

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

FORTIS ADVISORS LLC, solely in its)
capacity as representative of former)
stockholders of Auris Health, Inc.,)
)
Plaintiff,)
)
v.) C.A. No. 2020-0881-LWW
)
JOHNSON & JOHNSON, ETHICON,)
INC., ALEX GORSKY, ASHLEY)
MCEVOY, PETER SHEN, and SUSAN)
MORANO,)
)
Defendants.)

MEMORANDUM OPINION

Date Submitted: September 14, 2021

Date Decided: December 13, 2021

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WILL, Vice Chancellor

In April 2019, Johnson & Johnson—through its subsidiary Ethicon, Inc.—acquired robotic medical company Auris Health, Inc. The merger agreement provided for an upfront payment of \$3.4 billion with post-closing earnout payments of up to \$2.35 billion available upon the achievement of predetermined milestones. Several milestones were tied to Auris’s iPlatform surgical robot achieving regulatory clearance through the Food and Drug Administration’s 510(k) premarket approval pathway.

In August 2019, the FDA informed the parties that iPlatform was no longer eligible for 510(k) clearance, requiring that a different pathway called De Novo be followed instead. The merger agreement did not contemplate De Novo regulatory approval.

After J&J announced that it had released its reserves for the earnout payments in April 2020, plaintiff Fortis Advisors filed this litigation as the representative of Auris’s aggrieved former stockholders. Fortis contends that Ethicon breached the merger agreement. Fortis also asserts that J&J, its officers, and Ethicon made false promises during negotiations about the development of iPlatform that induced Auris to enter into the merger agreement.

The plaintiff brings twelve claims based on a variety of legal theories. The defendants have moved to dismiss the majority of those claims. The individual defendants have also moved for dismissal based on a lack of personal jurisdiction.

In this decision, I grant the motion to dismiss for lack of personal jurisdiction. I also conclude that Fortis has failed to state a claim for equitable fraud, reformation based on mutual mistake, and civil conspiracy. The motion to dismiss is otherwise denied.

I. BACKGROUND

The following facts are based on the plaintiff's Verified Complaint and the documents it incorporates by reference.¹ Any additional facts are either not subject to reasonable dispute or are subject to judicial notice.²

A. Johnson & Johnson Enters the RASD Market.

Defendant Johnson & Johnson ("J&J") is one of the largest healthcare companies in the world, with over 260 operating companies.³ The company's

¹ Verified Compl. ("Compl.") (Dkt. 1). See *Winshall v. Viacom Int'l, Inc.*, 76 A.3d 808, 818 (Del. 2013) ("[A] plaintiff may not reference certain documents outside the complaint and at the same time prevent the court from considering those documents' actual terms." (quoting *Fletcher Int'l, Ltd. v. ION Geophysical Corp.*, 2011 WL 1167088, at *3 n.17 (Del. Ch. Mar. 29, 2011))); *Freedman v. Adams*, 2012 WL 1345638, at *5 (Del. Ch. Mar. 30, 2012) ("When a plaintiff expressly refers to and heavily relies upon documents in her complaint, these documents are considered to be incorporated by reference into the complaint"); *Elf Atochem N. Am, Inc. v. Jaffari*, 727 A.2d 286, 287 n.1 (Del. 1999) (confining review in the context of a Rule 12(b)(1) motion to the allegations of the complaint and attached exhibits).

² See, e.g., *In re Books-A-Million, Inc. S'holders Litig.*, 2016 WL 5874974, at *1 (Del. Ch. Oct. 10, 2016) (explaining that the court may take judicial notice of "facts that are not subject to reasonable dispute" (citing *In re Gen. Motors (Hughes) S'holder Litig.*, 897 A.2d 162, 170 (Del. 2006))); *Omnicare, Inc. v. NCS Healthcare, Inc.*, 809 A.2d 1163, 1167 n.3 (Del. Ch. 2002) ("The court may take judicial notice of facts publicly available in filings with the SEC.").

³ Compl. ¶ 25.

operations are separated into several divisions, including the Medical Devices division, which generates about a third of J&J's total sales.⁴ In the mid-2000s, the Medical Devices division was generating billions of dollars in revenue from endomechanical devices—tools used during laparoscopic surgeries.⁵

After 2012, the growth of J&J's Medical Devices division was increasingly challenged by the development of Robotically Assisted Surgical Devices (“RASDs”).⁶ RASDs enable surgeons to perform invasive operations using a computer system that controls surgical instruments through small incisions in the patient's body.⁷ RASDs, such as Intuitive Surgical's RASD platform da Vinci Surgical System, began to replace traditional endomechanical tools in the medical device market.⁸ By the third quarter of 2015, J&J's Medical Devices division was the “poorest-performing segment” of its business and faced scrutiny from analysts and investors.⁹

J&J sought to develop its own RASD as an answer to Intuitive's success. In March 2015, J&J announced that its wholly owned subsidiary defendant Ethicon,

⁴ *Id.* ¶ 34; *see* Johnson & Johnson, *Products*, <https://www.jnj.com/healthcare-products> (last visited Dec. 13, 2021).

⁵ Compl. ¶ 34.

⁶ *Id.* ¶¶ 3, 35-36.

⁷ *Id.* ¶¶ 2, 36.

⁸ *Id.* ¶¶ 36-38.

⁹ *Id.* ¶ 35.

Inc.—a major producer of surgical mesh, sutures, and medical instruments—had entered into a joint venture with Google affiliate Verily Life Sciences.¹⁰ The joint venture, Verb Surgical Inc., began developing a new RASD called the Verb Surgical Robot.¹¹

J&J executives publicly touted the development and commercialization of the Verb Surgical Robot, suggesting that it would be commercialized in 2020.¹² Questions about the commercial viability of the product began to emerge within J&J.¹³ Meanwhile, RASDs and Intuitive continued to gain market share.¹⁴

B. J&J Explores Acquiring Auris.

In addition to Ethicon's investment in Verb, a separate J&J subsidiary made an investment in Auris Health, Inc. in 2017.¹⁵ Auris was formed by the founder of Intuitive, Dr. Frederic Moll, and focused on the development of new RASDs.¹⁶ In late 2018, J&J approached Auris about a potential acquisition of Auris by Ethicon.¹⁷

¹⁰ *Id.* ¶¶ 4, 40.

¹¹ *Id.* ¶¶ 4, 41.

¹² *Id.* ¶ 42.

¹³ *Id.* ¶¶ 5, 43, 46.

¹⁴ *Id.* ¶ 45.

¹⁵ *Id.* ¶ 48.

¹⁶ *Id.* ¶ 47.

¹⁷ *Id.* ¶ 49.

At that time, Auris had two main RASD platforms in development: Monarch and iPlatform.¹⁸

Monarch, a robotic endoscope designed to detect and treat lung cancer, had already obtained FDA clearance for one use indication.¹⁹ iPlatform was designed to be the next generation successor to the da Vinci Surgical System that Moll had developed while at Intuitive.²⁰ iPlatform was still in development and had yet to receive FDA approval.²¹

C. The Merger Negotiations

Arm's length negotiations began in December 2018.²² Defendants J&J Chief Executive Officer Gorsky, Executive Vice President and Worldwide Chairman of Medical Devices Ashley McEvoy, Vice President of Business Development Susan Morano, and Global Head of R&D of Medical Devices Peter Shen led negotiations for J&J and Ethicon.²³ Moll, with Auris's then-Chief Operating Officer Josh DeFonzo and then-Chief Financial Officer David Styka, led negotiations for Auris.²⁴

¹⁸ *Id.*

¹⁹ *Id.* ¶¶ 2, 50, 127.

²⁰ *Id.* ¶ 51.

²¹ *Id.* ¶¶ 52, 128, 136.

²² *Id.* ¶ 54.

²³ *Id.* ¶¶ 28-30, 54.

²⁴ *Id.* ¶¶ 52, 54.

The parties' negotiations lasted for two months. The defendants proposed that Ethicon would acquire Auris for a base amount with the potential for billions of dollars in future payments to Auris's stockholders based primarily on iPlatform meeting regulatory and sales milestones.²⁵ Given that structure, Auris's representatives raised concerns about the relationship between Auris and Verb, which they viewed as a potential competitor.²⁶ In response, J&J's representatives described the Verb Surgical Robot as "complementary to" or "different from" iPlatform, explaining that the products would "co-exist" post-acquisition and that the Verb robot was "on track" to launch.²⁷ Auris was told that J&J planned for Auris to operate "independently from Verb" with "minimal oversight" from J&J following the merger, with Auris retaining its independence as a distinct unit within J&J.²⁸ Auris was assured that its "space expansion and hiring needs" would be met and that Auris employees' compensation would be "align[ed]" with agreed-upon earnout payments.²⁹

²⁵ *Id.* ¶ 55.

²⁶ *Id.* ¶ 58.

²⁷ *Id.* ¶¶ 8, 62-63, 165-66, 172-73.

²⁸ *Id.* ¶¶ 8, 63-65, 165.

²⁹ *Id.* ¶¶ 52, 63-71, 165, 172.

D. The Merger Agreement

On February 12, 2019, the parties' agreement for Ethicon to acquire Auris was memorialized in an Agreement and Plan of Merger between Ethicon, Antwerp Merger Sub, Inc., Auris, and Fortis (the "Merger Agreement").³⁰ Under the Merger Agreement, Ethicon agreed to pay Auris's former stockholders \$3.4 billion dollars at closing.³¹ Ethicon also agreed to pay up to an additional \$2.35 billion in earnout payments based on Monarch and iPlatform meeting eight regulatory milestones and two sales milestones.³²

Section 2.07(a) of the Merger Agreement set out the conditions for triggering each of the ten earnout payments.³³ The eight regulatory milestones trigger earnout payments totaling \$1.35 billion, with two related to Monarch and six related to iPlatform.³⁴ The iPlatform regulatory milestones hinge on iPlatform obtaining regulatory approval by certain deadlines through the FDA's "510(k) premarket notification process," allowing for the marketing and sale of iPlatform for a specified medical indication.³⁵

³⁰ *Id.* ¶¶ 10, 79.

³¹ *Id.* ¶ 80.

³² *Id.* ¶¶ 81-82.

³³ Defs.' Opening Br. Ex. A § 2.07(a) ("Merger Agreement") (Dkt 24).

