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Case Number 490,2024

IN THE SUPREME COURT OF THE STATE OF DELAWARE

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

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NATURE OF PROCEEDINGS

The Court of Chancery jeopardized one of the most common risk allocation tools in merger and acquisition contracts: earnout provisions. The buyer agrees to pay an upfront amount and an additional "earnout" if the seller's business achieves specified targets by a deadline. Such provisions are often essential to reach agreement, because the contingent payment reduces the buyer's risk of overpaying when the seller's future performance is uncertain. But parties will refuse to agree to earnouts—and deals will not get done—if they harbor doubts that courts will enforce earnout provisions as written.

The decision below casts just such a pall of doubt. The court found Johnson & Johnson and its subsidiary (collectively, J&J) liable for over $1 billion in damages related to an earnout provision in J&J's merger contract with Auris Health, Inc., a surgical robotics start-up. In arriving at that massive judgment—the largest earnout award in Delaware history—the court impermissibly rewrote the parties' contract in multiple ways.

J&J paid Auris's stockholders $3.4 billion up front, and agreed to make $2.35 billion in additional earnout payments *if* Auris's surgical robots achieved carefully defined milestones. The "regulatory milestones" all depended on obtaining 510(k) clearance from FDA for specified surgical and other medical procedures ("surgeries," for simplicity). 510(k) clearance is the least burdensome and most

certain pathway through which FDA authorizes the sale of medical devices. J&J agreed to use "commercially reasonable efforts" to meet the 510(k) clearance milestones. The parties defined that term to preserve J&J's broad discretion to weigh achieving those milestones against a range of business priorities.

Meeting the milestones would have been a win-win. Had the Auris legacy team at J&J achieved them all in the narrow window of market opportunity, J&J would have earned tens of billions, and would have paid Auris's stockholders another $2.35 billion. Everyone agrees J&J accordingly invested massive resources in Auris. Beyond the purchase price, J&J poured over $2.25 billion into the program, more than it had ever spent on any medical device. It added hundreds of highly experienced engineers to the team. It even acquired two additional companies in service of developing Auris's robots.

The contract recognized, however, that "achievement of each of the Milestones is subject to a variety of factors and uncertainties, including many outside of" J&J's control. A2847. Sure enough, shortly after the merger closed, FDA foreclosed the crucial 510(k) pathway to Auris's key robot, iPlatform. Meanwhile, iPlatform was plagued with technical challenges that slowed its development—problems for which Auris's own CEO could not "conceive of an adequate" solution and that Auris personnel never solved. A4326.

When it became evident that the milestones were unachievable, Auris's former stockholders, represented by Fortis Advisors LLC, sued J&J. Following a bench trial, the court found for Fortis based on several fundamental errors. First, the court invoked the implied covenant of good faith and fair dealing to strike the express 510(k) clearance requirement, rewriting the contract to require J&J to pursue a more burdensome and far less certain form of FDA approval instead. It then converted J&J's limited obligation to use "commercially reasonable efforts" to achieve the milestones, in the exercise of sound business discretion, into a limitless mandate for J&J to prioritize achieving them above all other corporate goals. And it found J&J liable for fraud based on a truthful statement J&J made during negotiations, while excising an exclusive-remedy provision that expressly barred the fraud claim.

Left to stand, the court's decision will chill value-generating mergers and acquisitions, and threaten Delaware's reputation as a state that enforces contracts as written. This Court should reverse.

SUMMARY OF ARGUMENT

I. Implied Covenant

1. No phrase appears more often in the regulatory milestones than "510(k) premarket notification(s)," also known as 510(k) clearance. The contract repeatedly emphasized that to earn any payout, iPlatform would need to obtain *510(k) clearance* for particular types of surgeries by set deadlines. That condition was highly consequential; the 510(k) pathway is much more advantageous than the alternative De Novo or Pre-Market Approval pathways. 510(k) clearance offers far higher odds of obtaining FDA approval—nearly double those of De Novo applications. And it is the fastest, least burdensome, and least costly pathway. But the availability of 510(k) clearance was never guaranteed, and when FDA later decided that iPlatform was not eligible for 510(k) clearance, it made the first iPlatform regulatory milestone unachievable—no matter what else J&J did. That was a glaring problem with Fortis's case. But, invoking the implied covenant of good faith and fair dealing, the Court of Chancery rewrote the contract to replace the "510(k) clearance" requirement for the first iPlatform milestone with "De Novo approval." That was legally improper for at least four reasons, each an independent basis for reversal: (1) the contract explicitly addressed the issue; (2) the unavailability of 510(k) could have been anticipated; (3) J&J would not have agreed to the same milestone payouts on the same terms had the contract required De Novo approval rather than 510(k)

clearance; and (4) the 510(k) pathway's unavailability was FDA's decision, not a consequence of J&J acting arbitrarily or unreasonably. The court had no authority to rewrite the express contractual terms of this milestone.

2. Likewise, the court had no authority to enforce the remaining iPlatform milestones or GI milestone (which J&J planned to meet with iPlatform) by inserting a non-existent contractual obligation to seek De Novo approval in order to potentially unlock the 510(k) pathway for the remaining milestones. Thus, the awards for the remaining iPlatform and GI milestones must also be reversed.

3. At minimum, the court's erroneous ruling as to the first iPlatform milestone undermined the court's entire damages analysis for all the other milestones. To calculate damages, the court relied upon an assessment of the probabilities of achieving each milestone that the parties calculated before the merger—and thus before FDA changed the pathway. But the court failed to account for the undisputed fact that the odds of success plummeted once J&J could no longer directly access the 510(k) pathway for iPlatform.

II. Breach Of Contract

4. The court misinterpreted the contract's "commercially reasonable efforts" clause in two fundamental ways. It converted J&J's commitment to use efforts consistent with other "priority" J&J devices into an unyielding dictate that J&J must prioritize achieving the milestones above all else, including profitability and

commercial viability. And it effectively excised a list of ten contractual factors that preserve J&J's broad discretion to exercise its business judgment to pursue the milestones in a manner that was consistent with its corporate objectives.

5. There is no dispute that J&J expended extraordinary and unprecedented funds and efforts to achieve the milestones, and the court did not find the resources J&J dedicated to be insufficient. Yet the court applied its flawed interpretations to find that J&J breached its overall efforts obligation because of certain strategic decisions about *how* to deploy those resources—for instance, by conducting a technical assessment of iPlatform and another robot J&J was developing, and by pursuing a development strategy that the court acknowledged was supported by the ten contractual factors. The court also faulted J&J for a proposal it considered, but did not actually implement at the time. Under the proper interpretation of the contract, none of J&J's actions were breaches.

III. Fraud

6. The court also erred in determining that J&J committed fraud when its CEO said he thought one of the milestones was "highly certain" to be achieved. Fortis presented no evidence J&J knew that statement to be false when he said it; the undisputed evidence was that J&J fully believed it was true. Moreover, J&J affirmatively made public the material fact that the court found J&J "actively

concealed." In any event, the contract foreclosed any fraud claim based on representations outside of its express terms.

STATEMENT OF FACTS

A. Aspiring To Break Into The Lucrative Surgical Robotics Market, J&J Negotiates To Acquire Auris

This case is the story of an unsuccessful effort to achieve an audacious goal that no company has yet accomplished: to break into the surgical robotics market and compete with Intuitive Surgical, the $100 billion behemoth whose robot has monopolized that market for decades. Ex. B, Post-Trial Memorandum Opinion ("Op.") 10-11.

J&J, already a leader in medical devices, aspired to "win … big" in that market. A2620. To do so, J&J set two ambitious goals: breakneck speed and product differentiation. Time was of the essence, because J&J had to "disrupt the … market before more competitors could enter the space." Op.19-20. That meant J&J had to race to market with an *actual* product that was safe and effective. A2249. Second, it could not be just any product. It had to be "differentiated" from—i.e., better than, or at least significantly different from——Intuitive's robot. A1751; *see* A1536, A2246-47, A2249. Meeting those goals was key to persuading surgeons and hospitals to switch robots, particularly given Intuitive's decades-long first-mover advantage. A1536, A1590, A1882. The two imperatives could conflict, since it takes more time to develop, test, and secure regulatory approval for an innovative design. A1541. But both were essential.

J&J bet on two different ventures in hopes of threading that needle. The first was a partnership J&J launched with Google in 2015 to jointly develop a surgical robot called Verb. Verb had a novel architecture and an improved user-input device, Op.18, and promised advanced data analytics, A3538.

The other was Auris, a start-up developing two surgical robots: iPlatform and Monarch. Op.21; A1653, A1805, A2557-59. Auris focused on features that Intuitive lacked. For iPlatform, "a big part of differentiation from Intuitive" was that it had six robotic arms—compared to Intuitive's four. A1552; Op.14. Also, while Intuitive's robot required a large standalone boom, iPlatform's arms were mounted to movable bars attached underneath the surgical bed, reducing the robot's "footprint" in the operating room. Op.14.

Auris emphatically subscribed to J&J's view of the dual imperatives. As to differentiation, Auris CEO Fred Moll relished reciting his "3F's" mantra: If you are not "first" in the market, you must be "fabulous"; otherwise, you will fail (the actual third "F" is unprintable). A1856. In its merger discussions with J&J in 2018, Auris emphasized that iPlatform's "very differentiated robot with six arms" would make it "very competitive" with Intuitive. A1882; *see* A1552, A2273, A2543, A3430-31. As to speed, Auris devised an ambitious timeline to get that highly differentiated iPlatform robot to market by 2021, because Moll "was always concerned that if you didn't do it all at first, everything might not come along." A1552; *see* A1915, A2543,

A3385-87. With that combination of speed and differentiation, Auris assured J&J that its design would "leapfrog Intuitive" "in the next five years or so"—by 2023. A2706; *see* A2273.

