IN THE SUPREME COURT OF THE STATE OF DELAWARE

JOHNSON & JOHNSON and ETHICON, INC.,	§	
	§	
	§	
Defendants Below, Appellants,	§	No. 490, 2024
	§	
	§	Court Below: Court of Chancery
	§	of the State of Delaware
FORTIS ADVISORS LLC, solely in its capacity as representative of former stockholders of Auris Health, Inc.	§	
	§	
	§	C.A. No. 2020-0881-LWW
	§	
Plaintiff Below, Appellee.	§	
	§	

Submitted: October 15, 2025
Decided: January 12, 2026

Before **SEITZ**, Chief Justice; **VALIHURA**, **TRAYNOR**, **LEGROW**, and **GRIFFITHS**, Justices, constituting the Court *en Banc*.

Upon appeal from the Court of Chancery, **AFFIRMED in part, REVERSED in part, and REMANDED.**

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LEGROW, Justice:

This appeal arises out of a post-closing earnout dispute following Johnson & Johnson's ("J&J") acquisition of Auris Health, Inc. ("Auris"), a medical robotics company. Under the parties' Agreement and Plan of Merger ("Merger Agreement"), Auris's former stockholders could receive up to $2.35 billion in additional consideration if J&J used "commercially reasonable efforts" to shepherd Auris's robotic-assisted surgical devices ("RASDs") through a series of regulatory and sales milestones, with each regulatory milestone expressly conditioned on obtaining "510(k) premarket notification" for specified devices and surgical indications. When no milestones were achieved, Fortis Advisors LLC ("Fortis"), acting as the stockholders' representative, filed a complaint, alleging that J&J had failed to honor its contractual efforts obligations and had fraudulently induced Auris to accept a contingent payment instead of additional upfront consideration.

After a ten-day trial, the Court of Chancery largely agreed with Fortis. The court held that J&J breached the Merger Agreement by failing to devote the contractually required level of effort to Auris's iPlatform Surgical System ("iPlatform"), and that J&J acted with the contractually prohibited intent to avoid the earnouts. To reach that conclusion with respect to the first regulatory milestone, the court held that although a change at the U.S. Food and Drug Administration ("FDA") closed the 510(k) regulatory pathway that the milestones referred to, the implied covenant of good faith and fair dealing required J&J to pursue the alternate

pathway for iPlatform's first regulatory milestone and to treat that approval as the functional equivalent of the 510(k) clearance specified in the contract. The court also found that J&J, through its CEO, fraudulently induced Auris to accept a $100 million contingent payment, payable only if the FDA cleared Auris's separate lung-robotics platform, Monarch, to perform soft tissue lung ablation. J&J portrayed the milestone as essentially certain while failing to disclose a recent patient death and resulting FDA investigation that threatened timely approval. The court entered judgment for Fortis in excess of $1 billion in contract and fraud damages, plus pre-judgment interest.

On appeal, J&J argues that the Court of Chancery misapplied the implied covenant by rewriting the parties' bargain, misconstrued the "commercially reasonable efforts" clause by effectively eliminating J&J's contractual discretion, clearly erred in finding fraud, and failed to give effect to the Merger Agreement's exclusive remedy provision. Fortis responds that the court properly used the implied covenant to address an unforeseen regulatory development, correctly measured J&J's efforts, and permissibly found that J&J's conduct in marketing the Monarch lung ablation milestone constituted actionable fraud that the contract cannot insulate.

We agree with J&J as to the implied covenant. Applying our precedents, we hold that there is no genuine contractual gap for the covenant to fill. The Merger Agreement repeatedly and expressly conditioned the regulatory earnouts on

obtaining 510(k) premarket notification and allocated to Auris's stockholders the risk that FDA "developments" might affect the route, timing, or cost of approval. In the sophisticated, highly regulated setting of this transaction, the risk that the FDA would require heightened "De Novo" review for a complex RASD was both foreseeable and addressed in the parties' carefully negotiated agreement. We therefore reverse the Court of Chancery's ruling that J&J breached its implied obligation to pursue De Novo clearance for iPlatform's first milestone and the portion of the damages award attributable to that milestone.

We otherwise affirm. We adopt the Court of Chancery's interpretation of the Merger Agreement's efforts clause and, in light of the court's well-supported factual findings, we uphold its conclusion that J&J breached its express obligation to use commercially reasonable, "priority" device efforts to achieve the remaining iPlatform regulatory milestones. We also uphold the court's damages methodology for those milestones. We likewise affirm the court's determination that J&J, through its CEO, fraudulently induced Auris to accept a $100 million contingent payment for Monarch's lung ablation milestone instead of a higher upfront payment, and we hold that the Merger Agreement's exclusive remedy clause does not bar Fortis's claim for extra-contractual fraud in the absence of an express anti-reliance provision running against Auris. Accordingly, we **AFFIRM** in part, **REVERSE** in part, and **REMAND** for recalculation of the judgment consistent with this opinion.

I. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND[1]

A. The Parties

J&J is a global healthcare company whose medical devices segment, including its Ethicon, Inc. subsidiary, generates substantial revenue from surgical instruments. As robotic surgery expanded, J&J came to view surgical robots as critical to protecting that business. In the early 2010s, Intuitive Surgical, Inc.'s da Vinci system emerged as the dominant RASD and was widely adopted in hospitals. Because hospitals using da Vinci purchased Intuitive-branded instruments rather than traditional tools from Ethicon, J&J internally characterized Intuitive's growth as an "existential threat" to its instrument business and sought to secure a share of the RASD market.

In 2012, shortly after Alex Gorsky became J&J's CEO, the company set out to develop an RASD to compete with da Vinci. When that internal project showed commercial promise in 2015, J&J and Verily Life Sciences LLC, an Alphabet subsidiary, formed a joint venture—Verb Surgical Inc. ("Verb")—to bring the system to market. J&J assigned senior engineering talent to Verb and invested heavily in the program. Verb's platform featured a table-mounted center with

[1] Unless otherwise noted, the recited facts are taken from the Court of Chancery's September 4, 2024 Post-Trial Memorandum Opinion. *See Fortis Advisors LLC v. Johnson & Johnson*, 2024 WL 4048060 (Del. Ch. Sept. 4, 2024) (footnotes and record citations omitted) [hereinafter the "Opinion at __"]. These factual findings are largely uncontested by the parties on appeal.

multiple robotic arms, a surgeon's console, and a tower housing the controller and vision system. J&J publicly promoted Verb as its answer to Intuitive with a targeted commercial launch around 2020. But the technology proved difficult to perfect. Verb encountered dexterity and stability challenges, fell behind schedule, and by late 2018, J&J had scaled back the program's ambitions and began to look externally for robotics expertise.

While J&J was struggling to bring Verb to market, Auris was emerging as a competitor in medical robotics. Auris was founded in 2012 by Dr. Frederic Moll, a robotic surgery pioneer and one of Intuitive's co-founders. Dr. Moll started Auris to push robotic technology beyond the da Vinci platform into new, minimally invasive procedures, particularly in endoscopy. Under his leadership as CEO, Auris operated as a mission-driven startup and attracted senior engineering and clinical talent from across the robotics field.

By 2016, Auris was developing two flagship RASDs: the Monarch platform and iPlatform. Monarch was a robotic endoscopy system aimed at diagnosing and ultimately treating lung cancer. Using a thin, flexible scope advanced through the airways, Monarch allowed physicians to navigate to peripheral lung lesions and obtain biopsies that would be difficult or impossible with conventional bronchoscopes.

iPlatform was Auris's operating-room system—a versatile robotic surgical platform designed to compete directly with da Vinci and extend beyond it. Unlike da Vinci's cart-based configuration, iPlatform was bed-mounted, giving it a smaller footprint in the operating room. It featured six robotic arms (two more than da Vinci's four), a surgeon's console, and a central control tower. Auris initially targeted laparoscopic surgeries comparable to da Vinci's core procedures but designed iPlatform to evolve over time into a multi-modality system capable of supporting both laparoscopic and endoscopic procedures on the same platform. By late 2017, Auris had built functional prototypes and successfully demonstrated iPlatform in lab settings, including key procedures on cadavers. By the end of 2018, iPlatform had reached "concept freeze": Auris had locked the core design and was preparing for regulatory review.[2]

The regulatory approval process for medical devices is managed by the FDA. For Class I and II medical devices—devices posing low to moderate risk—the FDA offers two principal pathways to market: 510(k) clearance and De Novo classification. Under the 510(k) pathway, a manufacturer seeks clearance by showing that a new device is substantially equivalent to a legally marketed predicate device; this route has historically been the fastest and least burdensome path to

[2] *Id.* at 15.

approval.[3] The De Novo pathway, by contrast, is intended for novel devices that lack an appropriate predicate; this pathway typically requires more extensive data and a longer review. High-risk Class III devices follow a different regime: if no appropriate predicate exists, they must undergo Premarket Approval ("PMA"), the most rigorous and time-intensive of the FDA's approval pathways.[4]

To avoid the intensive PMA pathway, the medical-device industry often employs a "minimally viable product" ("MVP") strategy for complex devices like surgical robots. Instead of seeking initial approval for a full-feature robot capable of performing complex, high-risk procedures, the sponsor first pursues clearance for a simpler configuration performing narrower, lower-risk indications—using 510(k) if a suitable predicate exists or De Novo if it does not. Once that stripped-down device is cleared, it can serve as its own predicate for future 510(k) submissions,

[3] In general, a 510(k) submission must include detailed device descriptions, proposed indications for use, labeling, and bench, animal, or clinical data as needed to demonstrate that any differences from the predicate device do not raise new questions of safety or effectiveness. *See* 21 C.F.R. § 807.87(e)–(g) (specifying required contents of a 510(k) premarket notification).

[4] PMA is the FDA's most demanding premarket pathway because it applies to Class III, high-risk devices "supporting or sustaining human life" or that "present a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(C)(ii). A PMA application must include full reports of clinical investigations, detailed manufacturing and quality-system information, device design and engineering data, labeling review, and often requires FDA inspections of manufacturing facilities and, in many cases, advisory-panel input before approval. *See* 21 U.S.C. § 360e(c). By contrast, De Novo classification applies to novel Class I or II devices and focuses on whether general and special controls can reasonably assure safety and effectiveness. Its evidentiary demands are materially lighter, often requiring more limited clinical data and avoiding the exhaustive premarket review, facility inspections, and multi-layered evaluations characteristic of PMA. 21 U.S.C. § 360c(f)(2).

allowing the manufacturer to add features and indications over time while building a safety and performance record and reducing the likelihood that the FDA will require the onerous PMA process reserved for high-risk Class III devices.

For years, the RASD industry followed this simple playbook: build a minimum viable product and seek FDA approval through the 510(k) pathway. Intuitive's da Vinci platform and Auris's Monarch system both received approval that way.[5] Consistent with that practice, Auris initially pursued a 510(k) strategy for iPlatform. In August 2018, Auris submitted a formal 510(k) pre-submission for iPlatform, proposing a da Vinci system as the predicate device and seeking a bronchoscopy indication. In October 2018, the FDA responded that iPlatform would require supporting clinical data and that the proposed indication did not match the cited predicate. Auris refined its regulatory strategy—removing bronchoscopy from the initial indication and identifying a more appropriate da Vinci model as the predicate—and, with plans to generate the requested data, continued to view iPlatform as a 510(k) candidate. As discussed below, however, contemporaneous changes in the FDA's approach to the 510(k) program would later become central to the parties' dispute over the earnout milestones.

[5] Monarch was granted 510(k) clearance by the FDA in March 2018 for use in bronchoscopy procedures. This approval allowed Auris to commercialize Monarch for minimally invasive lung-cancer diagnosis.

B. J&J's Acquisition of Auris

J&J had tracked Auris for years as part of its effort to accelerate entry into the surgical robotics market. By 2015, J&J personnel were aware of Auris and "impressed" by its technology, and by early 2017, J&J was evaluating a strategic investment in Auris as a "key hedge" for its own Verb program.[6] That interest materialized in May 2017 when a J&J subsidiary, J&J Innovation, invested $45 million in Auris's Series D financing and obtained a board-observer seat.

In May 2018, J&J's Chief Scientific Officer, Dr. William Hait, visited Auris's headquarters in connection with J&J's Lung Cancer Initiative. After seeing Monarch's ability to reach peripheral lung lesions for diagnosis and potential treatment, Hait became, in his words, "maniacally focused" on securing access to Auris's technology.[7] He returned to J&J, presented Monarch's capabilities to senior leadership, and at Gorsky's request agreed to serve as a point person on a team exploring a "deeper relationship" with Auris.[8] J&J simultaneously commissioned further technical diligence on Auris's technology.

By July 2018, J&J was considering an additional $200 million equity investment in Auris (code-named "Antwerp") to accelerate Monarch's adoption.

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[6] Opinion at 21.

[7] *Id.* at 22.

[8] *Id.*

iPlatform quickly became a crucial part of that analysis. J&J's Global Head of MedTech R&D, Peter Shen, told Business Development Vice President Susan Morano that he was "very concerned" that Verb was "significantly behind" and suggested using iPlatform "as a backup plan" for Verb.[9] Gorsky, in turn, told Morano that he wanted "Antwerp added to Verb," with Auris's "back end tech" shared across the programs.[10]

By late summer 2018, J&J's focus had shifted from incremental investment to control. J&J approved an acquisition assessment to be done "VERY quietly" because Verb was in a "fragile state," and internal documents framed acquiring Auris as a "fail safe" strategy for J&J's robotics portfolio.[11] After additional diligence, Gorsky authorized formal outreach regarding a buyout, and Hait made the first approach on October 1, 2018.

Auris was initially reluctant to sell to J&J. Auris's leadership worried that, inside a large corporate parent, it would lose the autonomy that had fueled its rapid innovation, and they were particularly concerned that J&J's Verb program could be positioned as a rival to iPlatform rather than a complement. Regardless, the parties conducted arm's-length negotiations and diligence. J&J learned about iPlatform's

[9] *Id.*

[10] *Id.*

[11] *Id.* at 23–25.

remaining technical challenges, but the parties agreed that a deeper technical review could be postponed until after closing through a post-merger "technology audit."[12]

Because so much of Auris's value lay in future regulatory and commercial success, J&J proposed to bridge the valuation gap with contingent consideration. J&J's offer paired a large upfront cash payment with substantial earnouts tied to post-closing milestones. Auris was willing to accept that structure only if J&J committed to drive the Auris platforms hard after closing. During negotiations, J&J assured Auris that it would bring to bear J&J-scale resources, allow Auris to continue operating with a "light touch" integration model, and treat Auris's robots as priority programs.[13] Auris pushed to capture those assurances in a negotiated agreement. The Merger Agreement therefore included a tailored "commercially reasonable efforts" clause requiring J&J to pursue the regulatory milestones with efforts consistent with its usual practice for "priority medical device products" of comparable potential.

In a phone call on January 24, 2019, Gorsky delivered the proposal that Auris "would not refuse": $3.4 billion in upfront cash plus up to $2.35 billion in contingent earnouts.[14] The earnouts were tied to ten milestones—eight regulatory milestones

[12] *Id.* at 29, 40.

[13] *Id.* at 115.

