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IN THE

Supreme Court of the State of Delaware

JOHNSON & JOHNSON and ETHICON, INC.,

Defendants-Below,
Appellants,

v.

FORTIS ADVISORS LLC, solely in its capacity as representative of former stockholders of Auris Health, Inc.,

Plaintiff-Below,
Appellee.

No. 490, 2024

COURT BELOW:

COURT OF CHANCERY OF THE STATE OF DELAWARE
C.A. No. 2020-0881-LWW

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NATURE OF PROCEEDINGS

Appellants Johnson & Johnson and Ethicon (collectively, "J&J"), facing "existential threats" to their surgical business from robotics, were desperate to acquire Auris Health ("Auris") and its transformative robotically assisted surgical devices ("RASDs"). Auris, founded by the "father" of robotic surgery following his success with Intuitive Surgical (now the $170-billion industry leader), was determined not to be lost in a competition for resources and priorities within J&J. To get a deal done, therefore, J&J had to agree to "highly customized" post-merger obligations limiting its business discretion. But J&J did not honor its contract. Immediately after closing, J&J cannibalized Auris's robots to salvage its own failing programs, ensuring it never would pay the $2.35 billion of milestone-based earnouts.

After 10 days of trial and extensive post-trial briefing, submissions, and argument, and on a record including 23 fact and 9 expert trial witnesses, 78 deposition transcripts, and 6,209 exhibits, Vice Chancellor Will issued a meticulous 144-page opinion ("Op.") that examined the bespoke terms of J&J's "commercially reasonable efforts" ("CRE") obligations, the structure and sequence of the regulatory milestones, the parties' reasonable expectations when contracting, the credibility of the witnesses, and the exhaustive record. The Court held J&J liable for certain earnout breaches as well as a single fraud, and awarded $960 million in damages,

plus interest—less than half the damages sought by Fortis Advisors ("Fortis") as representative of the former Auris stockholders.

J&J's narrative on appeal is divorced from the record, the text of the Merger Agreement, and the post-trial Opinion. There is nothing generic about the inward-facing and heavily negotiated CRE clause here, which, as defined—and as agreed by all parties below—turns uniquely on the facts regarding J&J's "usual practice" for its priority medical device (Velys). Nor can J&J escape liability by pointing to money spent on goals other than the milestones. Consistent with Delaware's objective contractarian focus, the Court below hewed closely to the terms of the agreement. It is J&J's advocacy for a judicially imposed "buyer takes all" rule in M&A transactions, not the Court of Chancery's careful application of *this* contract's clear text, that would upend dealmaking. In any event, J&J's contractual breaches were so egregious as to be "antithe[tical]" to *any* standard of reasonable conduct.

J&J urges this Court to hold that an unexpected FDA change in regulatory pathways for RASDs—announced *after* J&J breached—excused its misconduct and relieved it, both retroactively and prospectively, from all duties to achieve the milestones. The Court below rejected J&J's play for such a windfall, properly holding that the implied covenant protects the parties' "obvious goal" and reasonable expectation that regulatory approval still would be sought. J&J resorts to generalizations about differences between the De Novo and 510(k) pathways, but,

as with its generalizations about CRE provisions, J&J's hypotheticals are irrelevant. The Court below found, as to Auris's *iPlatform* RASD and on *the specific facts of this case*, that the FDA change was "immaterial" to the timing, burden, and odds of success in obtaining regulatory approval. Nevertheless, J&J used that immaterial change as an excuse for past breaches and as a pretext to abandon the milestones. It does not seek appellate review of these findings. With no rejoinder on the actual record (much less "clear error"), J&J cannot sustain its appeal of the implied covenant holding.

Finally, the Court below found that, to induce the merger, J&J's former CEO (who, just before trial, declined to testify) misrepresented a proposed milestone as "high certainty" despite a recent patient death in a J&J study resulting in an FDA investigation into the J&J device needed to achieve that milestone. The record amply supports the finding that J&J actively concealed these critical facts, knowing they rendered the milestone far from a "certainty."

The Court of Chancery's judgment should be affirmed.

SUMMARY OF ARGUMENT

I. IMPLIED COVENANT

1. Denied. The Court of Chancery found that (i) the parties never negotiated the path of regulatory approval because 510(k) was the "only logical pathway" at the time of contracting; (ii) the parties did not and could not reasonably anticipate the FDA change; and (iii) as to the first generation of iPlatform, the differences between 510(k) clearance and De Novo approval were "immaterial." Op.99, 103. J&J does not seek appellate review of these findings, which underpin the Court's fact-intensive holding that J&J breached the implied covenant by failing to make commercially reasonable efforts toward achieving De Novo approval for the first iPlatform milestone.

2. Denied. It is uncontested that, under the Merger Agreement, J&J had to make commercially reasonable efforts toward achieving 510(k) clearance for the later iPlatform regulatory milestones. It is further uncontested that all generations of a device may achieve 510(k) clearance after a first generation is approved. Once the FDA's change required that iPlatform's first approval be achieved through De Novo (with "immaterial" difference from 510(k)), J&J had to exercise commercially reasonable efforts to achieve such approval and thus enable 510(k) clearance for all the later milestones. Op.49, 92, 103. It is "reasonably certain" that J&J's breaches caused all iPlatform and GI regulatory milestones to be missed. Op.68, 96, 104, 111.

3. Denied. J&J's "coinflip" damages argument was not raised below and is waived. J&J's argument is also precluded by its concession on appeal regarding the "reasonable certainty" of causation. The argument also fails because the "odds of success" as to all iPlatform regulatory milestones remained materially unchanged after the FDA's change for first-generation RASDs, which was "immaterial" for iPlatform. Op.103, 130.

II. BREACH OF CONTRACT

4. Denied. The Court below correctly construed the Merger Agreement's "bespoke" efforts provisions to mean what they say: J&J was required to exercise commercially reasonable efforts toward achieving regulatory milestones consistent with its "usual practice" for "priority medical device[s]," taking into account enumerated factors, where the *only* comparator "priority" device was Velys. Op.62.

5. Denied. Applying the contract's plain language, the Court below methodically assessed whether J&J's actions were consistent with its usual practice for Velys, recognizing that J&J could "reasonably calibrate" its efforts within the bounds of such practice. Aside from a single challenge (which fails given the record supporting that finding), J&J does not seek appellate review of any of the Court's factual findings about Project Manhattan, the Verb combination and integration, J&J's refusal to adopt an MVP strategy for iPlatform, J&J's inconsistent employee incentives, or the sharp divergence of all these acts from J&J's Velys practice. The

Court properly held those J&J actions were "the antithesis of the commercially reasonable efforts expected for a 'priority' device." Op.69.

III. FRAUD

6. Denied. The Court below correctly held J&J liable for fraud in misrepresenting the proposed Monarch ablation milestone as a "high certainty" and "'effective' up-front consideration" while concealing (1) a recent death in a J&J clinical study and (2) a pending FDA investigation. These material facts, if disclosed, would have caused Auris to reject the milestone. Op.124. J&J's active concealment cannot be immunized absent unambiguous anti-reliance terms. The Merger Agreement's anti-reliance provision is one-sided, barring J&J, but not Auris, from relying on extracontractual representations. The exclusive remedy provision cannot be read to supersede and annul the limited reach of that anti-reliance provision.

COUNTERSTATEMENT OF FACTS

A. J&J's Determination to Acquire Auris

Auris's leader Dr. Fred Moll, a "visionary architect" and the "father" of robotic surgery, Op.1, 11, founded Intuitive Surgical in 1995 to create da Vinci, the first RASD for general laparoscopic surgery. Op.6-11. Intuitive was a technical and commercial success. Op.10-11. Years later, Moll founded Auris to further revolutionize the field with next-generation RASDs. Op.11. Auris rapidly iterated through various designs using Moll's industry-standard "minimal viable product" ("MVP") approach—starting with simple features and procedures and using real-world clinical feedback to introduce complexity. Op.8-9, 13, 33. Using this strategy, Auris developed and achieved 510(k) clearance for ARES, an early-stage robot designed for endoscopic procedures. Op.12-13. Auris next developed two robots with distinct architectural advantages over Intuitive's da Vinci: (i) Monarch, a flexible-arm robot designed for endoscopic procedures (the "commercial embodiment" of ARES), and (ii) iPlatform, an operating-table-based robot designed for laparoscopic and, ultimately, concomitant laparoscopic-endoscopic procedures. Op.13-17; B420.

