur*.") (emphasis added)).

207 Wu Dep. Tr. at 162:4–9.

208 *See* JX-708 at 5.

209 *Id.* at 6.

210 *Id.* at 31.

211 Trial Tr. at 221:17–19 (Menn).

212 *Id.* at 58:12–18 (Menn); Nguyen Dep. Tr. at 94:23–95:10.

213 JX-112 at 31.

214 *Id.* at 12.

215 Wu Dep. Tr. at 164:24–165:7.

216 *Id.* at 163:2–164:3.

217 *Id.*

218 JX-233 at 4–5.

219 Wu Dep. Tr. at 165:8–12.

220 JX-242 at 2 (September 25, 2015 email from Wu to Granger memorializing understanding that Granger would be "providing consultation on the SureClip"); *see also id.* at 1 (follow-up email).

221 JX-245 at 1 (September 30, 2015 report by Granger titled "Review of SureClip Project").

222 Trial Tr. at 1445:4–15 (Granger).

223 *Id.* at 1719:23–1720:5 (Peters); *see also id.* at 427:10–13 (Bookwalter) ("Q. But my question was simply the time that it takes to engage in that procedure costs the hospital money; right? A. It does, yeah."); *id.* at 1493:9–1494:20 (Granger) ("Q. All right. Well, you see here that under the manual cleaning that there's 15 minutes of ultrasonic cleaning as a second step? A. Yep. Q. And then there's a second stage of the manual cleaning, and, again, there's 10 minutes of cleaning initially. There's a flush-out of the device; correct? And then there's clean the outside of the device and, again, another 15 minutes of ultrasonic cleaning? A. Flush it with a flush port, right? Q. Yeah.").

224 SPA § 8.11.

225 JX-249 at 2.

226 JX-251.

227 *Id.* at 1–2.

228 *Id.*

229 JX-252 at 1–2.

230 Trial Tr. at 424:1–5 (Bookwalter).

231 JX-261 at 1.

232 *Id.*

233 *See also* JX-490 ("Azarbarzin Dep. Tr.") at 13:16–14:7.

234 Trial Tr. at 824:15–825:2, 825:11–17 (Williams); *see id.* at 727:22–728:11 (Trutza).

235 Azarbarzin Dep. Tr. at 43:24–44:19; 46:17–21.

236 Azarbarzin Dep. Tr. at 41:2–42:8 (stating that five former SurgiQuest employees who came over to ConMed had "core competencies" in developing clip appliers from prior work at U.S. Surgical).

237 *See* JX-506 ("Peters Dep. Tr.") at 113:14–20.

238 JX-259 at 7; *see also* Peters Dep. Tr. at 116:8–18.

239 Trial Tr. at 801:3–18, 802:13–16, 803:1–2, 803:22–804:3 (Williams).

240 *Id.* at 797:15–799:1 (Williams).

241 In his words, "Mason is our best" and "putting him on a project is as high a priority as [he] can make it. [Williams]'s on our high priority projects today, and he's grown in responsibilities." *Id.* at 1722:9–14 (Peters).

242 *Id.* at 804:2–3 (Williams).

243 *Id.* at 803:7–21 (Williams).

244 *Id.* at 809:23–810:17 (Williams).

245 *Id.* at 807:6–16 (Williams).

246 JX-454.

247 Trial Tr. at 805:24–806:4 (Williams).

248 JX-454.

249 JX-417.

250 *Id.* at 4.

251 JX-265 at 2.

252 *Id.* at 51.

253 JX-266 at 1.

254 JX-267.

255 JX-268 at 1–2.

256 *Id.* at 1.

257 *Id.*

258 JX-277 at 1.

259 JX-501 ("Jonas Dep. Tr.") at 219:9–13.

260 *See* JX-329 at 2.

261 *See* Wu Dep. Tr. at 356:2–5; JX-289.

262 JX-289 at 2–32.

263 *Id.* at 28.

264 *Id.* at 32.

265 JX-306 at 31.

266 Azarbarzin Dep. Tr. at 102:25–104:24; JX-305. Slide 3 of the presentation, titled "Reposable Handle Evaluation" identified ten concerns. JX-305 at 7 ((1)"The current design is extremely bulky and heavy;" (2) "Lubrication issues in handle may result in poor tractile feel and failure over time;" (3) "The handle will not clean well because it is laser welded;" (4) "If hospitals use ultrasonic cleaning before autoclaving, the aluminum will begin to put after 3 cycles;" (5) "Both devices use indexing mechanism to advance clips which uses too much of the handle stroke;" (6) "Universal handle has close to 100 independent parts;" (7) "10mm and 5mm have different lockout feature;" (8) "Jaw needs to be redesigned;" (9) "Clip pusher and feeding mechanism needs to be redesigned;" (10) "Cinch part does not work well and needs to be redesigned.").