[14] *Id.* at 30.

tied to 510(k) clearances (five for iPlatform, two for Monarch, and one that either platform could satisfy) and two net-sales milestones—designed around ambitious but, in Auris's view, achievable indications that its robots already were on track to secure. On that call, Gorsky highlighted one near-term regulatory milestone for Monarch as essentially risk-free: a $100 million payment if Monarch obtained 510(k) clearance for robotically driven lung tissue ablation using J&J's NeuWave FLEX catheter. He told Moll that the milestone was so "high[ly] certain" that J&J treated that payment as "effective up front" consideration.[15]

What Auris did not know was that the certainty around that Monarch lung ablation milestone had already been undermined. Although the NeuWave FLEX catheter was an approved soft tissue ablation tool, it was not yet approved for lung-specific use, and J&J had been running a ten-patient clinical study of the NeuWave FLEX device on lung lesions to support this combined use case. In early December 2018, a study participant died, prompting the FDA to open a for-cause, on-site inspection focused on whether J&J should have obtained an investigational device exemption ("IDE") for the lung-lesion study.[16] Depending on the outcome of that investigation, it could be years before the NeuWave FLEX device was approved.

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[15] *Id.*

[16] An IDE is an FDA authorization that permits a device that has not yet received the required approval for a particular use to be used in a clinical study to collect safety and effectiveness data. *See* 21 U.S.C. § 360j(g).

On January 14, 2019—ten days before Gorsky's "high certainty" pitch—J&J's deal team was briefed on the situation. Yet J&J did not disclose the death to Auris until after closing, setting up the fraud claim that the milestone had been sold to Auris as a near certainty when J&J knew that it was "not remotely certain to be met."[17]

C. The Merger Agreement

The parties signed the Merger Agreement on February 12, 2019.[18] The final price term was consistent with J&J's offer: $3.4 billion upfront cash, plus up to $2.35 billion in earnouts tied to the ten milestones.[19]

Section 2.07(a) spelled out each of the ten milestones' requirements and deadlines. Eight milestones were tied to regulatory approvals for Auris's robotic systems, and two milestones were tied to sales performance.[20]

The regulatory milestones for iPlatform were:

1. General Surgery Milestone: $400,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering, with a specific indication for one upper abdominal surgical procedure and one lower abdominal procedure" by the end of 2021 ("Milestone 1");[21]

[17] Opinion at 124.

[18] *See* App. to Appellants' Opening Br. at A2811–2931 [hereinafter the "Merger Agreement"].

[19] *See id.* Art. 2.

[20] *Id.* § 2.07(a).

[21] *Id.* § 2.07(a)(iii).

2. Upper Abdominal Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . upper abdominal Umbrella Procedure(s)" by the end of 2023 ("Milestone 2");[22]

3. Lower Abdominal Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . colorectal/lower abdominal Umbrella Procedure(s)" by the end of 2023 ("Milestone 3");[23]

4. Urologic Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . urological Umbrella Procedure(s)" by the end of 2023 ("Milestone 4");[24] and

5. Gynecologic Surgery Umbrella Milestone: $150,000,000 if iPlatform obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering(s) for . . . gynecological Umbrella Procedure(s)" by the end of 2023 ("Milestone 5").[25]

The Monarch-related milestones were:

6. Endourology Milestone: $100,000,000 if Monarch obtained "510(k) premarket notification(s) allowing marketing and sale of a Monarch product offering, with a specific indication for endourology procedure(s)" by the end of 2020;[26] and

7. Robotic Soft Tissue Ablation Milestone: $100,000,000 if Monarch obtained "510(k) premarket notification(s) allowing marketing and sale of a Monarch Product offering, with a specific indication for

[22] *Id.* § 2.07(a)(iv).

[23] *Id.* § 2.07(a)(v).

[24] *Id.* § 2.07(a)(vi).

[25] *Id.* § 2.07(a)(vii).

[26] *Id.* § 2.07(a)(i).

robotically driven (or controlled) soft tissue ablation" by the end of 2022 ("Soft Tissue Ablation Milestone").[27]

An additional regulatory milestone could be achieved by either iPlatform or Monarch:

8. Robotic GI Endoluminal Milestone: $150,000,000 if either iPlatform or Monarch obtained "510(k) premarket notification(s) allowing marketing and sale of an iPlatform Product offering (or, alternatively . . . a Monarch product offering), with a specific indication for procedure(s) specifically including Endoscopic Submucosal Dissection" by the end of 2023 ("Milestone 8").[28]

Finally, two milestones were tied to the commercial performance of J&J's robotics business, including iPlatform, Monarch, and Verb:

9. First Step Net Sales Milestone: $500,000,000 if Robotics Net Sales before the end of 2022 reached or exceeded "$575 million in the aggregate";[29] and

10. Second Step Net Sales Milestone: $500,000,000 if Robotics Net Sales before the end of 2024 reached or exceeded "$1,650 million in the aggregate."[30]

The milestones were structured to follow the industry-standard MVP approach, starting with simpler procedures and progressing to more complex ones.

[27] *Id.* § 2.07(a)(ii).

[28] *Id.* § 2.07(a)(viii).

[29] *Id.* § 2.07(a)(ix).

[30] *Id.* § 2.07(a)(x).

To protect the earnouts, J&J agreed to use "commercially reasonable efforts" to achieve the regulatory milestones.[31] This term was specifically defined in the contract and forms the crux of the parties' dispute in this case. Section 2.07(e)(ii) provides that "'commercially reasonable efforts'" means:

> the expenditure of efforts and resources in connection with research and development and obtaining and furnishing of information to and communications with applicable Governmental Entities in connection with obtaining the applicable 510(k) premarket notification with respect to the applicable Robotics Products consistent with the usual practice of [J&J] and its Affiliates with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle to the applicable Robotics Products . . . .[32]

In simpler terms, J&J was required to devote the same caliber of effort and resources to Auris's robots as it would to one of its own "priority" medical devices at a comparable stage. Both parties understood that J&J's surgical orthopedics robot, Velys, was the only example of such a "priority" medical device. Velys had been developed using an MVP strategy, and Velys's teams had been given aggressive timelines and cash incentives to achieve rapid FDA clearances. The expectation,

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[31] Opinion at 36–37; Merger Agreement § 2.07(e)(i):

> From and after the Closing Date until the earlier to occur of the latest Earnout Period End Date with respect to the Regulatory Milestones or the date on which each of the Regulatory Milestones have been achieved in accordance with this Agreement, Parent shall, and shall cause its Affiliates (including the Surviving Corporation) to, use commercially reasonable efforts to achieve each of the Regulatory Milestones (excluding, once achieved, any such Regulatory Milestones that may have been achieved.

[32] Merger Agreement § 2.07(e)(ii).

based on the contract, was that J&J would apply similar priority efforts to iPlatform and Monarch.

Section 2.07(e)(ii) further enumerated ten factors that J&J could consider in calibrating its efforts for such a priority device—including safety and efficacy issues, inherent development risks, market competitiveness, patent position, regulatory difficulty, pending legal matters, risk of recalls, regulatory input and guidance, and the product's expected profitability and return on investment.[33]

Additionally, Section 2.07(e)(iii) forbade J&J from acting "with the intention of avoiding" any earnout payment or from factoring the cost of an earnout into post-closing business decisions.[34]

The Merger Agreement also contained risk-allocation and integration clauses typical of a large M&A transaction. Section 4.08(b) included a one-sided anti-reliance clause, in which J&J—but not Auris—disclaimed reliance on any representations outside the four corners of the agreement.[35] Section 8.05(b) provided that the indemnification provisions were the exclusive remedy for claims made after closing that related to the Merger Agreement or the transactions it contemplated, with a carveout for fraud "with respect to making the representations

[33] *Id.* § 2.07(e)(ii).

[34] *Id.* § 2.07(e)(iii).

[35] *Id.* § 4.08(b).

and warranties in this Agreement."[36] Finally, Section 10.07 was a standard integration clause stating that the Merger Agreement and specified ancillary agreements constituted the parties' entire agreement and superseded all prior agreements and understandings concerning the subject matter of the merger.[37]

The acquisition closed on April 1, 2019. At closing, Auris's stockholders received the $3.4 billion upfront cash payment, and Fortis Advisors LLC ("Fortis") became the designated representative of the former Auris stockholders for purposes of administering the earnout. J&J integrated Auris into its Ethicon business, and Moll assumed a leadership role within J&J's robotics division. From that point forward, the development and regulatory progress of Monarch and iPlatform would determine whether Auris's stockholders received any additional consideration under the milestone structure.

D. J&J's Post-Merger Treatment of iPlatform and the Milestones' Failure

J&J's treatment of iPlatform quickly diverged from what the Merger Agreement contemplated. Rather than elevating iPlatform as a priority device and driving toward the agreed regulatory milestones, J&J undertook actions that the Court of Chancery found to be "the antithesis of the commercially reasonable efforts

[36] *Id.* § 8.05.

[37] *Id.* § 10.07.

expected for a 'priority' device."[38] The parties mostly do not contest these findings on appeal.

1. Project Manhattan

Within days of closing, J&J launched an initiative code-named "Project Manhattan"—ostensibly a technical assessment of Auris's iPlatform and J&J's Verb, but in practice a head-to-head internal competition between the two systems. Project Manhattan alarmed Auris's leadership, who had been told during negotiations to expect only a supportive post-closing "technology audit," not a direct "comparative assessment" pitting iPlatform against Verb.[39] Auris's concerns were well founded. In an internal document not shared with Auris, J&J described Project Manhattan as a plan to "assess the robotic system development status from Verb and Auris and recommend an optimal path to bring the system(s) to market," outlining three possible outcomes: develop both platforms in parallel, choose one, or merge them into a single system.[40] Around the same time as Project Manhattan's announcement, the Auris team learned that J&J had capped its overall robotics R&D budget. Auris quickly came to view Project Manhattan as a "bakeoff": a winner-

[38] Opinion at 69.

[39] *Id.* at 40–41.

[40] *Id.* at 39.

take-all showdown in which "only one robot" would be prioritized and the loser would likely "cease to exist."[41]

The bakeoff format pulled iPlatform squarely off its milestone track. Over an intensive 25-day period, eight leading surgeons were asked to perform seven demanding procedures—including a Roux-en-Y gastric bypass ("RYGB"), a low anterior resection, and a lobectomy—on both iPlatform and Verb. Those procedures were substantially more complex than the initial indications Auris had planned to use to satisfy the Milestone 1. To prepare, more than 80 Auris personnel were diverted from the development roadmap to ready a months-old alpha prototype for a rapid face-off against a more mature, post-beta Verb system. Auris engineers spent weeks patching bugs and stabilizing the system with ad hoc software and hardware fixes—"the engineering and software equivalent of Band-Aids, duct tape, and baling wire"—incurring "significant 'technical debt'" and driving the program "backwards rather than forwards in development."[42]

Although iPlatform ultimately "won" Project Manhattan—both robots completed all seven procedures, and J&J concluded that iPlatform was the better bet—the court held that "Project Manhattan alone is sufficient to find that J&J

[41] *Id.* at 42.

[42] *Id.* at 43.

breached its efforts obligation in Section 2.07(e)."[43] The exercise did not advance iPlatform's regulatory milestones, provide additional resources, or move the device closer to clearance; it "caused needless setbacks and resource drains" for iPlatform while generating synergies that primarily benefitted Verb and J&J's budget constraints.[44] The court observed that a priority device "would not have to endure a costly battle merely to remain operative."[45] Project Manhattan therefore marked the first and clearest point at which J&J's post-closing conduct diverged from its contractual promise to use "commercially reasonable efforts" to achieve the iPlatform regulatory milestones.

2. The combination and integration with Verb

The outcome of Project Manhattan drove J&J's second major departure from the Merger Agreement: J&J decided to merge iPlatform and Verb into a single combined project. In December 2019, J&J management formally recommended to J&J's board of directors that it proceed with "a combined platform where Auris's iPlatform is augmented by Verb assets including the open surgeon console, intra-procedure data capabilities and the surgeon portal," branding the resulting system "iPlatform+."[46]

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[43] *Id.* at 72.

[44] *Id.* at 70.

[45] *Id.* at 72.

[46] *Id.* at 49.

Although the Merger Agreement permitted J&J to achieve the milestones using a combined device, the court held that the manner in which J&J combined iPlatform and Verb breached its commercially reasonable efforts obligations.[47] The ensuing integration was, in the court's words, a "calamity of excess and redundancy."[48] Auris leadership was largely sidelined, and J&J initiated a "full speed migration" of more than 200 Verb employees onto the iPlatform team.[49] Hostility festered between the two groups, which had just battled against each other in Project Manhattan. Within a year, every engineer from the legacy iPlatform clinical engineering team had left and Verb software engineers insisted on rewriting iPlatform's code, prompting significant attrition among Auris's software developers as well. The combination effectively left iPlatform as "a parts shop for Verb."[50]

Contemporaneous documents showed that J&J knew this "[s]ingle, [o]ptimized [p]latform" strategy would slow iPlatform down.[51] A September 2019 financial update projected a "Single, Optimized Platform launching in 2024 (+1 Year Delay to Combine)," and internal decks and testimony acknowledged a "longer time

[47] *Id.* at 75; *see* Merger Agreement §§ 2.07(a)(iii)–(viii), 10.03 (defining "iPlatform Products" to include "derivatives of iPlatform" and conditioning the iPlatform regulatory milestones on FDA clearance allowing marketing and sale of an "iPlatform Product offering").

[48] Opinion at 50.

[49] *Id.*

[50] *Id.* at 3.

[51] *Id.* at 72.

to market for Auris," adverse effects on retention, and the need to revise milestones if the combination went forward.[52] When Gorsky questioned why the combined system had a lower valuation than iPlatform and Verb separately, J&J's Chief Financial Officer responded that the model "still assumes all Auris milestones being paid in full," but that the combined valuation improved "when you consider what will also happen with [the] contingent payment"—that being, the milestones not being achieved.[53] Considering this, Gorsky approved the combination as a "good overall value case."[54]

The Court of Chancery held that the Verb combination and integration directly violated J&J's contractual obligations. The meshing of iPlatform with Verb components "hampered iPlatform's launch and milestone achievement," and J&J pursued the "[s]ingle, [o]ptimized [p]latform" strategy despite knowing that it would delay iPlatform's development schedule and put at risk the iPlatform regulatory milestones.[55] The court further concluded that approving the combination based in part on "what would also happen with the contingent payment" was not only inconsistent with J&J's duty to use commercially reasonable efforts to achieve the milestones, but also contrary to Section 2.07(e)(iii)'s express prohibition on making

[52] *Id.* at 72 n.388.

[53] *Id.* at 47.

[54] *Id.* at 73.