During due diligence, J&J learned that Auris was wrestling with certain technical challenges. Op.29, 97 & n.504; *see* A2779. To "keep [negotiations] moving," Auris proposed prioritizing non-technical diligence items, A2699, and deferring further technical due diligence until after the acquisition. A1850, A2704; Op.29. In keeping with this approach, J&J and Auris discussed a post-merger "technology audit." A1336; *see* A1444.

B. J&J Acquires Auris For $3.4 Billion, With Further Contingent Payments Based Largely On Prompt FDA 510(k) Clearances

In February 2019, Auris and J&J executed an agreement in which J&J acquired Auris. Op.37. J&J paid Auris's stockholders $3.4 billion. A2913. The stockholders also stood to receive up to $2.35 billion more in "earnout payments," but only if Auris's products achieved a series of ambitious milestones. Op.34-36. Earnout structures like this are common in merger agreements to hedge against the sorts of technological and regulatory uncertainty Auris confronted and to incentivize top personnel to stick with the project. Op.1; A1354, A2070-71. Eight payments were contingent on using a particular regulatory pathway to secure FDA approval for specified surgeries, and two were contingent on sales of any of J&J's robots—

iPlatform, Monarch, and/or Verb—all by specified dates, as follows (with the Court of Chancery's enumeration):

Milestone	Requirement	Deadline	Earnout
iPlatform Regulatory Milestones			
1. General Surgery	"510(k) premarket notification(s) … for one upper abdominal surgical procedure and one lower abdominal procedure"	End of 2021	$400M
2. Upper Abdominal	"510(k) premarket notification(s) … for upper abdominal Umbrella Procedure(s)"[1]	End of 2023	$150M
3. Lower Abdominal Umbrella	"510(k) premarket notification(s) … for colorectal/lower abdominal Umbrella Procedure(s)"		$150M
4. Urologic Umbrella	"510(k) premarket notification(s) … for urological Umbrella Procedure(s)"		$150M
5. Gynecologic Umbrella	"510(k) premarket notification(s) … for gynecological Umbrella Procedure(s)"		$150M
Monarch Regulatory Milestones			
6. Endourology	"510(k) premarket notification(s) … for endourology procedure(s)"	End of 2020	$100M
7. Soft Tissue Ablation	"510(k) premarket notification(s) … for robotically driven (or controlled) soft tissue ablation"	End of 2022	$100M
GI Regulatory Milestone[2]			
8. Robotic GI Endoluminal	"510(k) premarket notification(s)" for either iPlatform or Monarch "for procedure(s) specifically including Endoscopic Submucosal Dissection"	End of 2023	$150M

[1] An umbrella procedure is a procedure that is especially "complex[] or risk[y]," such that FDA authorization for that procedure "cover[s] procedures of less complexity or lower risk within that specialty." A2924.

[2] Although the GI Milestone could be met by either iPlatform or Monarch, the parties expected pre-merger that it would be met with iPlatform, Op.109, and the GI team continued to pursue that approach after the merger, A1662, A1681-82, A2180, A4366-68.

Sales Milestones			
9. First Step Net Sales	Combined sales of iPlatform, Monarch, and Verb reach or exceed $575M	FY 2022	$500M
10. Second Step Net Sales	Combined sales of iPlatform, Monarch, and Verb reach or exceed $1.65B	FY 2024	$500M

A2840-42; Op.34-36.

The phrase common to every regulatory milestone (Milestones 1-8) is "510(k) premarket notification(s)," also known as 510(k) clearance. Op.29-30, 68. That is the easiest, fastest, and least risky of the three regulatory pathways through which FDA authorizes medical devices. Op.9-10; A5420-27. The 510(k) pathway requires the applicant to demonstrate only that the device is "substantially equivalent" to another FDA-approved "predicate device." Op.9-10, 102. The other two regulatory pathways—"De Novo" and "Pre-Market Authorization"—offer far lower approval rates, and are more "onerous" and time-consuming. Op.10, 101; A5424, A5454-55. The difference is stark: FDA clears 84-86% of 510(k) submissions, almost twice the 45-52% rate for De Novo submissions. A5455, A2311-12.

The contract expressed the parties' understanding that the milestones were aspirational, not guaranteed: "[T]he achievement of each of the Milestones is subject to a variety of factors and uncertainties, including many outside of the control of [J&J] … and as a result, some or all of the Earnout Payments may never be paid." A2847. The timelines were "ambitious." Op.2. Privately, Auris leaders—who had the greatest visibility into Auris's prospects—fretted that the iPlatform deadlines

were "crazy," A3483, "very tight," A2759, and "unlikely to [be] hit," A3494. In deal documents, Auris projected greater optimism, but still estimated only a "65% probability" of achieving Milestone 1 within the short milestone window. Op.93 & n.486.

Even so, both sides were highly motivated to achieve the milestones. Under the deal's win-win structure, Auris's stockholders (including key leaders) would be richly rewarded if the robots met the ambitious milestones. J&J, in turn, stood to reap enormous profits from beating competitors to the robotics market by the milestone deadlines. A1015, A1354, A1862. J&J projected that timely launches of operational, safe iPlatform and Monarch robots could generate as much as $305 million in 2022, ramping up to $6.1 billion per year by 2030. A2711-12, A2270. Conversely, missing the milestones would diminish the return on J&J's investment and hinder J&J's surgical robotics ambitions well into the future. A1862-63, A1994, A2273, A2324, A2805.

J&J committed to use "commercially reasonable efforts to achieve each of the Regulatory Milestones." A2845. The parties agreed to a "bespoke" definition (Op.4, 64) of "commercially reasonable efforts":

> expenditure of efforts and resources in connection with research and development and obtaining and furnishing of information to and communications with [FDA] in connection with obtaining the applicable 510(k) premarket notification with respect to the [Auris devices] consistent with the usual practice of [J&J] with respect to priority medical device products of similar commercial potential at a

> similar stage in product lifecycle to the [Auris devices], taking into account [ten enumerated factors].

A2845. Among those ten factors were:

- "issues of efficacy and safety";
- "risks inherent in the development and commercialization of such products";
- "expected and actual competitiveness of alternative products";
- "likelihood and difficulty of obtaining FDA and other regulatory approval";
- "guidance or developments from the FDA," including "as it may affect the data required to obtain premarket approval"; and
- "expected and actual profitability and return on investment of the product."

A2845.

C. After Assessing Synergies Between Verb And iPlatform, J&J Chooses To Bring Just iPlatform To Market

The earnout structure achieved its intended motivational objective: Virtually Auris's entire leadership continued working on the program after the merger. A1361. Auris CEO Moll became the Chief Development Officer for J&J's entire robotics program. A2275. Auris's R&D, regulatory, clinical engineering, and project management teams also all remained, maintaining their pre-merger roles. A1361, A1535.

In April 2019, shortly after the merger, J&J embarked on a short-term initiative to "find synergies between [iPlatform and Verb] to decrease project risk and accelerate time to commercialization." Op.39-40, 50. The initiative—dubbed

"Project Manhattan"—involved a "deep dive" assessment of Verb and iPlatform. Op.41. Surgeons would conduct various "cadaver labs"—surgeries on cadaver torsos—using both Verb and iPlatform and rate their respective performance. Op.43-44; A1527. Moll said he was "excited to get going" with Project Manhattan. A3404.

J&J told the Auris legacy team that iPlatform "should stay as it is" for the assessment; there was "no need" to "dress[] [iPlatform] up[] for review." Op.41. But the Auris team viewed the assessment as a "bakeoff" between iPlatform and Verb. Op.42; A3500-01. The team therefore accelerated its preplanned work to develop solutions for iPlatform's system "stability" issues—its propensity to freeze or even crash mid-surgery. Op.43; A986, A1526, A1553-54, A3419, A3500-01.

Project Manhattan lasted about two months, spanning April to June 2019. A1912, 3892. The cadaver labs took under two weeks. A1914. At the time, the Auris team considered Project Manhattan "an overall favorable forcing function for the program's development" that helped "stabilize the platform." A3895; *see* A1553. They estimated the exercise resulted in just a "[s]light delay in timeline," A3895, of about "1 quarter," A3806.

The direct consequence of Project Manhattan was J&J's decision to shelve Verb and devote all of J&J's surgical robotics resources to bringing only iPlatform to market—the very result the Auris team leaders had ardently advocated. Op.45; *see* A3528-29.

D. FDA Rejects The 510(k) Pathway For iPlatform

From the start, iPlatform encountered setbacks. First came a regulatory setback. Given the centrality of the 510(k) pathway to Milestones 1-8, both parties put a lot of stock in the prospect that FDA would allow Auris to use that pathway for iPlatform's regulatory approval. A1880. But the 510(k) pathway was never a certainty. *See, e.g.*, A2508 (disclosure, signed by Moll when he was at Intuitive, cautioning that FDA could require another regulatory pathway "instead of accepting a 510(k) submission"); 21 C.F.R. § 807.100(a) (FDA decides whether 510(k) clearance is appropriate only after receiving a 510(k) submission). Between 2018 and 2022, FDA declined to accept around one-third of submissions requesting to proceed via the 510(k) pathway. FDA, *Agenda for Quarterly Meeting on MDUFA IV (FY2018-22) Performance* 144 (Nov. 16, 2022), https://tinyurl.com/3hj46c8s. Punctuating the uncertainty, in October 2018, three months before the merger agreement was signed, FDA told Auris it was "unclear if the 510(k) pathway is appropriate for [iPlatform]." A2675. As Auris personnel recounted, "FDA explained that our device has technological characteristics different from the predicate" in multiple ways. A3938-40. One difference was that iPlatform included a bronchoscope. A3938, A3940; *see* Op.15-16, 101. Auris hoped to assuage FDA by removing that feature; but even with that adjustment, FDA still questioned whether the 510(k) pathway would be suitable. A5439-41, A3938-41.