J&J feared that the rise of RASDs, with their proprietary surgical instruments, posed an "existential threat" to its conventional surgical instruments business. Op.17; B2193-99. Despite J&J's lack of robotics expertise, CEO Alex Gorsky

commissioned development of a competing general RASD, Verb, starting in 2012. Op.17. By 2017, Verb was failing and far behind schedule. Op.18-20, 23. Gorsky, however, remained irreversibly committed to Verb, misreporting to the market that Verb was "on track" to launch in 2020 even while he internally complained "[h]ow did we get this so wrong … ?" *Id.*; B2204; *see also* B2220-21; B2228; B2421; B2442-69.

As a hedge, J&J turned to Auris, investing $45 million in May 2017 and gaining a board observer seat. Op.21; B2185-92. J&J became fixated on acquiring Auris's robots: Monarch for J&J's Lung Cancer Initiative, and iPlatform as a "backup plan" for Verb. Op.21-23; B2207-08. Well before the merger, Gorsky set his sights on "add[ing]" iPlatform "to [V]erb," with "back-end tech" shared, and he directed J&J's MedTech team to develop a plan to "mesh" the two robots. Op.22-23; A2257; B2209; B2424-37. When J&J learned in late 2018 that its competitor Medtronic might acquire Auris—J&J's "doomsday scenario"—it accelerated acquisition efforts. Op.24-25; B2222; B2213-17; B2223-24.

Auris "was not searching for a buyer" and knew nothing of J&J's view that iPlatform was "plan B" for Verb. Op.24-26. Auris wanted autonomy to develop its robots, had ample funding, and distrusted J&J's overtures, given its Verb program. Op.26; B2282-84; B2285-86; B2351-52; B2359-60. To persuade Auris, given the merger's "criticality" to J&J, Gorsky made the unusual decision, in his own words,

to "lead from the top." Op.23, 26; B2278. He and other senior J&J executives relied on carefully crafted "talk tracks" to say "what matter[ed] most" to Auris. Op.26-28; A1334-36 (Moll); B2287-2343; B2353-58. J&J assured Auris that it would prioritize development and regulatory approval of Auris's robots, that the Verb and Auris robots would not compete for resources, and that J&J would fund and launch iPlatform and Verb in parallel. Op.26-28. In light of the scope of these representations, Auris bargained for a one-way anti-reliance provision in the Merger Agreement that did not bar its reliance upon J&J's statements. Op.36-37.

B. J&J's Merger Commitments to Auris

Auris agreed to an acquisition only after negotiating "several layers of protection." Op.67; B2543-55; B2556-2797; B2812-3060; B3063-92; B3095-38; B3339-72. Under the contract's earnout structure, Auris deferred $2.35 billion in consideration contingent on achievement of milestones for regulatory approval ($1.35 billion)[1] and post-approval sales ($1 billion). Op.33-37, 58; A2840-42 § 2.07(a); A2913 § 10.03(l). In exchange, J&J undertook "bespoke" efforts obligations to achieve the regulatory milestones. Op.4, 64; Appellants' Opening Brief ("AOB") 13.

[1] Five regulatory milestones were for iPlatform; a sixth was for iPlatform or Monarch (the "GI milestone"); and two were for Monarch. A2840-42 § 2.07(a).

The Merger Agreement's CRE standard is unique, and memorializes J&J's commitment to prioritize regulatory approval of Auris's robots. First, J&J's "commercially reasonable efforts" had to be directed to "*achieve each of the Regulatory Milestones*"—not J&J's robotics plans generally, and "not J&J's other corporate goals." A2845 § 2.07(e)(i); Op.2, 37, 62; A1439-40. Auris understood the risk of competing programs and agendas within J&J's bureaucracy, and thus the importance of keeping post-merger development efforts oriented to regulatory approval of the Auris robots. A1334 (Moll). As J&J's expert admitted, the CRE provisions addressed the "moral hazard" that regulatory approvals could be delayed to avoid earnout payments. B1027; B1032.

Second, the level of J&J's regulatory efforts was determined by facts extrinsic to the contract: J&J's "usual practice" with respect to "*priority medical device[s]*," taking into account various factors. A2845 § 2.07(e)(i)-(ii); Op.64-65. This was "doubly advantageous" to Auris compared to a generic outward-facing CRE standard, Op.62: (1) as "J&J assured Auris" during negotiations, J&J's standards as "the biggest healthcare company in the world … exceed[ed] the industry"; and (2) at Auris's insistence, the standard was further elevated to that for J&J's "priority" devices. Op.37. J&J's Global Head of R&D for MedTech, Peter Shen, admitted the contract required J&J to "*exercise priority efforts to achieve the regulatory milestones*," "continu[ing] until those milestones expired." A1698 (emphasis

added). The only comparable "priority" device J&J ever identified (through interrogatory responses, its 30(b)(6) deposition, and trial) was its orthopedic RASD Velys. Op.67.[2]

Third, to prevent J&J from deprioritizing the regulatory milestones and avoiding billions in earnouts, the Merger Agreement barred J&J from acting *either* with the intent to avoid earnout payments *or even* "based on taking into account the cost of making any Earnout Payment(s)," A2845-46 § 2.07(e)(iii). As the Court below found, this was "more restrictive than the typical requirement" not to thwart earnout payments. Op.62-63.

Fourth, the structure and sequence of the regulatory milestones were designed to be "in line with [Auris's] MVP strategy that began with less complex procedures and built to more complex procedures." Op.33-34, 75; A2416 (admission of J&J's robotics expert); B415; B3061-62. The parties sequenced the iPlatform milestones to start with the easiest procedures, Op.75-76, contrary to J&J's post-merger assertion that iPlatform must leapfrog da Vinci upon launch, AOB.50. J&J had proposed a complex "general surgery" "umbrella" indication for the first milestone, but Auris successfully bargained for a simple initial goal: approval of *any* "upper

[2] J&J never contended Verb was a comparable "priority" device until this appeal. AOB.46.

abdominal" and *any* "lower abdominal" procedure rather than broad approval for "general surgery" procedures. A2841 § 2.07(a)(iii); Op.34; A1435.

Further, each iPlatform regulatory milestone was agnostic as to architecture and procedure, allowing any number of arms. A2840-42 § 2.07(a); Op.75-76; *contra* AOB.9, 51 (misreading the deal as requiring a "fully finished" iPlatform at launch with six functioning arms). Each indication could be satisfied with laparoscopy; none required the intended future capability for concomitant laparoscopic-endoscopic procedures. Op.34; A1337. Finally, the milestones were based solely on regulatory approval with no additional requirement of sales (which was the subject of *separate* milestones) or profitability. Op.34-36; A1347; *contra* AOB.51 (erroneously asserting the device must be "commercializ[able]" as of first regulatory approval).

Based on decades of uniform FDA practice for every RASD, and the FDA's pre-closing guidance for iPlatform, both parties expected regulatory approval of iPlatform and Monarch to be achieved by 510(k) clearance. B4004-07. That pathway "involves a comprehensive review of appropriate safety and performance data to determine if a new device is substantially equivalent to an approved predicate" device. Op.9-10. Pre-trial, J&J contended that 510(k) clearance was a "highly negotiated" term, B244-45, but at trial J&J's most senior testifying executive, Ashley McEvoy, admitted the regulatory pathway was ***not*** "negotiated"

and the parties instead "assumed" that iPlatform would pursue 510(k) clearance. A2257-58; B4004-07; *see* Op.99 & n.512; *see also* A1339 (Moll) (J&J's assertion that "the choice of a 510(k) pathway … was highly negotiated" is "a complete falsehood"). J&J "did not press [its] argument after trial." Op.99 n.512.