267 JX-305 at 7; Azarbarzin Dep. Tr. at 115:14–117:10.

268 Azarbarzin Dep. Tr. at 98:22–25.

269 JX-307 at 2.

270 JX-312 at 1.

271 *See id.*

272 JX-313 at 1, 9.

273 *Id.*

274 JX-320 at 1 (emphasis added).

275 JX-322 at 12.

276 *Id.*

277 *Id.*

278 JX-324 at 1.

279 Thomas Dep. Tr. at 71:14–20.

280 JX-382.

281 Trial Tr. at 1751:9–14 (Peters) ("We had made significant efforts and had invested, you know, as the documents will show, over $10 million in the project and weren't getting to a place where we could viably commercialize something, both from what was acceptable and what would be profitable."); Wu Dep. Tr. at 111:3–8 ("Q. How many engineering hours are reflected on this exhibit that were devoted to the SureClip project? ... THE WITNESS: In total, 14-, almost 15,000.") citing JX-248)); Trial Tr. at 996:21–997:3 (Bergé) ("Now, in preparation for your testimony today, did you have the opportunity to determine the total amount of research and development expenditures which were shown on Joint Exhibit 382 that CONMED recorded towards the SureClip device? A. I believe it was approximately 600,000.") citing JX-382)); *id.* at 992:5–11 (Bergé) ("Q. Mr. Bergé, how much money did CONMED authorize, in total, for the CAR numbers that are

reflected on Joint Exhibit 276? A. 1,792,150. Q. And how much of that money did CONMED spend, of the authorized amount? A. 1,437,833.").

282 JX-321 at 1, 8.

283 *See id.* at 8.

284 JX-328 at 12–14.

285 *Id.* at 14.

286 JX-327 at 1, 3.

287 JX-338 at 9; *see also* JX-376 at 35 (December 2016 presentation to ConMed's board of directors reporting "Sure[C]lip developments discontinued" as a "Current Year Disappointment[ ]"); Azarbarzin Dep. Tr. at 129:12–130:5 (confirming that, after the May 25, 2016, board meeting, "the direction was to focus on fixing the current 10 millimeter clip applier, the disposable clip applier, and come up with a 5 millimeter disposable device," which would be "a completely disposable device").

288 JX-339 at 4.

289 JX-329 at 2.

290 *Id.* at 3.

291 *Id.*

292 Jonas Dep. Tr. at 238:7–11.

293 JX-334 at 1.

294 Menn Dep. Tr. at 186:25–187:8.

295 JX-362 at 1–3.

296 JX-385 at 1–4.

297 Dkt. 1, Verified Compl. ("Compl.").

298 *Id.* ¶¶ 39–46.

299 *Id.* ¶¶ 47–52.

300 *Id.* ¶¶ 53–56.

301 Dkt. 51.

302 Dkt. 70.

303 Dkt. 71.

304 Dkts. 132–38.

305 Dkts. 142 (“Pl.’s Post-Trial Opening Br.”), 145 (“Defs.’ Post-Trial Ans. Br.”), 146 (“Pl.’s Post-Trial Reply Br.”), Post-Trial Oral Arg. Tr.

306 Dkts. 159 (“Defs.’ Supp. Post-Trial Br.”), 161 (“Pl.’s Supp. Post-Trial Br.”).

307 Under the Agreement, EndoDynamix had the same contractual obligation to sell and develop the Clip Applier Products. But Menn understands from experience and discovery in this action that the EndoDynamix operations were integrated into the Advanced Surgical Division of ConMed. *See* PTO ¶ 44. Thus, for purposes of this argument, EndoDynamix is treated together as one with ConMed.

308 Plaintiff waived any other aspects of their claims by failing to press them at trial and in post-trial briefing. *See Oxbow Carbon & Mins. Hldgs., Inc. v. Crestview-Oxbow Acq., LLC*, 202 A.3d 482, 502 n.77 (Del. 2019) (noting that in the Court of Chancery “an issue not raised in post-trial briefing has been waived, even if it was properly raised pre-trial” (citing *SinoMab Bioscience Ltd. v. Immunomedics, Inc.*, 2009 WL 1707891, at *12 n.71 (Del. Ch. June 16, 2009))).

309 SPA § 4.03(h).

310 Pl.’s Post-Trial Opening Br. at 55–57.

311 *Id.* at 57–59.

312 Trial Tr. at 727:11–14 (Trutza) (“Q. And what was the business of SurgiQuest when you joined it? A. We were developing an innovative insufflation system.”); *see also* JX-261 at 1 (touting the “AirSeal System” which “consists of a valve-free trocar with continuous pressure sensing and an integrated insufflator and smoke evacuator” in a press release about ConMed's acquisition of SurgiQuest).