Several months after the merger, FDA determined that the 510(k) pathway would be "closed to iPlatform." Op.48, 102; A5026-28. This meant iPlatform would have to take one of the more "onerous" pathways to regulatory approval—either De Novo or Pre-Market Authorization. Op.10, 102; *see* A5028, A4050, A4065. Eventually, J&J persuaded FDA to allow iPlatform to proceed under the intermediate regulatory pathway, De Novo. A4311, A1393.

Losing the 510(k) pathway was highly consequential. Besides cutting the approval rate in half, as discussed above (at 12), shifting to De Novo required vastly more testing. A1881. Either pathway would require data from "bench" testing on cadavers and animals, as well as clinical testing on live humans. Under the 510(k) pathway, J&J could satisfy that requirement almost entirely with data FDA had already accepted when approving the predicate device, with only limited supplemental iPlatform-specific clinical testing. A4040. But FDA told J&J that De Novo required more: J&J now had to amass its own "data from the ground up." A4040. The additional clinical studies alone required surgeries on "30, 40 or 50 patients" for *every procedure*—far more than the Auris team had planned. A4115-16.

Everyone agrees the shift added months more to the approval timeline; the parties just disputed how many. After FDA changed the pathway, the Auris team concluded it could not secure FDA approval for any procedure before August 2022

even in the best-case scenario—eight months after the Milestone 1 deadline. A4156-57, A4184. The team's more realistic timeline estimated approval for one procedure in November 2023, almost two years past the deadline for Milestone 1. A4156. The pathway change was so significant that J&J determined it was unlikely to meet any of the iPlatform or GI regulatory milestones as a result. A4328, A1936-37.

The court found that the pathway shift "would only add two months of delay." Op.102. But that finding was based solely on the (disputed) evidence of how much longer it typically takes FDA to *review* De Novo applications. The court did not address the additional time it would take to: (1) recruit 60-100 study volunteers for the two procedures; (2) schedule and complete those surgeries; and (3) analyze the data. A4115-16. The court did not explain how all this could be accomplished by the Milestone 1 deadline, when the Auris team projected that step (2) alone would take *seven* months, A4156-57, and Auris's original 510(k) timeline allotted only a five-month "buffer" to accommodate any slippage. Op.93, 96.

Instead, the court relied solely on "numerous *lab reports* show[ing] that iPlatform had the capability to safely and effectively complete procedures to satisfy the milestone." Op.97 (emphasis added). But those "lab reports" involved testing on *cadavers*. Cadaver testing was not sufficient; FDA said it would require data from scores of surgeries on *live patients*. Right up to the end, iPlatform had never performed a single such surgery. A1349, A1535, A2129, A2147-48. Human testing

was prohibited without proof that iPlatform was safe. 21 C.F.R. §§ 812.1(a), 812.20(a)(2); A1659, A2014. And no one on the Auris team was ever prepared to tell FDA that iPlatform was safe enough to operate on a live human, for reasons discussed next.[3]

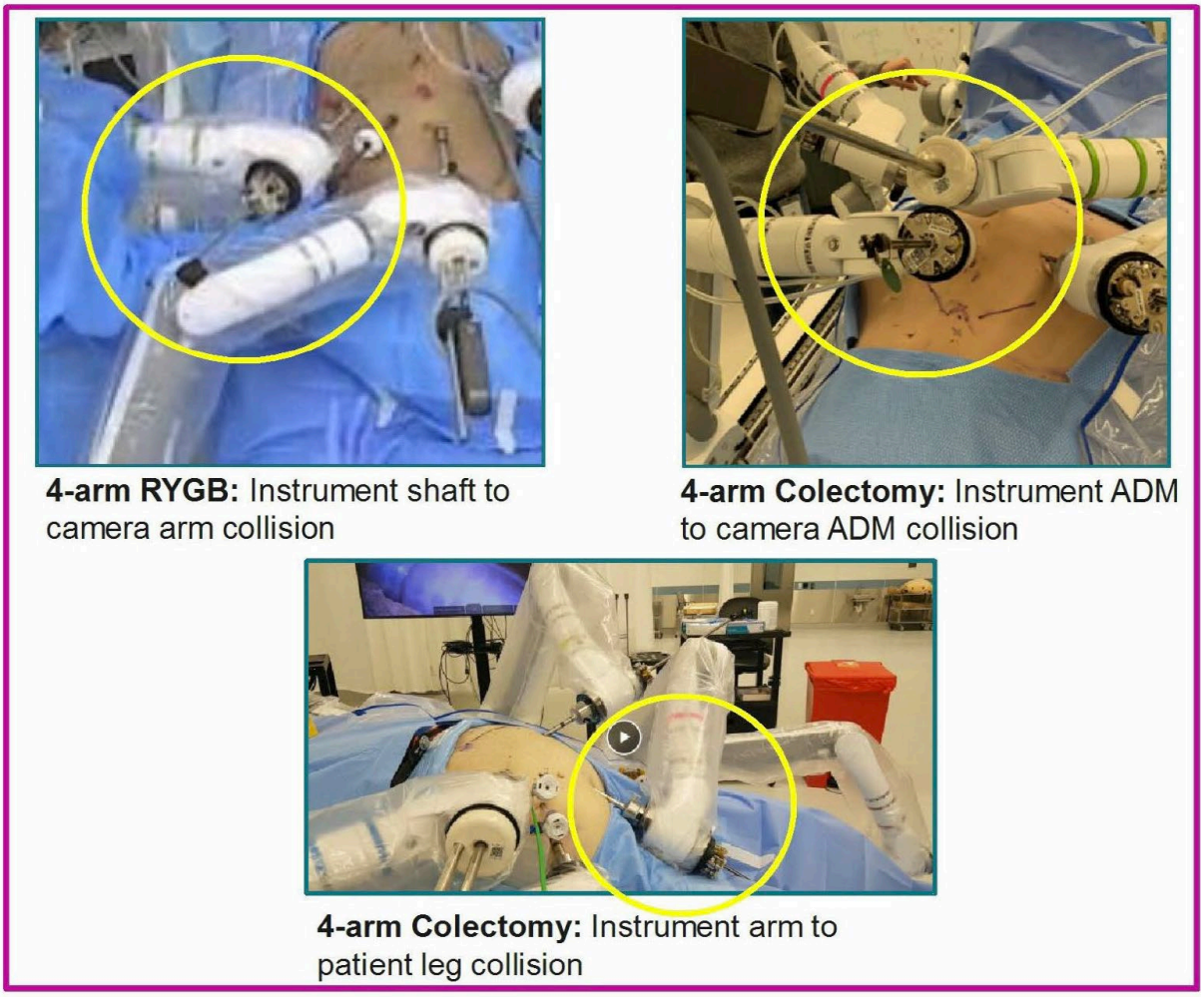
E. iPlatform Encounters "Existential" Technical Issues

Compounding the regulatory setback were multiple vexing "technical complications" that hindered iPlatform's development. Op.53; *see* Op.90. First, iPlatform's arms and instruments got dangerously hot—reaching up to 185°F, which risked scorching patients and medical personnel. Op.97; A3883-84, A1539-40. FDA would never let the device be tested on a live patient until its maximum temperature was brought down by at least 75°. A1539-40, A2073-74, A2172-73, A2411, A3883-84. Second, despite the stabilizing efforts during Project Manhattan, iPlatform remained prone to "break[ing] down in the middle of a procedure," sometimes for hours. A1548; *see* Op.97; A1584, A1634, A5127, A5270. Through 2021—the year of Milestone 1's deadline—iPlatform broke down 50% of the time. A5270, A2165-66. That is a nonstarter for live-patient testing, since patients could "bleed out" if the

[3] For these reasons, the evidence was legally insufficient to find that J&J's alleged breaches, rather than FDA's pathway change, caused iPlatform to miss Milestone 1. But since there are multiple other bases for reversing the judgment on Milestone 1, *see infra* §§ I-II, in the interest of judicial efficiency, J&J does not raise the court's causation finding in this appeal.

robot broke down mid-surgery with instruments stuck in their torsos. A987, A1548, A2144, A2391-92. Third, iPlatform's unique architecture yielded a "worst-case scenario," Op.97, in which a patient could become "caged inside" iPlatform's robotic arms, blocking medical personnel from accessing the patient in an emergency, A2169; *see* A5364, A1924-25.

Of all iPlatform's technical issues, the most dire were iPlatform's "workspace" problems. They arose directly from iPlatform's major differentiating feature—its unique bed-mounted, six-arm architecture. Crowding six arms into the tight space between the medical personnel and the patient made it harder for iPlatform to access the patient's anatomy. A5041, A4814. The arms also would regularly collide into each other or hit patients, as depicted here:



A4929; *see* A1345, A1410-12, A1539, A1575, A2287, A4829, A4831, A5143-45, A5395_16:30:00-22 (video), A5396_09:12:03-52 (video). At one point, a rogue arm almost poked out a bedside assistant's eye. A2144. In February 2020, Moll pronounced the "collision/work space issue" a "huge risk" that "threaten[ed] the differentiated value of the i[P]latform." A4326. He emphasized the need to solve the issue "ASAP" and fretted, "I cannot, in my own mind, conceive of an adequate beta software solution that, it appears, we are counting on." A4326; *see* A4734 (describing collisions that "no amount of software can solve"). Months later, in May

2020, the Auris team's principal surgeon consultant declared iPlatform's workspace issues an "existential threat" to iPlatform's "success." A4466. In February 2021, just 10 months before Milestone 1's deadline, that same surgeon warned J&J that the iPlatform architecture was "clinically unacceptable" and had "too many constraints … to be a commercially viable platform." A4804-10, A4777.

Nevertheless, the Court of Chancery expressed "overarching cynicism" about whether these technical issues caused iPlatform to miss the milestones. Op.92. The court suggested that J&J "concocted" these issues only after Fortis filed this suit. Op.4, 90-92. But Moll and other legacy Auris employees raised alarms well before the lawsuit, and J&J and the Auris team were working on these technical issues extensively before then. *E.g.*, A4438-40, A4326, A4466, A3500-01, A3446, A3455, A3464, A1546-48. The court also deemed these issues "solvable." Op.4; *see* Op.53-54; 96-97. But no witness testified *how* they would be solved, much less that they could be solved before the milestone deadlines—and the Auris team never solved any of them.