³⁴ *Id.* §§ 2.07(a)(i)-(viii).

³⁵ Compl. ¶¶ 86-87; Merger Agreement §§ 2.07(a)(iii)-(viii).

Ethicon promised in Section 2.07(e)(i) that it and its affiliates would “use commercially reasonable efforts to achieve each of the Regulatory Milestones.”³⁶ Section 2.07(e)(ii) defines “commercially reasonable efforts” as the expenditure of effort and resources toward “obtaining the applicable 510(k) premarket notification . . . consistent with the usual practice of [Ethicon] and [J&J] with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle to [Monarch and iPlatform].”³⁷

The Merger Agreement contains a one-sided anti-reliance provision in which Ethicon disclaimed reliance on any representations made outside of the Merger Agreement.³⁸ The Merger Agreement includes a set of indemnification provisions under which the parties agreed to indemnify each other against losses deriving from any breach, inaccuracy, or failure to perform a representation, warranty, or covenant found in the Merger Agreement.³⁹ The parties agreed that the indemnification provisions “will be the exclusive remedy with respect to claims made after the Closing that relate to this Agreement or the transactions contemplated by this Agreement,” subject to specified exceptions.⁴⁰ Those exceptions include Auris’s

³⁶ Merger Agreement § 2.07(e)(i).

³⁷ *Id.* § 2.07(e)(ii).

³⁸ *Id.* § 4.08(b).

³⁹ *Id.* §§ 8.01-02.

⁴⁰ *Id.* § 8.05(b).

former stockholders’ right to the earnout payments and “in the case of fraud by the Company, Parent or Merger Sub with respect to making the representations and warranties in th[e] [Merger] Agreement.”⁴¹

E. The FDA Requires De Novo Approval.

In November 2018—three months before the Merger Agreement was signed—the FDA publicly announced “steps ‘to modernize’ its 510(k) program and consider more products” through the alternative 513(f)(2) regulatory pathway referred to as “De Novo” approval.⁴² The announcement explained that the FDA planned on developing policy proposals that would limit the use of the 510(k) pathway for certain new devices.⁴³

De Novo and 510(k) approval are two pathways the FDA provides for Class I and II medical devices—i.e., those posing low to moderate risk to patients—to receive clearance to be marketed and sold in the United States.⁴⁴ The 510(k) pathway is a premarket submission made to the FDA demonstrating that the medical device is at least as safe and effective as a substantially equivalent device that has already received FDA approval.⁴⁵ The De Novo pathway is designed to evaluate

⁴¹ *Id.*

⁴² Compl. ¶¶ 125, 131; *see also* 21 U.S.C. §§ 360, 360c (2021); 21 C.F.R. §§ 807.81-100 (2021); 83 Fed. Reg. 63127 (proposed Dec. 7, 2018) (to be codified at 21 C.F.R. § 860).

⁴³ Defs.’ Opening Br. Ex. D. at 3-8.

⁴⁴ Compl. ¶¶ 124-25.

⁴⁵ *Id.* ¶ 124; Defs.’ Opening Br. Ex. B.

medical devices for which there is not a substantial equivalent that has received FDA approval.⁴⁶ For decades, the FDA had evaluated RASDs under the 510(k) pathway, including for Monarch in 2018.⁴⁷ And in late 2018, the FDA had indicated to Auris that the 510(k) pathway would be appropriate for iPlatform.⁴⁸

On August 5, 2019, the FDA informed Ethicon, Verb, and Auris that it no longer considered the 510(k) pathway to be appropriate for first-generation RASDs like iPlatform.⁴⁹ Instead, the FDA explained, RASDs would be required to use the De Novo pathway.⁵⁰

F. Auris's Development Post-Merger

Following the FDA's guidance, J&J and Ethicon directed Verb to shift toward securing De Novo approval for the Verb Surgical Robot.⁵¹ Auris was asked to confirm with the FDA that iPlatform was not eligible for the 510(k) pathway and, after obtaining that confirmation, that it would not require iPlatform to undertake the

⁴⁶ Compl. ¶ 125; Defs.' Opening Br. Ex. C.

⁴⁷ Compl. ¶ 127.

⁴⁸ *Id.* ¶ 128.

⁴⁹ *Id.* ¶ 138.

⁵⁰ *Id.* ¶¶ 134, 138.

⁵¹ *Id.* ¶ 140.

more onerous approval process for Class III medical devices.⁵² Auris did not begin preparing a De Novo application for iPlatform until January 2020.⁵³

Meanwhile, Auris was (allegedly) pitted against Verb in a covert “bakeoff” competition to determine whether iPlatform or Verb’s robot was superior.⁵⁴ Auris employees and resources were diverted toward developing tests and comparisons between iPlatform and the Verb Surgical Robot.⁵⁵ Auris was also not permitted to increase its employee hiring or acquire additional space.⁵⁶ In October 2019, J&J declared iPlatform the winner.⁵⁷ In early 2020, Ethicon bought out Verily’s stake in Verb and integrated Verb into Auris.⁵⁸

G. This Litigation

In April 2020, J&J publicly announced that it had “released” most of the reserves it had been carrying for potential earnout payments to former Auris stockholders.⁵⁹ On October 12, 2020, Fortis filed this action against J&J, Ethicon,

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* ¶ 99.

⁵⁵ *Id.* ¶¶ 11, 103.

⁵⁶ *Id.* ¶¶ 104-05.

⁵⁷ *Id.* ¶ 107.

⁵⁸ *Id.* ¶ 112.

⁵⁹ *Id.* ¶ 155.

and individual defendants Gorsky, McEvoy, Shen, and Morano.⁶⁰ Fortis's complaint alleges breaches of contract in connection with the earnout provisions, along with a panoply of additional causes of action.⁶¹

II. LEGAL ANALYSIS

The defendants have moved to dismiss Fortis's claims, other than its breach of contract and indemnification claims, under Court of Chancery Rule 12(b)(6).⁶² Specifically, they seek dismissal of two fraud claims (Counts I and II), a claim for breach of the implied covenant of good faith and fair dealing (Count VI), two mutual mistake claims pleaded in the alternative (Counts VII and VIII), an unjust enrichment claim pleaded in the alternative (Count IX), a civil conspiracy claim (Count X), and a claim seeking specific performance (Count XII). When considering such a motion:

- (i) all well-pleaded factual allegations are accepted as true;
- (ii) even vague allegations are well-pleaded if they give the opposing party notice of the claim;
- (iii) the Court must draw all reasonable inferences in favor of the non-moving party; and
- (iv) dismissal is inappropriate unless the plaintiff would not be entitled to recover under any reasonably conceivable set of circumstances susceptible of proof.⁶³

⁶⁰ Dkt. 1.

⁶¹ *Id.*

⁶² All twelve counts of the Complaint were brought against Ethicon. Counts I, II, and X were also brought against J&J and the individual defendants.

⁶³ *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896-97 (Del. 2002) (internal citation omitted).

“[T]he pleading standards for purposes of a Rule 12(b)(6) motion ‘are minimal,’” and the operative test is “one of ‘reasonable conceivability,’” which “asks whether there is a ‘possibility’ of recovery.”⁶⁴

The individual defendants have also moved to dismiss the claims brought against them for lack of personal jurisdiction under Court of Chancery Rule 12(b)(2). When a defendant moves to dismiss a complaint under Rule 12(b)(2), “the plaintiff bears the burden of showing a basis for the court’s exercise of jurisdiction over the defendant.”⁶⁵ “[T]he court may consider the pleadings, affidavits, and any discovery of record, and may even hold an evidentiary hearing.”⁶⁶ “If, as here, no evidentiary hearing has been held, plaintiffs need only make a *prima facie* showing of personal jurisdiction and ‘the record is construed in the light most favorable to the plaintiff.’”⁶⁷

This decision begins by addressing whether the court has jurisdiction over the individual defendants. After finding that it does not, I address the remaining claims against J&J and Ethicon. For the reasons stated below, I conclude that Fortis has

⁶⁴ *In re China Agritech, Inc. S’holder Deriv. Litig.*, 2013 WL 2181514, at *23-24 (Del. Ch. May 21, 2013) (quoting *Cent. Mortg. Co. v. Morgan Stanley Mortg. Cap. Hldgs. LLC*, 27 A.3d 531, 536-37 (Del. 2011)).

⁶⁵ *Ryan v. Gifford*, 935 A.2d 258, 265 (Del. Ch. 2007).

⁶⁶ *Cornerstone Techs., LLC v. Conrad*, 2003 WL 1787959, at *3 (Del. Ch. Mar. 31, 2003).

⁶⁷ *Ryan*, 935 A.2d at 265 (citing *Benerofe v. Cha*, 1996 WL 535405, at *3 (Del. Ch. Sept. 12, 1996) and quoting *Cornerstone Techs.*, 2003 WL 1787959, at *3).

failed to state viable claims for civil conspiracy, equitable fraud, and reformation based on mutual mistake, but has adequately pleaded claims for common law fraud, breach of the implied covenant of good faith and fair dealing, unjust enrichment, rescission based on mutual mistake, and specific performance.

A. Personal Jurisdiction and the Civil Conspiracy Claim

Delaware courts engage in a two-step analysis to determine whether the court has jurisdiction over non-resident defendants.⁶⁸ First, the court must determine whether service of process is authorized by statute.⁶⁹ If so, the court will consider whether the defendant has sufficient minimum contacts with Delaware such that the exercise of jurisdiction “does not offend traditional notions of fair play and substantial justice.”⁷⁰

Fortis argues that this court has personal jurisdiction over Gorsky, McEvoy, Shen, and Morano under Delaware’s long arm statute, 10 *Del. C.* § 3104(c)(3). Fortis also asserts that the conspiracy theory of personal jurisdiction applies. Because the latter argument rests on whether the plaintiff has pleaded a viable conspiracy claim, this section resolves the Rule 12(b)(2) motion entirely and the Rule 12(b)(6) motion as to the civil conspiracy claim.

⁶⁸ *Matthew v. Fläkt Woods Grp. SA*, 56 A.3d 1023, 1027 (Del. 2012).

⁶⁹ *Id.*

⁷⁰ *Id.* (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)).