As the Court below found, the regulatory pathway was not negotiated "because at the time of the Merger Agreement, a '510(k) process' was the 'only logical pathway for a robotic device.'" Op.99. J&J's appellate assertion that the parties "had good reason to choose 510(k) clearance," AOB.30, is simply wrong: The parties did not make a *choice* of pathway, much less one based on generic and inapplicable *average* differences between 510(k) and De Novo. The parties knew pre-merger that regulatory approval of iPlatform was always going to require human clinical trials, even under 510(k). *See infra* 22-23. *As to iPlatform*, De Novo was not materially different than 510(k) in timing, burden, or odds of success. Op.48, 96, 102-03, 130.

Unlike in many earnout agreements, the Merger Agreement's earnout provisions did not bridge a "valuation gap" between the parties: As J&J's expert admitted, the parties had "remarkably close" valuations of Auris at closing, Op.130; A2247-48, grounded in their diligence-based determinations that the milestones likely would be achieved. Op.23-24, 89-90. The earnout structure here reflects a different bargain: J&J "paid less upfront" but had to relinquish "unchecked

discretion." Op.63-64. The Auris robots were too important to leave to ordinary business practices within J&J. iPlatform and Monarch were the culmination of Moll's lifelong efforts, with "transformative potential" for millions of patients. Op.5. The milestones, while "ambitious," "corresponded to approvals for procedures that the Auris robots were on track to complete." Op.2.[3]

C. J&J's Misrepresentation of a Monarch Milestone as "Highly Certain" While Concealing a Death and Investigation

In December 2018, during merger negotiations, a patient died in J&J's clinical testing of NeuWave FLEX, a J&J device to be paired with Auris's Monarch for the $100 million soft tissue ablation milestone. Op.30-31. Nine days later, the FDA launched a "for-cause inspection." Op.31. J&J concealed the death and investigation from Auris. Op.125. Gorsky instead told Moll there was such "high certainty" of achieving the ablation milestone that it was "'effective' up front" payment. Op.124; B471; B2474; B2509; A2730-34. "This representation was false because the milestone was not remotely certain to be met." Op.124.

Gorsky refused to testify at trial about his misrepresentation. J&J's documents and trial admissions proved it understood, pre-merger, that the milestone was far from a "certainty." Op.124-26; B472. Following the death, J&J's Chief Scientific Officer expected the FDA to *halt* the FLEX study. Op.31. On January 14,

[3] Though J&J ignores this finding and related findings, AOB.12, it concedes causation on this appeal, AOB.19 n.3.

2019, shortly before Gorsky's representation to Moll, J&J's deal team was "briefed" on the death and investigation and considered "whether the 'patient death was going to affect the overall value of Auris.'" Op.32 (quoting A1873); B2422. "Team members preparing talking points for Gorsky to deliver to Moll were mindful of the 'nuances' to the Monarch lung tissue ablation milestone 'and what will be required for the FDA approval (still in discussion).'" Op.32 (quoting B2514). J&J likewise knew that Auris, unaware of these risks from the J&J patient death, had negotiated and planned for a Monarch "soft tissue ablation" milestone believing it "would not require clinical testing" (unlike the iPlatform milestones). Op.33; B3093. None of J&J's 15 fact witnesses testified that J&J believed Gorsky's representation of "high certainty." The lone suggestion that the milestone might still have been "achievable" was "very different" from the representation of "'effective' up-front consideration," as the Court below observed. Op.124 n.635.

Aware only of Gorsky's statements, Auris reasonably regarded the ablation milestone as a "chip shot." Op.125 n.642 (quoting B2541). The Court found "[i]t is unknown" whether, pre-merger, the FDA made J&J's mandatory report of the death public; regardless, "Auris would have had no reason to search the FDA's website" given Gorsky's misrepresentations of "high certainty." Op.124-26 & n.643. Had Auris known the truth, it would have demanded higher payment upfront

rather than the earnout. Op.125 n.642, 126; A1337 (Moll); A1442. J&J did not disclose the death to Moll until post-closing. Op.33.

The concealed death and investigation "[d]estroy[ed] the value of the milestone." Op.126. The FDA "concluded the use of [J&J's device] FLEX on lung lesions posed a 'significant risk' to participants" and required new clinical studies before FLEX could be approved for lung and paired with Monarch. Op.32 (citing A2015-16; A3343); *contra* AOB.58 (mischaracterizing FDA review as finding "no issues" with FLEX). That delayed achievement of the milestone by years. Op.32.

D. J&J's Covert Budget Cuts (the "Ashley Challenge")

Further unbeknownst to Auris, during merger negotiations, J&J capped its robotics budget (including for the Auris robots) at $500-600 million annually for 2019-2022. Op.28-29, 42; B2384; B2394; B2409; B2345; B2367. J&J dubbed its budget cap, initiated by Head of MedTech McEvoy, the "Ashley Challenge." Op.28; A2249 (McEvoy); B401; B450-51. Although "J&J had the funds to develop and launch both robots," Op.121, the Ashley Challenge forced J&J's MedTech division to choose between iPlatform and Gorsky's Verb. Op.29, 41-42; B3446. This self-imposed limitation required J&J to determine *which* program would progress: iPlatform, Verb, or (as Gorsky insisted) a combination of the robots "mesh[ed]" together. Op.23, 38-39; B3394; B2211; B2212. The Ashley Challenge precluded J&J's "priority" pursuit of iPlatform milestones from the get-go, pitting iPlatform

and Verb against one another in a zero-sum contest. Op.39, 71; *contra* AOB.13 (asserting J&J was "highly motivated" to achieve iPlatform milestones). J&J's Opening Brief ignores all these facts.

E. J&J's Breaches of the Merger Agreement

The merger closed on April 1, 2019. J&J breached the Merger Agreement immediately.

1. Project Manhattan

Within hours of closing, disregarding J&J's priority CRE obligations to achieve the iPlatform milestones (but consistent with Gorsky's demands), MedTech leader Shen instructed his team that "[d]elivering of *Verb* milestones is our No. 1 priority." Op.38 (emphasis added); B3395. Four days later, Shen doubled down, circulating to J&J's Verb team—but withholding from the iPlatform team—his "Plan to Technically Assess Verb Platform and iPlatform." Op.39, 40 n.229; B3399; A1342-43 (Moll); A1698-99 (Shen).

Shen posited three outcomes for his "Project Manhattan": (1) "[d]evelop both systems in parallel and the[n] make the final commercialization decision"; (2) "choose one of the two systems"; or (3) "[m]erge them into a single development by combining the best of each." Op.39; B3399; B3404. After Verb's lead engineer recommended "framing the project objective in a way that is less controversial,"

Op.40, B3409, Shen deleted his unguarded language and substituted spin about finding "synergies." Op.40; A3406.

Even without complete information, the Auris team was "aghast" (not "excited," AOB.15) at the "existential threat" from J&J's Manhattan Project. Op.40, 42.[4] Manhattan was nothing like the information-gathering "audit" the parties discussed pre-merger. Op.40-41; B3373-79. But J&J had decided, after the Ashley Challenge, that it would not "run[] parallel path [V]erb-Auris all the way" to regulatory approval. Op.42; B3415; B3887.

Faced with the Ashley Challenge, J&J's leadership was "all in for Verb." Op.71 n.384; B3394. Because "[t]he probable end goal was to find ways to 'mesh' the robots," consistent with Gorsky's earlier aspirations and the budget set by the Ashley Management Decision [the Ashley Challenge]," Op.42, the months-long Project Manhattan became a vehicle to cannibalize iPlatform for Verb, Op.46, with the milestones "sacrificed to aid the Verb program." Op.71; *see also* B3412; *contra* AOB.15.