[55] *Id.* at 72.

decisions "based on taking into account the cost of making any Earnout Payment(s)."[56]

3. Departure from an MVP strategy

The regulatory milestones were structured consistently with an MVP strategy, whereby Auris would first obtain regulatory clearance for simpler procedures, then incrementally build up to more complex surgeries in the later milestones. Milestone 1 could be satisfied by any qualifying upper and lower abdominal procedures, with subsequent 2023 milestones broadening to "umbrella" procedures of greater complexity. Auris had considered a non-MVP approach, using a complex RYGB procedure so that iPlatform might achieve Milestones 1 and 2 together by obtaining general surgery and upper abdominal approval at once. Auris, however, had concluded that RYGB was "out of reach for 2021" and had negotiated to simplify the milestones to achieve regulatory approval and the earnouts more quickly.[57] In practice, this meant focusing the device on basic laparoscopic

[56] *Id.* at 73. J&J disputes the Court of Chancery's chronology of the Verb/iPlatform "combination." In its opening brief, J&J contends that the 2019–2020 documents that the court cited reflect only a proposed "iPlatform+" strategy and that no actual "mesh[ing]" of Verb hardware into iPlatform occurred until late 2021—after the FDA had already closed the 510(k) pathway to iPlatform and with Milestone 1 effectively out of reach. Under that view, any eventual combination could not have breached Section 2.07(e) or caused the missed regulatory milestones. *See* Appellants' Opening Br. at 52. The Court of Chancery, however, found breach based on when J&J "endorsed" the combination, not necessarily on when the combination took place. Opinion at 73 & n.390. J&J does not dispute the court's factual finding that the endorsement occurred in late 2019 and so we do not need to address whether J&J's factual dispute affects the analysis.

[57] Opinion at 76.

procedures (such as single-quadrant gallbladder or hernia repairs) that the prototype was "very capable" of performing, thereby expediting a 510(k) submission with minimal added complexity.[58]

After the acquisition, J&J abandoned the MVP strategy and instead insisted on pursuing RYGB to create a full-featured, commercially attractive system that was better able to compete head-to-head with the da Vinci system and promote high-margin Ethicon instrument sales. Internal J&J communications reveal that management was uneasy with Auris's single-minded focus on hitting the earnout milestone "for the sake of [the] timeline."[59] One J&J executive cautioned that the Auris team was too fixated on speedy clearance "as opposed to a great product with commercial viability."[60]

The Court of Chancery held that this pivot away from MVP toward an RYGB-first specification violated J&J's efforts obligations. The court credited Auris's showing that an MVP strategy better aligned with the factors listed in Section 2.07(e)(ii): issues of "efficacy and safety" favor starting with a basic device and simple procedures; development risk is lower when the system is simplified for speed, flexibility, and reliability; the "likelihood and difficulty" of FDA clearance

[58] *Id.* at 77.

[59] *Id.* at 77 n.409.

[60] *Id.* at 77 n.410.

favors beginning with a narrow indication; and even "profitability," "competitiveness of alternative products," and commercialization risks support an MVP path.[61] For RASDs in particular, the court described an MVP approach as "highly efficient," noting that J&J followed an MVP approach for other "priority" RASD devices like Velys and that Gorsky had requested an MVP strategy for Verb.[62] The court concluded that J&J's insistence that iPlatform pursue a RYGB specification for Milestone 1 "impeded the achievement of the 2021 milestone," and the court emphasized that J&J was "not . . . permitted to prioritize commercialization, product differentiation, or short-term profitability at the expense of achieving the milestones."[63]

4. J&J's response to the FDA's pathway change

J&J's response to a shift in the FDA's regulatory pathway for RASDs marked another point of divergence from its contractual efforts' obligation. The milestones were tied specifically to 510(k) clearance. By the time the parties signed the Merger Agreement, however, the FDA had signaled that this pathway might change. In November 2018, the FDA publicly announced plans to "modernize" the 510(k) program and indicated that certain novel devices—including new RASDs—might

[61] *Id.* at 78–79.

[62] *Id.* at 80.

[63] *Id.* at 78.

require De Novo review.[64] Auris reached out to the FDA after this announcement, and the FDA told Auris that the 510(k) pathway would remain appropriate for iPlatform. The parties proceeded on that understanding when they negotiated the milestone language, leaving the Merger Agreement silent on what would happen if the FDA later changed course.[65]

That is precisely what occurred after closing. On August 5, 2019, the FDA informed J&J and Auris that first-generation RASDs like iPlatform would no longer be eligible for 510(k) clearance. Internally, J&J's regulatory team initially treated that development as manageable: it projected "no significant timeline differences compared to a 510(k)" review.[66] There was concern, however, that iPlatform might be required to navigate the more onerous PMA approval rather than De Novo. Consequently, when the FDA confirmed on January 6, 2020 that De Novo classification was available for iPlatform, J&J and Auris regarded that outcome as "positive."[67] Auris had built a five-month buffer into Milestone 1 in case of unexpected situations, and the De Novo shift was not predicted to extend the approval timeline beyond that point. Further, once iPlatform obtained De Novo

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[64] *Fortis Advisors LLC v. Johnson & Johnson*, 2021 WL 5893997, at *9 (Del. Ch. Dec. 13, 2021) [hereinafter the "Motion to Dismiss Opinion at __"].

[65] *Id.* at 10.

[66] Opinion at 48.

[67] *Id.*

clearance for Milestone 1, that grant could also serve as the 510(k) predicate for the remaining milestones. Nothing about the policy change, as J&J initially evaluated it, made the milestones impossible or even impracticable.

Yet, J&J treated the FDA's regulatory shift as excusing its obligations to achieve the earnouts. On April 14, 2020, during its quarterly earnings call, J&J disclosed that the company had written down to zero the value of all the milestones. The write-down produced an immediate financial benefit for J&J: by releasing the reserves associated with the earnout, J&J recorded a gain of approximately $983.6 million in the first quarter of 2020. An internal memorandum identified the FDA's shift from 510(k) to De Novo for iPlatform as the trigger, framing the regulatory change as a new obstacle that justified removing the milestones from J&J's books, and J&J gave the same explanation to Auris's leadership. In substance, the write-down signaled that J&J no longer expected the iPlatform milestones to be achieved and regarded the pathway change as having effectively extinguished the earnout.

J&J then aligned its internal incentives with this "new reality."[68] Two months after the write-down, J&J implemented a revised employee incentive program that no longer rewarded Auris personnel for achieving the regulatory milestones defined in the Merger Agreement. The new plan offered a single bonus tied to the FDA clearing iPlatform for a "general surgery" indication by the end of 2023—later than

[68] *Id.* at 51–52.

the 2021 deadline for Milestone 1 and keyed to a broader, vaguer approval rather than the two specific procedures that Milestone 1 required. Incentive awards tied to the remaining umbrella milestones were eliminated entirely. J&J executives told Auris employees that the original earnout milestones had been "canceled," undercutting any expectation that the contractual milestones remained the operative targets.[69] Together with the write-down, those changes reflected J&J's view that once the FDA closed the 510(k) pathway for iPlatform's first indication, its obligations to pursue the earnouts had effectively come to an end.

The Court of Chancery rejected J&J's position that the FDA's pathway change excused its efforts obligation to work toward the milestones. The court held that the implied covenant of good faith and fair dealing filled the contractual gap regarding a De Novo approval pathway and required J&J to pursue De Novo clearance for Milestone 1 with commercially reasonable diligence to achieve the same regulatory result for which the parties bargained.[70] Once iPlatform obtained De Novo clearance for Milestone 1, that approval could serve as the 510(k) predicate for the remaining milestones, preserving the earnout structure that the parties designed. J&J's write-down of the milestones and its changes to the employee

[69] *Id.* at 81.

[70] *Id.* at 99–100 (invoking the implied covenant based on its finding that both sides assumed at signing that 510(k) would be available, the added burden of the De Novo application was modest, and the Merger Agreement was silent about what would happen if that pathway closed).

incentive structure were therefore further evidence that it had not used commercially reasonable efforts to achieve the earnouts as it would have for its other priority products.

Ultimately, J&J pulled the plug on iPlatform by the end of 2021. By that time, nearly three years had passed since the merger, and iPlatform still had not been submitted for FDA approval. J&J's leadership concluded that iPlatform would not be viable within a commercially reasonable timeframe. J&J refocused its efforts on Velys and effectively shelved the iPlatform program. Monarch, for its part, remained on the market for bronchoscopy, but its expansion milestones for lung ablation and gastrointestinal procedures were not met by the contractual deadlines. None of the $2.35 billion earnouts was ever paid.

E. Procedural History

The failure of the milestones gave rise to the present dispute. On October 12, 2020, Fortis filed suit in the Delaware Court of Chancery.[71] Fortis alleged that J&J had not honored its contractual commitments and had intentionally thwarted the milestones to avoid making the contingent payments. The complaint asserted 12 causes of action against J&J, Ethicon, and certain J&J executives, including claims for (i) breach of contract (for failing to use the required "commercially reasonable

[71] Verified Complaint, *Fortis Advisors LLC v. Johnson & Johnson*, C.A. No. 2020-0881-LWW (Del. Ch. Oct. 12, 2020).

efforts" to achieve the milestones), (ii) breach of the implied covenant of good faith and fair dealing (to address the FDA's foreclosure of the 510(k) pathway), and (iii) fraudulent inducement (alleging that J&J and certain executives made false promises during negotiations to induce Auris's sale).[72]

On December 13, 2021, the Vice Chancellor issued a memorandum opinion granting the individual defendants' motion to dismiss for lack of personal jurisdiction and dismissing claims for equitable fraud, mutual mistake, and civil conspiracy.[73] The court denied J&J's motion to dismiss Fortis's principal contract and fraud claims. The court held that Fortis had sufficiently pleaded that J&J's conduct violated the express terms of the earnout covenants and that J&J's extra-contractual assurances could support a fraud claim notwithstanding the contract's exclusive-remedy clause.[74] The court noted that the Merger Agreement's anti-reliance provision was one-way—binding only J&J—and that Auris had not disclaimed reliance on J&J's representations.[75] The court ruled that the contract's exclusive-remedy provision, although clearly drafted to limit post-closing claims,

[72] *Id.*

[73] Motion to Dismiss Opinion at 2.

[74] *Id.* at 27 ("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.").

[75] *Id.* at 29.

could not bar a fraud claim based on extra-contractual representations in the absence of express anti-reliance language.[76]

Discovery followed. The parties produced over 1.5 million documents, conducted seventy-eight days of depositions, and tried the case in January 2024 over ten trial days with 23 fact and nine expert witnesses, supported by more than 6,200 joint exhibits. Post-trial briefing and argument were completed on May 22, 2024.

On September 4, 2024, the Court of Chancery issued a 144-page Post-Trial Opinion, ruling in Fortis's favor on the most significant issues. The court held that J&J breached its contractual obligations under Section 2.07(e) by failing to use the required commercially reasonable efforts to achieve the iPlatform regulatory milestones and by acting to avoid the earnouts.[77] As described above, the court meticulously examined J&J's conduct against the Merger Agreement's inward-facing efforts clause and concluded that J&J's post-merger actions fell far short of the efforts that J&J undertook for the only comparable priority project, Velys. The court found that Project Manhattan and the forced integration of Verb had "no

[76] *Id.*

[77] Opinion at 83. The court held that J&J did not breach Section 2.07(e) with respect to the Monarch regulatory milestones. Monarch was not subjected to Project Manhattan, was not combined with another robot, and was allowed to follow an MVP strategy. *Id.* at 84. The court further held that the efforts provision in Section 2.07(e) did not apply to the net sales milestones. Although the court held that J&J breached Section 2.07(e)(iii), which prevented J&J from taking actions with the intention of avoiding any earnout provision, Fortis did not prove that the breach was a reasonably certain cause of the missed net sales milestones. *Id.* at 44.

upside" for achieving the milestones and in fact "impeded and impaired" iPlatform's development.[78] Likewise, the court held that J&J's decision to write off the milestones in 2020 and pursue a different strategic direction was "antithetical" to any reasonable effort to meet the earnouts.[79]

The court invoked the implied covenant of good faith and fair dealing to address the FDA's regulatory shift from 510(k) to De Novo and to reject J&J's argument that the switch excused it from its obligations under Section 2.07(e). The court noted that the switch from a 510(k) to a De Novo process, although more onerous, would only have caused a relatively minor delay in iPlatform's timeline. Given that the effect on time and cost was "immaterial," J&J's decision to halt development appeared unreasonable and contrary to the deal's purpose. As the court put it, J&J "cannot avoid liability by scapegoating an unforeseen policy change" that did not materially alter its ability to perform.[80]

The court further determined that J&J, through Gorsky, committed fraud in the inducement of the merger. At the time Gorsky told Moll that the Soft Tissue Ablation Milestone was so "high[ly] certain" that J&J viewed it as "effective up front" consideration, J&J already knew that a patient in its FLEX lung-lesion study

[78] *Id.* at 70.

[79] *Id.* at 82.

[80] *Id.* at 103.

had died and the FDA had opened a for-cause investigation.[81] These events put FLEX's regulatory path, and therefore the milestone, in serious peril. J&J disclosed none of this to Auris and instead presented the milestone as essentially guaranteed. By giving Auris false confidence in the achievability of the milestone while withholding material information, the court found that J&J actively concealed material facts and fraudulently induced Auris to accept the $100 million contingent payment instead of immediate fixed consideration. The court further reiterated its holding from the motion-to-dismiss stage that the Merger Agreement's exclusive remedies clause did not bar Fortis's fraud claim because Auris had not unambiguously disclaimed reliance on extra-contractual statements.

The court rejected Auris's other fraud allegations. Auris had claimed that J&J also fraudulently induced the deal by promising vast resources and a "light touch" integration.[82] Such statements—praising J&J's "skills, experience, and resources" and offering access to J&J's "global candy store" of assets—were deemed mere puffery and too aspirational to form the basis of a fraud claim.[83]

The court awarded a total judgment amount of $1,011,271,291, inclusive of $900,000,000 in contract damages, $60,865,748 in fraud damages, and $42,405,543

[81] *Id.* at 125.

[82] *Id.* at 119–24.

[83] *Id.* at 121.

in pre-judgment interest. To calculate contract damages, the court awarded expectation damages equal to the value of the missed iPlatform milestones multiplied by the parties' estimated probability of each milestone's achievement at the time of the merger. The value of the missed iPlatform milestones totaled $1,150,000,000, with $400,000,000 awarded for Milestone 1 and $150,000,000 respectively for Milestones 2, 3, 4, 5 and 8. The court found that the parties' blended probability of FDA approval at the time of the merger was 75% for Milestone 1 and 80% for the remaining milestones. Weighting the value of the missed milestones by the parties' blended expected chance of approval, the court awarded contract damages of $900,000,000. The court adopted a similar expectation-damages approach for the fraud claim to award Auris its reasonable expectation of the Soft Tissue Ablation Milestone's value at the time of J&J's fraud—which the court found to be $60,865,748. The court then applied pre-judgment interest, calculated using the prime rate of interest for the contract award and the legal rate of interest for the fraud award to reach the total judgment amount of $1,011,271,291.

Final judgment was entered on October 28, 2024. J&J filed a timely notice of appeal on November 26, 2024.