1. Long-Arm Jurisdiction

Fortis asserts that personal jurisdiction exists under 10 *Del. C.* § 3104(c)(3) because the individual defendants “[c]ause[d] tortious injury in the State by an act or omission in this State.”⁷¹ Section 3104(c)(3) is “a ‘single act’ statute that establishes jurisdiction over nonresidents on the basis of a single act or transaction engaged in by the nonresident within the state.”⁷² Thus, Section 3104(c)(3) permits the exercise of “specific personal jurisdiction over claims arising from the jurisdictional contacts” at issue.⁷³

Fortis contends that the individual defendants, as officers of J&J, were “actively involved” in making false representations and omissions that defrauded Auris’s former stockholders during the merger negotiations. The merger negotiations did not take place in Delaware and the relevant statements were not made within this state. Because some of Auris’s former stockholders are Delaware corporations, Fortis argues that their injuries were suffered in Delaware.⁷⁴ But none

⁷¹ 10 *Del. C.* § 3104(c)(3).

⁷² *Carlton Invs. v. TLC Beatrice Int’l Hldgs., Inc.*, 1995 WL 694397, at *10 (Del. Ch. Nov. 21, 1995) (citing *Tabas v. Crosby*, 444 A.2d 250, 254 (Del. 1982) and *Eudaily v. Harmon*, 420 A.2d 1175, 1180 (Del. 1980)).

⁷³ *Carlton*, 1995 WL 694397, at *10; *Chandler v. Ciccoricco*, 2003 WL 21040185, at *11 (Del. Ch. May 5, 2003) (explaining that “single act” provisions of the long arm statute “will only support an exercise of personal jurisdiction with respect to those causes of action that have a nexus to the transaction of business that took place in the State”).

⁷⁴ Pl.’s Answering Br. 44 (Dkt. 32).

of those corporations are alleged to have a physical presence in Delaware. The harms had no effect in this state other than “to have been suffered by an entity whose only nexus to Delaware lies in its legal creation” here.⁷⁵

Fortis relies on the Delaware Superior Court’s decision in *Wavedivision Holdings, LLC v. Highland Capital Management, L.P.*, which explains that “when a Delaware corporation is injured, the court may view the plaintiff corporation’s injury as having taken place in Delaware.”⁷⁶ *Wavedivision* was not, however, a personal jurisdiction case. The court was assessing whether Delaware’s statute of limitations applied and was interpreting Delaware’s borrowing statute to determine whether an injured corporation was a resident of Delaware.⁷⁷ Fortis cites no authority holding that an injured party’s incorporation in Delaware is sufficient to show an injury in this state for purposes of personal jurisdiction.⁷⁸

Fortis also argues that the individual defendants committed an act in Delaware by causing the formation of a Delaware corporation, Antwerp Merger Sub, that was

⁷⁵ *Aeroglobal Cap. Mgmt., LLC v. Cirrus Indus., Inc.*, 2003 WL 77007, at *5 (Del. Super. Jan. 6, 2003).

⁷⁶ 2011 WL 5314507, at *8 (Del. Super. Nov. 2, 2011).

⁷⁷ *Id.*; see 10 Del. C. § 8121.

⁷⁸ *Cf. Sample v. Morgan*, 935 A.2d 1046, 1058 (Del. Ch. 2007) (finding that a Delaware entity was injured in Delaware as the “situs that reflects the center of gravity of the corporation for all issues involving internal affairs” where directors allegedly caused financial injury through breaches of fiduciary duty (citing *Chandler*, 2003 WL 21040185, at *11 n.46)).

merged into Auris.⁷⁹ Fortis’s theory is that the creation of the Delaware merger sub was a necessary action for completing the merger and engaging in the purported fraud alleged in the Complaint. The plaintiff does not, however, allege that the individual defendants had a role in forming the Delaware entity.

Even if they had, “merely participating in the formation of a Delaware entity, without more, does not create a basis for jurisdiction in Delaware.”⁸⁰ Instead, “the formation of a Delaware entity must be central to the plaintiff’s claims of wrongdoing.”⁸¹ The creation of the merger sub was a technically necessary step to complete the merger. But it has, at best, a tenuous link to the former stockholders’ claimed injuries and cannot reasonably be viewed as an integral part of the wrongdoing by the individual defendants alleged in the Complaint.⁸²

2. Conspiracy Theory of Jurisdiction and Civil Conspiracy

Fortis also maintains that jurisdiction exists over the individual defendants based on a conspiracy theory.⁸³ The Delaware Supreme Court established the

⁷⁹ Pl.’s Answering Br. 45-46.

⁸⁰ *Conn. Gen. Life Ins. Co. v. Pinkas*, 2011 WL 5222796, at *2 (Del. Ch. Oct. 28, 2011).

⁸¹ *Dow Chem. Co. v. Organik Kimya Hldg. A.S.*, 2017 WL 4711931, at *8 (Del. Ch. Oct. 19, 2017) (internal citation omitted).

⁸² The only references to the merger sub in the Complaint are when Fortis lists the parties to the Merger Agreement. *See* Compl. ¶¶ 10, 79.

⁸³ Pl.’s Answering Br. 46.

elements of the conspiracy theory of jurisdiction in *Instituto Bancario SpA v. Hunter Engineering Company*:

(1) a conspiracy to defraud existed; (2) the defendant was a member of that conspiracy; (3) a substantial act or substantial effect in furtherance of the conspiracy occurred in the forum state; (4) the defendant knew or had reason to know of the act in the forum state or that acts outside the forum state would have an effect in the forum state; and (5) the act in, or effect on, the forum state was a direct and foreseeable result of the conduct in furtherance of the conspiracy.⁸⁴

“The conspiracy theory of jurisdiction is narrowly and strictly construed.”⁸⁵

Satisfaction of this test depends on whether the plaintiff has sufficiently pleaded a claim for civil conspiracy. “[T]o state a claim for civil conspiracy, a plaintiff must plead facts supporting (1) the existence of a confederation or combination of two or more persons; (2) that an unlawful act was done in furtherance of the conspiracy; and (3) that the conspirators caused actual damage to the plaintiff.”⁸⁶ As with a substantive claim for civil conspiracy, the conspiracy theory of personal jurisdiction requires both the existence of an underlying wrong and legally distinct co-conspirators.⁸⁷

⁸⁴ 449 A.2d 210, 225 (Del. 1982).

⁸⁵ *Comput. People, Inc. v. Best Int’l Gp., Inc.*, 1999 WL 288119, at *6 (Del. Ch. Apr. 27, 1999).

⁸⁶ *Allied Cap. Corp. v. GC-Sun Hldgs., L.P.*, 910 A.2d 1020, 1036 (Del. Ch. 2006).

⁸⁷ See *Boulden v. Albiorix, Inc.*, 2013 WL 396254, at *8 (Del. Ch. Jan. 31, 2013, revised Feb. 7, 2013); *Amaysing Techs. Corp. v. Cyberair Commc’ns, Inc.*, 2005 WL 578972, at *7 (Del. Ch. Mar. 3, 2005).

Fortis cannot show the latter. Because “it is the general rule that the acts of the agent are the acts of the corporation . . . a corporation generally cannot be deemed to have conspired with its officers and agents.”⁸⁸ There is an exception “when the officer or agent of the corporation steps out of her role as an officer or agent and acts pursuant to personal motives.”⁸⁹ Fortis points to two motives it believes were personal to the individual defendants: “(1) to conceal their commitment of securities fraud through market misrepresentations about Verb,” and “(2) to inflate J&J’s share price and earnings per share for personal profit.”⁹⁰ Neither of these assertions is supported by the Complaint.

Fortis has not alleged that the individual defendants fraudulently induced Auris into a merger with Ethicon in order to conceal possible securities fraud. Unlike the precedent Fortis relies on, the individual defendants are not facing a securities fraud claim.⁹¹ And the facts described in the Complaint provide no indication that

⁸⁸ *Amaysing*, 2005 WL 578972, at *7.

⁸⁹ *Id.*

⁹⁰ Pl.’s Answering Br. 46.

⁹¹ *See Reich v. Lopez*, 38 F. Supp. 3d 436, 448, 465 (S.D.N.Y. 2014) (finding that individual defendants acted to further own personal motives to protect themselves from exposure to a RICO claim, where that claim had been pleaded against them).

the individual defendants made the alleged misrepresentations to cause J&J's stock price to inflate.⁹²

Fortis therefore cannot demonstrate that the individual defendants were members of a conspiracy and this court cannot exercise personal jurisdiction under the conspiracy theory.⁹³ The individual defendants are dismissed from this action.⁹⁴

The civil conspiracy claim is also pleaded against J&J and Ethicon. As with the individual defendants, Fortis cannot establish a conspiracy among distinct actors. “[A] corporation generally cannot be deemed to have conspired with its wholly owned subsidiary.”⁹⁵ “There are exceptions to this general principle. For example, the rule may not apply when a parent and its subsidiary do not ‘share common

⁹² Any financial gain would be unlikely to satisfy the exception anyway because it would not be a “benefit independent of their financial interest resulting from their employment.” *Amaysing*, 2005 WL 578972, at *8.

⁹³ The plaintiff also argues that “to the extent the [i]ndividual [d]efendants contend they are entitled to take advantage of Section 8.05(b) of the Merger Agreement,” jurisdiction is proper “by operation of the forum selection clause in the Merger Agreement.” Pl.’s Answering Br. 44. Each party to the Merger Agreement submitted to jurisdiction in Delaware in the forum selection clause. *See* Merger Agreement § 10.10. But the individual defendants are not parties to the Merger Agreement and did not become parties by virtue of the fact that they rely on the exclusive remedy provision in Section 8.05(b) in seeking dismissal of Fortis’s fraud claims. *See infra* Part II.B.

⁹⁴ Because the plaintiff has failed to allege a non-frivolous basis for personal jurisdiction, the court declines to grant the plaintiff jurisdictional discovery. “[T]he decision to grant jurisdictional discovery is discretionary.” *Neurvana Med., LLC v. Balt USA, LLC*, 2019 WL 5092894, at *2 (Del. Ch. Oct. 10, 2019). “Before ordering personal jurisdiction discovery there must be at least ‘some indication that this particular defendant is amenable to suit in this forum.’” *Id.*, at *1 (quoting *In re Am. Int’l Gp., Inc.*, 965 A.2d 763, 831 n.195 (Del. Ch. 2009)). There is no such indication here.