J&J conducted Project Manhattan throughout spring and summer 2019. Op.41-45. Contrary to J&J's fiction, AOB.15, Manhattan "had no upside for Auris." Op.70. It "came at a crippling cost," Op.72, forcing the iPlatform team to suspend

[4] Moll described himself as "excited" about a "technical assessment" Shen pitched to him about "finding synerg[ies] and accelerating time to market." A3404. But that was not, as the Court below found, Project Manhattan. Op.70; *infra* 47.

its plans. Op.43; A1525-26 (legacy-Auris head iPlatform engineer); A3500; B3414; *contra* AOB.15 (arguing delays were limited). The iPlatform engineers had to invent "workarounds" to prepare for early competition against Verb, incurring "technical debt" and paralyzing ordinary-course development. Op.43. Meanwhile, "J&J delayed making resource decisions for Auris until the assessment was complete." Op.70-71.

Notwithstanding these challenges, "iPlatform 'performed well and managed to complete' all [Project Manhattan] procedures," Op.45 (quoting B3417); B3420, in certain cases achieving ratings "equal to that of da Vinci." Op.44.[5] Shen and Celine Martin, J&J's robotics and digital surgery leader, concluded iPlatform won the bakeoff, but—given Gorsky's commitment to Verb and J&J's self-imposed budget—decided the robots should be combined anyway. Op.45-46; *contra* AOB.15 (ignoring finding of J&J's combination plan). At this stage, "[t]he first iPlatform milestone (the General Surgery Milestone) was still 2.5 years away, with subsequent milestones to be completed in 4.5 years." Op.45.

[5] By contrast, Verb never overcame the fatal weaknesses of its surgeon-side master console, which, as J&J's own engineers admitted, "was not deemed to be safe or effective." A2132; B3391. The Court below found the Verb console was "novel," Op.18, not "improved," *contra* AOB.9.

2. Gorsky's Order to Combine iPlatform With Verb, and J&J's Blocking of iPlatform's MVP Strategy

Following Manhattan, Gorsky demanded that "more elements of Verb" be combined with iPlatform. Op.46; A1446. Martin complied. Op.46-47; B3784. After Gorsky noticed the combination robot "would lead[] to some delay" and had a lower projected financial valuation, McEvoy flatly told him the combined valuation improved "when you consider what will also happen with contingent payment." Op.47. McEvoy and Gorsky thus explicitly discussed how the delay from combining the robots would allow J&J to avoid earnout payments for iPlatform milestones. *Id.*; A4030; A2266-67 (McEvoy). Despite the contract's prohibition against acting "based on taking into account the cost of making any Earnout Payment(s)," A2845-46 § 2.07(e)(iii)(B), Gorsky gave the "green light" to mesh iPlatform and Verb and asked J&J's Board to fund the combination. Op.47, 49; B3863; *contra* AOB.52. iPlatform thereafter became, in effect, a "parts shop" for Verb. Op.3.[6] "J&J knew pursuing the '[s]ingle, [o]ptimized [p]latform' would negatively affect iPlatform's development schedule. Worse, J&J anticipated that the delay would frustrate the iPlatform regulatory milestones." Op.72-73 (quoting B3691); B3723; B3737; B3763; B3525; B3669.

[6] J&J's forthcoming "Ottava" RASD is the very "combination" robot that Gorsky and Shen targeted pre-closing: "mesh[ing]" iPlatform's surgeon console and instrument tower with Verb's patient-side table and arms. A1689-90; A1766.

To enable Gorsky's "combination," J&J "sidelined" Auris's team by "[m]igrat[ing]" over "200 [Verb] employees" into the iPlatform program. Op.50; A4099. The integration brought hostility toward iPlatform from Verb employees, poor morale, and "devastating" attrition of legacy-Auris engineers. Op.50, 74-75; A4099; A1450-51 (legacy-Auris COO); A1532-33 (legacy-Auris head iPlatform engineer); B3974-75; B4002-03; *contra* AOB.24 (J&J's assertion of a boon for iPlatform). "The iPlatform team went from nimble and focused to redundant and divided," further jeopardizing the milestones. Op.74.

Still, the iPlatform team did not give up. Consistent with the MVP strategy reflected in the Merger Agreement, A2415-16, Moll asked J&J to let the iPlatform team focus on the simplest procedures that would satisfy the 2021 regulatory milestone, and thus offset Manhattan's delays. Op.76-77; A3523. J&J "rebuffed" the request to prioritize the 2021 milestone, instead focusing on "Ethicon instrument sales and broad commercialization" and demanding pursuit of the Roux-en-Y gastric bypass ("RYGB") procedure required by a later *2023* milestone. Op.76-77; A3504-06; A0376-77.

3. J&J's Misuse of the FDA's New Regulatory Guidance to Deprioritize iPlatform Milestones

On August 5, 2019, shortly before Gorsky ordered the robots combined, J&J learned of an FDA policy change: New RASDs no longer would be cleared through the 510(k) pathway. Op.48. Fortunately, the FDA confirmed in January 2020 that

iPlatform could use the De Novo pathway, not "the more complex PMA pathway." *Id.* J&J leadership recognized the change from 510(k) to De Novo would have an "*immaterial effect on the time and cost* for iPlatform to gain FDA clearance," Op.103, 48; A1703,[7] and internally concluded De Novo would cause "[n]o significant timeline differences"—just two more months of FDA review time, Op.48, 102; B394; B3463; B3466, well "within the five-month buffer" for iPlatform's first 2021 milestone, Op.49; A3386.[8]

While De Novo is "*generally* more onerous" than 510(k), Op.102 (emphasis added); AOB.12, the difference *for iPlatform* was minimal because iPlatform, unlike most 510(k) devices, already needed to complete "extensive clinical testing" on live humans, Op.102; A2011; B3385; *contra* AOB.17 (contending change "was highly consequential").[9] The change did not affect the "reasonable certainty" of regulatory

[7] The two-month difference was particularly "immaterial," Op.103, given J&J's admitted multi-billion-dollar revenue opportunity, AOB.13.

[8] J&J incorrectly asserts that Auris admitted the first milestone could not be met after the FDA switch. AOB.17-18. But the cited December 2019 schedule (1) already accounted for delays from J&J's Manhattan breaches, and (2) was prepared without input from Auris's regulatory leader, and later abandoned. B547-48.

[9] J&J asserts De Novo required "far more" clinical study patients. AOB.17. The Court below did not make such a finding, which is contradicted by J&J's own documents. B3461 (for De Novo, the FDA was "*not asking for any additional testing, verification, validation or pre-clinical data*" (emphasis added)). The FDA's feedback related to the more difficult RYGB procedure that J&J forced Auris to pursue, A4040-41, not the simple indications sufficient for the first milestone, Op.76-77.

approval but-for J&J's breaches. Op.89, 68, 96, 104, 111, 130 (pre-merger estimates remain "[t]he best evidence of how the milestones would have fared" after post-merger pathway change); *contra* AOB.12 (comparing approval rates for other devices). Moreover, once iPlatform obtained De Novo approval for *any* indication, it could use 510(k) for all subsequent indications. Op.49, 92 & n.480; A0142-43; *contra* AOB.36-37.

In April 2020, with iPlatform already relegated to a Verb "parts shop" for the "combination" robot, J&J seized upon the changed FDA guidance as a pretext to write down *all* iPlatform and GI milestones to zero. Op.3, 80; A4328; B3985. J&J told the iPlatform team the milestones were "canceled," Op.81; B3998, despite internal admissions that 510(k) clearance and De Novo approval were similar for iPlatform, and although most milestones were still three-and-a-half years away. Op.3, 49.

With written-off milestones and looming litigation, J&J announced a "new reality," instituting a "revised" employee "milestone" incentive plan. Op.51-52. Those new "milestones" were incompatible with the Merger Agreement, changing not just the original "timelines," AOB.55, but substantive targets, including milestones that Auris had rejected during merger negotiations, Op.34, 52; A4770. Two months later, J&J replaced iPlatform's longtime lead engineer, David Mintz, with a J&J employee without RASD experience. Op.52.

F. Fortis's Suit, and J&J's Attempt to Scapegoat Auris

In October 2020, Fortis sued J&J for breach of contract, breach of the implied covenant of good faith and fair dealing, and fraud, among other claims. Op.53.