II. STANDARD OF REVIEW

We review a final, post-trial judgment of the Court of Chancery under well-settled standards. Questions of law, including contract interpretation and the application of the implied covenant of good faith and fair dealing, are reviewed *de novo*.[84] We review the court's factual findings for clear error and will not disturb them if they are "sufficiently supported by the record and are the product of an orderly and logical deductive process."[85] Finally, we review the court's choice and measurement of a damages remedy for abuse of discretion.[86]

III. ANALYSIS

J&J raises three arguments on appeal. *First*, J&J contends that the Court of Chancery incorrectly applied the implied covenant of good faith and fair dealing as a matter of law.[87] J&J asserts that the Merger Agreement explicitly tied the regulatory milestones to 510(k) clearance only, and it was legal error to imply an obligation that J&J pursue De Novo approval after the FDA made 510(k) unavailable. *Second*, J&J argues that the court misinterpreted the Merger

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[84] *Glaxo Grp. Ltd. v. DRIT LP*, 248 A.3d 911, 918 (Del. 2021); *Oxbow Carbon & Mins. Hldgs., Inc. v. Crestview-Oxbow Acq., LLC*, 202 A.3d 482, 502 (Del. 2019); *Eagle Force Hldgs., LLC v. Campbell*, 187 A.3d 1209, 1228 (Del. 2018).

[85] *SIGA Techs., Inc. v. PharmAthene, Inc.*, 132 A.3d 1108, 1128 (Del. 2015); *Nationwide Emerging Mgrs., LLC v. NorthPointe Hldgs., LLC*, 112 A.3d 878, 889 (Del. 2015).

[86] *Coster v. UIP Cos., Inc.*, 255 A.3d 952, 960 (Del. 2021); *Gatz Props., LLC v. Auriga Cap. Corp.*, 59 A.3d 1206, 1212–13 (Del. 2012); *William Penn P'ship v. Saliba*, 13 A.3d 749, 758 (Del. 2011).

[87] Appellants' Opening Br. at 29.

Agreement's "commercially reasonable efforts" clause, effectively excising the ten factors in Section 2.07(e)(ii) that preserved J&J's discretion and commercial judgment.[88] J&J asserts that such a legal error infects every breach of contract finding. *Third*, J&J challenges the fraud ruling on two grounds. J&J contends that the elements of fraud are not met here and that, regardless, the exclusive remedy clause in Section 8.05(b) bars Fortis's fraud claim entirely.[89]

A. The implied covenant

The Merger Agreement, like every Delaware contract, contains an implied covenant of good faith and fair dealing.[90] The covenant functions as a limited "gap-filler": it enforces the parties' reasonable expectations in circumstances that they could not foresee and did not address in their written agreement, but it may not be used to rewrite or contradict express terms.[91]

After concluding that the FDA's post-signing decision to require De Novo review for iPlatform's first approval was an unanticipated development that the Merger Agreement did not address, the Court of Chancery used the implied covenant

[88] *Id.* at 39.

[89] *Id.* at 57.

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

[91] *Gerber v. Enter. Prods. Hldgs., LLC*, 67 A.3d 400, 418 (Del. 2013); *Nemec v. Shrader*, 991 A.2d 1120, 1126 (Del. 2010); *Cincinnati SMSA Ltd. P'ship v. Cincinnati Bell Cellular Sys. Co.*, 708 A.2d 989, 992 (Del. 1998).

as the foundation for both its liability and damages analysis.[92] On appeal, J&J frames the use of the implied covenant as the first tile in a "domino effect." First, the court invoked the covenant to imply an obligation that J&J use commercially reasonable efforts to obtain De Novo clearance for Milestone 1 and treat that clearance as the functional equivalent of the 510(k) approval specified in the Merger Agreement.[93] The court found that, for iPlatform, the shift from 510(k) to De Novo did not materially change the time, cost, or likelihood of obtaining the first regulatory clearance and therefore did not materially alter the parties' bargain as to Milestone 1.[94] The court further reasoned that obtaining De Novo clearance for the general surgery indication would allow the approved device to serve as the predicate for future 510(k) submissions, keeping the remaining milestones attainable under their express terms.[95] Building on those conclusions, the court then valued the missed milestones by reference to the parties' pre-merger, 510(k)-based probabilities of success under the view that the post-signing regulatory developments neither altered J&J's contractual obligations nor materially changed the risk profile for which the parties bargained.[96]

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[92] Opinion at 100.

[93] *Id.* at 100–01.

[94] *Id.* at 102–03.

[95] *Id.* at 103.

[96] *Id.* at 132.

J&J appeals every step of this "domino effect." J&J's primary argument is that the implied covenant never should have been invoked and the dominoes never should have fallen.[97] J&J contends that the Merger Agreement specifies 510(k) clearance as the exclusive form of regulatory approval that triggers the milestones, so the contract is not "truly silent" on the regulatory pathway, and the court could not replace 510(k) with De Novo by invoking the covenant.[98] In J&J's view, the risk that the FDA might deny access to the 510(k) pathway for Milestone 1 was foreseeable and allocated in the contract, and there is no evidence that J&J would have agreed to assume a more onerous De Novo obligation on the same price terms had the parties anticipated such a change.[99] J&J further maintains that the implied covenant is unavailable absent arbitrary or unreasonable conduct by the promisor, and that the FDA's decision to close the 510(k) pathway was an external regulatory choice rather than the product of any bad faith conduct by J&J.[100] Without an implied obligation to pursue De Novo approval, the argument goes, J&J had no contractual duty to perform once the FDA closed the 510(k) pathway.

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[97] Appellants' Opening Br. at 29.

[98] *Id.* at 32 ("Far from being 'truly silent,' this contract explicitly requires '510(k) premarket notification' as the regulatory pathway—eight times over.").

[99] *Id.* at 32–34.

[100] *Id.* at 34.

J&J then challenges the court's second and third dominoes—upholding J&J's obligations for the remaining milestones and awarding damages on the pre-merger probabilities of success. J&J argues that the court's conclusion that the shift from 510(k) to De Novo was "immaterial" rested on a "daisy chain" of assumptions: (i) Milestone 1 would be approved under De Novo despite lower odds of success; (ii) approval would come soon enough to serve as a 510(k) predicate for the remaining milestones; (iii) the FDA would, in fact, accept iPlatform's De Novo approval as an appropriate predicate; and (iv) the remaining milestones then would be achieved within their contractual deadlines.[101] Once those assumptions are removed, the FDA's decision to close the 510(k) pathway either excused J&J from any obligation to deliver the remaining milestones or, at a minimum, made them substantially less likely to be met.[102] Because of this, J&J contends that, at a minimum, the damages award, which applied pre-merger, 510(k)-based probabilities, must be vacated.[103]

Fortis responds that the dominos should fall as the court held because the FDA's regulatory shift is precisely the kind of unforeseen development that the implied covenant is meant to address: the Merger Agreement is silent on what happens if the only expected pathway becomes unavailable, and the parties did not

[101] *Id.* at 35–36.

[102] *Id.* at 36–37.

[103] *Id.* at 37–38.

and could not anticipate that the FDA would close the 510(k) pathway for first-generation RASDs.[104] In Fortis's view, implying a De Novo-based efforts obligation simply preserves the parties' shared expectation that J&J would seek regulatory clearance for iPlatform rather than treat an immaterial procedural change as an excuse to abandon the milestones.[105]

As to J&J's "daisy chain" and damages arguments, Fortis answers that the court's holdings are grounded in uncontested factual findings and in the Merger Agreement's express efforts obligations.[106] J&J remained contractually bound to use commercially reasonable, priority efforts to achieve the remaining milestones. The record, Fortis notes, supports the court's findings that De Novo approval for Milestone 1 was likely, obtainable within the contractual timeline, and sufficient to serve as a 510(k) predicate for later indications. Fortis argues that J&J's criticisms simply repackage factual disputes that the court resolved against it.[107] Because the court did not clearly err by finding the difference between De Novo and 510(k) for Milestone 1 "immaterial," Fortis concludes that the damages award, which applied the parties' pre-merger probabilities of success, should be affirmed.[108]

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[104] Appellee's Answering Br. at 29–32.

[105] *Id.* at 33–35.

[106] *Id.* at 36–37.

[107] *Id.* at 38.

[108] *Id.* at 39–40.

We begin by (1) examining the implied covenant doctrine and whether the Court of Chancery properly invoked it to supply a De Novo approval option for Milestone 1. Concluding that the court erred as a matter of law in holding that the covenant applied, we then (2) consider whether that error compels reversal of either (a) the court's determination that J&J remained obligated to use commercially reasonable efforts to obtain 510(k) clearance for the remaining milestones, or (b) the court's damages award, which relied on the parties' pre-merger probabilities of success. We hold that reversal is not warranted as to the later milestones or the damages award.

1. The court erred by invoking the implied covenant of good faith and fair dealing for Milestone 1.

The implied covenant of good faith and fair dealing inheres in every contract and ensures that neither party acts arbitrarily or unreasonably to frustrate the fruits of their bargain.[109] It authorizes a court to imply terms only "where obligations can be understood from the text of a written agreement but have nevertheless been omitted in the literal sense," and only to protect the "reasonable expectations" that the parties shared at signing.[110] The implied covenant is not, however, a license for the court to "rewrite the contract to appease a party who later wishes to rewrite a

[109] *Dunlap*, 878 A.2d at 442; *Nemec*, 991 A.2d at 1126; *Dieckman v. Regency GP LP*, 155 A.3d 358, 361 (Del. 2017).

[110] *Cincinnati*, 708 A.2d at 992.

contract [it] now believes to have been a bad deal."[111] Rather, the covenant is a narrow gap-filling tool of last resort.[112] Used properly, the implied covenant functions like a scalpel, not a brush. A court should apply the implied covenant surgically to vindicate the parties' shared expectations at the time of contracting and not to paint over contractual provisions that one side later regrets.

The implied covenant operates in two primary ways. The first is when a contract allocates discretionary authority to one party over a central aspect of the contract.[113] When the party exploits that discretion in a manner that defeats the "overarching purpose" of the bargain, courts may imply a requirement that such discretion be exercised reasonably and in good faith to ensure that the discretionary power is applied consistently with what reasonable parties would have agreed to at signing.[114] This principle has deep roots in Delaware law. In *Blish v. Thompson*

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[111] *Nemec*, 991 A.2d at 1126.

[112] *Gerber*, 67 A.3d at 418.

[113] *Wood v. Duff-Gordon*, 118 N.E. 214, 215 (N.Y. 1917) (Cardozo, J.) ("His promise to pay the defendant one-half of the profits and revenues resulting from the exclusive agency and to render accounts monthly was a promise to use reasonable efforts to bring profits and revenues into existence."); Steven J. Burton, *Breach of Contract and the Common Law Duty to Perform in Good Faith*, 94 HARV. L. REV. 369, 379–85 (1980) (framing the implied covenant in terms of legitimate and illegitimate uses of discretion).

[114] *Dunlap*, 878 A.2d at 442 ("[P]arties are liable for breaching the covenant when their conduct frustrates the overarching purpose of the contract by taking advantage of their position to control implementation of the agreement's terms."); *E.I. DuPont de Nemours & Co. v. Pressman*, 679 A.2d 436, 443 (Del. 1996); *Airborne Health, Inc. v. Squid Soap, LP*, 984 A.2d 126, 146–47 (Del. Ch. 2009) ("When a contract confers discretion on one party, the implied covenant requires that the discretion be used reasonably and in good faith.").

Automatic Arms Corp., a merger agreement permitted the underwriter to cancel the asset sale whenever, "in [the underwriter's] absolute judgment," market conditions rendered the sale "impractical or inadvisable."[115] We held that the grant of "absolute" discretion was implicitly conditioned on "sincerity, honesty, fair dealing and good faith."[116] The implied covenant acted to ensure that the underwriter used its discretionary power reasonably as the parties expected.

The second use is relevant to this case: the covenant may be used to address unforeseen developments—contingencies neither anticipated nor resolved by the contract—that threaten the parties' bargained-for economic expectations. The law recognizes that "[n]o contract, regardless of how tightly or precisely drafted it may be, can wholly account for every possible contingency."[117] When such an

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[115] *Blish v. Thompson Automatic Arms Corp.*, 64 A.2d 581, 597 (Del. 1948).

[116] *Id.* Delaware jurisprudence has consistently reiterated this principle. *Winshall v. Viacom Int'l, Inc.*, 76 A.3d 808, 816 (Del. 2013) ("It is true that when a contract confers discretion on one party, the implied covenant of good faith and fair dealing requires that the discretion . . . be used reasonably and in good faith."); *Squid Soap*, 984 A.2d at 146–47 ("When a contract confers discretion on one party, the implied covenant requires that the discretion be used reasonably and in good faith."); *Bay Center Apartments Owner, LLC v. Emery Bay PKI, LLC*, 2009 WL 1124451, at *7 (Del. Ch. Apr. 20, 2009) (TABLE) (holding that even where an agreement granted one party broad managerial powers, the party had to exercise this discretion in good faith and could not take arbitrary or unreasonable action that prevented the other party from receiving the fruits of the bargain); *Amirsaleh v. Bd. of Trade*, 2008 WL 4182998, at *8 (Del. Ch. Sept. 11, 2008) (TABLE) ("Simply put, the implied covenant requires that the 'discretion-exercising party' make that decision in good faith."); *Gilbert v. El Paso Co.*, 490 A.2d 1050, 1055 (Del. Ch. 1984) ("[I]f one party is given discretion in determining whether the condition in fact has occurred that party must use good faith in making that determination."), *aff'd*, 575 A.2d 1131 (Del. 1990).

[117] *Glaxo Grp.*, 248 A.3d at 919 (quoting *Amirsaleh*, 2008 WL 4182998, at *1).

unanticipated development arises, "the court has in its toolbox the implied covenant of good faith and fair dealing to fill in the spaces between the written words."[118]

We have repeatedly emphasized that this gap-filling power is a "limited and extraordinary remedy"; a "cautious enterprise" that applies only where there is a true contractual gap about how to handle an unforeseen event.[119] In *Nemec v. Shrader*, we held that the implied covenant only applied to "developments that could not be anticipated, not developments that the parties simply failed to consider."[120] In *Nemec*, retired executives argued that the implied covenant should be invoked to prevent the corporation from redeeming the retirees' shares immediately before a lucrative sale, depriving the retirees of the substantially higher merger consideration.[121] We rejected the retirees' claims. Though harsh in hindsight, the stock plan under which the shares were issued authorized the corporation to redeem the shares at book value "at any time," and a later sale of the company fell within the gamut of events that "could have been anticipated" when the stock plan was enacted.[122] The implied covenant, we held, is "not an equitable remedy for rebalancing economic interests after events that could have been anticipated, but

[118] *Glaxo Grp.*, 248 A.3d at 919.

[119] *Nemec*, 991 A.2d at 1125, 1128; *Oxbow Carbon*, 202 A.3d at 507.

[120] *Nemec*, 991 A.2d at 1126.

[121] *Id.* at 1123–25.

[122] *Id.* at 1123, 1128.

were not, that later adversely affected one party to a contract."[123] As *Nemec* teaches, hindsight cannot correct oversight.