⁹⁵ *In re Transamerica Airlines, Inc.*, 2006 WL 587846, at *6 (Del. Ch. Feb. 28, 2006).

economic interests.”⁹⁶ Fortis does not allege that any such exceptions apply. The civil conspiracy claim is therefore dismissed pursuant to Rule 12(b)(6).

B. The Fraud Claims

Fortis contends that J&J and Ethicon committed fraud by making false extra-contractual representations to and withholding material facts from Auris during the merger negotiations.⁹⁷ Before analyzing the merits, I must consider whether the Merger Agreement bars Fortis from pursuing those claims.

Delaware law respects bargained-for contractual rights negotiated between sophisticated parties.⁹⁸ At the same time, “Delaware’s public policy is intolerant of fraud.”⁹⁹ Delaware courts have balanced those interests by refusing to “insulate a party from liability for its counterparty’s reliance on fraudulent statements made outside of an agreement absent a clear statement by that counterparty—that is, the

⁹⁶ *Dow Chem.*, 2017 WL 4711931, at *12 (quoting *Allied Cap.*, 910 A.2d at 1042) (finding a conspiracy where a subsidiary was insolvent and the parent and the subsidiary conspired to strip the subsidiary of its assets).

⁹⁷ Counts I and II are also pleaded against the individual defendants. Because I have found that no personal jurisdiction exists over them, I only address the claims as brought against J&J and Ethicon.

⁹⁸ See *Anschutz Corp. v. Brown Robin Cap., LLC*, 2020 WL 3096744, at *13 (Del. Ch. June 11, 2020) (“Delaware courts have consistently held that ‘sophisticated parties to negotiated commercial contracts may not reasonably rely on information that they contractually agreed did not form a part of the basis for their decision to contract.’” (quoting *H-M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 142 n.18 (Del. Ch. 2003))).

⁹⁹ *Abry P’rs V, L.P. v. F & W Acq. LLC*, 891 A.2d 1032, 1059 (Del. Ch. 2006).

one who is seeking to rely on extra-contractual statements—disclaiming such reliance.”¹⁰⁰

Prior decisions of this court have found that a standard integration clause, without anti-reliance language, cannot disclaim reliance on representations outside of the written contract.¹⁰¹ In *Abry Partners V, L.P. v. F & W Acquisition LLC*, then-Vice Chancellor Strine explained that an agreement “must contain ‘language that . . . can be said to add up to a clear anti-reliance clause by which the plaintiff has contractually promised that it did not rely upon statements outside the contract’s four corners in deciding to sign the contract.’”¹⁰² That approach strikes a “sensible

¹⁰⁰ *FdG Logistics LLC v. A&R Logistics Hldgs., Inc.*, 131 A.3d 842, 859 (Del. Ch. 2016); *see also Anschutz*, 2020 WL 3096744, at *13 (stating that provisions disclaiming reliance must be “explicit and comprehensive, meaning the parties must forthrightly affirm that they are not relying upon any representation or statement of fact not contained in the contract” (quoting *Kronenberg v. Katz*, 872 A.2d 568, 593 (Del. Ch. 2004))); *Kronenberg*, 872 A.2d at 593 (“Because Delaware’s public policy is intolerant of fraud, the intent to preclude reliance on extra-contractual statements must emerge clearly and unambiguously from the contract.”).

¹⁰¹ *Anschutz*, 2020 WL 3096744, at *14 (“While our law does not require ‘magic words’ to disclaim reliance, when the contract does not actually include a specific acknowledgement by a party that it is only relying on information contained within the four corners of the agreement, that party is not shirking its bargain when it later alleges that it did, in fact, rely on extra-contractual representations.”); *Anvil Hldg. Corp. v. Iron Acq. Co., Inc.*, 2013 WL 2249655, at *8 (Del. Ch. May 17, 2013) (“Delaware courts will honor clauses in which sophisticated parties disclaim reliance on extra-contractual representations. This Court, however, will not give effect to so-called merger or integration clauses that do not clearly state that the parties disclaim reliance upon extra-contractual statements.” (internal citation omitted)).

¹⁰² 891 A.2d at 1059 (quoting *Kronenberg*, 872 A.2d at 593).

balance between fairness and equity—parties can protect themselves against unfounded fraud claims through explicit anti-reliance language.”¹⁰³

Here, the Merger Agreement contains a one-way anti-reliance provision disclaiming reliance by Ethicon on extra-contractual representations.¹⁰⁴ Auris made no such disclaimer. According to Fortis, because the parties did not follow the well-worn path laid by *Abry* and its progeny, it cannot be foreclosed from pursuing its fraud claims. But this case presents a twist. The defendants argue that anti-reliance language was not necessary to bar Fortis’s fraud claims based on statements outside the contract because the exclusive remedy provision in the Merger Agreement serves that purpose.

The exclusive remedy provision is far from the “murky” integration clauses this court is often confronted with when asked to assess whether a party has disclaimed reliance on extra-contractual statements.¹⁰⁵ Section 8.05(b) of the

¹⁰³ *Id.*

¹⁰⁴ See Merger Agreement § 4.08 (“Except for the representations and warranties contained in Article III [of the Merger Agreement], [Ethicon] and Merger Sub acknowledge that none of [Auris] or any person on behalf of the [Auris] makes, and neither [Ethicon] nor Merger Sub have relied upon, any other express or implied representation or warranty with respect to [Auris] or any of its Subsidiaries or with respect to any other information provided or made available to [Ethicon] or Merger Sub in connection with the transactions contemplated by this Agreement Each [Ethicon] and Merger Sub disclaims any representations and warranties other than those that are expressly set forth in Article III.”).

¹⁰⁵ *Abry P’rs*, 891 A.2d at 1059; see also *Anschutz*, 2020 WL 3096744, at *14 (finding that a standard integration clause was insufficient to disclaim reliance on extra-contractual statements); *FdG Logistics*, 131 A.3d at 860 (“[T]he integration clause . . . merely states in general terms that the Merger Agreement constitutes the entire agreement between the

Merger Agreement is a detailed provision stating that, except as otherwise provided, “the indemnification provisions contained in [the Merger Agreement] will be the exclusive remedy with respect to claims made after the Closing that relate to th[e] [Merger] Agreement or the transactions contemplated by th[e] [Merger] Agreement.”¹⁰⁶ Fortis’s fraud claims were brought more than a year post-closing and are not indemnification claims. The claims therefore must be viewed as barred by the exclusive remedy provision, the defendants maintain, unless they fall within an express exception. The exceptions listed in Section 8.05(b) include fraud claims “with respect to making the representations and warranties in this Agreement.”¹⁰⁷ But fraud claims based on extra-contractual representations—like those pressed by Fortis—are not.¹⁰⁸

The exclusive remedy provision in the Merger Agreement reflects careful drafting evidencing the parties’ intention to limit the scope of claims that could be brought after the merger closed.¹⁰⁹ This court has recognized that provisions, such

parties, and does not contain an unambiguous statement by [the] Buyer disclaiming reliance on extra-contractual statements.”); *Kronenberg*, 872 A.2d at 594 (“The integration clause in the LLC Agreement is not an unambiguous acknowledgement by the plaintiffs that they were not relying on factual statements not contained within the LLC Agreement itself.”).

¹⁰⁶ Merger Agreement § 8.05(b); *see also* Defs.’ Opening Br. 17 (Dkt. 23).

¹⁰⁷ Merger Agreement § 8.05(b); *see also* Defs.’ Opening Br. 17-18.

¹⁰⁸ Defs.’ Opening Br. 18.

¹⁰⁹ *See Khushaim v. Tullow Inc.*, 2016 WL 3594752, at *3 (Del. Super. June 27, 2016) (“While no ‘magic words’ are required to create a sole remedy clause, the parties must demonstrate some showing of intent that they planned to create one.”).

as “deal-related indemnification provisions,” that address post-closing risk allocation “serve the laudable purpose of making the contractual structure feasible or more attractive to the participants.”¹¹⁰ But in the context of a fraud claim based on a knowingly false contractual representation, Delaware courts have declined to enforce such provisions in keeping with the state’s strong public policy against intentional fraud.¹¹¹ Consistent with that principle, the Merger Agreement explicitly preserves fraud claims based on representations in the contract.

That leaves the question of whether an exclusive remedy provision can foreclose a plaintiff from pursuing intentional fraud claims based on extra-contractual statements in the absence of anti-reliance language. The defendants cite to *Airborne Health, Inc. v. Squid Soap, LP* in support of their position that the

¹¹⁰ *EMSI Acq., Inc. v. Contrarian Funds, LLC*, 2017 WL 1732369, at *8 (Del. Ch. May 3, 2017) (internal citation omitted); *see also* 2 Bradley W. Voss, *Voss on Delaware Contract Law* § 8.144[10][b] (2021).

¹¹¹ *See EMSI Acq.*, 2017 WL 1732369, at *8 (“‘Delaware’s strong public policy against intentional fraud’ will not permit a party to a contract to disclaim or eliminate a claim that it made ‘a knowingly false contractual representation.’” (quoting *Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 136-37 (Del. Ch. 2009))); *Abry P’rs*, 801 A.2d at 1064 (holding that the “public policy of this State will not permit the Seller to insulate itself from the possibility that the sale would be rescinded if the Buyer can show either (1) that the Seller knew that the Company’s contractual representations and warranties were false; or (2) that the Seller itself lied to the Buyer about a contractual representation and warranty”); Edward P. Welch et al., *Mergers & Acquisitions Deal Litigation Under Delaware Corporation Law* § 6.06 (2020) (“Delaware courts have stated that an agreement cannot disclaim fraud claims that are based on false representations of fact made within the contract itself.”).

Section 8.05(b) of the Merger Agreement does just that.¹¹² In *Squid Soap*, the court considered whether an exclusive remedy provision that carved out “claims involving fraud or intentional misrepresentation” was limited to fraud based on intra-contractual representations, excluding extra-contractual fraud claims.¹¹³ Vice Chancellor Laster observed that the provision was not so circumscribed because “[w]hen drafters specifically preserve the right to assert fraud claims, they must say so if they intend to limit that right to claims based on written representations in the contract.”¹¹⁴ The court did not, however, indicate that if the parties had explicitly carved out fraud claims based on contractual representations, claims based on representations outside of the contract would be barred by the provision despite the absence of anti-reliance language.¹¹⁵

The defendants also point to the United States District Court for the District of Delaware’s decision *Harland Clarke Holdings Corp. v. Milken*, where the court rejected the argument that an exclusive remedy provision barring fraud claims was “unenforceable on public policy grounds.”¹¹⁶ The court noted that the plaintiffs

¹¹² 984 A.2d 126 (Del. Ch. 2009).