J&J then devised a "new narrative" to blame iPlatform's delays on supposed "design problems" and "technical issues." Op.53-55; B4100; B4104; B4108-28; B4129-30; B4131; B4231. After assessing the testimony and credibility of 15 J&J fact witnesses at trial, the Court below rejected this narrative as mere "tactical backfilling," Op.91: The so-called "existential technical issues" were "imminently solvable" absent J&J's breaches. Op.4, 53, 89-111; *contra* AOB.19-22, 24-26 (repeating its "new narrative" on appeal).

Pre-merger, both parties' estimates of success were high. Op.90; A2810; A4327; A2247-48; *contra* AOB.12-13 (asserting pessimism based on texts). J&J based its pre-merger estimates on "multiple rounds of due diligence, involving experienced Verb engineers and outside robotics experts" and "direct insight" gained "through its Auris board observer seat." Op.90-91; *contra* AOB.10 (asserting that "technical due diligence" was "deferr[ed]").

At trial, records from *hundreds* of iPlatform labs showed it could safely and effectively perform procedures necessary to meet all milestones. Op.94-96, 105-09; B4761-854; B4855-61. As J&J acknowledged below (but now disputes), the cadaver labs were "highly reliable indicators of iPlatform's development status."

B208.[10] J&J admitted iPlatform would be capable of performing many different procedures satisfying regulatory milestones. Op.95, 105-08. Multiple knowledgeable witnesses testified "about iPlatform's technical challenges and what it took to solve them." Op.92 n.478; *see also* Op.94 n.489; *contra* AOB.22 (asserting "no witness" testified how to solve challenges). J&J's own witnesses conceded that many of the issues J&J raised were "surmountable." Op.97; *see also* B4055; B4323-27.

G. Procedural History

On December 13, 2021, the Court below largely denied J&J's partial motion to dismiss, allowing Fortis's principal claims to proceed. Discovery followed; the parties produced more than 1.5 million documents and conducted 78 days of depositions. At a 10-day trial in January 2024, 23 fact and 9 expert witnesses testified, and the parties submitted 6,209 joint exhibits. The parties then submitted post-trial briefing and event timelines, and the Court heard post-trial argument.

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[10] The Court below did *not* find that the labs were independently sufficient for FDA approval, *contra* AOB.18, but instead found that they evidenced iPlatform's capabilities. *See* Op.96-97 (rejecting J&J's assertion of flawed iPlatform architecture where "numerous lab reports show that iPlatform" in fact could "safely and effectively complete procedures"); Op.91 n.477 (finding J&J's robotics expert had "limited exposure" to iPlatform, and attaching "little weight" to his opinion); *contra* AOB.22. Though J&J withheld or destroyed "[r]ecords for [additional] hundreds of iPlatform labs," "even without [those records], Fortis proved by a preponderance of the evidence that iPlatform was on track to meet the milestones before J&J's breaches." Op.106-07 n.549.

In its Memorandum Opinion, the Court below held: (1) J&J breached its contractual obligation to make efforts consistent with its usual practice for priority medical devices to achieve the iPlatform and GI regulatory milestones, but did not breach its obligations as to the Monarch milestones; (2) J&J breached the implied covenant of good faith and fair dealing "when it failed to devote efforts to achieve the revised regulatory pathway"; and (3) J&J defrauded Auris regarding the Monarch ablation milestone, but did not otherwise commit fraud. Op.4-5. The Court also held J&J breached its obligation not to act "based on taking into account the cost of making any Earnout Payment(s)" when it decided, based on savings from avoided earnouts, to combine iPlatform and Verb. Op.73, 112; *see* AOB Ex. C. ("Final Judgment") 7.

ARGUMENT

I. THE COURT BELOW CORRECTLY FOUND J&J BREACHED THE IMPLIED COVENANT OF GOOD FAITH AND FAIR DEALING

A. Question Presented

Whether the Court below correctly held an implied covenant required J&J to exercise efforts to achieve De Novo regulatory approval to satisfy the first iPlatform milestone, where: (1) the parties did not and could not reasonably anticipate the FDA pathway change from 510(k) to De Novo because, at contracting, the "'510(k) process' was the 'only logical pathway for a robotic device,'" Op.99; (2) the Merger Agreement did not address such a pathway change; (3) the change had an "immaterial effect on the time and cost for iPlatform to gain FDA clearance," Op.103; (4) it is "reasonably certain" J&J would have achieved De Novo approval of iPlatform for the first milestone if it had exercised commercially reasonable efforts, Op.96; (5) J&J's decision to abandon efforts to achieve regulatory approval caused the loss of all iPlatform regulatory earnouts, A2840-47 § 2.07, and allowed J&J to recognize $1 billion in windfall profits in 2020, Op.51; and (6) J&J misused the FDA change as a "pretext" to excuse its material breaches, including cannibalizing iPlatform to salvage its failing Verb robot and pursuing goals inconsistent with the milestones, Op.3, 51-52. Preserved at Op.98-103; A0243; B56-60; B139-144; A0446-47.

B. Scope of Review

This Court reviews contract interpretation regarding the implied covenant, but not factual findings relating to such interpretation, *de novo*. *Nationwide Emerging Managers, LLC v. Northpointe Hldgs., LLC*, 112 A.3d 878, 889 (Del. 2015); *Baldwin v. New Wood Res. LLC*, 283 A.3d 1099, 1115 (Del. 2022).

The damages award is reviewed for abuse of discretion. *SIGA Techs., Inc. v. PharmAthene, Inc.*, 132 A.3d 1108, 1130 (Del. 2015) (damages awards "based upon conscience and reason, as opposed to capriciousness and arbitrariness" should be upheld).

C. Merits of Argument

1. The Court Below Correctly Held the Implied Covenant Protects the Parties' Reasonable Expectations When the Contract Is Silent About an Unforeseen Development

As the Court below held, the facts here present "precisely the sort of situation where the implied covenant comes into play," Op.100 n.518: namely, to protect the parties' reasonable expectations following an unforeseen development on which the contract is silent. The Court below found the parties did not and could not reasonably foresee the FDA's change from 510(k) clearance to De Novo approval for all first-generation RASDs. That change, as to *iPlatform*, had an "immaterial" impact on timing, cost, and odds for approval. J&J's decision to abandon the milestones, therefore, was not a response to reduced expectations of regulatory approval but rather opportunism clothed in pretext. Because application of the

implied covenant is warranted on these findings, which J&J does not appeal, its arguments fail.

a. The Parties Did Not and Could Not Reasonably Anticipate the FDA Regulatory Pathway Change from 510(k) to De Novo

The Court below found, and J&J does not appeal, that the parties did not and could not reasonably anticipate the FDA's pathway change. At contracting, the "'510(k) process' was the '*only logical pathway* for a robotic device.'" Op.99 (emphasis added). For 20 years, every prior RASD had been cleared through the 510(k) pathway, B4005; A2197; Op.9, including Auris's robots ARES and Monarch, Op.13. Moreover, "[t]he FDA had indicated in October 2018 that iPlatform [specifically] could receive 510(k) clearance." Op.100-01 (rejecting J&J's counterfactual assertion, repeated on appeal, AOB.16, 31, that Auris knew 510(k) might be unavailable based on October 2018 FDA guidance).

Because "all parties assumed that 510(k) would be an available pathway for iPlatform," Op.100, the risk that the "only logical pathway" of 510(k) might disappear was "never even discussed," Op.99 & n.512—much less allocated to Auris. Thus, J&J's arguments as to (1) risk-allocation, AOB.31, (2) a deliberate choice of 510(k) clearance, AOB.30, (3) the parties' freedom "to bargain to delete" 510(k), AOB.30-31; and (4) "[r]egulatory unpredictability," AOB.33, all fail. In

fact, J&J was "surprised" and "shocked" when it learned of the FDA's decision to require De Novo approval for RASDs. Op.101-02; B4005.