F. J&J Invests Unprecedented Resources To Overcome iPlatform's Challenges

In the years following the acquisition, the Auris program was the "top priority" for J&J's MedTech division. A2277. Moll testified that during his four years at J&J, no other project received "more resources or … more people or money" than iPlatform. A1410. J&J's Worldwide Chair of MedTech described Auris as a

"mission critical" project that received more "love and attention … than anything I've ever experienced in my 27-year career." A2277; *see* Op.119-20.

Funding: On top of the $3.4 billion purchase price, "J&J invested over $2.25 billion in the Auris program (broadly speaking) from 2019 to 2022." Op.82. J&J's investment in Auris "vastly exceed[ed] that of … any other medical device program at J&J." Op.82; *see* A5791-92. That amount also far exceeded what the Auris team said would be "necessary to achieve all ten milestones" in the six-year proposal it presented to J&J immediately after the merger. A3348, A3362-64; *see* A5805. For instance, in 2021, J&J budgeted $516.6 million for iPlatform R&D alone, nearly six times the corresponding allocation in the proposal. A4788, A3363.

Regulatory support: J&J also gave the Auris program extensive regulatory support. Op.48-49, 85-87. For example, in September 2019, upon learning the 510(k) pathway would be unavailable to iPlatform and that FDA might impose the most onerous pathway, Moll expressed the "need to elevate this to the highest JNJ level—they need to use their resources to push back." A3989. J&J responded by enlisting "some of the most senior folks within J&J" to persuade FDA to allow the De Novo pathway rather than the even more onerous Pre-Market Authorization pathway. A2187-88, A4083-84.

Verb & Vytronus resources: Among the Auris program's most significant challenges were critical personnel shortages, most notably highly trained engineers

with experience in surgical robotics. A1554, A2161-62, A4573. J&J solved that problem in early 2020 by purchasing Google's interest in Verb for $155 million. Op.49-50. J&J reassigned more than 200 Verb employees to the iPlatform team, Op.50; A1923, including "experienced engineers who had worked on a surgical robotics program," A1554. That allowed the Auris team to meet the hiring targets in its six-year plan. A3364, A5091. The legacy Auris team praised the Verb acquisition as "a giant leap forward for the Digital Surgery effort." A4222; *see* A4220-21, A4322.

"[A]t Moll's request," J&J also "purchased a company called Vytronus for $20 million to buttress Auris's capabilities." Op.82-83; A4216. The acquisition helped the Auris team "immediately strengthen[] the digital robotics talent pool." A4216; *see* A1922, A1187.

G. J&J Pivots Once It Becomes Clear iPlatform Will Never Be Viable In A Commercially Reasonable Timeframe

Despite J&J's efforts and investment, by 2021, with Milestone 1's deadline looming, iPlatform was still not "ready to be used on patients for any procedure." A2143; *see* A1762, A2129, A2135, A2162-63, A0759-60. Auris's own leaders admitted that iPlatform "never got to the point of being safe" to use on a live human for even the simplest procedure. A1557, A1551 ("there [were] quite a few reasons" iPlatform was "not ready" for use in live patients); A0759-60. That meant it could

not even be tested on a live patient—much less the scores of live surgeries needed for regulatory approval.

J&J explored options to salvage the project. One option was a revised two-stage strategy for bringing iPlatform to market: (1) a limited-release iPlatform "R1" system with a significantly reduced scope and no prospect of profitability, followed by (2) a fundamentally redesigned "R2" system. A4881, A4883, A4886, A4904, A1924. But even the diminished R1 system would not receive FDA approval until late 2025 or launch until 2026 or later. A5076, A5291, A5024. And the commercially viable R2 system would not launch until at best 2029, eight years past the first iPlatform milestone deadline and six years past the last. A5291.

Confronted with this reality, in December 2021, J&J made the "extremely difficult" decision to abandon iPlatform as a standalone system. A1925. J&J pivoted to the "Apollo" system—a hybrid of Verb's surgical bed and arms, iPlatform's surgeon console, and a computing tower that merges iPlatform and Verb technologies. A1925, A2159. Apollo outperformed the iPlatform R1 system in every procedure assessed. A5339, A5341, A2298. It also presented J&J's "fastest internal option" by far for bringing a product to market, A5264, and it would be "immediately" commercially viable, A2076. The Apollo system has since made significant progress toward FDA authorization. A2298. To date, however, no company has yet managed to achieve the market disruption that Auris and J&J set

out to achieve back in 2018, A1790, and J&J has yet to bring any surgical robot to market.

H. Fortis Sues J&J On Behalf Of Auris's Former Stockholders, And The Court Awards Fortis Over $1 Billion In Damages

In October 2020, Fortis sued J&J on behalf of Auris's stockholders. Op.53. After a bench trial, the Court of Chancery ruled in Fortis's favor on several key claims. Regarding Fortis's contract claims, the court recognized that iPlatform regulatory milestones were expressly "tied to" 510(k) clearance, Op.29, 68, and that FDA's pathway change made that impossible, at least for the first iPlatform milestone. Op.99. To overcome this "wrinkle in [Fortis's] breach of contract claim," the court ruled that J&J "had an implied obligation—at least for Milestone [1]—to use commercially reasonable efforts to achieve De Novo clearance." Op.99-102. "Doing so would facilitate 510(k) approval for the subsequent milestones." Op.103.

The court then concluded that J&J breached its purported obligation to use commercially reasonable efforts to obtain De Novo approval with respect to the first iPlatform milestone and 510(k) approval for the remaining iPlatform and GI milestones. The court did not find that the billions J&J expended or resources it supplied were inadequate, which should have ended the inquiry. The court instead found that J&J breached based on four management decisions: (i) Project Manhattan; (ii) J&J's decision to stick with the Milestone 1 strategy Auris had originally proposed rather than shifting to a stripped-down robot that was not

commercially viable; (iii) an unimplemented proposal to combine Verb hardware with iPlatform in late 2019/early 2020;[4] and (iv) J&J's decision in 2020 to offer supplemental employee bonuses that accounted for FDA's pathway change. Op.68-83. The court also criticized the integration of Verb's workforce into the Auris team, though it did not view this as a separate breach. Op.74 n.392. The court found that J&J's breaches—not FDA's pathway change or iPlatform's dire technical issues—caused J&J to miss the iPlatform and GI milestones. Op.89-113.

Separately, the court found that Milestone 7 (related to Monarch) became unattainable after the merger due to new FDA requirements that were not J&J's fault. Op.84-87. Yet, the court awarded damages on this milestone, finding that J&J committed fraud when, shortly before the acquisition, then-CEO Alex Gorsky told Moll that he thought there was a "high certainty" of achieving the milestone. A2734-35; *see* Op.124-26. The court did not, however, find that J&J believed that estimate to be false at the time. Nor did it address J&J's contemporaneous internal assessments putting the odds of achieving the milestone at 85%. A4242.

[4] The court found that this proposed combination also breached another contract provision, § 2.07(e)(iii). Op.73. But it found that the breach did not cause J&J to miss the net sales milestones, Op.112, and dismissed as moot Fortis's claim as to the regulatory milestones, Ex. C, Final Judgment 7. Because this breach finding does not support any liability, J&J does not raise this issue in this appeal.

In total, the court awarded Fortis more than $1 billion: $900 million for the missed iPlatform and GI milestones, $60.8 million on the fraud claim, and $122.6 million in prejudgment interest. Final Judgment ¶ 9.

ARGUMENT

I. The Court Erred In Using The Implied Covenant Of Good Faith And Fair Dealing To Rewrite The Contract's Express Terms.

A. Question Presented.

Whether the Court of Chancery erred in using the implied covenant of good faith and fair dealing to rewrite the contract's express terms. J&J raised this question below, A590-91, and the court considered it, Op.99-103.

B. Scope of Review.

The construction of a contract, including application of the implied covenant, is a pure question of law that this Court reviews de novo. *Oxbow Carbon & Mins. Holdings, Inc. v. Crestview-Oxbow Acquisition, LLC*, 202 A.3d 482, 502 (Del. 2019). This Court likewise reviews de novo a trial court's "application of law to its factual … determinations." *DCV Holdings, Inc. v. ConAgra, Inc.*, 889 A.2d 954, 960 (Del. 2005). Findings as to damages are reviewed for abuse of discretion. *Gotham Partners, L.P. v. Hallwood Realty Partners, L.P.*, 817 A.2d 160, 175 (Del. 2002).

C. Merits of Argument.

1. The implied covenant cannot be used to rewrite an explicit and critical term of the regulatory milestone provisions.

No phrase appears in the milestones more frequently or more prominently than "510(k) premarket notification(s)." Every single regulatory milestone includes an unambiguous contractual condition requiring FDA 510(k) clearance for a particular sort of surgery, by a specified date. A2840-42; Op.34-36. Especially

relevant here, achieving Milestone 1, for "general surgery," required obtaining 510(k) clearance for two specific types of surgeries—"one upper abdominal surgical procedure" and "one lower abdominal surgical procedure"—by December 31, 2021. A2841. Obtaining that 510(k) clearance would earn Auris stockholders $400 million. A2841. But the contract is clear that failing those conditions would mean J&J owed nothing. A2847. The parties even defined "commercially reasonable efforts" to require "efforts" only "in connection with … obtaining the applicable 510(k) premarket notification." A2845. That means no efforts are required towards any other type of regulatory approval.

The parties had good reason to choose 510(k) clearance—rather than the more onerous De Novo or Pre-Market Authorization pathways—as a required component of the milestone conditions. As explained above, *supra* 12, 17-18, 510(k) clearance offers multiple advantages over the other two pathways. It is far more reliable, with much higher approval rates—nearly double that of De Novo submissions. *Supra* 12; A5455. It is also the least costly, and generally requires less testing than the others. *Supra* 17; A5423. And consequently, it is the fastest pathway. *Supra* 17-18; Op.102; A5420-27, A5455.