¹¹³ *Id.* at 140-41.

¹¹⁴ *Id.* at 141.

¹¹⁵ *Id.*; see also *Cont’l Ill. Nat. Bank & Tr. Co. of Chi. v. Hunt Int’l Res. Corp.*, 1987 WL 55826, at *6 (Del. Ch. Feb. 27, 1987) (finding that an exclusive remedies provision did not bar the plaintiff from bringing a claim for common law fraud).

¹¹⁶ 2015 WL 12868204, at *3 (D. Del. Mar. 4, 2015).

“fail[ed] to distinguish between fraud within the contract and fraud outside of the contract.”¹¹⁷ Despite that, the agreement at issue in *Harland* contained both an anti-reliance provision and an exclusive remedy provision, which effectively reinforced the parties’ expression of their intent to disclaim reliance on extra-contractual statements and bar fraud claims based on such statements.¹¹⁸

No Delaware court has found that an exclusive remedy provision bars a plaintiff from bringing a fraud claim based on extra-contractual representations in the absence of express anti-reliance language. To be sure, there is no “general rule prohibit[ing] parties from using contracts to shield themselves for liability from their own fraud.”¹¹⁹ As the Delaware Supreme Court has recognized, sophisticated parties may craft provisions insulating them from “fraud claims based on representations made outside of a merger agreement.”¹²⁰ But to do so, the claims must “be disclaimed through non-reliance language.”¹²¹

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *RAA Mgmt. LLC v. Savage Sports Hldgs., Inc.*, 45 A.3d 107, 116-18 (Del. 2012); *see also Great Lakes Chem. Corp. v. Pharmacia Corp.*, 788 A.3d 544, 556 (Del. Ch. 2001) (“To allow [a plaintiff] to assert, under the rubric of fraud, claims that are explicitly precluded by contract, would defeat the reasonable commercial expectations of the contracting parties and eviscerate the utility of the written contractual agreements.”).

¹²⁰ *RAA Mgmt.*, 45 A.3d at 117.

¹²¹ *Id.* (citing *Abry P’rs*, 891 A.2d at 1059).

In my view, Delaware’s policy of restricting the circumstances for which fraud claims can be eliminated by contract does not extend only to written contractual representations. Where there is no applicable anti-reliance provision, extra-contractual or contractual representations can equally induce an agreement and give rise to a claim for intentional fraud. In *Abry Partners*, the court found that when a party lies intra-contract, Delaware public policy will not permit a contractual provision to limit the remedies of the counterparty to a capped damages claim.¹²² Although the holding in *Abry Partners* was focused on contractual misrepresentations, its logic extends to extra-contractual misrepresentations where a party asserting a fraud claim did not promise to rely exclusively on representations made in the agreement.

Much like the exclusive remedy provision in *Abry Partners*, Section 8.05(b) of the Merger Agreement evidences a bargained for allocation of risk that limited the defendants’ exposure to extra-contractual fraud claims post-closing.¹²³ That is not the end of the inquiry. Because of the policy concern inherent in respecting “the law’s traditional abhorrence of fraud,” this court must then look to whether the parties’ agreement “clearly state[s] that the parties disclaim reliance on extra

¹²² *Abry P’rs*, 891 A.2d at 1064.

¹²³ Merger Agreement § 8.05(b); *Abry P’rs*, 891 A.2d at 1044, 1053.

contractual statements.”¹²⁴ “If parties fail to include unambiguous anti-reliance language, they will not be able to escape responsibility for their own fraudulent representations made outside of the agreement’s four corners.”¹²⁵

Unlike the parties in *Abry Partners*, Auris did not disclaim reliance on extra-contractual statements anywhere in the Merger Agreement.¹²⁶ Indeed, the fact that Ethicon expressly disclaimed reliance but Auris did not suggests that Auris was permitted to rely on the defendants’ assurances. The exclusive remedy provision therefore cannot, by itself, eliminate Fortis’s fraud claims. To find otherwise would ignore the delicate balance that Delaware courts have struck between supporting freedom of contract and condemning fraud. If the defendants intentionally misrepresented a fact that induced Auris to enter into the Merger Agreement, and Auris did not explicitly disclaim reliance on extra-contractual representations, it cannot be barred from recovering for that purported fraud.

1. Common Law Fraud

Having concluded that the exclusive remedy provision does not bar Fortis’s fraud claims, I next consider whether it has adequately pleaded a claim for common law fraud. To state a claim for common law fraud, a plaintiff must allege that:

¹²⁴ *Abry P’rs*, 891 A.2d at 1058.

¹²⁵ *Id.* at 1059.

¹²⁶ *See* Merger Agreement § 4.08; *Abry P’rs*, 891 A.2d at 1041-43.

(1) the defendant falsely represented or omitted facts that the defendant had a duty to disclose; (2) the defendant knew or believed that the representation was false or made the representation with a reckless indifference to the truth; (3) the defendant intended to induce the plaintiff to act or refrain from acting; (4) the plaintiff acted in justifiable reliance on the representation; and (5) the plaintiff was injured by its reliance.¹²⁷

Court of Chancery Rule 9(b) requires that “the circumstances constituting fraud . . . be stated with particularity.”¹²⁸

Fortis alleges that the defendants made numerous misrepresentations to Auris and its former stockholders during merger negotiations to induce them to enter into the Merger Agreement.¹²⁹ The alleged misrepresentations concern statements falsely portraying the Verb Surgical Robot as both successful and differentiated from iPlatform and describing the defendants’ plans for operating Auris post-acquisition.¹³⁰

The defendants do not dispute that Fortis has pleaded actionable misrepresentations with particularity. They contend that dismissal is warranted

¹²⁷ *Abry P’rs*, 891 A.2d at 1050.

¹²⁸ Ct. Ch. R. 9(b); *see also Abry P’rs*, 891 A.2d at 1050 (“To satisfy Rule 9(b), a complaint must allege: (1) the time, place, and contents of the false representation; (2) the identity of the person making the representation; and (3) what the person intended to gain by making the representations.”).

¹²⁹ Pl.’s Answering Br. 17.

¹³⁰ Compl. ¶¶ 172-73.

because Fortis has failed to sufficiently show justifiable reliance and the necessary intent for those statements.¹³¹ I disagree.

First, Fortis has adequately pleaded justifiable reliance. The defendants' alleged statements about Verb are not, as the defendants contend, "so vague as to be nearly meaningless."¹³² The plaintiff states that during merger negotiations, the defendants represented to Auris that they viewed the Verb Surgical Robot as "different from" and "complementary to" iPlatform and that the two products would be developed and marketed in parallel.¹³³ The Complaint also specifies that, after Auris raised concerns about Verb during meetings, the defendants allegedly assured Auris that Verb was not a threat.¹³⁴ Among other things, Fortis alleges that Auris was told that it would operate independently within J&J, that its hiring and space requirement would be met, and that Auris and Verb would not have to compete for resources.¹³⁵

The defendants insist that Auris could not have justifiably relied on those extra-contractual assurances given the specific provisions of the Merger Agreement

¹³¹ Defs.' Opening Br. 16-17.

¹³² *Id.* at 24.

¹³³ Compl. ¶¶ 58, 62.

¹³⁴ *Id.* ¶¶ 60-66. The plaintiff has met the particularity requirement of Rule 9(b). The Complaint describes when those alleged meetings occurred, who attended, what was said, and indicates what the defendants hoped to gain.

¹³⁵ *Id.* ¶¶ 62-65; *see supra* notes 27-29.

about the post-closing conduct of the business.¹³⁶ The Merger Agreement, for example, committed Ethicon to use “commercially reasonable efforts” to achieve the regulatory milestones and detailed what factors Ethicon would account for in doing so.¹³⁷ But as I previously discussed, the Merger Agreement also contains a one-sided anti-reliance provision applicable to Ethicon.¹³⁸ The parties’ choice to permit Auris, but not Ethicon, to rely on extra-contractual representations like those about Auris’s operations post-merger supports an inference that its reliance was justified.¹³⁹

The defendants also argue that, to the extent that Fortis’s fraud claims rest on statements about the Verb Surgical Robot, it cannot show justifiable reliance because Auris had the ability to assess Verb’s technology during due diligence.¹⁴⁰ “To establish justifiable reliance, [a plaintiff] must demonstrate he did not have either

¹³⁶ Defs.’ Opening Br. 26.

¹³⁷ *E.g.*, Merger Agreement §§ 2.07(e)(i)-(iii).

¹³⁸ *Id.* § 4.08.

¹³⁹ *See Surf’s Up Legacy P’rs, LLC v. Virgin Fest, LLC*, 2021 WL 117036, at *14 (Del. Super. Jan. 13, 2021) (denying motion to dismiss where sophisticated parties did not include anti-reliance language); *TrueBlue, Inc. v. Leeds Equity P’rs IV, LP*, 2015 WL 5968726, at *7 (Del. Super. Sept. 25, 2015) (same); *compare ChyronHego Corp. v. Wight*, 2018 WL 3642132, at *4-5 (Del. Ch. July 31, 2018) (finding that an anti-reliance clause prevented a finding that the plaintiffs had acted in justifiable reliance on extra-contractual representations, requiring dismissal).

¹⁴⁰ Defs.’ Opening Br. 23.

the awareness or opportunity to discover the accurate information.”¹⁴¹ A sophisticated party generally cannot justifiably rely on extra-contractual representations that could have been discovered with adequate due diligence.¹⁴² Viewing the facts in the light most favorable to the plaintiff, including allegations that Auris repeatedly inquired about Verb during negotiations, I cannot conclude that Auris’s due diligence was so lacking that it could not have justifiably relied on the defendants’ representations.¹⁴³

Whether the defendants acted with intent to defraud Auris likewise cannot be resolved on the defendants’ Rule 12(b)(6) motion.¹⁴⁴ The parties debate whether Fortis only needs to plead fraud “generally” or if the higher pleading standard for a claim based on promissory fraud—requiring it to allege “specific facts that lead to a reasonable inference that the [promisor] had no intention of performing at the time

¹⁴¹ *Tekstrom, Inc. v. Savla*, 2006 WL 2338050, at *11 (Del. Super. July 31, 2006).