313 Pl.’s Post-Trial Opening Br. at 58 (quoting SPA § 4.03(h)) (internal quotation marks omitted).

314 JX-305 at 7; Azarbarzin Dep. Tr. at 115:14–117:10.

315 Azarbarzin Dep. Tr. at 98:22–25.

316 JX-307 at 2.

317 JX-313 at 1, 9.

318 JX-382.

319 JX-320.

320 JX-324.

321 JX-328 at 12–14.

322 JX-338 at 9; *see also* Azarbarzin Dep. Tr. at 129:12–130:5 (confirming that, after the May 25, 2016, board meeting, “[t]he direction was to focus on finalizing the current 10 mm clip applier, the disposable clip applier, and come up with a 5mm disposable device,” which would be “a completely disposable device”).

323 JX-339 at 4.

324 Trial Tr. at 971:7–13 (Jonas).

325 *Id.* at 738:20–739:8, 770:21–771:2 (Trutza) (testifying that the all-disposable clip applier incorporated "some pockets that were designed into the clip"); JX-516B (Zimmerli Dep. Tr.) at 65:24–66:8 (ConMed's Chief IP counsel testifying that the all-disposable clip applier incorporated claims of a design patent and a utility patent covering a "train track pattern on the [interior of] the legs of the clip"); *see also* JX-361 at 1 (ConMed's R&D Senior Manager responding to a question about whether the new product is different from SureClip and stating "I do not know any details regarding the sure clip project. This is a totally new device and has no attachment to that project. This should be approached as if it is a clean sheet of paper.").

326 SPA § 4.03(h) (emphasis added).

327 Trial Tr. at 766:3–7 (Trutza) (admitting, when asked whether any of the models for the all-disposable clip applier "use[d] the cartridge from the SureClip clip applier," "[t]he exact cartridge, no"); *id.* at 689:23–690:3 (Verna) (admitting that the SureClip cartridges would work only with the SureClip handle).

328 SPA § 4.03(h)(iv).

329 Defs.' Supp. Post-Trial Br. at 1–2; Pl.'s Supp. Post-Trial Br. at 10; *see also S'holder Representative Servs. LLC v. Shire US Hldgs., Inc.*, 2020 WL 6018738, at *19 (Del. Ch. Oct. 12, 2020) (holding that the party seeking to avoid its contractual obligation based on an event terminating a duty bears the burden of proving the event occurred), *aff'd,* 267 A.3d 370 (Del. 2021) (TABLE).

330 Pl.'s Supp. Post-Trial Br. at 12; Defs.' Supp. Post-Trial Br. at 4–5.

331 Pl.'s Supp. Post-Trial Br. at 10–11 (citing *Shire*, 2020 WL 6018738, at *6; *Channel MedSystems, Inc. v. Bos. Sci. Corp.*, 2019 WL 6896462, at *27 (Del. Ch. Dec. 18, 2019)).

332 Defs.' Supp. Post-Trial Br. at 2–3 (citing *Gilbert v. El Paso Co.*, 490 A.2d 1050, 1055 (Del. Ch. 1984)).

333 *See id.* at 16–25.

334 JX-134 at 3–4.

335 Wu Dep. Tr. at 29:13–35:4.

336 *Id.* at 37:12–38:3 ("Yeah, many of these. Most notably, as I look at this, number 2 is probably the biggest one, so clip closure and security. When we talk about devices and risk to patients, there's obviously the direct single-fault actions that could lead to patient harm, but on top of that, even as a delay in a procedure, which just could be from something that the device itself is not happening, not performing as expected, that presents a risk to the patient too. So yes, number 2 directly, but all of these could contribute to just risk to a patient.")

337 JX-108 at 168–69; Trial Tr. at 1316:4–16, 1318:2 –1320:23 (Donaldson) (testifying that the pre-acquisition animal labs identified patient safety issues related to the design changes listed on Schedule 8.10).

338 Trial Tr. at 1324:23–1333:22 (Donaldson) (testifying that the devices failed specifications related to patient safety during the September 2014 lab, and that among the unresolved safety issues identified were clip scissoring, clip loading, clip stability, tissue being pushed out of the jaws, and last-clip lockout).

339 JX-144; Trial Tr. at 323:11–24 (Kennedy).

340 Wu Dep. Tr. at 56:24-57:25.

341 Trial Tr. 1337:7–1338:1 (Donaldson).

342 Wu Dep. Tr. at 80:9–84:23, 80:9–83:22; *see also* JX-185.

343 Wu Dep. Tr. at 80:9–83:22.

344 JX-205; JX-202; Trial Tr. at 1697:15–21 (Peters).

345 Trial Tr. at 1699:20–1700:12, 1721:15–1722:15 (Peters).

346 JX-205; Trial Tr. at 1351:11–15, 1357:10–19 (Donaldson); *id.* at 1711:8–12, 1721:15–24 (Peters).

347 JX-196.

348 Trial Tr. at 1593:14–22 (Blom) ("Well, I just had concerns that there really isn't a last clip lockout. There is a last clip color change, that a clip comes out that's a different color. ... I had concerns about it pushing tissue or traumatizing tissue. So I was concerned about the lack of a last clip lockout actually locking the user out from using the instrument.").