In *Oxbow Carbon*, we underscored that the threshold inquiry is whether there is genuine contractual silence to the unforeseen development. There, the dispute arose from a joint venture among Oxbow's founder, Koch affiliates, and two private equity funds—Crestview and Load Line—which negotiated an LLC agreement with detailed capital-structure provisions and two distinct exit-sale rights.[124] One exit right benefitted Oxbow's founder alone and required a 2.5x return to Crestview and Load Line; the other was designed for the private equity investors and allowed them to force a sale so long as all "Members" received at least a 1.5x return.[125] Years later, however, the Board admitted so-called "Small Holders" at a much higher valuation, producing the unusual result that these new, relatively minor investors could single-handedly block the private equity funds' exit sale by virtue of the 1.5x return condition.[126] The Court of Chancery viewed this blocking scenario as an "extreme and unforeseen result" and used the implied covenant to preserve what it believed were Crestview's and Load Line's original economic expectations.[127] We

[123] *Id.* at 1128.

[124] *Oxbow Carbon*, 202 A.3d at 485.

[125] *Id.* at 504.

[126] *Id.* at 490.

[127] *Id.* at 498–500.

reversed, emphasizing that the proper inquiry is not whether this exact configuration was expected, but whether the contract structure as a whole showed that the parties "anticipated differing scenarios regarding the [unforeseen event]" even if they did not foresee this exact event.[128]

Several contractual markers confirmed that the parties had anticipated differing scenarios regarding a possible exit sale. The LLC Agreement authorized the admission of new Members "on such terms and conditions as the Directors may determine," and the definition of "Member" expressly encompassed later-admitted holders.[129] The agreement also contained a suite of negotiated protections—preemptive rights, related-party safeguards, and calibrated 1.5x and 2.5x exit thresholds—that "contemplated that new Members could be admitted" and "anticipated differing scenarios regarding a possible Exit Sale."[130] Even if this specific blocking scenario was improbable, the parties' "sloppiness and failure to consider the implications of the Small Holders' investment" did not make it unanticipated in the *Nemec* sense.[131]

[128] *Id.* at 504.

[129] *Id.* at 491.

[130] *Id.* at 504.

[131] *Id.* at 505.

We reiterated in *Glaxo Group Ltd. v. DRIT LP* that the implied covenant "cannot be invoked when the contract addresses the conduct at issue."[132] There, a patent license and settlement agreement required Glaxo to pay royalties until the last "Valid Claim" of certain patents expired, and "Valid Claim" was defined to exclude claims that had been "disclaimed."[133] After Glaxo statutorily disclaimed a key patent to end its royalty obligation, the Superior Court treated that strategic disclaimer as an unanticipated development and invoked the implied covenant to preserve the licensee's expected royalty stream.[134] We reversed, holding that the implied covenant "cannot be invoked when the contract addresses the conduct at issue."[135] Because the agreement's definition of "Valid Claim" expressly contemplated that Glaxo might "disclaim" a patent and excluded disclaimed patents from the royalty base, "there [wa]s no gap to fill," and the licensee could not "use the implied covenant to vary the express terms of the Agreement."[136] As we explained, "[t]he time to demand restrictions on an express contractual right was during negotiations—not years later through the implied covenant."[137]

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[132] *Glaxo Grp.*, 248 A.3d at 919.

[133] *Id.* at 914.

[134] *Id.* at 915–16.

[135] *Id.* at 920.

[136] *Id.* at 920–21.

[137] *Id.* at 920.

Our decision in *Cincinnati SMSA Ltd. Partnership v. Cincinnati Bell Cellular Systems Co.* is perhaps the most useful analog to this case since it deals with an unforeseen regulatory development. There, a limited partnership agreement barred the general partner from competing in "Cellular Service," a term defined by reference to then-existing Federal Communications Commission ("FCC") "cellular" licenses.[138] Years later, the FCC created a new class of personal communications services ("PCS") licenses.[139] The limited partners urged us to treat PCS as an unforeseen development and to deploy the implied covenant to expand the non-compete to this new technology. We declined. We held that, because the agreement unambiguously tied the non-compete to "Cellular Service" as then defined, the covenant could not be used to enlarge the scope of the restriction to cover PCS—even if the emergence of PCS had not been specifically foreseen at signing.[140] The parties had chosen their unit of reference, and we would not use the implied covenant to supply a broader one after the fact.

Nemec, *Oxbow Carbon*, *Glaxo Group*, and *Cincinnati* define how "limited and extraordinary" the implied covenant is as a remedy in sophisticated, contract-driven commercial settings. The covenant applies only where there is a genuine

[138] *Cincinnati*, 708 A.2d at 991.

[139] *Id.* at 991.

[140] *Id.* at 993.

contractual gap about a truly unanticipated development and only then to vindicate the parties' shared expectations at signing.[141] If a development could have been anticipated, even if it was unlikely to occur, the implied covenant cannot be invoked to provide protections that "easily could have been drafted" at the bargaining table.[142]

Applying these principles, we conclude that there is no genuine contractual gap in the Merger Agreement for the implied covenant to fill. The Agreement does not speak in general terms about "regulatory approval"; it conditions each regulatory

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[141] See, e.g., *Gerber*, 67 A.3d at 419–22 (holding that a limited partner stated an implied-covenant claim where the LPA created a "Special Approval" safe harbor based on a fairness opinion but was silent as to how that opinion would be obtained and what it had to opine on; the complaint alleged the general partner relied on an opinion that did not assess the fairness of the actual consideration received in the challenged transaction, conduct the Court concluded the parties "could hardly have anticipated" when they agreed to the safe harbor); *Dieckman*, 155 A.3d at 367–69 (recognizing an implied-covenant claim where a conflicts-committee and unaffiliated-unitholder "safe harbor" did not address the general partner's use of a structurally conflicted committee and misleading proxy disclosures to create the false appearance of independence; the Court held that implied in those safe-harbor provisions was an obligation not to undermine the protections unitholders reasonably expected when they agreed to the conflict-resolution mechanisms).

[142] *Nationwide Emerging Mgrs.*, 112 A.3d at 897 (quoting *Allied Capital Corp. v. GC-Sun Hldgs., L.P.*, 910 A.2d 1020, 1035 (Del. Ch. 2006)). The Court of Chancery's decision in *Squid Soap* further supports this proposition. In *Squid Soap*, the seller argued that the buyer breached the implied covenant by failing to spend at least $1 million on marketing to support an earnout. 984 A.2d at 132. The asset purchase agreement, however, contained no mandatory minimum spend obligation; instead, it provided for an earnout and an asset return mechanism if performance targets were not met. *Id.* at 133. The court rejected the implied covenant claim, holding that the seller could not convert its assumptions about how the buyer would operate the business into an implied obligation to devote a specific budget to marketing when a mandatory spend covenant "easily could have been drafted." *Id.* at 146. From *Squid Soap*, we learn that the implied covenant cannot be used to retrofit an earnout to match the disappointed seller's expectations after-the-fact about how the buyer would pursue the earnout.

earnout, in express and repeated language, on achieving "510(k) premarket notification." As in *Cincinnati*, where the parties tied their non-compete to "Cellular Service" as that term was then defined by the FCC and could not later invoke the implied covenant to expand that restriction to a new PCS regime, Auris and J&J anchored their milestones to a specific regulatory category and nothing more. That drafting choice forecloses any claim that the contract is silent about what form of FDA clearance would suffice. If anything, the hindsight problem was more acute in *Cincinnati*: PCS did not exist at the time of contracting, whereas here the De Novo pathway was established and available to the parties when they elected to condition each regulatory milestone on 510(k) alone.

Other provisions within the Merger Agreement acknowledged differing possible regulatory scenarios. The carefully negotiated definition of "commercially reasonable efforts" expressly permitted J&J to calibrate its efforts in light of "guidance or developments from the FDA" and the "likelihood and difficulty of obtaining FDA or other regulatory approval."[143] Elsewhere, the contract underscored this allocation of risk, warning that the milestones were "subject to a variety of factors and uncertainties, including many outside of [J&J's] control, and as a result, some or all of the Earnout Payments may never be paid."[144] As in *Oxbow*

[143] Merger Agreement §§ 2.07(e)(ii)(E), (I).

[144] *Id.* § 2.07(e)(v).

Carbon, where the authorization to admit new "Members" and the calibrated 1.5x and 2.5x thresholds "anticipated differing scenarios regarding a possible Exit Sale," these provisions show that the parties contemplated that FDA developments could affect the value and achievability of the contingent right.

Yet Auris and J&J chose to explicitly tie every regulatory milestone—totaling hundreds of millions of dollars—to "510(k) premarket notification," and only to that pathway. They neither defined the milestones by reference to "regulatory approval by 510(k) or any successor or alternative pathway" nor provided that the earnouts would adjust if the FDA closed the 510(k) route or extended its review. Reading the Merger Agreement in the light of *Cincinnati* and *Oxbow Carbon*, there is no contractual gap for the implied covenant to fill. J&J and Auris recognized the possibility that FDA "developments" could affect the route, timing, and cost of approval, and they nonetheless chose to condition the earnout on 510(k) clearance alone.[145]

[145] Our decision in *Dieckman* does not alter the analysis. *See Dieckman*, 155 A.3d at 366–71. *Dieckman* involved a contract that left meaningful room for discretion—specifically, discretion in pursuing contractual safe-harbor approvals that would cleanse a conflicted transaction—and the implied covenant operated to prevent conduct that would make those bargained-for protections illusory. Here, by contrast, the Merger Agreement left no room for discretion: Milestone 1 turns on a binary, objective trigger—FDA "510(k) premarket notification." Fortis's implied-covenant theory therefore would not police the exercise of contractual discretion; it would instead treat a different FDA pathway as satisfying the express 510(k) condition, rewriting the parties' chosen trigger rather than filling any contractual gap.

We also conclude that the FDA's regulatory switch from 510(k) to De Novo, although believed to be unlikely, was not unforeseeable at the time of contracting. Auris and J&J contracted in a field in which FDA discretion determines outcomes. Auris had already experienced the 510(k) process for earlier devices and understood that the FDA would ultimately select a suitable pathway based on the device's novelty.[146] Federal regulations make clear that the FDA alone determines whether a device is eligible for 510(k) clearance and that the agency may, after reviewing a submission, require a different pathway if the device presents novel technological characteristics.[147] A sophisticated acquiror and a serial device innovator operating in that environment can reasonably foresee that a first-generation RASD with new features may be steered away from 510(k), even if 510(k) remained the likeliest route at signing.

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[146] Opinion at 30–31 (noting that "Monarch . . . had already attained FDA clearance for bronchoscopy and was approved only for lung procedures").

[147] *See* 21 C.F.R. § 807.100(a).

> After review of a premarket notification, FDA will:
>
> (1) Issue an order declaring the device to be substantially equivalent to a legally marketed predicate device;
> (2) Issue an order declaring the device to be not substantially equivalent to any legally marketed device;
> (3) Request additional information; or
> (4) Withhold the decision until a certification or disclosure statement is submitted to FDA under part 54 of this chapter.
> (5) Advise the applicant that the premarket notification is not required. Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.

The record confirms that this was not a theoretical concern. Months before signing, Auris specifically probed the availability of the 510(k) pathway for iPlatform and received pointed feedback from the FDA that 510(k) clearance was uncertain. In an October 2018 pre-submission interaction, the FDA warned that "510(k) might be unavailable" because it was "unclear if the 510(k) pathway is appropriate" for iPlatform, given its "technological characteristics different from the predicate." At the time, the FDA flagged the need for clinical data.[148] At a follow-up meeting on November 8, 2018, the FDA again emphasized iPlatform's divergence from the proposed da Vinci predicate, including its bronchoscope integration and additional robotic arms.[149] Although Auris later removed bronchoscopy from the initial indication, those communications made clear that the FDA viewed iPlatform as meaningfully different from the predicate and that the suitability of 510(k) remained in doubt.[150]

At the same time, the FDA was publicly signaling a broader policy shift. By late 2018, the agency had publicly announced that it was "taking steps to modernize" the 510(k) program and had proposed a rule discouraging "inappropriate" 510(k)

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[148] *See* Opinion at 101; App. to Appellants' Opening Br. at A3938–40 (explaining the differences between iPlatform and its predicate device).

[149] App. to Appellants' Opening Br. at A5441 (quoting the minutes of the November 8, 2018 meeting where the "FDA noted the difference of having six (6) robotic arms and asked for a clinical scenario where 5 or 6 arms would be used").

[150] Opinion at 101.

submissions for novel devices that should proceed through the De Novo pathway instead.[151] Those public statements, combined with the FDA's private feedback to Auris, meant that a sophisticated medical device company and acquiror could reasonably foresee the risk that a first-of-its-kind RASD flagged as potentially too novel for 510(k) might ultimately be routed to De Novo review.

Fortis responds by emphasizing the Court of Chancery's finding that, at signing, 510(k) was the "only logical pathway" and that the FDA had previously accepted 510(k) submissions for other RASDs, such as da Vinci and Monarch.[152] Those points go to likelihood, not foreseeability. The implied covenant does not ask whether the parties expected a particular risk to materialize or whether one result seemed the most "logical." It asks whether the possibility of a different outcome fell within the range of risks that reasonable parties in their position could anticipate and bargain over. Although the parties believed that 510(k) was the most probable and commercially attractive pathway for iPlatform—indeed, that is why they chose it—

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[151] *See* Motion to Dismiss Opinion at 9 ("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."); *see also* 83 Fed. Reg. 63,127 (proposed Dec. 7, 2018) (to be codified at 21 C.F.R. pt. 860) (proposing a rule to encourage greater use of the De Novo pathway by streamlining the De Novo approval process for Class I and II medical devices); *see also* U.S. Food & Drug Admin., *Medical Device De Novo Classification Process (Proposed Rule) Regulatory Impact Analysis* (Feb. 1, 2019), https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/medical-device-de-novo-classification-process-proposed-rule-regulatory-impact-analysis ("We expect that the rule would reduce the likelihood that medical device manufacturers submit inappropriate 510(k) requests for their De Novo devices and improve the quality of De Novo requests.").

[152] Appellee's Answering Br. at 29.

they still could reasonably foresee that the FDA might exercise its discretion differently for a complex, first-generation RASD in a policy environment that the FDA was actively "modernizing." Prior comfort with 510(k) for earlier Auris products did not guarantee that the FDA would reach the same conclusion for later devices; it simply showed that the risk that the FDA would change its pathway requirements was a low risk, but a risk nonetheless.

Therefore, the implied covenant has no role to play here. The doctrine is reserved for "developments that could not be anticipated, not developments that the parties simply failed to consider," and it cannot be invoked as "an equitable remedy for rebalancing economic interests after events that could have been anticipated but were not."[153] Here, as in *Oxbow Carbon*, *Glaxo*, and *Cincinnati*, the type of risk that materialized was both foreseeable and addressed in the parties' agreement. The Merger Agreement acknowledged that FDA "developments" may affect the route, timing, and cost of approval, yet expressly conditioned the earnouts on 510(k) clearance alone and omitted any obligation to pursue De Novo review or to treat any FDA approval as sufficient.[154] This additional protection for Milestone 1 "easily could have been drafted," and should have been secured *ex ante* at the bargaining

[153] *Nemec*, 991 A.2d at 1126, 1128.

[154] Merger Agreement §§ 2.07(e)(ii)(E), (I).

table, rather than *ex post* in the courtroom.[155] We therefore reverse the Court of Chancery's holding that J&J had an implied obligation to pursue De Novo review for Milestone 1 once the FDA closed the 510(k) pathway to iPlatform's first indication.[156]

2. Our implied covenant holding does not disturb the Court of Chancery's rulings as to the remaining iPlatform milestones.