¹⁴² *See Edinburgh Hldgs., Inc. v. Educ. Affiliates, Inc.*, 2018 WL 2727542, at *12 (Del. Ch. June 6, 2018) (dismissing a fraud claim based on representations made “prior to . . . due diligence” about “future performance of the business and management capabilities”).

¹⁴³ *See* Compl. ¶¶ 62-63, 66; *compare Squid Soap*, 2010 WL 2836391, at *10 (dismissing fraud claim where the seller did not allege any acts of due diligence, including “the simple expedient of asking questions” of its counterparty and the counterparty remained silent rather than affirmatively made misrepresentations).

¹⁴⁴ *See TrueBlue*, 2015 WL 5968726, at *7 (“The question of whether one’s reliance was reasonably generally is a question of fact.”); *Vague v. Bank One Corp.*, 850 A.2d 303 (Del. 2004) (TABLE); *Work Cap., LLC v. AlphaOne Cap. P’rs LLC*, 2020 WL 3475887, at *4 (Del. Super. June 25, 2020) (explaining that matters of intent present “factual question[s] . . . inappropriate for resolution on a Rule 12(b)(6) motion to dismiss”).

the promise was made”—applies.¹⁴⁵ Fortis maintains that the challenged statements are ones of “present fact” rather than future intent because they concern the defendants’ plans at that moment in time for Verb and Auris.¹⁴⁶ The defendants, on the other hand, describe Fortis’s theory as “fraud by hindsight.”¹⁴⁷

The allegations in the Complaint are sufficient to meet either standard. For example, Fortis alleges that the purported bakeoff and the defendants’ restrictions on Auris’s hiring and expansion needs began immediately upon closing.¹⁴⁸ A reasonable inference can be drawn that the defendants planned those actions during negotiations.¹⁴⁹ Fortis has also alleged that the defendants’ post-closing intentions during negotiations, which were inconsistent with the defendants’ statements, were

¹⁴⁵ *Grunstein v. Silva*, 2009 WL 4698541, at *13 (Del. Ch. Dec. 8, 2009).

¹⁴⁶ Pl.’s Answering Br. 24.

¹⁴⁷ Defs.’ Opening Br. 29.

¹⁴⁸ Compl. ¶¶ 99, 104-05, 110.

¹⁴⁹ See *Maverick Therapeutics, Inc. v. Harpoon Therapeutics, Inc.*, 2020 WL 1655948, at *29 (Del. Ch. Apr. 3, 2020) (“The third element of fraud requires that the defendant made the false statements recklessly or with the specific intent to obtain the desired action. Such scienter may be demonstrated through circumstantial evidence, including demonstrating motive and opportunity for the inducement. In cases where a fraud claim centers on a transaction, the transaction itself may serve as both the motive and opportunity to commit the fraud.”); *Winner Acceptance Corp. v. Return on Cap. Corp.*, 2008 WL 5352063, at *3, 10 (Del. Ch. Dec. 23, 2008) (finding that events occurring months after misrepresentations were made supported an inference of fraudulent intent).

known to the defendants and within the defendants’—rather than Auris’s—control.¹⁵⁰

Fortis has therefore adequately pleaded a claim for common law fraud.

2. Equitable Fraud

I reach a different conclusion with regard to the viability of Fortis’s equitable fraud claim, though it is based on the same factual allegations cited in support of its common law fraud claim. An equitable fraud (or negligent misrepresentation) claim is essentially a fraud claim with a reduced state of mind requirement, requiring “proof of all of the elements of common law fraud except that [the] plaintiff need not demonstrate that the misstatement or omission was made knowingly or recklessly.”¹⁵¹ “Scienter is replaced by negligence, but the doctrine requires additional elements to compensate for this significant concession.”¹⁵² “An equitable

¹⁵⁰ Compl. ¶¶ 54, 75, 111; see *Brightstar Corp. v. PCS Wireless, LLC*, 2019 WL 3714917, at *9 (Del. Super. Aug. 7, 2019) (“When the necessary facts are typically within the opposing party’s control, less particularity is required and the claim can prevail so long as the claimant describes the circumstances of fraud with detail sufficient to apprise the defendant of the basis for the claim.” (internal citation omitted)); compare *Neurvana Med., LLC v. Balt USA, LLC*, 2020 WL 949917, at *25 (Del. Ch. Feb. 27, 2020) (finding that a forward-looking statement could not support a fraud claim because the complaint did not plead that the declarant knew the statement was false at the time it was made); *Edinburgh*, 2018 WL 2727542, at *12 (holding that whether a forward-looking revenue forecast would be achieved was unknowable and the fact that “actual performance” fell below the forecast was not enough to infer intent).

¹⁵¹ *Williams v. White Oak Builders, Inc.*, 2006 WL 1668348, at *7 (Del. Ch. June 6, 2006) (internal citations omitted).

¹⁵² *Corp. Prop. Assoc. 14 Inc. v. CHR Hldg. Corp.*, 2008 WL 963048, at *8 (Del. Ch. Apr. 10, 2008).

fraud or negligent misrepresentation claim lies only if there is either: (i) a special relationship between the parties over which equity takes jurisdiction (like a fiduciary relationship) or (ii) justification for a remedy that only equity can afford.”¹⁵³

Fortis has not pleaded that the defendants had a fiduciary relationship or other relationship of trust with Auris or its former stockholders.¹⁵⁴ And there is no reason put forth by Fortis why an equitable remedy (as opposed to damages) is required to make it whole.¹⁵⁵ Fortis has sought expectancy damages in the alternative to remedy the defendants’ alleged equitable fraud.¹⁵⁶ It can also seek an adequate remedy at law through certain of its other claims.¹⁵⁷ The equitable fraud claim is therefore dismissed.

¹⁵³ *Envo, Inc. v. Walters*, 2009 WL 5173807, at *6 (Del. Ch. Dec. 30, 2009).

¹⁵⁴ *See Fortis Advisors LLC v. Dialog Semiconductor PLC*, 2015 WL 401371, at *9 (Del. Ch. Jan. 30, 2015) (explaining that where “the gravamen of the . . . dispute arises from a transaction that ostensibly was the product of arm’s length negotiation between sophisticated parties,” a special relationship does not exist).

¹⁵⁵ *See Bamford v. Penfold, L.P.*, 2020 WL 967942, at *22 (Del. Ch. Feb. 28, 2020) (dismissing an equitable fraud claim because there was not reason to believe that monetary damages could make the plaintiff whole).

¹⁵⁶ Compl. ¶ 170.

¹⁵⁷ *See Paul Elton, LLC v. Rommel Del., LLC*, 2020 WL 2203708, at *12 (Del. Ch. May 7, 2020) (dismissing an equitable fraud claim and explaining that the plaintiff could “seek an adequate remedy at law through its claims for breach of contract and specific performance”).

C. The Implied Covenant of Good Faith and Fair Dealing Claim

The plaintiff next contends that Ethicon’s conduct violated the implied covenant of good faith and fair dealing by frustrating the parties’ expectation that development for iPlatform should be pursued under whichever pathway the FDA required. Although “an implied covenant of good faith and fair dealing inheres in every contract,”¹⁵⁸ Delaware courts apply it only in “narrow circumstances.”¹⁵⁹ One such circumstance is “when it is argued that a situation has arisen that was unforeseen by the parties and where the agreement’s express terms do not cover what should happen.”¹⁶⁰

According to Fortis, the parties failed to anticipate that the FDA might alter its policy and require iPlatform to receive clearance through a regulatory pathway other than 510(k).¹⁶¹ Had the parties anticipated the change in the FDA’s approval process, Fortis asserts, they would have tied the regulatory milestones to the De Novo pathway.¹⁶² Fortis therefore advocates for the inclusion of two implied terms

¹⁵⁸ *Chamison v. HealthTrust, Inc.—The Hosp. Co.*, 735 A.2d 912, 920 (Del. Ch. 1999), *aff’d*, 748 A.2d 407 (Del. 2000).

¹⁵⁹ *Allied Cap.*, 910 A.2d at 1032; *Cincinnati SMSA, Ltd. P’r v. Cincinnati Bell Cellular Sys. Co.*, 708 A.2d 989, 992 (Del. 1998) (explaining that application of the implied covenant “should be rare and fact-intensive, turning on issues of compelling fairness”).

¹⁶⁰ *Oxbow Carbon & Mins. Hldgs., Inc. v. Crestview-Oxbow Acq., LLC*, 202 A.3d 482, 504 n.93 (Del. 2019).

¹⁶¹ Pl.’s Answering Br. 48.

¹⁶² *Id.*

in the Merger Agreement: (1) in Section 2.07(e)(i) requiring Ethicon to use commercially reasonable efforts to achieve each of the regulatory milestones for the iPlatform product offerings using the De Novo pathway, and (2) in Section 2.07(a) requiring Ethicon to make the earnout payments connected to regulatory milestones if Ethicon timely obtains regulatory approval for iPlatform through the De Novo pathway.¹⁶³ The defendants argue that the implied covenant cannot be invoked because the Merger Agreement speaks to the type of regulatory clearance (i.e., 510(k) clearance) that triggers the associated milestone payments and that Ethicon must use commercially reasonable efforts to obtain.¹⁶⁴

The implied covenant comes into play in precisely this scenario, where “the parties simply failed to foresee the need for the term and, therefore, never considered to include it.”¹⁶⁵ Fortis alleges that the FDA had routinely cleared RASDs through the 510(k) pathway for decades and that the parties to the Merger Agreement believed the FDA would clear iPlatform through the 510(k) pathway.¹⁶⁶ Fortis also asserts that the FDA indicated to Auris in late 2018 that the 510(k) pathway would

¹⁶³ *Id.*; Compl. ¶¶ 203-04.

¹⁶⁴ Defs.’ Opening Br. 51-52 (citing Merger Agreement §§ 2.07(a), (e)(ii)).

¹⁶⁵ *In re El Paso Pipeline P’rs, L.P. Deriv. Litig.*, 2014 WL 2768782, at *18 (Del. Ch. June 12, 2014).