349 *Id.* at 1588:2–1588:8 (Blom) ("Again, this is the concept I spoke of earlier where you're trying to visualize the structure you're ligating with the clip. So a smaller opening allows you less ability to see and to place the clip exactly where you want it. So I was having more difficulty visualizing what I was doing with the SureClip device than the Ethicon device.").

350 *Id.* at 1597:12–16 (Blom) ("Q. And you used the term 'tip-first closure' during that video clip. Were you able to achieve tip-first closure using the SureClip 5-millimeter during this animal lab? A. I was not.").

351 *Id.* at 1591:3–1591:8 (Blom) ("And it allows -- I was concerned that the tissue could go out the front, either from being pushed out or actually squeezed out as you're closing the jaws. And, actually, we demonstrated that in using the instrument. It happened during placement of the clips.").

352 *Id.* at 1588:14–16 (Blom) ("At the very beginning of the video, we had two malfunctions of the instrument with the clips not loading correctly.").

353 *Id.* at 1587:19–22 (Blom) ("It was my opinion that the SureClip device clips were less secure than the LIGAMAX clips, even when I used a 10-millimeter SureClip and a 5-millimeter LIGAMAX.").

354 *Id.* at 1594:2–6 (Blom) ("I had concerns that the handle being so much heavier being made of metal as opposed to plastic, I was concerned that it would be easier to drop. And then, if it was dropped, it could cause more trauma or damage inside a patient.").

355 *Id.* at 1604:15–18 (Blom) ("Q. And after you completed the April 2015 animal lab, would you have switched from the LIGAMAX device to the SureClip? A. No. I made that clear I would not."); *id.* at 1604:19–1605:4 (Blom) ("Q. And does your opinion regarding that relate in any way to patient safety? A. It basically only relates to patient safety. The reason you change to new devices is because they may bring down costs, but not at the expense of safety. Or they improve safety, even if their cost is more. So my determination was you're asking me to switch to an instrument that's harder to use, makes me more uncomfortable, makes the operation harder and, therefore, makes it less safe.").

356 JX-196 at 2–3 (noting that the other surgeon in the April 2015 Voice of Customer Lab with Blom also would not switch to SureClip because of issues with clip stability and device weight); JX-185 at 2–10 (Wu's March 2015 presentation noting issues with visualization, tips-first closure, and clip stability); JX-215 (noting multiple failures in the April and June 2015 Voice of Customer Labs in the categories of device weight, force to fire, last-clip lockout, visualization, and tips-first closure); JX-234 at 20 (NAMSA report noting that lack of tips-first closure led to clips closing "before the tissue was fully encompassed," necessitating additional clips to fully ligate the site).

357 JX-224.

358 Wu Dep. Tr. at 100:25–101:6 (Wu testifying that after the June 2015 Animal Lab the product was still not ready to launch).

359 *Id.* at 104:3–11.

360 JX-226.

361 Trial Tr. at 1715:14–24 (Peters).

362 JX-245 at 2.

363 Trial Tr. at 1462:12–1464:21 (Granger).

364 *Id.* at 804:4–20 (Williams).

365 *Id.* at 828:1–10 (Williams); *see also id.* 1724:11–16 (Peters) (testifying that as of December 2015, the device still lacked tips-first closure)

366 *Id.* at 1734:19–1735:20 (Peters).

367 JX-305 at 6.

368 JX-309 at 7.

369 Trial Tr. at 1736:8–11 (Peters).

370 *Id.* at 1738:2–13 (Peters).

371 JX-388 at 8.

372 JX-9, at 3, 10, 17, 30, 31–32.

373 SPA § 4.03(h)(iv).

374 *Commercially Reasonable*, *Black's Law Dictionary* (11th ed. 2019); *see also Commercially Reasonable*, Merriam-Webster Legal Dictionary, https://www.merriamwebster.com/legal/commerciallyreasonable (last visited June 28, 2022). (defining commercially reasonable as "fair, done in good faith, and corresponding to commonly accepted commercial practices").

375 *Hicklin v. Onyx Acceptance Corp.*, 970 A.2d 244, 250 (Del. 2009) (interpreting the meaning of "commercially reasonable" under 6 *Del. C.* § 9-610(a)); *see also* *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347,

at *88 (Del. Ch. Oct. 1, 2018) (determining whether the defendant used "commercially reasonable efforts to operate in the ordinary course of business" by comparing the defendant to a generic company in the same industry), *aff'd*, 198 A.3d 724 (Del. 2018).

376 *See Bardy Diagnostics, Inc. v. Hill-Rom, Inc.*, 2021 WL 2886188, at *27 (Del. Ch. July 9, 2021).