J&J wrongly argues the implied covenant protects contracting parties only when the unexpected event was entirely outside "the realm of *possibility*." AOB.33. But contracting parties cannot account for every possible contingency (nor would it be reasonable or efficient to try), and J&J's unworkable standard is not the law. *E.g.*, *Amirsaleh v. Bd. of Trade*, 2008 WL 4182998, at *1 (Del. Ch. Sept. 11, 2008) ("No contract, regardless of how tightly or precisely drafted it may be, can wholly account for every possible contingency.").

Contracts are based on reasonable expectations, and the implied covenant protects "the fruits of the bargain that the asserting party *reasonably expected*" in circumstances "neither party anticipated." *Nemec v. Shrader*, 991 A.2d 1120, 1125-26 (Del. 2010) (emphasis added); *see also Baldwin*, 283 A.3d at 1117 (implying covenant where "the parties would have bargained for a contractual term proscribing the conduct that allegedly violated the implied covenant *had they foreseen* the circumstances under which the conduct arose" (emphasis added)); *Katz v. Oak Indus. Inc.*, 508 A.2d 873, 880 (Del. Ch. 1986) ("'[U]nderstandings or expectations [may be] so fundamental that [the parties] did not need to negotiate about those expectations.'" (quoting *Corbin on Contracts* § 570 (Kaufman Supp. 1984))). *Nemec*'s rule that the implied covenant cannot protect against eventualities the

parties could have anticipated, but "failed to consider," 991 A.2d at 1126, is not offended where 510(k) was the "only logical pathway." Op.99.

b. The Merger Agreement Does Not Address an FDA Regulatory Pathway Change from 510(k) to De Novo

Contrary to J&J's position, AOB.32, the Court below correctly held "[t]he Merger Agreement lacked a term to address what would occur if the 510(k) pathway were closed to iPlatform" for its first-generation approval. Op.103. The contract is silent on the issue because the parties did not foresee a change in "the only logical pathway" and thus did not negotiate for that contingency. Op.99-102.

J&J tries to equate the Merger Agreement's silence regarding a pathway change with its supposed silence regarding "what would occur if iPlatform hit a milestone a year late" (which J&J asserts "can mean only … no earnout payment when the condition is not met"). AOB.32. But the Merger Agreement is *not* silent on the latter issue: It expressly states earnouts are not payable if milestones are not achieved by certain dates. *See* A2842 § 2.07(b)(iv). By contrast, there is no analogous term barring earnouts in the event of an immaterial pathway change. *See, e.g.*, *In re El Paso Pipeline P'rs, L.P. Derivative Litig.*, 2014 WL 2768782, at *19 (Del. Ch. June 12, 2014) (contract silent on whether partner was obligated to share information where no provision explicitly created or excused such obligation); *contra* AOB.30 (relying upon a provision that does not address what happens if the regulatory pathway changes).

J&J's citation to *Oxbow Carbon* is unavailing. There, this Court refused to imply a right that would contradict express contractual terms. *Oxbow Carbon & Mins. Hldgs., Inc. v. Crestview-Oxbow Acq., LLC*, 202 A.3d 482, 507-08 (Del. 2019) (declining to imply right for minority LLC members to force a sale of the company where such implied right would have conflicted with express limitations to forcing any sale).[11] Here, the implied obligation does not conflict with any provision if 510(k) becomes unavailable. For iPlatform, De Novo and 510(k) were materially equivalent pathways toward the same goal of regulatory approval.

c. The Court Below Correctly Found the Parties Would Have Agreed to the Implied Term

To fill the Merger Agreement's silence on the unforeseen FDA change, the Court below considered what best reflected the parties' reasonable expectations at contracting. *See Dieckman v. Regency GP LP*, 155 A.3d 358, 367 (Del. 2017) (implied covenant "is used to infer contract terms to handle developments … neither party anticipated" to protect "reasonable expectations of the contracting parties"). The Court found the implied covenant required J&J to pursue De Novo approval for the first milestone because the "obvious goal of the General Surgery Milestone was

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[11] *See also Nemec*, 991 A.2d at 1126-28 (declining to imply term requiring board to wait to exercise redemption right where contract expressly permitted earlier exercise); *Cincinnati SMSA LP v. Cincinnati Bell Cellular Sys. Co.*, 708 A.2d 989, 993 (Del. 1998) (declining to imply expansion of noncompete provision where separate provision expressly permitted competition in "other business ventures of every kind and description").

for iPlatform to obtain FDA approval" and the regulatory pathway change to De Novo was "immaterial … for iPlatform." Op.99, 103.

J&J does not appeal the critical finding that the change from 510(k) to De Novo "had an immaterial effect on the time and cost for iPlatform to gain FDA clearance." Op.103. At closing, the parties knew iPlatform had to submit clinical (*i.e.*, live human) testing data for regulatory approval, Op.102; A2673; B2809, and thus iPlatform's pathway (like Verb's) was already more onerous than the average 510(k) clearance. Op.102 & n.533 (citing A2313 (J&J's expert admitting iPlatform was in the "minority of 510(k) submissions that require clinical data")). When the FDA changed the first-generation RASD pathway to De Novo, J&J therefore concluded "[n]o significant timeline differences as compared to a 510(k)." Op.102 & n.533 (quoting B3463).

Before this litigation, J&J internally acknowledged that, under the newly applicable De Novo pathway for these RASDs, the FDA was "*not asking for any additional testing, verification, validation or pre-clinical data*." B3461 (emphasis added). The "primary difference [between De Novo and 510(k)] … was FDA review time, which J&J predicted would only add two months of delay." Op.102 (citing B3466 (De Novo review would change Verb projected launch from April to

June 2022)).[12] J&J's assertion that 510(k) *generally* requires less testing than De Novo, AOB.30, is irrelevant to *this case*; the difference was "immaterial" for iPlatform. Op.103.

J&J wrongly asserts the Court below "ignored [the] essential legal requirement" that it find the parties would have agreed to the implied term had they considered the unforeseen development. AOB.34. In fact, the Court below made just such a finding: "The obvious goal of the General Surgery Milestone was for iPlatform to obtain FDA approval," Op.99, and thus, "[h]ad the parties known that 510(k) would become unavailable for RASDs, they logically would not have listed 510(k) as the method of obtaining regulatory approval in the Merger Agreement," Op.103.

J&J advances the red herring that it "never demonstrated a willingness to agree to earnouts tethered to any other pathway." AOB.30-31. Of course not: The parties never considered, much less discussed, this issue, Op.99 & n.512, so there was no occasion for any such demonstration. The Court below determined what the parties would have done *had* they considered a regulatory change. *See Nationwide*, 112 A.3d at 897-98 (courts should consider "evidence of the parties' bargaining history" to determine what they "would have agreed" had they considered a subject).

[12] Thus, J&J saw the switch from 510(k) to De Novo (rather than to the materially different PMA pathway) as a win. Op.48-49, 99.

An "immaterial" FDA pathway change would have led the parties to accept the implied term as itself an "immaterial" change to the Merger Agreement—unlike J&J's unconscionable demand for a billion-dollar windfall and abandonment of all obligations to achieve regulatory approval. It is fully consistent with the terms and purposes of the Merger Agreement to imply an obligation to seek De Novo approval where (1) 510(k) clearance unexpectedly became unavailable; (2) the differences in time, costs, and odds for De Novo approval rather than 510(k) clearance were immaterial *for iPlatform on the facts of this case*; and (3) De Novo approval achieved the same goals as 510(k) clearance. By contrast, it would contradict the parties' reasonable expectations to resolve the silence, as J&J demands, by writing in an option for J&J to cease performance and avoid all (or any) earnouts in the event of an immaterial regulatory change.

d. J&J Unreasonably Used the Pathway Change as a Pretext for Contractual Breaches and Abandoning the Milestones

J&J does not appeal the findings that it used the FDA change as a pretext to (1) excuse its breaches, (2) "cancel" the milestones, and (3) "redirect[] efforts" toward goals Auris had *rejected* during merger negotiations. Op.3, 70-74, 80-82. Instead, J&J offers the non sequitur that it did not itself cause the FDA change. AOB.34. That does not answer the finding that J&J acted arbitrarily and unreasonably in "scapegoating an unforeseen policy change" to avoid its contractual

obligations, Op.103,[13] frustrating "the fruits of the bargain that [Auris] reasonably expected," *Nemec*, 991 A.2d at 1126.[14]

2. J&J Is Liable for Its Breaches of the Later iPlatform and GI Milestones Regardless of the Implied Covenant

Because the implied covenant holding should be affirmed, this Court need not consider J&J's "daisy chain" argument. AOB.35-36. In any event, J&J misconstrues the Opinion: J&J is liable for its breaches of the later iPlatform and GI milestones regardless of the implied covenant.