¹⁶⁶ Compl. ¶¶ 127-28.

be appropriate for iPlatform.¹⁶⁷ The implied covenant is well situated to address such “unanticipated developments” as a means to assess what the parties would have agreed to had they known about the FDA’s policy change when they executed the Merger Agreement.¹⁶⁸

The defendants point to additional provisions of the Merger Agreement that recognize the potential for uncertainty as demonstrating that the parties understood the FDA’s regulatory regime might change.¹⁶⁹ But the Merger Agreement is silent on how Ethicon’s best efforts and earnout payment obligations would be affected in that circumstance. Moreover, the defendants argue, under *Nemec v. Shrader*, the implied covenant “only applies to developments that could not be anticipated, not developments that the parties failed to consider.”¹⁷⁰ It is reasonable to infer, however, that the parties were unaware of the FDA’s shift from a 510(k) to De Novo pathway for RASDs when the Merger Agreement was signed and reasonably expected that approval would be obtained in the former manner. According to the

¹⁶⁷ *Id.* ¶ 128.

¹⁶⁸ *Oxbow Carbon*, 202 A.3d at 506; see *Blaustein v. Lord Balt. Cap. Corp.*, 84 A.3d 954, 959 (Del. 2014) (“[T]he implied covenant is used in limited circumstances to include what the parties would have agreed to themselves had they considered the issue in their original bargaining positions at the time of contracting.” (internal citation omitted)).

¹⁶⁹ Defs.’ Reply Br. 32-33 (Dkt. 35) (quoting Merger Agreement §§ 2.07(e)(v), 10.03(f)).

¹⁷⁰ *Id.* at 33 (quoting *Nemec v. Shrader*, 991 A.2d 1120, 1126 (Del. 2010) (“When conducting this [implied covenant] analysis, we must assess the parties’ reasonable expectations at the time of contracting and not rewrite the contract to appease a party who later wishes to rewrite a contract he now believes to have been a bad deal.”)).

Complaint, after the FDA publicly changed its guidance in the summer of 2019, Ethicon called the shift “shocking.”¹⁷¹ In view of these allegations, I cannot find that Fortis would be unable to recover on its implied covenant claim under any reasonably conceivable set of circumstances.

D. The Mistake Claims

The FDA’s manner of regulatory approval also forms the basis of two claims for mistake. “Mutual mistake occurs when both parties were mistaken as to a material portion of the written agreement, or when both parties are under substantially the same erroneous belief as to the facts.”¹⁷² Mistake claims take two forms. When the parties both have a mistaken about such facts, the contract is potentially voidable by the adversely affected party.¹⁷³ When parties enter into an agreement but fail to accurately express the agreement in writing, the court may reform the writing to express the party’s agreement.¹⁷⁴

Fortis brings a claim for mutual mistake under both theories. First, Fortis avers that it is entitled to rescission of the Merger Agreement—or in the alternative,

¹⁷¹ Compl. ¶ 135.

¹⁷² *CC Fin. LLC v. Wireless Prop., LLC*, 2012 WL 4862337, at *7 (Del. Ch. Oct. 1, 2012) (internal citations omitted).

¹⁷³ Restatement (Second) of Contracts § 152 (1981); *see also Am. Bottling Co. v. Crescent/Mach I P’rs, L.P.*, 2009 WL 3290729, at *2 (Del. Super. Sept. 30, 2009) (“The Restatement (Second) of Contracts test for mutual mistake is followed by the Delaware Courts.”).

¹⁷⁴ Restatement (Second) of Contracts § 157 (1981).

rescissory damages—because the parties each held the erroneous belief that the FDA would review iPlatform using the 510(k) pathway.¹⁷⁵ Second, Fortis claims that it is entitled to reformation of the Merger Agreement to reflect the parties’ intent that “Auris would be paid if any regulatory clearance were timely achieved.”¹⁷⁶ Each claim is addressed in turn.

1. Rescission Based on Mutual Mistake

A party seeking rescission of a contract based on mutual mistake must show that “(1) both parties were mistaken as to a basic assumption; (2) the mistake materially affects the agreed-upon exchange of performances; and (3) the party adversely affected did not assume the risk of the mistake.”¹⁷⁷ “The mistake must be as to a fact which enters into, and forms the very basis of, the contract; it must be of the essence of the agreement, the *sine qua non* or, as it is sometimes expressed, the efficient cause of the agreement.”¹⁷⁸

The satisfaction of the second element regarding materiality is not in dispute. The defendants contend that Fortis has failed to adequately plead the first and third elements: that the parties were mistaken at the time of signing and that Auris

¹⁷⁵ Pl.’s Answering Br. 53-54.

¹⁷⁶ *Id.* at 59.

¹⁷⁷ *Liberto v. Bensinger*, 1999 WL 1313662, at *12 (Del. Ch. Dec. 28, 1999).

¹⁷⁸ *Am. Bottling*, 2009 WL 3290729, at *2 (internal citation omitted).

assumed the risk of the mistake at issue.¹⁷⁹ The parties' arguments largely come down to when the FDA's policy change went into effect and when Auris anticipated the change. Neither issue can be resolved at the pleadings stage.

A mutual mistake claim must stem from a mistake of fact that existed at the time of contracting.¹⁸⁰ Fortis alleges that, when signing the Merger Agreement, the parties believed that iPlatform would only obtain regulatory approval through 510(k) clearance.¹⁸¹ The Complaint explains that the FDA announced steps to modernize the 510(k) program and consider more products through the De Novo pathway in November 2018.¹⁸² Though the FDA did not inform the parties that first-generation RASDs like iPlatform would be required to use the De Novo pathway until the summer of 2019, Fortis alleges that those discussions were the result of an earlier policy change being implemented.¹⁸³

¹⁷⁹ Defs.' Opening Br. 40.

¹⁸⁰ Restatement (Second) of Contracts § 151 (1981) (“[T]he erroneous belief must relate to the facts as they exist at the time of the making of the contract.”); *Hicks v. Sparks*, 89 A.3d 476 (Del. 2014) (TABLE) (“[T]he mutual mistake ‘must relate to a past or present fact material to the contract and not to an opinion respecting future conditions as a result of present facts.’” (quoting *Alvarez v. Castellon*, 55 A.3d 353, 354 (Del. 2012))).

¹⁸¹ Compl. ¶¶ 128-29.

¹⁸² *Id.* ¶ 131.

¹⁸³ *Id.* ¶ 209 (“In reality, in connection with its November 2018 policy announcement, the agency reversed its guidance to Auris and determined that first-generation RASDs should not rely on older predicate devices—preventing a successful submission via the 510(k) pathway for an iPlatform product.”).

There are two reasonable inferences that flow from the allegations in the Complaint. One is that the FDA changed its policy on the availability of the 510(k) pathway for first generation RASDs in the nearly three months between its November 26, 2018 announcement and the signing of the Merger Agreement. The other is that—as the defendants argue—the FDA’s November announcement merely reflected that it was “considering” modernizing the 510(k) pathway but did not change its policy until after the Merger Agreement was executed.¹⁸⁴ Additional evidence will be needed to adduce which is correct.¹⁸⁵ At this stage in the litigation, I must draw the inference that favors the plaintiff and conclude that Fortis has alleged a mistake of fact about a central aspect of the parties’ agreement that existed at the time of contracting.

¹⁸⁴ Defs.’ Opening Br. 40 (citing the FDA’s November 26, 2018 announcement and arguing that the FDA was merely “considering” modernizing the 510(k) pathway and “developing proposals” to revise it); Defs.’ Opening Br. Ex. D at 3-4.

¹⁸⁵ See *Lang v. Koziarz*, 1987 WL 15554, at *5 (Del. Ch. Aug. 11, 1987) (finding mistake proven at trial where a party showed that an agency had “changed its enforcement policy” before contract execution without the knowledge of the parties); *Joyce v. RCN Corp.*, 2003 WL 21517864, at *4 (Del. Ch. July 1, 2003) (“[T]he Court makes an informed judgment to determine if the allegations, if assumed to be true, would plead the elements of a mutual mistake, and would put the defendants on notice of the nature of their mutual mistake.”); *In re TIBCO Software Inc. S’holders Litig.*, 2015 WL 6155894, at *12 (Del. Ch. Oct. 20, 2015) (“[T]he facts upon which a plaintiff relies in pleading reformation must be set forth with at least some particularity in order to put the defendant on notice of what is charged against him, but does not go so far as to require a textbook pleading or the use of specific words or phrases.”).

I also reject the defendants' argument that Auris assumed the risk of a change in the FDA's regulatory regime. A party assumes the risk of a mistake where:

(i) the contract expressly assigns the risk to that party; (ii) the mistaken party undertook to perform under a contract aware that his knowledge was limited with respect to the facts to which the mistake relates; or (iii) the court finds that it is reasonable to assign the risk to the party seeking rescission.¹⁸⁶

The defendants argue that the Merger Agreement allocated the risk to Auris, that the FDA's November 2018 announcement put Auris on notice that the FDA was developing proposals to alter its 510(k) pathway, and that it is reasonable to assign the risk to Fortis. After considering the allegations in the Complaint, I cannot conclude that dismissal is warranted under any of those theories.

First, the Merger Agreement does not expressly allocate to either party the risk that 510(k) clearance would become unavailable. Section 2.07(e)(v) provides that the "achievement of [the milestones] is subject to a variety of factors and uncertainties, including many outside of the control of [Ethicon]" and that the associated earnout payments are "contingent on the achievement of the applicable [milestone] . . . which may not be achieved, and as a result . . . may never be paid."¹⁸⁷ But that provision is simply an acknowledgement that purports to limit the claims Fortis could bring if a milestone was not achieved. It does not expressly allocate to

¹⁸⁶ *Am. Bottling*, 2009 WL 3290729, at *2.

¹⁸⁷ Merger Agreement § 2.07(e)(v).

Auris the risk that the parties were mistaken about the appropriate regulatory pathway at the time that they signed the Merger Agreement.