377 JX-234 at 20 (emphasis added).

378 *Enforcement Report*, FDA, https://www.accessdata.fda.gov/scripts/ires/index.cfm?Product=118061 (last visited June 28, 2022) (noting that the reason for recalling Ethicon's LIGACLIP clip applier was "due to potential clip formation and feeding issues which may result in improper clip formation"); *see also* JX-9 at 62–65 (noting that "Clips did not deploy properly" was a major reason for FDA MDR filings by manufacturers of clip appliers between 2006 and 2011). This court can take judicial notice of public FDA filings. *See Fortis Advisors LLC v. Allergan W.C. Hldg. Inc.*, 2019 WL 5588876, at *4 (Del. Ch. Oct. 30, 2019) (taking judicial notice of FDA premarket approval letters because they were publicly filed but declining to take judicial notice of the defendant's nonpublic correspondence with the FDA).

379 Trial Tr. at 1539:11–22 (Blom).

380 *Id.* at 1539:23–1540:21, 1542:3–23 (Blom).

381 *Id.* at 1540:20–24, 1544:18–22 (Blom).

382 JX-469; *see also* Trial Tr. at 1605:1–4 (Blom) ("So my determination was you're asking me to switch to an instrument that's harder to use, makes me more uncomfortable, makes the operation harder and, therefore, makes it less safe.").

383 Wu Dep. Tr. at 180:8–24 (testifying that at the time he worked on SureClip he was a "project leader" responsible for acting as a "project lead[ ] from an engineering perspective" and that he had some experience with clip appliers from working on ConMed's 10mm clip applier); Trial Tr. at 1304:1–21, 1306:12–14 (Donaldson) (testifying that at the time he worked on SureClip he was the Vice President of Research and Development and that before joining ConMed he worked on products to support orthopedic implants at a different medical device company); Trial Tr. at 801:9–18, 8023–6 (Williams) (testifying that at the time he worked on SureClip he was a "senior mechanical engineer" responsible for "project management" and "engineering duties" and that before SureClip he worked on a vessel sealing instrument); Trial Tr. at 1681:22–1682:2, 1684:18–1689:7 (Peters) (testifying that at the time he worked on SureClip he was an Executive Vice President and General Manager of the Advanced Surgical division and that before working at ConMed he held various positions with other medical device companies primarily in sales and marketing).

384 Trial Tr. at 1735:6–20 (Peters).

385 Having found the existence of the risk-of-injury exception, this decision does not reach ConMed's alternative argument under another exception to the Acceleration Payments obligation, which eliminated liability in the event that "then-existing or future market conditions that could reasonably be expected to cause gross profit as a percentage of net sales for such clip applier product(s) to be less than 30%." SPA § 4.03(h).

386 Pl.'s Post-Trial Reply Br. at 26–27.

387 *Id.* at 64–65.

388 Pl.'s Post-Trial Opening Br. at 65–66.

389 *See* JX-470 at 6 (Blom's Rebuttal Expert Report arguing that flat and rounded "atraumatic" jaws can still cause trauma if not used correctly, that falsely believing there is a clip in the absence of a last-clip lockout could result in "catastrophe," that the inclusion of colored last clips to alert the surgeon that the clips were exhausted evidences the danger that a last-clip lockout is designed to prevent, and that modified instructions for use would not ameliorate the risk posed by lack of tips-first closure because the instructions are often not available during procedures and no reasonable medical device company attempts to remedy known deficiencies through modified instructions and disclaimers); JX-473 at 2–3 (Granger's Rebuttal Expert Report arguing that rounded jaws are not a replacement for last-clip lockout, that the risk of injury posed by the lack of a last-clip lockout is exacerbated on the SureClip by the lack of surgeon tactile feel when using the device, that "all the established clip appliers in the marketplace have a last-clip lockout mechanism," and that modified instruction for use would be ineffective to mitigate a lack of tips-first closure because the surgeon is unlikely to be able to stop applying the clip mid-application before damaging a large vessel).

390 *See, e.g.*, JX-202 at 10; JX-226 at 5; JX-185 at 4; Trial Tr. at 1588:2–1588:8 (Blom).

391 *See, e.g.*, Wu Dep. Tr. at 29:13–25; Trial Tr. at 1309:19–23 (Donaldson); *id.* at 1588:14–16 (Blom).

392 *See, e.g.*, Wu Dep. Tr. at 30:2–10; Trial Tr. at 1309:24–5 (Donaldson); *id.* at 1587:19–22 (Blom).

393 *See, e.g.*, JX-202 at 4; JX-226 at 4; Trial Tr. at 1344:5–20 (Donaldson); *id.* at 1594:2–6 (Blom).

394 *See, e.g.*, Wu Dep. Tr. at 163:2–164:3, 280:25–281:19; Trial Tr. at 1444:23–15 (Granger).

395 Pl.'s Post-Trial Opening Br. at 69–70.

396 *Id.* at 47.

397 *Id.* at 60–63.