Had Auris wanted to eliminate the 510(k) condition, it was free to bargain to delete it, or to insert "or De Novo." But J&J never demonstrated a willingness to agree to earnouts tethered to any other pathway, much less to accept a more onerous

burden at the same price tag and on the same terms. Eager to obtain the $3.4 billion upfront payment and strike a deal with J&J, Auris took on the risk that the 510(k) pathway would not be available for iPlatform—and did so fully aware of FDA's October 2018 feedback. *Supra* 16; A2675, A3938, A3940-41, A5439-41.

No one disputes that once FDA informed J&J in September 2019 that 510(k) was not "an appropriate regulatory pathway" for iPlatform, A5026-28, it was literally impossible to achieve Milestone 1 as written. As the Court of Chancery put it, the milestones "expressly contemplate[]" 510(k) approval. Op.99. This was no mere "wrinkle in [Fortis's] breach of contract claim." Op.99. It was an explicit contract condition.

The court committed clear legal error by overriding that contract condition and concluding that J&J nevertheless "had an implied obligation … to use commercially reasonable efforts to achieve De Novo clearance"—at least for Milestone 1. Op.99-103. The implied covenant is "not a license to rewrite contractual language," *Winshall v. Viacom Int'l Inc.*, 76 A.3d 808, 816 (Del. 2013), especially where "the parties are sophisticated business persons or entities," *Oxbow*, 202 A.3d at 508. It is a "limited and extraordinary legal remedy." *Nemec v. Shrader*, 991 A.2d 1120, 1128 (Del. 2010). The court violated four strict limits on this doctrine, each independently fatal to the implied covenant claim.

Contract addresses the issue. First, the implied covenant "does not apply when the contract addresses the conduct at issue." *Oxbow*, 202 A.3d at 507. It applies only "when the contract is truly silent concerning the matter at hand." *Id.* (cleaned up). Far from being "truly silent," this contract explicitly requires "510(k) premarket notification" as the regulatory pathway—eight times over. A2840-42.

The court could not turn that explicit condition into silence with the assertion that the contract "lacked a term to address what would occur if the 510(k) pathway were closed to iPlatform." Op.103. The contract also lacks a term to address what would occur if iPlatform hit a milestone a year late. But the absence of a contingency plan for failing to meet an explicit condition—whether temporal or regulatory—can mean only one thing: no earnout payment when the condition is not met.

Developments could be anticipated. Second, the court violated the rule that the implied covenant "only applies to developments that could not be anticipated." *Nemec*, 991 A.2d at 1126. "Even where the contract is silent, an interpreting court cannot use an implied covenant to re-write 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." *Oxbow*, 202 A.3d at 507 (cleaned up). There is no dispute that the contract here "could easily have been drafted," *id.*, to allow for *any* form of FDA approval, rather than limiting it to 510(k) at every turn.

The court did not overcome this legal bar by suggesting the parties had no "reason to believe that a more onerous pathway would be required." Op.101. The relevant legal question is not whether there were specific reasons to "believe" FDA "*would*" require a different path. *Id.* (emphasis added). The question is whether it was within the realm of *possibility* that FDA might deem iPlatform ineligible. *See Nemec*, 991 A.2d at 1126; *Oxbow*, 202 A.3d at 507-08. Of course it was. There was no legal right to a particular pathway; FDA always has discretion over whether to allow 510(k) clearance. *See In re Orthopedic Bone Screw Prod. Liab. Litig.*, 264 F.3d 344, 364 (3d Cir. 2001) ("Substantial equivalence determinations as well as the manner in which those decisions get made are functions committed to the discretion of the FDA."). Regulatory unpredictability is a major risk factor in this industry. *E.g.*, A2508; *supra* 16. Indeed, the contract expressly anticipates the sort of scenario that occurred here: that "developments from the FDA" might "affect the data required to obtain [FDA] approval," and that J&J could consider the "likelihood and difficulty of obtaining [FDA] approval." A2845. And the contract acknowledges that "factors and uncertainties … outside of the control" of J&J might render the milestones unachievable. A2847. Auris accepted the risk of those "developments from the FDA."

Not clear from the contract that the parties would have agreed. Third, "a court can only imply terms when it is clear from the contract that the parties would

have agreed to the omitted terms." *Nationwide Emerging Managers, LLC v. Northpointe Holdings, LLC*, 112 A.3d 878, 898 (Del. 2015) (cleaned up). The contract does not give any indication—much less make it "clear," *id.*—that the parties would have agreed to eliminate the condition of 510(k) clearance, and the court did not find otherwise. Nor does extrinsic evidence supply reason to believe that J&J would have agreed to anything other than 510(k) clearance—much less that J&J would have done so on the same economic terms in the current deal, given the extra expense, time, and resources required to obtain De Novo approval, as well as the significantly greater risk of failure. *See supra* 12, 17-18, 30; A1881. Indeed, the only evidence on this point was clear that J&J would *not* have done so. A1880 ("If it was anything beyond [510(k)], it would add time, investment, and it would impact the valuation."). The court never found that J&J would have agreed to the court's rewritten version of the contract; it simply ignored this essential legal requirement.

No arbitrary conduct. Finally, the implied covenant is unavailable without proof that J&J "acted arbitrarily or unreasonably, thereby frustrating the fruits of the bargain that the asserting party reasonably expected." *Nemec*, 991 A.2d at 1126. Fortis does not suggest—and the court did not find—that FDA's choice of regulatory pathway for iPlatform had anything to do with J&J, much less with J&J acting arbitrarily or unreasonably. The decision to foreclose 510(k) clearance for iPlatform was FDA's decision alone.

* * *

The court's improper revision of the milestones gave Auris an impermissible "windfall"—to the tune of hundreds of millions of dollars. *Paul v. Deloitte & Touche, LLP*, 974 A.2d 140, 146 (Del. 2009). And the implications extend beyond the enormous stakes in this case. Earnouts are a critical piece of many M&A deals, particularly in the acquisition of start-ups or other high-risk businesses. *See, e.g.*, Op.1; Richard De Rose, *The Ins and Outs of Earn-Outs: A Delaware Perspective*, Am. Bar Assoc. Business Law Today (Mar. 15, 2022), https://tinyurl.com/2h4dduvu. If courts will not enforce earnout provisions as written, parties will be hesitant to include them at all—which would mean deals that may be critical to advancing science and society will simply never get done. And if parties cannot trust Delaware courts to "[h]old[] sophisticated contracting parties to their agreement" in a way that "promotes certainty and predictability in commercial transactions," *Glaxo Grp. Ltd. v. DRIT LP*, 248 A.3d 911, 919 (Del. 2021), they will stop treating Delaware as their preferred forum.

2. The judgment must be reversed as to all iPlatform and GI milestones.

The consequences of FDA's decision to close the 510(k) pathway to iPlatform extend beyond the court's erroneous breach ruling as to Milestone 1. The court also erred in finding J&J liable for the remaining iPlatform and GI regulatory milestones. The court's reasoning depended on a daisy chain of assumptions:

1. J&J was obligated to use the De Novo pathway to satisfy Milestone 1 (based on the court's improper rewrite of that provision);

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, *supra* 17-18;

4. following a De Novo grant, 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," Op.104, by the contractual deadlines.

Just as assumption 1 fails—for lack of any contractual duty to use the De Novo pathway to meet Milestone 1—so do all the others. There was no contractual duty to execute a regulatory bank shot of using the De Novo pathway for one milestone in hopes of unlocking 510(k) review for others; each milestone speaks only to using the 510(k) pathway, as does the definition of commercially reasonable efforts. And there was no guarantee that FDA would grant De Novo approval for Milestone 1, nor that FDA would then allow J&J to use that De Novo grant as a predicate for 510(k) submissions for subsequent milestones.

The court erred in imposing the extra-contractual obligation of seeking De Novo approval for Milestone 1 as a (theoretical) key to unlock 510(k) clearance for the other milestones. The parties negotiated all the milestones, timelines, and payments without any contractual obligation to use the De Novo pathway, at any

point, to meet any milestone. The undisputed testimony was that "[i]f it was anything beyond [510(k)], it would add time, investment, and it would impact the valuation." A1880. As this Court has recognized, there is no reason to believe a buyer like J&J would have "nonetheless [been] willing to commit" to all the exact same earnout payments on the same timelines if a critical term of those earnout provisions changed. *Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1270-71 (Del. 2017).

3. At minimum, the damages award for all the regulatory milestones must be vacated.

Separately, the legal error regarding Milestone 1 infected the damages awarded for all the iPlatform and GI regulatory milestones. The court calculated damages for each milestone based on each party's pre-merger estimates of the probabilities of success. Op.130. But those probabilities were premised on the availability of the 510(k) pathway. Once FDA required the De Novo pathway for at least Milestone 1, it drastically decreased the odds of achieving both Milestone 1 and every remaining milestone that depended on Milestone 1's success. It is undisputed 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. A5455. If, as the court hypothesized, all the other milestones were contingent on achieving that objective, then the odds of achieving them would also decline by at least the same proportion.

But the court made no such adjustment to the pre-merger probabilities of success. That failure to consider such a consequential factor in calculating expectation damages was an abuse of discretion. *See Gotham Partners*, 817 A.2d at 177.

II. The Court Misinterpreted The Contract's "Commercially Reasonable Efforts" Provision.

A. Question Presented.

Whether the Court of Chancery misinterpreted the contract's "commercially reasonable efforts" provision. J&J raised this question below, A558-68, and the court considered it, Op.56-83.

B. Scope of Review.

This Court reviews de novo the Court of Chancery's contract interpretation and application of law to factual determinations. *Exelon*, 176 A.3d at 1266-67; *DCV Holdings*, 889 A.2d at 960. This Court will reverse "clearly erroneous" factual determinations. *Nationwide Emerging Managers*, 112 A.3d at 889.