Second, the allegations in the Compliant belie the notion that Auris assumed the risk of a change in the FDA’s clearance practices through its own “conscience ignorance.”¹⁸⁸ Fortis alleges that neither party understood, when executing the Merger Agreement, that the FDA was changing its enforcement policy for first-generation RASDs.¹⁸⁹ Even if Auris was put on notice by the FDA’s November 2018 announcement that a change was possible (which is not alleged and would require the court to draw an inference against the plaintiff), Fortis alleges that Auris took reasonable steps to avoid a mistake by communicating with the FDA in late 2018 about the applicability of the 510(k) pathway to iPlatform.¹⁹⁰

Third, it would not be reasonable for the court to assign the risk of any mistake to Auris. Allocating the risk of a mistake to a party based on reasonableness is a

¹⁸⁸ *Am. Bottling*, 2009 WL 3290729, at *3 (“[D]etermining whether a party assumed the risk of a mistake by way of conscious ignorance depends upon whether the party seeking rescission took steps to avoid the mistake.”).

¹⁸⁹ Compl. ¶¶ 127-29, 134-35.

¹⁹⁰ *Id.* ¶ 128; *see Lang*, 1987 WL 15554, at *6 (holding that a party with limited knowledge as to the mistaken fact did not assume the risk of mistake when the party took reasonable steps to avoid the mistake); *Am. Bottling*, 2009 WL 3290729, at *3 (finding that a plaintiff with limited knowledge as to a mistaken fact did not assume the risk of mistake because the plaintiff consulted with and relied on advice of an expert advice); *see also Shore Builders, Inc. v. Dogwood, Inc.*, 616 F. Supp. 1004, 1019 (D. Del. 1985) (finding that a plaintiff’s lack of knowledge regarding the extent of a federal agency’s jurisdiction over its property raised a matter of fact that would “require the Court to consider the issue of allocation of risk at trial”).

highly factual inquiry best suited for a later phase of the litigation.¹⁹¹ The defendants cite no authority suggesting otherwise.¹⁹²

For these reasons, Fortis has stated a claim for rescission based on mutual mistake.

2. Reformation Based on Mutual Mistake

A party seeking reformation of a contract on the grounds of mutual mistake must allege “(i) the terms of an oral agreement between the parties; (ii) the execution of a written agreement that was intended, but failed, to incorporate those terms; (iii) the parties’ mutual-but mistaken-belief that the writing reflected their true agreement; and (iv) the precise mistake.”¹⁹³ A “specific meeting of the minds regarding a term that was not accurately reflected in the final, written agreement” must be shown.¹⁹⁴

¹⁹¹ See Restatement Second of Contracts § 154(d) cmt. a (1981) (“In dealing with such issues, the court will consider the purposes of the parties and will have recourse to its own general knowledge of human behavior in bargain transactions.”); *Liberto*, 1999 WL 1313662, at *16 (finding, on a summary judgment record, that it was reasonable to allocate to a party the risk of mistake).

¹⁹² Defs.’ Opening Br. 46-47. The only case the defendants cite concerns a motion for summary judgment where the court found that it was reasonable to assign the risk of mistake to the plaintiff, after finding that the plaintiff had assumed the risk of mistake under the other tests. See *Liberto*, 1999 WL 1313662, at *15-16.

¹⁹³ *Joyce*, 2003 WL 21517864, at *4.

¹⁹⁴ *Glidepath Ltd. v. Beumer Corp.*, 2018 WL 2670724, at *10 (Del. Ch. June 4, 2018).

Fortis argues in its brief that the parties came to an understanding during negotiations that regulatory milestones could be achieved through alternate regulatory pathways if 510(k) clearance became unavailable.¹⁹⁵ The parties then, it asserts, mistakenly drafted Sections 2.07(a) and 2.07(e)(ii) to refer solely to the 510(k) pathway. But that argument is unsupported by the allegations in the Complaint.

The Complaint contains no factual allegations indicating that the parties had an understanding that pathways other than 510(k) could satisfy the regulatory milestones in the Merger Agreement. Rather, Fortis alleges that the parties believed while negotiating that the FDA would evaluate iPlatform under the 510(k) pathway and “memorialized this shared understanding in the Merger Agreement.”¹⁹⁶ “It is not enough that the parties would have come to a certain agreement had they been aware of the actual facts. Reformation requires an antecedent agreement, which the written instrument attempts to express.”¹⁹⁷ Fortis has not alleged such an agreement, requiring the dismissal of its reformation claim.

¹⁹⁵ Pl.’s Answering Br. 59-60; *see* Compl. ¶¶ 128-29, 216-17.

¹⁹⁶ Compl. ¶ 129.

¹⁹⁷ *Interim Healthcare, Inc. v. Sherion Corp.*, 2003 WL 22902879, at *7 (Del. Ch. Nov. 19, 2003) (quoting Richard A. Lord, *Williston on Contracts* § 70:19, at 255 (4th ed. 2003)).

E. The Unjust Enrichment Claim

The plaintiff also brings a claim, pleaded in the alternative to its breach of contract claims, that Ethicon was unjustly enriched by its false representations. Ethicon was enriched, Fortis contends, by causing Auris and its former stockholders to agree to a lower guaranteed payment and allocate a greater share of the consideration toward potential earnout payments.¹⁹⁸ Because the defendants' purported false representations made the earnout payments less valuable, Fortis believes that Ethicon paid a fraction of Auris's true value.¹⁹⁹

To state a claim for unjust enrichment, a plaintiff must prove: “(1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and impoverishment, (4) the absence of justification, and (5) the absence of a remedy provided by law.”²⁰⁰ “Before a court engages in this analysis, however, it must consider the threshold question of ‘whether a contract already governs the relevant relationship between the parties.’”²⁰¹ Unjust enrichment claims are generally

¹⁹⁸ Compl. ¶¶ 219-21.

¹⁹⁹ *Id.* ¶ 220.

²⁰⁰ *Jackson Nat. Life Ins. Co. v. Kennedy*, 741 A.2d 377, 393 (Del. Ch. 1999).

²⁰¹ *SerVaas v. Ford Smart Mobility LLC*, 2021 WL 3779559, at *11 (Del. Ch. Aug. 25, 2021) (quoting *BAE Sys. Info. & Elec. Sys. Integration, Inc. v. Lockheed Martin Corp.*, 2009 WL 264088, at *7 (Del. Ch. Feb. 3, 2009)).

dismissed “when the complaint alleges an express, enforceable contract that controls the parties’ relationship.”²⁰²

“Although merely suggesting that the validity of a contract may be in doubt is insufficient to support a claim for unjust enrichment, a claim that the underlying agreement is subject to rescission due to fraudulent conduct or omissions is sufficient to do so.”²⁰³ I have already found that Fortis has pleaded viable claims for fraud and a claim for mutual mistake seeking the remedy of rescission. Thus, the unjust enrichment claim cannot be dismissed.²⁰⁴

F. The Specific Performance Claim

Finally, Fortis seeks specific performance of a provision of the Merger Agreement requiring the parties to address terms that become incapable to enforce.²⁰⁵ Section 10.11 of the Merger Agreement provides that:

[i]f any term or other provision of [the Merger Agreement] is invalid, illegal or incapable of being enforced by any rule of law or public policy . . . the parties . . . shall negotiate in good faith to modify [the Merger Agreement] so as to effect the original intent of the parties as closely as possible to the fullest extent permitted by applicable law.²⁰⁶

²⁰² *Bakerman v. Sidney Frank Importing Co., Inc.*, 2006 WL 3927242, at *18 (Del. Ch. Oct. 10, 2006).

²⁰³ *Haney v. Blackhawk Network Hldgs., Inc.*, 2016 WL 769595, at *9 (Del. Ch. Feb. 26, 2016).

²⁰⁴ *See Anschultz*, 2020 WL 3096744, at *18.

²⁰⁵ Pl.’s Answering Br. 51.

²⁰⁶ Merger Agreement § 10.11.

According to Fortis, Section 2.07(a) regarding 510(k)-based regulatory milestones and the associated commercially reasonable efforts discussed in Section 2.07(e)(ii) are now “incapable of enforcement” following the FDA’s revised approach to the availability of 510(k) clearance for first-generation RASDs.²⁰⁷

The defendants argue that—despite the FDA’s policy change—the Merger Agreement can technically be enforced as written.²⁰⁸ The result of doing so would be that the contractual condition of achieving 510(k) clearance to trigger certain earnout payments (at least for the first iPlatform-related regulatory milestone) cannot be satisfied.²⁰⁹ In other words, the FDA’s policy change might render the regulatory milestones “unachievable” but not necessarily “unenforceable,” as Section 10.11 requires.

Applying the plaintiff-friendly motion to dismiss standard, I view that distinction to be one without a difference. Auris did not fail to achieve 510(k) approval after attempting to follow the pathway. The pathway is no longer available to it—at least for one regulatory milestone. And I cannot find, out of hand, that the FDA’s shift toward requiring RASDs to follow the De Novo pathway does not reflect a public policy determination. The FDA’s announcement explained that the

²⁰⁷ Pl.’s Answering Br. 52; Compl. ¶¶ 238-39; Merger Agreement §§ 2.07(a), 2.07(e)(ii).

²⁰⁸ Defs.’ Opening Br. 56-58.

²⁰⁹ *Id.*; see Merger Agreement § 2.07(a).

change was “aimed at continuing the ensure that new and existing devices meet our gold standard for safety and effectiveness.”²¹⁰

A fair reading of Section 10.11 is that the relevant contractual provision must be rendered “incapable of being enforced” by an applicable “public policy,” rather than requiring that the provision must itself offend the policy to be considered unenforceable.²¹¹ I am unable to conclude that there is no reasonably conceivable set of circumstances under which the plaintiff could recover on its specific performance claim and decline to dismiss it on that basis.

III. CONCLUSION

For the reasons explained above, the individual defendants’ motion to dismiss for lack of personal jurisdiction under Court of Chancery Rule 12(b)(2) is granted. The defendants’ partial motion to dismiss for failure to state a claim under Court of Chancery Rule 12(b)(6) is granted in part and denied in part. The motion is granted as to Counts I, VIII, and X. The motion is denied as to Count II, VI, VII, IX, and XII.

²¹⁰ Compl. ¶ 131; *see id.* ¶¶ 131-37.

²¹¹ Merger Agreement § 10.11; *see* Defs.’ Opening Br. 57-58 (arguing that the “provision at issue here stands in stark contrast to the kinds of provisions that courts have previously held unenforceable as against public policy, where the provision itself offended an applicable public policy or principle of law”). Whether Section 10.11 requires that the relevant provision be rendered unenforceable by public policy concerns or must itself violate the public policy is ambiguous, further precluding dismissal of the specific performance claim.