398 Plaintiff cites to *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349–50 (2001), for the proposition that the Supreme Court of the United States "has recognized that the 501(k) clearance process in intended 'to ensure ... that medical devices are reasonably safe and effective.' " Pl.'s Post-Trial Opening Br. at at 61. But the language surrounding this quote recognizing that the FDA had to balance the competing interests of "ensur[ing] ... that medical devices are reasonably safe and effective" and getting a product that qualifies under the 501(k) to market "within a relatively short period of time." *Buckman*, 531 U.S. at 350. In any event, *Buckman* did not hold that, after seeking 501(k) clearance for a device, a party is barred in all circumstances from determining that the device posed a risk of injury to plaintiffs.

399 JX-437 at 1.

400 JX-251 at 1.

401 Pl.'s Post-Trial Opening Br. at 61–63.

402 *Banther v. State*, 977 A.2d 870, 884 (Del. 2009).

403 *Motorola Inc. v. Amkor Tech., Inc.*, 958 A.2d 852, 859–60 (Del. 2008) (emphasis in original) (citation omitted)).

404 Plaintiff cites to various federal court decisions holding that judicial estoppel applies to representations made to administrative agencies. Pl.'s Post-Trial Opening Br. at 61–62 (citing *Siuzdak v. Sessions*, 295 F. Supp. 3d 77, 111 (D. Conn. 2018) ("The prior inconsistent assertion need not be made to a court of law: statements to administrative agencies ... may also give rise to judicial estoppel."); *In re Pursuit Cap. Mgmt., LLC*, 595 B.R. 631, 675 (Bankr. D. Del. 2018) ("The doctrine of judicial estoppel prevents "a litigant from asserting a position that is inconsistent with one he or she previously took before a court or agency." (citing *Montrose Med. Gp. Participating Sav. Plan v. Bulger*, 243 F.3d 773, 779 (3d Cir. 2001))). The parties did not identify any Delaware decision reaching a similar conclusion.

405 *JPMorgan Chase Bank, N.A. v. Ballard*, 213 A.3d 1211, 1223 (Del. Ch. 2019) ("The 'persuaded to accept' element is important [because] parties raise many issues throughout a lengthy litigation and only those arguments that persuade the court can form the basis for judicial estoppel." (citation omitted)).

406 *See* JX-188 at 2.

407 *RBC Cap. Mkts., LLC v. Jervis*, 129 A.3d 816, 872–73 (Del. 2015); *see also Barton v. Club Ventures Invs. LLC*, 2013 WL 6072249, at *6 (Del. Ch. Nov. 19, 2013) ("Under the doctrine of quasi-estoppel, the Court may preclude[ ] a party from asserting, to another's disadvantage, a right inconsistent with a position it has previously taken.") (citations omitted). The opposing party need not demonstrate reliance on the other litigant's inconsistency. *In re Rural/Metro Corp. S'holders Litig.*, 102 A.3d 205, 247 (Del. Ch. 2014).

408 *RBC*, 129 A.3d at 872–73 (citations omitted).

409 *Id.* at 873 (emphasis added).

410 Pl.'s Post-Trial Opening Br. at 61; JX-251 at 2.

411 Plaintiff argues that "[t]here would be something wrong with a system in which CONMED could, based on its representations of safety and supporting documents, obtain clearance to sell the SureClip clip applier and then argue to this Court that the product was unsafe." Pl.'s Post-Trial Opening Br. at 63.

412 SPA § 4.03(g) (emphasis added). In the same provision, the parties agreed that "[e]xcept where inconsistent with the foregoing, the Parties understand that the Buyer expects to be able to freely run the Company's business in its discretion following the Closing, and the Buyer will have full control and direction over the Company's business following the Closing, including decisions regarding the Products, strategic initiatives, management, staffing and employment matters (subject to Section 8.02(b)), sales and customer relations, legal structure, accounting and finance, branding, acquisitions and development, network development, office space, expenses, and other matters (including, without limitation, the right to make changes with respect to product specifications as expressly permitted pursuant to Section 8.10), provided, however, that, Buyer shall submit the 5 mm Clip Applier Product and the 10 mm Clip Applier Product for FDA 510(k) clearance no later than 120 days following the date on which a payment obligation is triggered by clause (A) of Section 4.02(b) hereto, if applicable." *Id.* Defendants argue that this language, along with other aspects of the Agreement, effectively qualify (or at least clarify) their efforts obligation. This decision does not reach this issue because Plaintiff failed to prove that Defendants breached an unqualified version of their efforts obligation.

413 *Akorn*, 2018 WL 4719347, *86 (holding that "reasonable best efforts" and "commercially reasonable efforts" obligations recognize that "a party's ability to perform its obligations depends on others or may be hindered by events beyond the party's control").

414 *Williams Cos., Inc. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 272 (Del. 2017) (citing *Hexion Specialty Chems., Inc. v. Huntsman Corp.*, 965 A.2d 715, 755–56 (Del. Ch. 2008)).

415 *Akorn*, 2018 WL 4719347, at *86.