C. Merits of Argument.

1. The court misinterpreted the contract's defined "commercially reasonable efforts" provision in two fundamental ways.

The contract obligates J&J to use "commercially reasonable efforts" to achieve the regulatory milestones, but defines that obligation to reserve to J&J broad discretion over how to calibrate those efforts based on its own business judgment regarding potential profitability, competitiveness, and other factors. Having just spent $3.4 billion to acquire Auris, J&J bargained for the latitude to run the business as it saw fit. The Court of Chancery committed two interrelated, fundamental errors in excising from the contract the broad discretion that J&J expressly bargained for.

a. The contract does not prioritize the milestones above all else. The contract repeatedly reinforces J&J's right to exercise its discretion and commercial judgment. The contract defines J&J's required efforts as "the expenditure of efforts and resources … in connection with obtaining the applicable 510(k) premarket notification." A2845. The efforts must be measured not against industry standards, but "the usual practice of [J&J] with respect to priority medical device products." A2845. Moreover, the contract affirmatively recognizes J&J's right to take "into account" factors that J&J considers in making any important product-development judgment, including "issues of efficacy and safety," "competitiveness" against other companies' products, "risks inherent in … commercialization of such products," "guidance … from the FDA," and the "expected … profitability … of the product." A2845.

The court overrode all these expressly reserved factors by isolating one word—"priority"—and reading it out of context to mean that J&J must prioritize achieving the regulatory milestones above all of J&J's commercial interests or goals. The court used a lone dictionary definition to conclude that "a 'priority' device is one given 'superiority in rank, position, or privilege.'" Op.67 (quoting *Priority*, Merriam-Webster). The court then leveraged this definition into a pronouncement that J&J had no discretion to "deprioritize the milestones." Op.82. It held that "J&J was not, for example, permitted to prioritize" iPlatform's "commercialization,

product differentiation, or short-term profitability at the expense of achieving the milestones," Op.78, even though the contract expressly allows J&J to take these considerations "into account" when calibrating its efforts to meet the milestones. A2845. The court likewise treated efforts that "might have been beneficial to [J&J's] broader robotics program, its profit margins, or its commercialization strategy"—no matter how compelling—as impermissible insofar as they did not "prioritize" achieving the iPlatform milestones above all else. Op.64, 78. *Any* step J&J undertook had to advance the "end goal" of "achiev[ing] the iPlatform regulatory milestones." Op.75.

The contract's plain language does not, however, require J&J to prioritize iPlatform's milestones above J&J's other priority medical devices or its corporate goals. It does not require J&J to take all efforts, nor "reasonable *best* efforts," as other sections of the contract require. *E.g.*, A2886 (emphasis added). It requires J&J to take only those efforts that are commercially reasonable for J&J. And it provides only that J&J must use "efforts" to achieve the milestones that are "consistent with" J&J's own "usual practice" with respect to other "priority medical device[s]." A2845. J&J's "usual practice" was not to prioritize seeking regulatory approval for early-stage medical devices over its business goals for its "broader [device] program, its profit margins, or its commercialization strategy." Op.64; *see* A2179. No sound

business does that—a merger agreement is not a suicide pact—and J&J did not agree to it here.

b. The court effectively excised the ten factors. A consequence of the court's approach was to improperly read the ten-factor definition of "commercially reasonable efforts" out of the contract. J&J went out of its way to bargain for these factors—including judgment calls by J&J regarding the "risks inherent in … commercialization," "competitiveness'" with third-party products, and potential "profitability" and "return on investment"—to protect its discretion and business judgment in running the $3.4 billion company it was buying. A2845. 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. It also means that the court could not find a breach without assessing the ten factors and concluding that no balance of the factors could reasonably support the challenged decision.

The court downgraded these key factors to near irrelevance in concluding that "[a]lthough J&J was entitled to consider certain factors in devoting efforts and resources to iPlatform, … J&J was not … permitted to prioritize" *any* of them over achieving a milestone. Op.78. This analysis so completely supplanted the ten factors that the court found most of the breaches without even mentioning any of the factors—much less methodically analyzing them.

The court justified demoting the ten factors by citing to the "mandate that J&J follow its 'usual practice' for 'priority medical device[s].'" Op.67. The court reasoned that this requirement "cabined" the "discretion" that the ten factors otherwise reserve to J&J. *Id*. This inverts the contract. The ten factors expressly qualify the "priority medical device" clause, not the other way around: J&J may "tak[e] into account" each factor when setting the level of efforts "consistent with" its "usual practice" with respect to a "priority medical device." A2845. The factors recognize there is not one right way of doing things. The factors plainly 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 effort 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. In concluding that J&J could not take *any* action "at the expense of achieving the milestones" *regardless* of all these factors, Op.78, the court erroneously ignored the contract terms and supplanted J&J's business judgment with its own.

* * *

These two interrelated errors flout this Court's direction that "[i]n giving sensible life to a real-world contract, courts must read the specific provisions of the contract in light of the entire contract." *Chicago Bridge & Iron Co. N.V. v. Westinghouse Elec. Co.*, 166 A.3d 912, 913-14 (Del. 2017). "[E]specially … when

the contract at issue involves a definitive acquisition agreement addressing the sale of an entire business," *id.*, it makes no real-world sense to elevate one word ("priority") over a lengthy and nuanced standard, and posit that this word requires an acquirer paying $3.4 billion to elevate any narrow regulatory goal over profitability or commercial viability of the entire enterprise.

2. The court's legal errors infected every breach finding.

The contract's "efforts" requirement addresses J&J's "expenditure of efforts and resources" toward achieving the milestones. A2845. There is no dispute that J&J devoted *unprecedented* "efforts and resources" to iPlatform, including:

- spending $2.25 billion, Op.82, and devoting "more people [and] money" than to "any other medical device [program at] J&J," A1410;
- spending far more than what Auris projected as necessary "to achieve all ten milestones," A3348, A3362-64; and
- buying two companies for a combined $175 million to give the Auris program additional technology and meet its need for 200 highly experienced employees, Op.50, 82-83.

Notably, the court took no issue with the *level* of resources J&J dedicated to iPlatform. Instead, the court found breaches because it disagreed with a few of J&J's strategic decisions about *how* to go about developing iPlatform. That by itself is grounds for reversal. The contract authorizes a court to assess *overall* "efforts and resources" throughout the entire milestone period, not to flyspeck individual strategic management decisions. In any event, the court's interpretive errors pervaded each breach finding.

a. Project Manhattan. The central facts about Project Manhattan are undisputed:

- When J&J raised concerns about iPlatform's technical challenges, Auris persuaded J&J to "defer" some of its "technical due diligence" on iPlatform until after the merger. Op.29.
- In February 2019, before the merger closed, Auris recommended identifying "post-merger synergies" between iPlatform and Verb. A2933.
- J&J believed a "deep dive assessment" of Verb and iPlatform would give J&J important insight into both robots, Op.41 (quoting A3502-03), and enable J&J to "find synergies between platforms to decrease project risk and accelerate time to commercialization," Op.40 (quoting A3406).

It was eminently reasonable for a company to perform a detailed analysis of an asset it just spent $3.4 billion to acquire. The court did not question as much. Project Manhattan enabled J&J to assess at least the following contractually authorized considerations with respect to iPlatform: "issues of efficacy and safety"; "risks inherent in [iPlatform's] development and commercialization"; and "expected and actual competitiveness of alternative products." A2845. That would have been dispositive but for the court's central error of reading the contract as a "mandate" to prioritize achieving iPlatform's milestones above all else—including the ten factors that J&J was expressly allowed to consider. Op.67.

The court found that Project Manhattan was a breach for two reasons, both incompatible with the contract. First, in the court's view, the exercise prompted the Auris team to redirect resources and attention toward the assessment, causing

iPlatform "needless setbacks and resource drains." Op.69-71. Second, the court found that Project Manhattan somehow "aid[ed]" Verb with "no upside for Auris," Op.70-71, even though it yielded a decision to shelve Verb and devote all those resources to iPlatform alone. Op.45.

Even accepting these characterizations, the court's breach finding was legally erroneous. The contract did not prohibit J&J from conducting post-merger technical due diligence on iPlatform that everyone agreed was necessary, nor from identifying "synergies" between iPlatform and Verb. Nor did it prohibit J&J from pursuing otherwise reasonable business strategies just because they might have an ancillary short-term effect of "hinder[ing], rather than promot[ing], iPlatform's achievement of the regulatory milestones." Op.3. The contract also did not require J&J to prioritize iPlatform above Verb: Verb was another "priority" medical device, *see* Op.38, and the parties expressly agreed that sales of Verb would count toward the net sales milestones, A2842, A2920-22. J&J committed only to employ efforts "consistent with" its usual practice with respect to other "priority" devices. It did not agree to treat achieving iPlatform's milestones as its *sole* objective, regardless of commercial reasonableness under the ten factors.

b. Declining to adopt a watered-down "MVP" strategy to obtain regulatory approval for a robot that would not be commercially viable. One element of Milestone 1 was 510(k) clearance for an "upper abdominal surgical procedure."

A2841. Before and immediately after the merger, Auris communicated to both FDA and J&J its intention to meet that requirement with a gastric bypass surgery called RYGB, using at least five surgical arms. Op.76; A1399, A1551-52, A3652, A3513, A2673.

After Project Manhattan in 2019, and 2.5 years before Milestone 1's deadline, some Auris personnel proposed a dramatic "shift" in strategy. A607; *see* Op.76; A3504-05, A3523-24. While the proposal was vague, they apparently contemplated focusing solely on a simpler surgery and scaling back iPlatform to as few as "just three functioning arms"—a marked downgrade from Intuitive's robot, which had four functioning arms and was cleared for numerous surgical procedures. A640; *see* A1346-47, A1590. The idea was not to devise a product with any commercial value. A1417. Rather, the sole goal was to seek FDA approval for a "basic pre-commercial" stripped-down prototype, A327, that might "never even" get to market, A3504-05. *See* Op.9, 76; A1346-47, A1701, A3523-24. iPlatform would not be commercially viable unless J&J continued developing—and separately secured FDA authorization for—additional capabilities. A1347, A1417. At trial, Fortis dubbed this a "minimally viable product," or "MVP." J&J did not pursue this strategy because it did not meet J&J's high standards for the use of MVPs and would not serve the aims of competitiveness and profitability (business concerns the contract's ten factors expressly protected). A3504, A1752.