The Merger Agreement expressly required J&J to exercise commercially reasonable efforts consistent with those for its designated priority medical device Velys to achieve 510(k) clearance for the five later regulatory milestones. Op.64-65, 104. J&J admits 510(k) clearance depends upon prior regulatory approval for a

[13] The record is replete with other evidence of J&J's unreasonable conduct and bad faith. For example, despite its litigation position that the FDA change made performance impossible, J&J withheld news of the change from Fortis for *seven months*. B3485-3502 (quarterly update not disclosing change); B3818-22 (same); B3967-72 (same); *see also* B3472-84 (J&J scrubbed reporting of Project Manhattan delays, hiring delays, facility expansion delays, and NeuWave FLEX regulatory issues from report to Fortis). J&J decided to write down the milestones in fall 2019, *e.g.*, B3823-26; B3815, when it thought the FDA might require the PMA pathway, but proceeded anyway after learning the change was only an "immaterial" shift to De Novo. Op.48, 51, 103.

[14] Because Fortis prevailed on the implied covenant, the Court below did not address J&J's obligation to "negotiate in good faith" to "effect the original intent of the parties." *See* Op.103 n.537 (citing A2927 § 10.11). If this Court reverses on implied covenant, it should remand for consideration of Fortis's alternative specific performance claim.

predicate device. AOB.12. The FDA did not foreclose 510(k) clearance for later generations of each RASD; it simply made such clearance dependent upon prior approval for any indication for that RASD's first generation. Thus, as the Court below found and J&J admitted, "once iPlatform obtained De Novo approval, it could use the 510(k) pathway for future indications by serving as its own predicate device." Op.49; *see also* Op.92, 99 n.515; A0142-43.

J&J's "priority" efforts obligation to achieve 510(k) clearance for later milestones therefore required it to seek De Novo approval of an initial indication on a first-generation iPlatform. The Merger Agreement nowhere relieved J&J of its burden to make "priority" efforts just because of a regulatory change that created, for iPlatform, an "immaterial" difference for such first approval. Op.103. Further, while *any* De Novo approval for an initial iPlatform indication would suffice to enable 510(k) clearance for the later milestones, it is "reasonably certain" J&J could have achieved this approval with indications that satisfied the first milestone, Op.92, 96, "facilitat[ing] 510(k) approval for the subsequent milestones." Op.103. Allowing J&J to abandon such efforts would deliver it an arbitrary windfall.

The other elements of J&J's "daisy chain" argument contradict the unappealed and well-supported factual findings below. *First*, J&J cannot argue "the odds were about half as good" for De Novo as 510(k) *for iPlatform*, AOB.36, given the unappealed finding that, but-for J&J's breaches, it is "reasonably certain" J&J

would have obtained De Novo approval of required indications in time for the first milestone. Op.96. Because the change was "immaterial" for iPlatform, the pre-merger odds of success remained the same. Op.103. Weighing the evidence, the Court found that, absent J&J's breaches, iPlatform would have secured De Novo approval by year-end 2021, Op.96, allowing ample time to achieve the 2023 milestones, Op.103-04.

Second, the Court below did not "assum[e]" that "following a De Novo grant," the FDA would have allowed "J&J to use the 510(k) pathway for subsequent iPlatform and GI milestones." AOB.35-36. Instead, the Court found as a fact that the FDA would have done so, based on reliable expert testimony. Op.92, 102 n.532; B4367; A2014.

Third, the Court did not "assum[e]" the later iPlatform and GI milestones were likely to be met. AOB.35-36. Rather, it systematically weighed the record on iPlatform's capabilities and found each milestone likely would have been met absent J&J's breaches. Op.104-111; B3829; B3852-53.[15]

Because J&J does not appeal these factual findings—or *any* findings as to causation, AOB.19 n.3—they are dispositive.

[15] J&J does not appeal the findings that it (1) never tried to meet the GI milestone with *Monarch*, despite Monarch's GI capability, but instead (2) "deprioritized GI." Op.110-11. Regardless of J&J's contentions as to the *iPlatform* regulatory pathway, its failure to appeal the Monarch GI rulings requires affirmance on liability and damages for that milestone.

3. J&J Cannot Show Abuse of Discretion on Damages

J&J argues the Court below abused its discretion by not reducing expectation damages based on "De Novo applications hav[ing] at best a coinflip's odds of receiving approval." AOB.37. Because that argument was not raised before appeal, it is waived. Del. Sup. Ct. R. 8; *AT&T Corp. v. Lillis*, 953 A.2d 241, 252 (Del. 2008); *see* B340-43 (no discussion of effect of pathway change on damages); A0592-94 (same).

Independently, J&J's concession on appeal that causation is "reasonably certain" for the iPlatform and GI regulatory milestones, *see* Op.68, 96, 104, 111; AOB.19 n.3 (not appealing the causation rulings), precludes its new "coinflip" damages argument.

J&J's argument also fails because it erroneously assumes the odds of achieving the iPlatform regulatory milestones were reduced by the regulatory change. But the differences between De Novo and 510(k) were "immaterial," Op.103, and the Court below therefore properly concluded (in unappealed findings) that the parties' pre-merger estimates of success remained "[t]he best evidence of how the milestones would have fared" *after* the FDA change, Op.130; B4541-43. Because the odds of achieving approval were materially unchanged, the Court below did not abuse its discretion by awarding damages based on pre-merger probabilities of success. *E.g.*, *SIGA Techs.*, 132 A.3d at 1130-37 (deferring to damages awards

based on "conscience and reason"). Indeed, the Court below exercised its discretion *in J&J's favor* by discounting milestone amounts based on the parties' risk-adjusted probabilities, Op.134-36; it would have been justified in awarding the full milestone amounts. *E.g.*, *S'holder Representative Servs. LLC v. Shire US Hldgs., Inc.*, 2020 WL 6018738, at *28 (Del. Ch. Oct. 12, 2020).

II. THE COURT BELOW CORRECTLY FOUND J&J BREACHED THE MERGER AGREEMENT

A. Question Presented

Whether the Court below correctly construed the contract's "bespoke" and "highly customized" efforts provisions, Op.62, 64, by enforcing the unambiguous requirement that J&J exercise "commercially reasonable efforts *to achieve each of the Regulatory Milestones … consistent with* [its] usual practice … with respect to *priority medical device[s]*," A2845 § 2.07(e)(i)-(ii) (emphases added), where J&J identified Velys as the only comparable "priority" device. Preserved at Op.57-114; A0182-0221, A0235-43; A0416-45.

B. Scope of Review

This Court interprets contracts *de novo*, "determin[ing] 'what a reasonable person in the position of the parties would have thought'" the contractual provisions meant. *AT&T*, 953 A.2d at 252-53 (quoting *Rhone-Poulenc Basic Chem. Co. v. Am. Motorists Ins. Co.*, 616 A.2d 1192, 1196 (Del. 1992)).

This Court will only reverse factual findings for clear error, *SIGA Techs.*, 132 A.3d at 1128, including findings about J&J's "usual practice" for its priority device Velys that are necessary to construe the bespoke CRE terms of this contract, *see AB Stable VIII LLC v. MAPS Hotels & Resorts One LLC*, 268 A.3d 198, 214-15 (Del. 2021) (deferring to Court of Chancery's "factual finding" about "past practice" to construe covenant requiring acts consistent with past practice).