416 2018 WL 6822708, at *6–8 (Del. Ch. Dec. 28, 2018) (denying motion to dismiss a claim for breach of commercially-reasonable-efforts provision in a post-closing earn-out context when the plaintiffs alleged that the defendant refused to commercialize an antibody treatment that peer companies were commercializing, and noting that "the actions of other similarly situated companies are a relevant yardstick to decide at this stage in the pleadings whether [the defendant] used 'commercially reasonable efforts' ").

417 2020 WL 949917, at *15–18 (Del. Ch. Feb. 27, 2020) (dismissing claim for breach of commercially-reasonable-efforts provision in a post-closing earn-out context when the seller only a poor relationship and disagreement over strategy with the buyer).

418 In *Himawan*, the buyer was required to expend the efforts and resources of "a company with substantially the same resources and expertise." *Himawan*, 2018 WL 6822708, at *8. In *Neurvana*, the buyer was required to use "efforts and resources comparable to those which an entity in the medical device industry of similar resources and expertise." *Neurvana*, 2020 WL 949917, at *16.

419 *Akorn*, 2018 WL 4719347, at *86.

420 *Id.* at *86–87.

421 ABA Mergers and Acqs. Comm., *Model Stock Purchase Agreement with Commentary* 213 (2d ed. 2010) (stating that "case law offers little support for the position that" similar efforts clauses impose a "separate standard[ ] less demanding than 'best efforts' "); *Channel MedSystems*, 2019 WL 6896462, at *37 n.410 (citing *Akorn*, 2018 WL 4719347, at *87 & n.796 ("Although the Agreement here refers to the use of 'commercially reasonable efforts' while the provision in *Akorn* referred to the use of 'reasonable best efforts,' Delaware 'case law [contains] little support for ... distinctions' between these two clauses.")); *Akorn*, 2018 WL 4719347, at *87 (surveying cases and stating that "[t]he high court did not distinguish between [commercially reasonable efforts and reasonable best efforts]").

422 The phrase "commercially best efforts" has not been interpreted by a Delaware court, and at least one commentator has questioned whether "commercially" works as an adverb in this context. *See* Kenneth A. Adams, *Interpreting and Drafting Efforts Provisions: From Unreason to Reason*, 74 Bus. Law. 677, 680 (2019) (noting that the term "commercially" is sometimes used to modify "best efforts" but that this language "doesn't make any sense" because "one describes something as being *commercially reasonable*, but not *commercially best* ..." (emphasis in original)).

423 *Snow Phipps Gp., LLC v. KCAKE Acq., Inc.*, 2021 WL 1714202, at *41 (Del. Ch. Apr. 30, 2021) (quoting *Akorn*, 2018 WL 4719347, at *91–92).

424 *Id.* (citing *AB Stable VIII LLC v. Maps Hotels and Resorts One LLC*, 2020 WL 7024929, at *91–92 (Del. Ch. Nov. 30, 2020); *Hexion*, 965 A.2d at 749).

425 *Akorn*, 2018 WL 4719347, at *86 (quoting ABA Mergers and Acqs. Comm., *Model Stock Purchase Agreement with Commentary* 212 (2d ed. 2010)); *see also* *In re Cambridge Biotech Corp.*, 186 F.3d 1356, 1375 (Fed. Cir. 1999) (best efforts requires "that the party put its muscles to work to perform with full energy and fairness the relevant express promises and reasonable implications therefrom").

426 *See* *KCAKE*, 2021 WL 1714202, at *50 (finding that a buyer breached a reasonable-best-efforts provision by not " 'work[ing] with [its] counterparties' in such a way that was likely to solve the problems it faced" (quoting *Akorn*, 2018 WL 4719347, at *91); *Channel MedSystems*, 2019 WL 6896462, at *38 (finding that a buyer breached a commerciallyreasonable-efforts provision when, upon determining that the merger agreement should be terminated, the buyer "made no reasonable efforts to engage with [the seller] or to take other appropriate actions to attempt to keep the deal on track"); *Akorn*, 2018 WL 4719347, at *90 (finding that a buyer breached a commercially-reasonable-efforts provision by "submit[ing] fraudulent data to the FDA ... [and then] failing to be fully transparent with the FDA").

427 *See* *BTG Int'l Inc. v. Wellstat Therapeutics Corp.*, 2017 WL 4151172, at *14 (Del. Ch. Sept. 19, 2017) (finding that a buyer breached a diligent-efforts provision by "deploy[ing] a sales force that was far too small to achieve [ ] revenue potential."); *WaveDivision Hldgs, LLC v. Millennium Digit. Media Sys., L.L.C.*, 2010 WL 3706624, at *18 (Del. Ch. Sept. 17, 2010) (finding that a buyer breached with a reasonable-best-efforts provision by "spen[ding] most of its energy and resources helping to develop an alternative"); *Hexion*, 965 A.2d at 749–56 (finding that a buyer breached a reasonable-best-efforts provision by working to obtain an insolvency opinion that would kill future financing prospects); *Pegasystems, Inc. v. Carreker Corp.*, 2001 WL 1192208, at *9 (Del. Ch. Oct. 3, 2001) (finding that a buyer breached a best-efforts provision by "ma[king] no effort[ ] to sell or market the [ ] products" and instead "giving [ ] customers a choice between the jointly developed products or the competing ... products" (internal citations omitted)).