The Court of Chancery found that J&J breached by staying the course. Op.78-80. This was another iteration of the court's misapprehension of the import of the ten factors. The court correctly characterized the approach that Auris originally proposed (and J&J pursued) as "ideal" for multiple reasons, each reflecting one or more of the ten considerations. Op.76. First, "Auris would have met two milestones at once (the General Surgery and Upper Abdominal Milestones)." Op.76. Besides furthering the interests of Auris's stockholders who would cash in for both milestones, this strategy was consistent with J&J's contractual right to consider "the likelihood and difficulty of obtaining FDA" authorization, A2845; as the court found, that factor "reasonably include[s] focusing on an indication necessary for a subsequent clearance." Op.88. Second, J&J's approach was consistent with considering "commercial … risks": Obtaining clearance for an umbrella procedure (Milestone 2) would have promoted "broad commercialization" for iPlatform, Op.77, by enabling J&J to market iPlatform for a wide variety of surgical procedures, A1398. Third, the original approach "furthered" J&J's interest in iPlatform's "'profitability,'" Op.77-78 (quoting A2845), because RYGB would require users to purchase J&J's other "high margin" surgical instruments. Op.77 (citing A1347). Fourth, pursuing initial clearance for five or more arms would "improve" iPlatform's "'expected and actual competitiveness'" against Intuitive's four-arm robot, Op.78 (quoting A2845). All this is why Moll did *not* initially want

to pursue a scaled-back iPlatform. As he explained, "if you didn't do it all at first, everything might not come along." A1552.

Once the court confirmed that J&J's approach was consistent with the contract's ten factors, that made the approach "commercially reasonable" by definition under the contract. That should have been the end of the court's analysis. But the court found that was not enough, because—here, again—"J&J was not … permitted to prioritize" any of those considerations "at the expense of achieving the milestones." Op.78. It believed the contract required J&J to sacrifice all favorable considerations in favor of eking out an unmarketable product that could possibly achieve regulatory approval. And, on that basis, the court found the "milestone structure that J&J and Auris agreed upon reflected an MVP strategy, albeit not explicitly." Op.75.

Reading the contract to elevate milestone achievement above all else was incorrect for the reasons already explained. It was also wrong for several other reasons. First, nothing in the contract required J&J to pursue a stripped-down, unmarketable version of the robot. The court had no authority to insert an MVP term "not explicitly" in the contract. Op.75.

Second, the court stated that "[e]ven if" J&J could prioritize the ten factors that the contract enumerates, "those considerations were promoted through an MVP approach." Op.78. If so, that would just mean that pursuing an MVP was a

permissible option, not that it was the *only* permissible option. As Fortis conceded, the milestones "leave freedom to choose among multiple procedures" and "do not require specific features, numbers of arms, or architecture." A183-84. To conclude that J&J's efforts were commercially unreasonable, the court would have had to conclude that *no* assessment of the ten factors could have supported the approach that everyone previously agreed was the "ideal" approach. The court did not make—and could not have made—any such finding.

Third, the contract requires J&J to take only those efforts that are "*commercially* reasonable." The court read that critical word out of the contract. No reading of the contract required J&J to pursue a prototype that might "never" get to market. A3504; *see* A1417; Op.76, 94 & n.491, 112-13; A3504-05, A3523-24. The contract did not require J&J to expend resources seeking FDA approval for a design that eliminated the main feature that Auris touted would so differentiate iPlatform from Intuitive's robot as to "leapfrog" it: having six functional arms. *Supra* 9-10. The contract certainly did not require J&J to shift to a design with three functional arms that was markedly inferior to the competition along that dimension.

Fourth, the court observed that "it is industry standard to follow an MVP strategy." Op.79. Even assuming the Auris team members' proposed "'start-up' approach" actually represented the industry standard, A3504, it was legally improper to apply such a standard, because the contract expressly measures the reasonableness

of efforts against *J&J's* "usual practice." A2845; *see* Op.37. On that topic, the court found that "J&J's own practice … was to follow an MVP strategy," citing to J&J's approach for Verb and an orthopedic surgical robot called Velys. Op.67-68, 80. The record is uncontested, however, that J&J's MVP standards—which it applied for Verb and Velys—were fundamentally different from the Auris team's proposal: For J&J, an MVP has to be (1) "safe and efficacious"; (2) "commercially viable"; and (3) architecturally sound, meaning it does not require architectural redesign to make it commercially viable. A1752, A0814. Even if J&J managed to overcome the many obstacles to the first criterion, *see supra* 19-22, the Auris team's proposal failed the latter two requirements. A stripped-down version not intended to get to market was not commercially viable. A1590, A2290. And the three-armed robot would, of course, need to be redesigned to use all six arms without collisions or other workspace issues and to complete the more complex surgeries the market would demand. A1411-12, A1552, A1701, A1752.

In contrast, J&J's MVP approach for Verb and Velys, *see* Op.80, satisfied all three criteria. For each, J&J prioritized seeking approval for "fully finished," "elegantly designed product[s]," A2560, that "would be commercializeable" upon launch, A0814, and that would require "no architectural change" for later iterations or additional features. A1702; *see* A2628, A0896. J&J never undertook a contractual obligation to pursue a watered-down MVP strategy so fundamentally beneath its

own standards. Under the ten factors, J&J was well within its discretion to focus on commercially viable designs with the best prospects for getting to market quickly, competing with Intuitive's robot upon launch, and making a profit.

c. Proposal to combine Verb/iPlatform. The court further erred in finding that J&J breached by "mesh[ing]" iPlatform "with Verb components, including certain hardware" following Project Manhattan in late 2019 or early 2020. Op.72. This finding was so central to the court's opinion that the court mentioned it 15 times. But it is both clearly erroneous and legally flawed.

The undisputed record refutes the court's finding about "mesh[ing]" during that timeframe. Every 2019-2020 document the court cited showed only that J&J was *considering* this strategy, known as iPlatform+. *E.g.*, Op.72-73 nn.386, 388, 390. But, as even Fortis conceded, "J&J ultimately chose not to incorporate Verb components into iPlatform." A0638 n.21; *see* A289, A1531, A2131-33, A2161, A4227. J&J never actually combined the robots until long after 2019—in late 2021, by which time Milestone 1 was about to expire and iPlatform could not have launched until 2026 or later, years after the other milestones expired. A5291, A5024. Only then did J&J "pivot[]" to the Apollo system, a strategy that combined "Verb's bed-based architecture" "with certain iPlatform components and accessories." Op.55. The court's finding of breach based on a fictional combination was clear error.

Even if J&J had "meshed" Verb components with iPlatform at the earlier juncture, that would not have been a breach. The contract explicitly anticipates the milestones can be satisfied with "derivates" of and "enhancements" to iPlatform. A2917. J&J thus had every right to combine its robotics technologies if it was commercially reasonable under the ten contractual factors. As the court noted, the rationale behind the iPlatform+ proposal was to "elevate [the] surgeon experience [and] improve patient care," Op.49 (quoting A4206), and it "'ma[de] all the sense from [a] traditional development standpoint …' to compete with Intuitive," Op.46 (quoting A3521). These considerations fit squarely within J&J's discretion to "tak[e] into account" "risks inherent in the development," "competitiveness of" third-party products, "issues of efficacy," commercialization risk, and expected profitability. A2845.

d. Integrating Verb employees with iPlatform team. The court did not "view the integration [of Verb employees] as a separate breach" but just a "continuation of the injury from Project Manhattan and the [supposed] robot combination." Op.74 n.392. Accordingly, the court's findings with respect to the employee integration cannot independently support the judgment. Regardless, it was error to treat the employee integration as contributing to a breach.

Here, again, the court did not find that it was unreasonable for J&J to acquire a resource with 200 "experienced [robotics] engineers" that Auris desperately

needed and expressly requested. A1554; *see* A1923, A4573. The court did not dispute that the acquisition was necessary to fill critical "resource gaps" in areas that were "difficult" for Auris to staff, A2161-62; *see* A1554, A4573, and to forestall "long-term resource drain" and more "operating complexity," A4099.

Rather, the court found the integration was problematic based on its view that it contributed to milestone delays. The court cited a J&J presentation characterizing the step as a "[o]ne-time highly, disruptive change," Op.74 n.394 (quoting A4099), and blamed the integration for layoffs, attrition, and hostility between the legacy Verb and Auris factions, Op.50, 74-75. But even if the integration did not go perfectly or had a short-term impact on progress toward some of the milestones, that would not have contributed to a breach. Decisions about how to integrate a new workforce lie in the heartland of management discretion. Far from limiting J&J's inherent and essential discretion to determine how best to integrate a massive new workforce, the contract reserved for J&J decisions about how to overcome "risks inherent in the development" and achieve "return on investment," A2845. An otherwise essential infusion of talent did not become impermissible just because it may have caused short-term disruption.

e. Offering supplemental employee incentives. The court also found that J&J breached the contract in 2020 by offering employees *more* financial rewards in connection with securing FDA approval of iPlatform. Op.80-81. By way of

background, in 2019, to attract and motivate new hires for the Auris program, J&J implemented a cash incentive program that was aligned with the 510(k) pathway required by the milestones. A3517-19. J&J never revoked that program. But when FDA took the 510(k) pathway off the table for iPlatform, and J&J determined that the iPlatform and GI milestones were unattainable, J&J added "unprecedented" supplemental bonuses, A4467, that would reward employees with millions more dollars if iPlatform defied expectations and achieved some of the later regulatory milestones in the contract, and also if it achieved certain timelines revised to accommodate the change to the De Novo pathway. Op.80-81; *see* A4467 ("Yesterday you had 0 today you are back at 100%"); A3517-18, A2070-71, A4774.