The implied covenant was the necessary premise of the Court of Chancery's damages award for Milestone 1. After the FDA closed the 510(k) pathway for iPlatform's first clearance, the court invoked the implied covenant to treat De Novo as the functional equivalent of the Merger Agreement's 510(k) requirement. Only

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[155] *Nationwide Emerging Mgrs.*, 112 A.3d at 897 (quoting *Allied Capital*, 910 A.2d at 1035) ("An interpreting court cannot use the implied covenant to rewrite the agreement between the parties, and 'should be most chary about implying a contractual protection when the contract could easily have been drafted to expressly provide for it.'"); *Winshall*, 76 A.3d at 816 ("[T]he implied covenant cannot be used to give plaintiffs contractual protections they failed to secure at the bargaining table.").

[156] In a footnote, Fortis argues that if we reverse on the implied covenant as to Milestone 1, we should remand to the Court of Chancery for consideration of its specific performance claim that the court mooted. Appellee's Answering Br. at 36 n.14. That claim sought to enforce Section 10.11 of the Merger Agreement, which required the parties "[u]pon such determination that any term or other provision is invalid, illegal or incapable of being enforced . . . [to] negotiate in good faith to modify this Agreement so as to effect the original intent of the parties . . . ." Merger Agreement § 10.11. Since this argument was raised in a footnote, however, it is waived. Del. Supr. Ct. R. 14(b)(vi)(A)(3) ("The merits of any argument that is not raised in the body of the opening brief shall be deemed waived and will not be considered by the Court on appeal."); Del. Supr. Ct. R. 14(d)(iv) ("Footnotes shall not be used for argument ordinarily included in the body of a brief."); *Murphy v. State*, 632 A.2d 1150, 1152 (Del. 1993) ("The failure to raise a legal issue in the text of the opening brief generally constitutes a waiver of that claim on appeal."). Further, it is far from clear how specific performance of this contractual term could be accomplished at this stage. *See, e.g.*, *PharmAthene, Inc. v. SIGA Techs., Inc.*, 2014 WL 3974167, at *5 (Del. Ch. Aug. 8, 2014) (TABLE) (noting that specific performance would not be an appropriate remedy because it was no longer feasible to enforce the parties' intended bargain).

after making that substitution could the court value Milestone 1 as though the parties' original 510(k)-based bargain remained intact.

Reversing the implied covenant ruling undermines the fundamental premise of the court's Milestone 1 award. Milestone 1 does not require regulatory clearance in the abstract; it requires a "510(k) premarket notification." A De Novo approval is not a "510(k) premarket notification," and absent the implied covenant, we have no authority to treat it as one. The court's finding that the difference between 510(k) and De Novo approval for Milestone 1 had an "immaterial effect on the time and cost for iPlatform to gain FDA clearance" does not rescue the Milestone 1 damages award.[157] Immateriality bears on comparative burden; it does not rewrite a contractual requirement that the parties expressed in unambiguous terms. Accordingly, once 510(k) became unavailable for iPlatform's first clearance, Milestone 1's express condition could not be satisfied as written, and the damages award for Milestone 1 cannot stand.

The remaining milestones are different. Those milestones continue—by their plain terms—to require 510(k) notifications. The Court of Chancery found, and J&J does not challenge, that once iPlatform obtained De Novo approval for a first-generation indication, it could serve as its own predicate device and proceed through

[157] Opinion at 103.

the 510(k) pathway for additional indications.[158] Accordingly, although the implied covenant did not require J&J to pursue De Novo approval in order to achieve Milestone 1, J&J remained obligated to use commercially reasonable efforts to pursue 510(k) approval for the remaining milestones, including by seeking De Novo approval for an initial indication where necessary to facilitate 510(k) clearance for subsequent indications.[159] The unavailability of 510(k) for a general surgery indication did not excuse J&J from the later milestones. Reversing the implied covenant rewrite of Milestone 1 therefore does not disturb J&J's express obligations, or the damages awarded, for the remaining regulatory milestones.

Nevertheless, J&J argues that the De Novo requirement for Milestone 1 should relieve its obligations as to the remaining milestones, contending that De Novo review is so much more onerous that "all the milestones, timelines, and payments" would have changed had De Novo been required to unlock 510(k).[160] J&J notes that "De Novo applications have at best a coinflip's odds of receiving approval, as compared to the 84–86% approval rate for 510(k) applications."[161] J&J therefore characterizes the Court of Chancery's reasoning on the later milestones

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[158] *Id.* at 49 ("[O]nce iPlatform obtained De Novo approval, it could use the 510(k) pathway for future indications by serving as its own predicate device."); *see also id.* at 92, 99 n.515 (same).

[159] *Id.* at 104.

[160] Appellants' Opening Br. at 36.

[161] *Id.* at 37.

and associated damages as resting on a "daisy chain of assumptions" about the timing and likelihood of De Novo approval.[162]

Here, however, the court's immateriality finding does affect the analysis. The court found that, for iPlatform, the shift from 510(k) to De Novo had an "immaterial effect on the time and cost for iPlatform to gain FDA clearance."[163] The court credited contemporaneous J&J analyses that projected only a sixty-day delay for iPlatform's review; the FDA had already required extensive clinical data for iPlatform under 510(k), meaning that Milestone 1 would not require the additional testing, verification, or pre-clinical work that typically makes De Novo review more onerous.[164] Because the sixty-day delay was within the five-month buffer that Auris had built into the Milestone 1 schedule, the court found that there would be "no significant timeline differences" between 510(k) and De Novo for iPlatform, even if

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[162] *Id.* at 34–35. The "daisy chain of assumptions" were:

1. J&J was obligated to use the De Novo pathway to satisfy Milestone 1;
2. J&J would have obtained a De Novo grant for Milestone 1, even though the odds were about half as good;
3. J&J would have secured that grant for Milestone 1 quickly enough to use it as a predicate for the follow-on milestones, despite the extra time needed for the De Novo pathway;
4. following a De Novo grant, the FDA would then have exercised its discretion to allow J&J to use the 510(k) pathway for subsequent iPlatform and GI milestones; and
5. all the remaining iPlatform and GI milestones were 'likely to be met' by the contractual deadlines.

[163] Opinion at 103.

[164] *Id.* at 102.

there might be in general.[165] The general statistics comparing De Novo and 510(k) approval rates that J&J cites do not show clear error in the court's specific factual determinations regarding iPlatform.

The same logic explains why our reversal on Milestone 1 does not undo the court's damages awards for the remaining milestones. Having found that the pathway change did not materially alter iPlatform's prospects or timeline in the relevant sense—and that De Novo clearance could serve as a predicate enabling later 510(k) submissions—the court held that the parties' pre-merger probability-of-success estimates remained "[t]he best evidence of how the milestones would have fared."[166] J&J has shown no clear error in those factual determinations or abuse of discretion in the court's choice of damages methodology.[167]

Accordingly, we vacate the damages awarded for Milestone 1 only. We otherwise affirm the judgment, including the damages award for the remaining regulatory milestones.

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[165] *Id.* at 48.

[166] *Id.* at 130.

[167] J&J repeats its argument that De Novo approval rates in general are lower than 510(k), but this does not show clear error in the Court of Chancery's factual determination that the approval likelihoods were "immaterial[ly]" different as to Milestone 1 and iPlatform specifically. Appellants' Opening Br. at 37.

B. Breach of contract

We now turn to the Court of Chancery's holding that J&J breached the Merger Agreement as to the remaining iPlatform regulatory milestones. The court held that J&J breached Section 2.07(e) of the Merger Agreement by failing to use commercially reasonable efforts to meet the iPlatform regulatory milestones consistent with the efforts that J&J would give to another of its priority medical devices.[168] This failure, the court found, caused J&J to miss the remaining iPlatform regulatory milestones.[169]

Section 2.07(e)(i) of the Merger Agreement required J&J to use "commercially reasonable efforts to achieve each of the Regulatory Milestones."[170] The parties carefully negotiated a tailored definition of "commercially reasonable efforts." Section 2.07(e)(ii) defines "commercially reasonable efforts" as:

> the expenditure of efforts and resources in connection with research and development and obtaining and furnishing of information to and communications with applicable Governmental Entities in connection with obtaining the applicable 510(k) premarket notification with respect to the applicable Robotics Products ***consistent with the usual practice of Parent and its Affiliates with respect to priority medical***

[168] Opinion at 83.

[169] *Id.* at 104 ("The evidence demonstrates that each of these umbrella milestones were likely to be met had J&J provided commercially reasonable efforts and resources to iPlatform as a priority device.").

[170] Merger Agreement § 2.07(e)(i) ("Efforts; Certain Transfers").

> ***device products*** of similar commercial potential at a similar stage in product lifecycle to the applicable Robotics Products[.][171]

Although the phrase "priority medical device" is undefined in the Merger Agreement, the Court of Chancery identified Velys—an orthopedic RASD—as the only available comparator.[172] To assess whether J&J breached its efforts obligations, therefore, the court compared J&J's treatment of iPlatform and Monarch to its treatment of Velys.

Section 2.07(e)(ii) listed ten factors that J&J could "take into account" in setting its level of efforts for a "priority medical device":

> (A) issues of efficacy and safety, (B) the risks inherent in the development and commercialization of such products, (C) the expected and actual competitiveness of alternative products sold or licensed by third parties in the marketplace, (D) the expected and actual patent and other proprietary position of the product, (E) the likelihood and

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[171] *Id.* § 2.07(e)(ii) (emphasis added); *see also id.* § 10.03(eee) (defining "Robotics Products"). This efforts provision is often termed an "inward facing" efforts obligation, requiring the buyer to use a level of effort that the buyer would use in developing, marketing or selling its own similar products. Another common type of efforts provision is the "outward facing" efforts obligation, which requires the buyer to use the same level of effort that similar industry participants would use for similar products under similar circumstances. The parties could tailor an "outward facing" efforts obligation to define what "similar" participants or products to measure the buyer's efforts against. Typically, an "inward-facing" obligation is more buyer-friendly as the buyer's efforts are measured against its own past practice in similar situations. *See, e.g.*, F. Dario de Martino, Clare O'Brien, and Mara Goodman, *The Art and Science of Earn-Outs in M&A*, HARV. L. SCH. F. ON CORP. GOV. (July 11, 2025), https://corpgov.law.harvard.edu/2025/07/11/the-art-and-science-of-earn-outs-in-ma (discussing the benefits of different types of earnout efforts provisions). But where, as here, the buyer is an industry leader, an "inward-facing" obligation can become much more seller-friendly, especially if the efforts are tied to the industry leader's "priority" products. Opinion at 37 ("The efforts supplied were to be measured by J&J's own standards, which J&J assured Auris was beneficial since J&J was 'the biggest healthcare company in the world' with standards exceeding the industry.").

[172] Opinion at 67 ("J&J identified a single comparator 'priority medical device at a similar stage in product lifecycle' to iPlatform and Monarch: an orthopedic RASD called Velys.").

> difficulty of obtaining FDA and other regulatory approval given the nature of the product and the regulatory structure involved, (F) the regulatory status of the product and scope of any marketing approval, (G) pending or actual legal proceedings with respect to the applicable Robotics Product, (H) whether the product is subject to a clinical hold, recall or market withdrawal, (I) input from regulatory experts and any guidance or developments from the FDA or similar Governmental Entity, including as it may affect the data required to obtain premarket approval from the FDA or any similar approval from another Government Entity and (J) the expected and actual profitability and return on investment of the product, taking into consideration, among other factors, the expected and actual (1) third party costs and expenses, (2) royalty and other payments and (3) pricing and reimbursement relating to the product(s).[173]

Finally, Section 2.07(e)(iii) prohibited J&J from taking "any action":

> (A) with the intention of avoiding any of Parent's obligations to pay any Earnout Payment or (B) based on taking into account the cost of making any Earnout Payment(s) made, or actually or potentially to be made, pursuant to this Agreement.[174]

Taken together, Section 2.07(e) provided Auris with several layers of protection.[175]

After a two-week trial, the Court of Chancery made numerous factual findings in support of its conclusion that "J&J did not devote commercially reasonable efforts to achieve the [iPlatform] milestones consistent with those given to a priority device."[176] Specifically, the court held that a priority device benefitting from

[173] Merger Agreement § 2.07(e)(ii).

[174] *Id.* § 2.07(e)(iii).

[175] Opinion at 67.

[176] *Id.* at 64.

commercially reasonable efforts would not experience (i) Project Manhattan,[177] (ii) the Verb combination and integration,[178] (iii) a thwarting of its MVP strategy,[179] and (iv) the changed employee incentives.[180] Indeed, Velys—J&J's identified comparable priority device—was not exposed to any of this treatment.[181] Based on its factual findings, the court held that:

> Had J&J used commercially reasonable efforts in furtherance of the iPlatform General Surgery Milestone, the 510(k) pathway would have been open. The delays caused by Project Manhattan and dysfunction from the Verb combination/integration, among other breaches, led to compounding delays that put the milestones in peril. The evidence demonstrates that each of these umbrella milestones were likely to be met had J&J provided commercially reasonable efforts and resources to iPlatform as a priority device.[182]

J&J does not appeal these factual findings. Instead, J&J argues that the court misinterpreted the structure of Section 2.07(e). The court read Section 2.07(e) in order: (1) Section 2.07(e)(i) required J&J to use "commercially reasonable efforts"

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[177] *Id.* at 69–72 ("Project Manhattan alone is sufficient to find that J&J breached its efforts obligation in Section 2.07(e) of the Merger Agreement. A 'priority' device would not have to endure a costly battle merely to remain operative.").

[178] *Id.* at 72–75 ("A 'priority' device would not have its system, technology, and team diluted to fix another device's problems.").

[179] *Id.* at 75–80 ("J&J's insistence that iPlatform focus on a complex umbrella procedure to satisfy the General Surgery Milestone was not commercially reasonable in view of J&J's obligation to devote efforts befitting a priority medical device.").

[180] *Id.* at 80–82 ("These different inducements, coupled with J&J's communications to Auris that the milestones were 'canceled,' negatively affected employees' motivation to work towards the iPlatform and GI regulatory milestones in the Merger Agreement.").

[181] *Id.* at 82.

[182] *Id.* at 104.

to achieve the regulatory milestones; (2) Section 2.07(e)(ii) mandated that those efforts be in line with its "usual practice" for "priority medical device[s]"; and (3) Section 2.07(e)(ii) then provided guidance on what factors J&J could take into account to "reasonably calibrate its efforts" within the bounds of J&J's "usual practice" for a "priority medical device." Reading the contract this way, the court explained that "[a]lthough the ten factors J&J could consider in expending efforts and resources gave it some measure of discretion, the mandate that J&J follow its 'usual practice' for 'priority medical device[s]' cabined it."[183]

J&J argues that this approach "effectively excised the ten factors" in Section 2.07(e)(ii) and stripped away J&J's bargained-for right to exercise its discretion and commercial judgment.[184] In J&J's view, "the ten factors expressly qualify the 'priority medical device' clause" and "preserve J&J's discretion to make the sorts of business judgments that any acquiring company would insist on, including the prerogative to temper any efforts to meet the milestones based on J&J's own business judgments regarding commercial risk, profitability, competitiveness of the planned device, and return on investment."[185] Accordingly, J&J contends that the court committed legal error by reading Section 2.07(e)(ii) as requiring that "[a]ny

[183] *Id.* at 67.