428 This includes the initial payment of $1.25 million and $7.75 million in milestone payments. Defs.' Post-Trial Ans. Br. at 56; SPA §§ 2.02, 4.02.

429 JX-185 at 7.

430 *Id.* at 9.

431 *Id.* at 10.

432 Trial Tr. at 1230:4–24, 1244:3–1245:1 (Hermes).

433 *Id.* at 1258:14–18 (Hermes).

434 *Id.* at 171:6–8 (Menn).

435 Id. at 1130:10–18 (Stefanchik).

436 *Id.* at 1202:2–13 (Stefanchik).

437 *Id.* at 1721:18–24 (Peters).

438 *Id.* at 1722:11 (Peters).

439 *Id.* at 1722:12–13 (Peters).

440 *See* *In re IBP, Inc. S'holders Litig.*, 789 A.2d 14, 79–81 (Del. Ch. 2001) (finding in a post-trial decision that the defendant did not breach its "reasonable best efforts" to close the cash offer by delaying for two months to await the filing of restated financials with the SEC).

441 SPA § 4.03(i).

442 *See, e.g.*, SPA § 4.03(i) ("[N]o payment shall be made to the Representative for the benefit of the Shareholder Parties pursuant to Section 4.03(h) in respect of any Clip Applier Product in the event that at the time any of the delivery of any Acceleration Notice pursuant to Section 4.03(h) the Company or the Buyer have ceased the development or sale of such Clip Applier Product as a result of ... (b) a commercially reasonable determination by the Company or the Buyer in their sole discretion that the use of such product poses a risk of injury to either patients or surgeons").

443 Construing the two provisions in this fashion does not render the commercial-best-efforts provision meaningless or illusory, as Plaintiff argues. *See* Pl.'s Supp. Post-Trial Br. at 6. One could imagine a scenario where ConMed's failure to use commercial-best-efforts under Section 4.03(g) contributed to product's risk of injury to patients and an attendant risk-of-injury determination called for under Section 4.03(h) and Section 4.03(i). In that case, one could invoke the prevention doctrine (or something like it) to argue that the existence of the exception does not eliminate the obligation to pay liquidated damages or make Acceleration Payment because the breach of Section 4.03(g) caused the existence of the exception. *See* *KCAKE*, 2021 WL 1714202, at *52. The parties did not brief this issue, which is admittedly removed from their main dispute, and factually irrelevant in any event, given that Plaintiff failed to prove that any failure by ConMed to use commercial-best-efforts contributed to the risk-of-injury determination. The purpose of this point is limited to demonstrating that the court's construction of Sections 4.03(g), 4.03(h), and 4.03(i) can be harmonized despite Plaintiff's arguments to the contrary.

444 *GRT, Inc. v. Marathon GTF Tech., Ltd.*, 2012 WL 2356489, at *6 (Del. Ch. June 21, 2012) ("Delaware law requires that this court attempt to give effect to the plain terms of all provisions of a contract, and to give them a harmonious reading" (citing *E.I. du Pont de Nemours & Co. v. Shell Oil Co.*, 498 A.2d 1108, 1114 (Del. 1985)).

445 *See, e.g.*, *Miller v. HCP Trumpet Invs., LLC*, 194 A.3d 908, 2018 WL 4600818, at *1 (Del. 2018) (TABLE), *reargument denied* (Oct. 9, 2018) (noting that "the mere vesting of 'sole discretion' " does not relieve a party of "its obligation to use that discretion consistently with the implied covenant of good faith and fair dealing").

446 *Dave Greytak Enters., Inc. v. Mazda Motors of Am., Inc.*, 622 A.2d 14, 23 (Del. Ch. 1992) ("[W]here the subject at issue is expressly covered by the contract, or where the contract is intentionally silent as to that subject, the implied duty to perform in good faith does not come into play.").

447 *Dunlap v. State Farm Fire & Cas. Co.*, 878 A.2d 434, 442 (Del. 2005).

448 *Oxbow*, 202 A.3d at 507 (quoting *Nemec v. Shrader*, 991 A.2d 1120, 1128 (Del. 2010)).

449 *Nemec*, 991 A.2d at 1125.

450 *Fortis Advisors LLC v. Dialog Semiconductor PLC*, 2015 WL 401371, at *5 (Del. Ch. Jan. 30, 2015) (holding that the "failure to achieve the earn-out revenue thresholds must be analyzed within the confines of the express contractual obligations set forth in that provision and any other applicable provision" and not through the implied covenant of good faith and fair dealing).

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