The court thought the additional incentives constituted a breach because they "negatively affected employees' motivation to work towards the [earlier] … milestones in the" contract. Op.81. But under no rational reading of the contract was it a breach to offer to pay employees more money for additional company successes. The incentive program is exactly the sort of discretionary action the contract protects, whether as a reaction to "developments from the FDA," a recognition of "the likelihood and difficulty of obtaining FDA … approval," or a way to overcome commercial and development "risks." A2845.

* * *

Because each of the court's breach findings was unfaithful to the clear contract language, this Court should reverse the judgment on the iPlatform and GI milestone breach-of-contract claims. At minimum, if this Court finds error as to any breach finding, it must vacate the judgment and direct the Court of Chancery to reassess causation and damages as to any remaining breach(es).

III. The Court Erred In Finding J&J Liable For Fraud.

A. Questions Presented.

1. Whether the Court of Chancery erred in finding that J&J committed fraud, where there was no evidence J&J actively concealed any fact and no evidence that J&J knew Gorsky's statement was false. J&J raised this question below, A0585-87, and the court addressed it, Op.124-26.

2. Whether the Court of Chancery erred in allowing Fortis's fraud claim to proceed despite contractual language foreclosing arguments based on extra-contractual fraud. J&J raised this question below, A0101-06, and the court addressed it, Ex. A, Motion to Dismiss Memorandum Opinion ("MTD-Op.") 21-29.

B. Scope of Review.

This Court reviews de novo "a ruling ... denying a motion to dismiss." *Terrell v. Kiromic Biopharma, Inc.*, 297 A.3d 610, 617 n.16 (Del. 2023) (citation omitted). Factual findings, like those supporting the court's finding of fraud, must be "sufficiently supported by the record and … the product of an orderly and logical deductive process." *Geronta Funding v. Brighthouse Life Ins. Co.*, 284 A.3d 47, 59 (Del. 2022) (citation omitted).

C. Merits of Argument.

Additional background is necessary to understand Fortis's fraud claim. In 2018, J&J initiated a study of its NeuWave Flex device in a non-robotic context. Flex was a therapeutic ablation instrument, already on the market, that J&J planned

to pair with Auris's Monarch robot to achieve Milestone 7, relating to soft tissue ablation in the lungs. In November 2018, a patient involved in the Flex study died. A2694. J&J promptly reported the death to FDA, which published it on FDA's website. A2696, A1367, A1884. Three separate reviews of the circumstances found no issues with the Flex device or the study. A3091, A3181 (FDA); A2690 (Data and Safety Monitoring Board); A2191-92 (J&J's clinical health and safety team).

In January 2019, Auris proposed a milestone involving 510(k) clearance of a combined Monarch-Flex device for robotic soft tissue ablation in the lungs. A2722. The proposed milestone deadline was December 2022. A2722. After reviewing the information available, including an initial review indicating that Flex did not cause the patient death in the Flex study, J&J calculated an 85% likelihood of achieving the milestone. A4242, A4327, A2724, A1883-85. Auris independently reached the same conclusion (although it claims to have been unaware of J&J's public disclosure of the death). A2810. On January 24, Gorsky delivered J&J's latest proposal to Auris, noting that he believed there was a "high certainty" of achieving Milestone 7, almost four years away. A2734-35.

After the merger closed, on April 3, 2019, J&J learned for the first time that FDA would impose additional requirements if J&J wanted to use Flex in a lung treatment. A3342. Specifically, J&J would have to seek an Investigational Device Exemption (IDE)—which allows a device to be used in a clinical study—and

conduct further clinical testing. A3343-44. FDA did not link that direction in any way to the patient death. A2193, A3343-45. These additional requirements contributed to Monarch's inability to achieve Milestone 7.

The Court of Chancery found that J&J did not cause the failure to meet Milestone 7. Op.85-86. Yet, the court ordered J&J to pay most of the milestone amount, finding that J&J committed fraud based on Gorsky's pre-merger comment about the likelihood of achieving Milestone 7. Op.125. That theory, which Fortis first raised three years into the litigation, is both lacking in any evidentiary support and foreclosed by the terms of the contract.

1. The undisputed evidence defeats Fortis's fraud claim.

A fraud claim requires proof of several elements, including "(1) a false representation, usually one of fact, made by the defendant; [and] (2) the defendant's knowledge or belief that the representation was false, or was made with reckless indifference to the truth." *Stephenson v. Capano Dev., Inc.*, 462 A.2d 1069, 1074 (Del. 1983). Fortis offered no evidence—and the court found no facts—supporting either.

a. No proof that J&J "actively concealed" any material fact. The court did not conclude that "Gorsky's statement [was] an 'overt misrepresentation'"; it considered the evidence of that "borderline." Op.125. Instead, it found J&J liable on

a theory of "deliberate concealment of material facts," *Capano*, 462 A.2d at 1074—specifically, that J&J actively concealed the patient's death. Op.125.

Fortis could not prevail on that theory without proving that J&J "took some action affirmative in nature designed or intended to prevent, and which does prevent, the discovery of facts giving rise to the fraud claim, some artifice to prevent knowledge of the facts or some representation intended to exclude suspicion and prevent inquiry." *Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 150 (Del. Ch. 2004). J&J took no such "affirmative action," and the court did not find it did. That alone defeats the claim.

The undisputed evidence shows the opposite of affirmative concealment: Upon learning of the death, 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. A2695-96. The law is clear that J&J cannot be found liable for "concealment"—much less "active concealment"—of a fact that it made "a matter of public record." *Bovay v. H. M. Byllesby & Co.*, 38 A.2d 808, 818 (Del. 1944); *see Garner v. Glob. Plasma Sols. Inc.*, 590 F. Supp. 3d 738, 747 (D. Del. 2022) (Bibas, J.).

b. Failure of proof that J&J knew Gorsky's statement to be false. The court did not find that J&J knew achieving Milestone 7 was not "highly certain." Nor could it have. The undisputed evidence is that J&J *believed* it was; its

contemporaneous internal documents assessed the milestone's achievability at 85%. A4242.

At trial, Fortis tried to show that J&J knew Gorsky's statement about "high certainty" was a lie by arguing that J&J (1) knew of the Flex study patient death; (2) knew the death would lead FDA to impose additional requirements on Flex; and (3) knew that would prevent J&J from achieving the milestone. But the court found that J&J *knew* only (1)—not that it knew consequences (2) and (3). Op.125.

Nor could the court have made those additional knowledge findings, because J&J's internal 85% assessment came after the death. A4232, A4242. The only evidence on the subject confirms that J&J believed the death would not affect the milestone because, by then: (1) the independent Data and Safety Monitoring Board had determined that the surgeon's "technique and not the device [was] the more proximate cause" of the death, A2695; *see* A1883-84; and (2) FDA was aware of the death and, at the time, made no adverse findings or otherwise indicated a regulatory change, A3091, A3181.

There was not a shred of evidence contradicting J&J's trial testimony—and the contemporaneous record—that J&J did not "believe that the patient death would have an impact on achieving the timeline proposed by Auris." A1885; *see* A2192. FDA never suggested a change in the regulatory requirements until April 2019, months after Gorsky's statement. A3342, A3372. Even then, FDA did not tie the

additional requirement to the patient death, but instead cited concerns about treatment of primary lesions in the lung. A3592-93.

Judgment on the fraud claim must be reversed for lack of any factual basis.

2. The contract's exclusive remedy provision bars Fortis's fraud claim.

Separately, the contract bars this fraud claim. Section 8.05(b) provides: "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." A2903 (emphasis added). Fortis's claims obviously were made "after the Closing," and "relate to this Agreement." Thus, the contract's "indemnification provisions" provide the only available remedies, unless the claims are otherwise exempted. As the court correctly found, § 8.05(b) does exempt some "fraud claims," but only those "'with respect to making the representations and warranties *in this Agreement*'"; it does not exempt "fraud claims based on extra-contractual representations—like those pressed by Fortis." MTD-Op.24 (emphasis added). In other words, the only recourse for Fortis's fraud claim was the contract's indemnification provisions, which provide no remedy.

Nevertheless, the court allowed the fraud claim to proceed, holding that such claims can never be disclaimed except in one specific way: "a clear anti-reliance clause by which the plaintiff has contractually promised that it did not rely upon statements outside the contract's four corners in deciding to sign the contract."

MTD-Op.22; *see* MTD-Op.27. That was legal error. While an anti-reliance clause is one way to limit fraud claims, it is not the only way. This Court recently applied an exclusive remedy provision much like the one here to block a fraud claim, even though the contract had no anti-reliance clause. *Express Scripts, Inc. v. Bracket Holdings Corp.*, 248 A.3d 824, 830-33 (Del. 2021). Specifically, the exclusive remedy provision "carved out deliberate fraud" but was silent about other "states of mind." *Id.* This Court held that the exclusive remedy provision was enough to disclaim those other categories of fraud. *Id.* So too here. This contract's exclusive remedy provision carved out one category of fraud claims but disclaimed all others (including those based on oral representations). A2903.

The court here then turned to the contract's anti-reliance provision, which states that J&J "disclaims any representations and warranties other than those that are expressly set forth in Article III." A2877. The court noted that Auris did not have a reciprocal disclaimer. MTD-Op.29. But that one-way structure simply reflects the reality that the seller is generally the one making representations about the item being sold to the buyer, not the other way around. A2851-74. Including that clause in no way suggests Fortis "was permitted to rely on [J&J's oral] assurances," MTD-Op.29, much less that it overrides the exclusive remedy provision's plain text.

CONCLUSION

For the foregoing reasons, this Court should reverse the Court of Chancery's judgment.

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