[184] Appellants' Opening Br. at 40–42.

[185] *Id.* at 43.

step J&J undertook had to advance the 'end goal' of 'achiev[ing] the iPlatform regulatory milestones'" no matter how compelling the business reason to do otherwise.[186]

According to J&J, under a legally correct reading of Section 2.07(e)(ii), Project Manhattan, the Verb integration and combination, the move away from an MVP strategy, and the changed employee incentives were "commercially reasonable efforts to achieve each of the Regulatory Milestones" because they were justified by one or many of the ten factors that the court erroneously excised.[187] To J&J: (i) Project Manhattan was an investigation of "issues of efficacy and safety," "risks inherent in [iPlatform's] development and commercialization," and "expected and actual competitiveness of alternative products";[188] (ii) the Verb combination and integration was an assessment of the "risks inherent in development," the "competitiveness of" third-party products, "issues of efficacy," commercialization risk, and expected profitability;[189] (iii) the decision not to pursue the MVP strategy was a business decision to better "serve the aims of competitiveness and

[186] *Id.* at 41 (quoting Opinion at 75); *see also* Appellants' Opening Br. at 42–43 ("No sound business does that—a merger agreement is not a suicide pact—and J&J did not agree to it here.").

[187] Appellants' Opening Br. at 42 ("In defining the required efforts based on these ten factors, the contract necessarily means that any one or combination of these factors could outweigh any imperative to achieve each milestone.").

[188] *Id.* at 45 (quoting Merger Agreement §§ 2.07(e)(ii)(A)–(C)).

[189] *Id.* at 53–54 (quoting Merger Agreement §§ 2.07(e)(ii)(A)–(C), (J)).

profitability";[190] and (iv) the change in employee incentives reflected "developments from the FDA" and a recognition of "the likelihood and difficulty of obtaining FDA . . . approval."[191] J&J asserts that "[u]nder the proper interpretation of the contract, none of J&J's actions were breaches."[192]

We disagree with J&J's reading and affirm the Court of Chancery's interpretation. Delaware law instructs courts to evaluate "the contract as a whole" and to give effect to all its provisions.[193] We avoid interpretations that render contractual language superfluous or internally inconsistent,[194] and we "must read the specific provisions of the contract in light of the entire contract."[195]

Read in that fashion, J&J's construction of Section 2.07(e) cannot be sustained. Section 2.07(e)(i) begins by imposing an affirmative obligation on J&J to "use commercially reasonable efforts to achieve each of the Regulatory Milestones."[196] Section 2.07(e)(ii) then defines "commercially reasonable efforts" by tying J&J's conduct to its "usual practice . . . with respect to priority medical device products of similar commercial potential at a similar stage in product

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[190] *Id.* at 47 (quoting Merger Agreement § 2.07(e)(ii)(J)).

[191] *Id.* at 55 (quoting Merger Agreement §§ 2.07(e)(ii)(E), (I)).

[192] Appellants' Opening Br. at 6.

[193] *Kuhn Constr., Inc. v. Diamond State Port Corp.*, 990 A.2d 393, 396 (Del. 2010).

[194] *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citation omitted).

[195] *Chi. Bridge & Iron Co. N.V. v. Westinghouse Elec. Co. LLC*, 166 A.3d 912, 926–27 (Del. 2017).

[196] Merger Agreement § 2.07(e)(i).

lifecycle," and only thereafter permits J&J to "tak[e] into account" ten specified considerations in calibrating the level of effort within those bounds.[197]

J&J's reading inverts that structure. It elevates the "taking into account" clause over the definition that precedes it, allowing the ten factors to swallow the "priority medical device" requirement and to justify deprioritizing the milestones whenever J&J believed profitability, competitive positioning, or other business concerns listed in the ten factors pointed in a different direction. That interpretation reduces to little more than surplusage the "priority" language and the express instruction in Section 2.07(e)(i) that efforts be directed "to achieve each of the Regulatory Milestones."

J&J's application of its construction of Section 2.07(e) to Project Manhattan and the Verb combination and integration highlights this surplusage. In factual findings that J&J did not appeal, the Court of Chancery found that "J&J knew that Project Manhattan would hinder, rather than promote, iPlatform's achievement of the regulatory milestones." The court likewise found that J&J's subsequent decision to pursue a combined Verb–iPlatform robot was made in the knowledge that the combination and the resulting internal chaos would "doom the milestones," and that senior leadership approved the "combined scenario" precisely because its "overall

[197] *Id.* § 2.07(e)(ii).

value case" improved "when you consider what will also happen with the contingent payment"—that is, when J&J failed to achieve the milestones.

Construing the contract to allow J&J to do what it did and still satisfy its efforts obligation would leave the "priority medical device" language in Section 2.07(e)(ii) with no work to do. That provision requires J&J to exert efforts "consistent with [its] usual practice . . . with respect to priority medical device products of similar commercial potential at a similar stage in product lifecycle."[198] The Court of Chancery found that J&J continued to resource and advance Velys—the only priority comparator device—without subjecting it to a head-to-head product competition, a product integration, an abandoned regulatory strategy, or a changed employee-incentive structure.[199] Under J&J's construction, the difference in treatment between iPlatform and Velys would carry no contractual consequence: so long as J&J could invoke one or more of the ten factors in Section 2.07(e)(ii), it was permitted to treat iPlatform in ways it never treated Velys and still claim to have satisfied its efforts obligation. Delaware law does not sanction leaving J&J's contractual agreement to exert efforts consistent with a "priority medical device" devoid of any meaning.

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[198] *Id.* § 2.07(e)(ii).

[199] Opinion at 67–68 (detailing J&J's treatment of Velys and noting that "iPlatform received starkly different treatment than Velys").

J&J's reading likewise would nullify Section 2.07(e)(iii), which prohibits J&J from "tak[ing] any action" either "with the intention of avoiding . . . any Earnout Payment" or "based on taking into account the cost of making any Earnout Payment(s)."[200] Under J&J's construction, J&J could use business concerns about "profitability" and "return on investment" to avoid the earnouts.[201] J&J endorsed the combined Verb–iPlatform scenario because its "overall value case" improved by avoiding the contingent payments.[202] In J&J's view, that is simply a rational assessment of profitability. Under the contract's terms, however, it is exactly the kind of earnout-avoiding decision making that the parties agreed to prohibit.[203] To read the contract otherwise would render Section 2.07(e)(iii) superfluous.

This is not to say that the ten factors served no purpose.[204] As the Court of Chancery's discussion of the Monarch milestones reflects, Section 2.07(e)(ii) leaves J&J room to calibrate its efforts within the "priority medical device" baseline.[205] Analyzing the Soft Tissue Ablation and Endourology milestones, the court held that

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[200] Merger Agreement § 2.07(e)(iii).

[201] *Id.* § 2.07(e)(ii)(J).

[202] Opinion at 73.

[203] *Id.* (quoting Merger Agreement § 2.07(e)(iii)) (holding that J&J's decision "was not only inconsistent with J&J's obligation to use commercially reasonable efforts to achieve the milestones . . . [but] was also contrary to J&J's promise not to act 'based on taking into account the cost of making any Earnout Payment(s)'").

[204] Appellants' Reply Br. at 17–18 (arguing that the court ignored the ten factors "when assessing each of the asserted iPlatform-related breaches").

[205] *See* Opinion at 83–88.

J&J's efforts, although "flawed" in hindsight, nonetheless were "commercially reasonable" because the ten factors gave J&J limited discretion over how to pursue those milestones.[206]

Consider the Soft Tissue Ablation Milestone. At trial, Fortis argued that after a patient death during the NeuWave FLEX catheter study left FLEX in "regulatory limbo," the efforts provision required J&J to promptly initiate a new clinical study.[207] J&J instead engaged in multiple discussions with the FDA to avoid additional clinical trials.[208] Those efforts ultimately resulted in delay; despite the discussions, the FDA still required further trials, and J&J missed the milestone deadline.[209] Even so, the court held that "J&J's efforts were commercially reasonable."[210] J&J's objective was to achieve the milestone;[211] and in selecting the route to get there, the ten factors permitted it to weigh "the regulatory status of the product and scope of any marketing approval, . . . whether the product is subject to

[206] *Id.* at 84 ("These actions, or lack thereof, were flawed and may [have] prompted unintended delays, but they are not commercially unreasonable under Section 2.07(e).").

[207] *Id.* at 85.

[208] *Id.*

[209] *Id.*

[210] *Id.* at 86.

[211] *Id.* at 87 ("Had J&J succeeded in persuading the FDA that [another clinical trial] was not needed for FLEX, it would have saved time for Monarch to meet the Soft Tissue Ablation Milestone.").

a clinical hold, recall or market withdrawal, [and] input from regulatory experts and any guidance or developments from the FDA."[212]

These aspects of the Monarch analysis confirm that the ten factors operated within the "priority medical device" requirement: the ten factors permitted J&J to choose among reasonable paths toward achieving the milestones, but they did not authorize J&J to take actions that predictably undermined the achievement of the iPlatform regulatory milestones in favor of other business objectives.

Because we agree with the Court of Chancery's legal interpretation of Section 2.07(e) and J&J does not challenge the court's factual findings, we affirm the court's determination that J&J breached Section 2.07(e) of the Merger Agreement as to the remaining iPlatform regulatory milestones.[213]

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[212] *Id.* (quoting Merger Agreement § 2.07(e)(ii)(F), (H)–(I)).

[213] J&J argues that even under this reading of Section 2.07(e), its efforts were commercially reasonable because it devoted substantial resources to Auris and iPlatform. *See* Appellants' Opening Br. at 44 (explaining that J&J spent $2.25 billion on the program and bought "two companies for a combined $175 million to give the Auris program additional technology and meet its need for 200 highly experienced employees"); Appellants' Reply Br. at 16 ("J&J spent at least $1.25 billion directly on developing the robot."). The Court of Chancery rejected that contention, finding that substantial portions of the cited expenditures were directed to Verb and other initiatives rather than to achieving the iPlatform regulatory milestones, and explaining that an obligation to use commercially reasonable efforts focuses on how a party deploys its resources toward the contractual objective, not on the absolute magnitude of its budget. Opinion at 83 ("An obligation to use commercially reasonable efforts in pursuit of iPlatform regulatory milestones is not equivalent to spending large sums on J&J's robotic program."). Because J&J has not shown that these factual findings are clearly erroneous, we agree with the Court of Chancery.

C. Fraud

Finally, J&J appeals from the Court of Chancery's finding that J&J fraudulently induced Auris to accept a $100 million earnout payment for Monarch's Soft Tissue Ablation Milestone.[214] J&J argues that: (1) the evidentiary record does not support the court's factual finding of fraud; and, regardless, (2) the contract's exclusive remedy provision bars Fortis's fraud claim.[215]

1. The court's fraud finding is supported by the record.

The Monarch Soft Tissue Ablation Milestone carried a $100 million earnout payment if, by the end of 2022, Monarch obtained 510(k) clearance for lung tissue ablation. To achieve the milestone, Monarch would need to use J&J's NeuWave FLEX catheter, which delivers microwave energy to ablate or destroy tissue. Although NeuWave FLEX had regulatory approval for soft tissue ablation, it was not yet approved for a lung-specific use. The milestone therefore depended on NeuWave FLEX achieving regulatory approval for lung procedures.

On January 24, 2019, J&J's Gorsky pitched the milestone to Auris, explaining that there was such a "high certainty" of achieving the milestone that J&J viewed it as an "effective up front payment."[216] In reality, the milestone "was not remotely

[214] Appellants' Opening Br. at 57.

[215] *Id.* at 59, 62.

[216] Opinion at 124.

certain to be met."[217] In June 2018, J&J had initiated a ten-patient study using FLEX to treat lung lesions.[218] On December 4, 2018, a study participant died weeks after being treated with FLEX.[219] On December 13, 2018, the FDA launched a for-cause, on-site inspection into whether the study had violated FDA rules.[220] Although J&J would not learn the outcome of the investigation until April 3, 2019, it was clear that the investigation risked substantial delay.[221] On January 14, 2019, J&J's deal team was briefed on the developments.[222] Ten days later, Gorsky represented to Auris that the milestone was an "effective up front payment." Auris did not learn of the patient death or the FDA investigation until after the merger closed.[223]

The Court of Chancery held that Gorsky's comment was fraudulent. Although it was "borderline" whether Gorsky's statement was an "overt misrepresentation," the court concluded that "it is undoubtedly active concealment

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[217] *Id.*

[218] *Id.* at 31.

[219] *Id.*

[220] *Id.* (explaining that the investigation was initiated because the study had not obtained an investigation device exemption in advance, which provides FDA approval to perform a clinical trial of a device that has not been cleared for marketing or the intended indication).

[221] *Id.* at 32, 125.

[222] *Id.* at 32 (noting that J&J's deal team "sought to understand whether the patient death was going to affect the overall value of Auris") (internal quotations omitted).

[223] *Id.* at 125. By this time, the FDA had informed J&J that they would need to conduct a new clinical study with an investigation device exemption. This process would take several years. *Id.* at 32.

of material facts."[224] J&J knew that a patient in the clinical study had recently died, the J&J Auris deal team had been briefed on the situation, and the investigation risked substantial delay.[225] Since "Gorsky's statement was intended to induce Auris to agree to a contingent payment and Auris justifiably relied on it" to their detriment, the court held J&J liable for common law fraud and awarded benefit-of-the-bargain damages.[226]

> The elements of common law fraud are:
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> > (1) a false representation, usually one of fact, made by the defendant; (2) the defendant's knowledge or belief that the representation was false, or made with reckless indifference to the truth; (3) an intent to induce the plaintiff to act or to refrain from acting; (4) the plaintiff's action or inaction taken in justifiable reliance upon the representation; and (5) damage to the plaintiff as a result of such reliance.[227]

The parties do not dispute that the final three elements are met. Gorsky's statement was made with the intent to induce Auris to accept the milestone payment in lieu of an upfront payment, and Auris relied on that statement in agreeing to the earnout. Auris was damaged when the milestone later proved unattainable within the contracted timeline. J&J, however, challenges the sufficiency of the evidence

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[224] *Id.* at 125 (internal quotations and citation omitted).

[225] *Id.*

[226] *Id.* at 125–26, 133 (quoting *LCT Cap., LLC v. NGL Energy P'rs LP*, 249 A.3d 77, 91 (Del. 2021)) ("Benefit of the bargain damages are 'equal to the difference between the actual and the represented values of the object of the transaction.'").

[227] *Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983).

supporting the first two elements, arguing on appeal that the record does not support finding that J&J (i) made a false representation by actively concealing material facts, or (ii) knew Gorsky's statement to be false.[228] J&J has not proven that the Court of Chancery committed clear error as to either element.

Active concealment requires an affirmative act designed or intended to prevent, and which does prevent, the discovery of facts giving rise to the fraud claim.[229] The affirmative act must be more than mere silence,[230] but not much more;[231] the act can be as small as "a single word, even a nod or a wink or a shake of the head or a smile or gesture intended to induce another to believe in the existence of a nonexisting fact . . . ."[232]

Gorsky's characterization of the milestone as "high[ly] certain" and an "effective up front" payment was just such an affirmative act. The fact that a patient in the FLEX clinical study had died, triggering a for-cause FDA inspection and

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[228] Appellants' Opening Br. at 59 (arguing that "Fortis offered no evidence—and the court found no facts—supporting either" element).

[229] *Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 150 (Del. Ch. 2004).

[230] *Renovaro Inc. v. Gumrukcu*, 2025 WL 3134533, at *9 (Del. Ch. Nov. 7, 2025) (TABLE); *Wiggs v. Summit Midstream P'rs, LLC*, 2013 WL 1286180, at *11 (Del. Ch. Mar. 28, 2013) (TABLE).

[231] *See, e.g., MKE Hldgs. Ltd. v. Schwartz*, 2020 WL 467937, at *10–12 (Del. Ch. Jan. 29, 2020) (TABLE) (where the board shared a slide deck that touted their earnings as "reliable" despite an ongoing audit); *Airborne Health, Inc. v. Squid Soap, LP*, 2010 WL 2836391, at *9 (Del. Ch. July 20, 2010) (TABLE) (explaining that a misleading partial disclosure to throw the seller "off the scent" would be active concealment).

[232] *Nicolet, Inc. v. Nutt*, 525 A.2d 146, 149 (Del. 1987) (quoting *Gibbons v. Brandt*, 170 F.2d 385, 391 (7th Cir. 1948)).

risking substantial delay, was indisputably material. Rather than disclose that regulatory uncertainty or the ongoing investigation, Gorsky presented the milestone as essentially guaranteed. That assurance suggested that no regulatory issue threatened timely achievement of the milestone and gave Auris no reason to inquire further.

J&J counters that it could not have affirmatively concealed the death because "J&J promptly took affirmative steps to make the death public, submitting a full report to FDA that was published on FDA's public database."[233] The Court of Chancery rejected that argument, finding that "[t]his does not excuse J&J's fraud. It is unknown when the report was posted. Even if it were made public pre-merger, Auris would have had no reason to search the FDA's website for information about problems with the NeuWave study."[234] On appeal, J&J identifies no evidence that the FDA report was publicly available before closing, and in any event a technical regulatory filing on a government website does not negate a deliberate effort, in direct negotiations, to portray a risky milestone as a near certainty.[235]

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[233] Appellants' Opening Br. at 60.

[234] Opinion at 126, n.643.

[235] *See Norton v. Poplos*, 443 A.2d 1, 6–7 (Del. 1982) (rejecting the notion that public record availability shields fraud); *Tam v. Spitzer*, 1995 WL 510043, at *9 (Del. Ch. Aug. 17, 1995) (TABLE) (holding that a buyer is entitled to rely on a seller's representations and "is under no duty to investigate the accuracy of representations made by the seller concerning its profitability and operational affairs, even when there is an opportunity to do so") (internal citation omitted).

J&J similarly cannot show that the Court of Chancery clearly erred in finding that J&J knew Gorsky's statement was false. J&J contends that it "*believed*" that the milestone was achievable, pointing to internal analyses that continued to assign an 85% likelihood of success despite the FDA investigation.[236] J&J characterizes Gorsky's statement that the milestone was "high[ly] certain" as good-faith business "confidence" rather than deceit, and insists that there is "not a shred of evidence" to conclude otherwise.[237] But, under Delaware law, scienter is satisfied if the defendant knew its representation was false or made it with reckless indifference to the truth; it does not necessarily require proof of the speaker's own belief.[238]

Applying that standard, the Court of Chancery found that by the time of the January 24 call, J&J knew that (i) a patient in the FLEX lung-lesion study had died, (ii) the FDA had opened a for-cause, on-site inspection, and (iii) the investigation risked substantial delay.[239] The court also found that (iv) J&J's Auris deal team had been briefed on the developments, and (v) the team was running a sensitivity analysis "to understand the impact to [the milestone's] valuation."[240] In light of those undisputed facts, presenting the milestone as "high[ly] certain" and an "effective up

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[236] Appellants' Opening Br. at 60–61.

[237] Appellants' Reply Br. at 30.

[238] *Stephenson*, 462 A.2d at 1074.

[239] Opinion at 125; *see also id.* at 31 (noting that a member of J&J leadership "suspected that the FDA would place [NeuWave FLEX] on hold for some period").

[240] *Id.* at 125 & n.640.

front payment" permitted the reasonable inference that J&J at least acted with reckless indifference to the statement's truth. This inference is directly supported by the record, and J&J has failed to identify any evidence that renders it implausible or demonstrates clear error in the court's scienter finding.

2. The exclusive remedy provision does not bar Fortis's claim.

J&J separately renews its contention that the exclusive remedy provision in Section 8.05(b) of the Merger Agreement bars Fortis's fraud claim.[241]

Section 8.05(b) provides:

> The parties each acknowledge and agree that, except as otherwise provided in this Agreement . . ., the indemnification provisions contained in this Article VIII 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 . . . [except] in the case of fraud by the Company, Parent or Merger Sub with respect to making the representations and warranties in this Agreement.[242]

J&J notes that Fortis's fraud claim was brought more than a year after closing and is not an indemnification claim.[243] J&J therefore concludes that the claim is barred unless it falls within the express carve-out for "fraud by the Company, Parent or Merger Sub with respect to making the representations and warranties in this Agreement." Because Fortis's claim rests on Gorsky's extra-contractual statement

[241] Appellants' Opening Br. at 62.

[242] Merger Agreement § 8.05(b). "Parent" refers to J&J and "Company" refers to Auris.

[243] Appellants' Opening Br. at 62.

that the Monarch Soft Tissue Ablation Milestone was "high[ly] certain" and "effective up front" consideration and not on a contractual representation, J&J contends that Section 8.05(b) forecloses any remedy.[244]

The Court of Chancery rejected J&J's reading. Applying *Abry Partners* and its progeny, the court began from two premises: "Delaware law respects bargained-for contractual rights between sophisticated parties,"[245] but "Delaware's public policy is intolerant of fraud."[246] The court drew on the well-settled rule that a party cannot be "insulate[d] 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 one who is seeking to rely on extra-contractual statements—disclaiming such reliance."[247]

The Merger Agreement contains such an anti-reliance clause—but only in one direction and not the direction that favors J&J's appeal. Section 4.08 provides that:

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[244] Appellants' Reply Br. at 33.

[245] Motion to Dismiss Opinion at 21. The court's analysis on this point was conducted at the motion to dismiss stage and the court saw "no basis to deviate from [that] prior ruling" after trial. Opinion at 116.

[246] *Id.* (quoting *Abry P'rs V, L.P. v. F & W Acq. LLC*, 891 A.2d 1032, 1059 (Del. Ch. 2006)).

[247] Motion to Dismiss Opinion at 21–22 (quoting *FdG Logistics LLC v. A&R Logistics Hldgs., Inc.*, 131 A.3d 842, 859 (Del. Ch. 2016)); *Anschutz Corp. v. Brown Robin Cap., LLC*, 2020 WL 3096744, at *13 (Del. Ch. June 11, 2020) (TABLE) (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"); *Kronenberg v. Katz*, 872 A.2d 568, 593 (Del. Ch. 2004) ("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.").

> Except for the representations and warranties contained in Article III, Parent and Merger Sub acknowledge that none of Company or any person on behalf of the Company makes, and neither Parent nor Merger Sub have relied upon, any other express or implied representation or warranty with respect to the Company or any of its Subsidiaries or with respect to any other information provided or made available to Parent or Merger Sub in connection with the transactions contemplated by this Agreement. . . . ***Each of Parent and Merger Sub disclaims any representations and warranties other than those that are expressly set forth in Article III.***[248]

The court held that "the fact that [J&J] expressly disclaimed reliance but Auris did not suggests that Auris was permitted to rely upon [J&J's] 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."[249]

We affirm the Court of Chancery's reading. *Abry Partners* remains the lodestar for contract-based limitations on extra-contractual fraud liability. In *Abry*, a sophisticated private-equity buyer sought to rescind a $500 million stock purchase agreement based on alleged contractual fraud.[250] The agreement contained both (i) an exclusive remedy provision that limited the buyer to indemnification claims, and (ii) an anti-reliance clause in which the buyer agreed that it was relying only on

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[248] Merger Agreement § 4.08 (emphasis added).

[249] Motion to Dismiss Opinion at 29 ("Unlike the parties in *Abry Partners*, Auris did not disclaim reliance on extra-contractual statement anywhere in the Merger Agreement.").

[250] *Abry*, 891 A.2d at 1046–47 (where the fraud claims were based solely on alleged falsity of the stock purchase agreement's representations and warranties, such as the accuracy of the company's financial statements and the absence of a material adverse effect).

contractual representations.[251] The court took the occasion to set out the framework for when and how sophisticated parties may contract out of fraud claims.[252]

Abry first explained how parties may allocate the risk of extra-contractual fraud. Delaware will enforce only "clear anti-reliance clauses" where the party has unambiguously "contractually promised that it did not rely upon statements outside the contract's four corners in deciding to sign the contract."[253] "[M]urky integration clauses, or standard integration clauses without explicit anti-reliance representations, will not relieve a party of its oral and extra-contractual fraudulent representations."[254] Because Delaware "has consistently respected the law's traditional abhorrence of fraud," a party must disclaim reliance on extra-contractual statements in unmistakable terms.[255]

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[251] *Id.* at 1043–44.

[252] Delaware decisions since *Abry* have adopted this framework. *See, e.g., RAA Mgmt., LLC v. Savage Sports Hldgs., Inc.*, 45 A.3d 107, 110, 116–18 (Del. 2012) (affirming dismissal of extra-contractual fraud claims because the sophisticated bidder had agreed that "[o]nly those representations or warranties that are made to a purchaser in the Sale Agreement . . . have any legal effect"); *Prairie Capital III, L.P. v. Double E Holding Corp.*, 132 A.3d 35, 51–53 (Del. Ch. 2015) (explaining that when a buyer affirmatively represents that contractual warranties are "the sole and exclusive representations and warranties" on which it relied, that "define[s] the universe of information that is in play for purposes of a fraud claim" and prevents the buyer from "escap[ing] through a wormhole into an alternative universe of extra-contractual omissions"); *FdG Logistics*, 131 A.3d at 860 (holding that Delaware courts "will not bar a contracting party from asserting claims for fraud based on representations outside the four corners of the agreement unless that contracting party unambiguously disclaims reliance on such statements").

[253] *Abry*, 891 A.2d at 1059 (quoting *Kronenberg*, 872 A.2d at 593).

[254] *Abry*, 891 A.2d at 1059.

[255] *Id.* at 1058.

Abry then turned to fraud in the contractual representations themselves and balanced two countervailing principles: Delaware's "strong tradition" against intentional fraud, and its equally "strong tradition of freedom of contract."[256] To reconcile those policies, *Abry* held that a party cannot, as a matter of public policy, "limit [its] exposure for its conscious participation in the communication of lies," but the counterparty may "knowingly accept the risk that the [party committing the fraud] will act in a reckless, grossly negligent, or negligent manner."[257]

J&J asks us to depart from this framework. J&J invites us to read Section 8.05(b) to do what Section 4.08 conspicuously does not: extinguish Auris's extra-contractual fraud claims. We decline to do so for two reasons. First, that interpretation would circumvent *Abry*'s core requirement that any waiver of extra-contractual fraud must be effectuated through "unambiguous anti-reliance language" from the party who is seeking to rely on extra-contractual statements.[258] Section 8.05(b) contained no clear anti-reliance language. Section 4.08 is a textbook *Abry*-style anti-reliance provision, but it runs solely against J&J. Auris never disclaimed reliance on extra-contractual statements. Under *Abry*, J&J therefore "will not be

[256] *Id.* at 1059.

[257] *Id.* at 1064.

[258] *Id.* at 1059.

able to escape the responsibility for [its] own fraudulent representations made outside of the agreement's four corners."[259]

Second, if, as J&J contends, Section 8.05(b) silently eliminated all extra-contractual fraud claims by both sides after closing, Section 4.08 would be largely superfluous. We avoid interpretations that twist contract language and leave negotiated provisions as surplusage,[260] particularly where—as here—the asymmetry of Section 4.08 makes commercial sense: Auris, unlike J&J, made extensive representations in the Merger Agreement itself; J&J agreed that it therefore would not rely on anything outside the contract.[261]

We therefore hold, consistent with *Abry*, that where (i) the contract contains a one-sided anti-reliance clause disclaiming reliance by only one party, and (ii) the other party to the contract made no comparable promise, an exclusive remedy clause cannot be invoked to bar the other party's post-closing claims for intentional extra-contractual fraud.

J&J argues that our decision in *Express Scripts* demands a different result.[262] It does not. *Express Scripts* involved a different question: whether sophisticated

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[259] *Id.*

[260] *Hallowell v. State Farm Mut. Auto. Ins. Co.*, 443 A.2d 925, 926 (Del. 1982); *Chi. Bridge*, 166 A.3d at 928.

[261] *See* Merger Agreement Arts. III–IV (detailing 24 sections of representations by Auris versus eight sections of representations by J&J and its subsidiaries).

[262] Appellants' Opening Br. at 63.

parties could, consistent with *Abry*, contractually limit remedies for non-deliberate fraud in connection with contractual representations and warranties.[263] There, the securities purchase agreement made recovery under a representations-and-warranties insurance policy the "sole and exclusive remedy" for post-closing breaches, unless the claim was for "deliberate fraud."[264] The Superior Court jury was instructed that it could find "deliberate fraud" based on recklessness.[265] We reversed, holding that "[a] deliberate state of mind does not equate to a reckless state of mind."[266] Since the parties had agreed that the insurance policy would be the sole and exclusive remedy absent "deliberate fraud," it was error to instruct the jury on recklessness.[267]

Express Scripts therefore applied *Abry*'s intra-contractual fraud framework; it did not displace *Abry*'s anti-reliance rule for extra-contractual fraud. *Express Scripts* recognized Delaware's "distaste for immunizing fraud" but confirmed that a party may "accept the risk" that the other party's contractual representations were made recklessly while preserving full recourse for deliberate misrepresentations.[268]

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[263] *Express Scripts, Inc. v. Bracket Hldgs. Corp.*, 248 A.3d 824, 828 (Del. 2021).

[264] *Id.* at 830.

[265] *Id.* at 829.

[266] *Id.* at 834.

[267] *Id.*

[268] *Id.* at 830.

Nothing in *Express Scripts* suggests that an exclusive remedy provision, standing alone, can operate as an *Abry*-compliant anti-reliance clause in favor of a party that never obtained an express non-reliance promise from its counterparty.

Accordingly, we affirm the Court of Chancery's determination that Section 8.05(b) does not bar Fortis's fraud claim.

IV. CONCLUSION

For the foregoing reasons, the judgment of the Court of Chancery is reversed as to the implied covenant, affirmed as to breach of contract and fraud, and remanded to the Court of Chancery to recalculate the interest award based on a damages calculation that excludes the Milestone 1 payment.