C. Merits of Argument

1. The Court Below Correctly Construed the Merger Agreement

J&J did not "bargain[] for the latitude to run [Auris] as it saw fit." AOB.39. Instead, J&J limited its post-merger discretion by agreeing to "use commercially reasonable efforts *to achieve each of the Regulatory Milestones*" until those milestones expired. A2845 § 2.07(e)(i). "Commercially reasonable efforts" are defined by reference to facts extrinsic to the contract:

> the expenditure of efforts and resources … in connection with obtaining the applicable 510(k) premarket notification … 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 applicable [Auris] Robotics Products, taking into account [ten enumerated factors (the "CRE Factors")].

A2845 § 2.07(e)(ii) (emphasis added). The Court below read this "highly customized" CRE term to mean what it says: J&J must (1) use efforts consistent with its "usual practice" for "priority" medical devices, where J&J identified Velys as the *only* "priority" device to benchmark such practice; and (2) direct those efforts *toward achievement of the milestones*.[16] Op.62, 67.

[16] Thus, the Merger Agreement is unlike more buyer-friendly earnout agreements. *E.g.*, *Akorn, Inc. v. Fresenius Kabi AG*, 2018 WL 4719347, at *18 (Del. Ch. Oct. 1, 2018) (requiring "commercially reasonable efforts to carry on its business in all material respects in the ordinary course of business"), *aff'd*, 198 A.3d 724 (Del. 2018). The *inward*-facing standard was also favorable to Auris. A1439-40; B1860-62.

J&J's obligations are confirmed by "look[ing] at the transaction from a distance" in its commercial context. *Heartland Payment Sys., LLC v. Inteam Assocs., LLC*, 171 A.3d 544, 557 (Del. 2017); *see also Chicago Bridge & Iron Co. N.V. v. Westinghouse Elec. Co.*, 166 A.3d 912, 913-14 (Del. 2017) ("In giving sensible life to a real-world contract, courts must read the specific provisions of the contract in light of the entire contract."). For an earnout structure deferring billions of dollars in consideration to make sense for Auris, J&J's post-merger discretion as to how to develop the robots had to be limited; otherwise, J&J could avoid payment by delay while still reaping the benefits of Auris's technology. The Court below properly acknowledged this reality, Op.1, 63-64, which J&J put at issue below, A0558-60, and on appeal, AOB.39.

Just as in the trial below, B718-19, J&J offers no coherent reading of the "priority" CRE terms. Instead, it asks this Court to rewrite the Merger Agreement as effectively bereft of limits on J&J's "discretion and commercial judgment," and of any obligation to use "priority" efforts "to achieve each of the Regulatory Milestones." AOB.13, 40; A2845 § 2.07(e)(i)-(ii). But this Court does not read contracts to render language "mere surplusage." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citation omitted).

J&J makes the straw-man argument that the Opinion required it to prioritize milestones "above all else." AOB.40-41. But the Court below gave effect to J&J's

ability to balance other concerns. For example, it found J&J's efforts on the Monarch milestones "flawed" but "not commercially unreasonable." Op.84.

Nor did the Court below "isolat[e]" the word "priority" and fixate on its "dictionary definition." *Contra* AOB.40. Rather, it properly examined J&J's efforts with reference to Velys, the "priority device" benchmark. Op.67; *supra* 10-11. At post-trial argument, signaling the importance of this extrinsic evidence to the contract construction, the Court *twice* asked J&J whether Velys was the relevant comparator, and J&J twice reconfirmed *Velys*—not Verb, *contra* AOB.46—was "*the* comparator that was identified." B639-40; B648. The Court then faithfully construed the Merger Agreement, methodically comparing J&J's treatment of Velys to its actions regarding the iPlatform and GI milestones, *e.g.*, Op.67-68. J&J cannot now substitute Verb for Velys. Del. Sup. Ct. R. 8; *Ravindran v. GLAS Tr. Co. LLC*, 327 A.3d 1061, 1078 (Del. 2024).

J&J's argument that the Court below "excised" the CRE Factors, AOB.42-43, is similarly wrong. J&J never contended below that the Court needed to assess every possible permutation of CRE Factors to ensure no "balance of the factors could reasonably support" its actions. *Id.* Regardless, J&J improperly elevates the CRE Factors above the "priority" efforts mandate.[17] The CRE Factors are in a

[17] The Court below did not find (and J&J cites no evidence) that J&J "went out of its way to bargain for" the CRE Factors, *contra* AOB.42, by contrast to the extensive negotiation over the "priority" CRE standard itself, Op.62-63.

grammatically subordinate clause of the sentence that defines CRE by reference to J&J's usual "priority" practices. A2845 § 2.07(e)(ii). J&J could "reasonably calibrate its efforts" to meet the milestones by "taking into account" the CRE Factors, A2845 § 2.07(e)(ii), but only within the bounds of J&J's "usual practice" for a "priority" device, Op.82; *accord S'holder Representative Servs. v. Alexion Pharm.*, 2024 WL 4052343, at *37 (Del. Ch. Sept. 5, 2024) (where contract defined CRE as typical industry efforts "taking into account" certain factors, buyer could consider those factors "only insofar as typical companies might typically consider" them). In light of the Court's factual findings that J&J's conduct was antithetical to its treatment of Velys or *any* priority device, Op.67-68, no "assess[ment]" of CRE Factors, AOB.42, could rehabilitate such conduct.

The parties could have defined CRE as ordinary-course efforts, or allowed J&J to abandon or deprioritize milestones for business reasons. *E.g.*, *Alexion*, 2024 WL 4052343, at *14 (contrasting definition of CRE). That was not the bargain here. Instead, the parties agreed J&J's efforts would be anchored to its practice for "priority" devices and directed toward achievement of the regulatory milestones. The Court below properly gave effect to these "heavily negotiated" terms. A1863.

2. The Court Below Correctly Found Multiple J&J Breaches of the Merger Agreement

a. Project Manhattan Breached the Merger Agreement

Immediately after closing, J&J launched Project Manhattan: a head-to-head "showdown" between iPlatform and Verb. Op.69. Manhattan was a huge focus at trial: 16 of 23 fact witnesses testified about it, and "Manhattan" appears in the transcript 411 times. On this exhaustive record, after assessing the credibility of all witnesses, the Court below concluded that "Project Manhattan alone is sufficient to find that J&J breached its efforts obligation." Op.72. "J&J knew Project Manhattan would hinder, rather than promote, iPlatform's achievement of the regulatory milestones." Op.3. J&J breached the Merger Agreement by subjecting iPlatform to a "costly battle merely to remain operative"—something no "'priority' device would … have to endure" and something Velys, J&J's only "priority" comparator, did not endure. Op.69-72 & n.385.

On appeal, J&J offers an alternative history based on counterfactual contentions rejected by the Court below. J&J does not appeal those factual findings, which are thus dispositive.

First, J&J misrepresents Manhattan's origin as post-closing "technical due diligence." AOB.45. That is false. Manhattan was *not* the promised "technology audit," Op.40-41, 70 n.379, but a distinct initiative necessitated by the Ashley Challenge (the budget cap J&J chose to impose on its robotics programs). Op.28-

29, 42; *see also* B401. J&J decided it would not develop both iPlatform and Verb, while telling Auris the opposite to secure the deal, Op.27, and implemented Manhattan to decide which robot to pursue. Op.42.[18]

Second, J&J misrepresents Manhattan's objectives as designed to achieve "synergies" between platforms, quoting Shen's sanitized memorandum presented to the Auris team. AOB.45 (quoting A3406). In so doing, J&J ignores the finding that Shen described the three *actual* Manhattan outcomes in an earlier, unscrubbed document never sent to Auris: (1) develop iPlatform and Verb for initial stages, then decide which to commercialize and which to abandon, (2) kill one system immediately, or (3) combine them. Op.39 (citing B3397-3402; B3403-08). The Court below found the third outcome was "[t]he probable end goal," "consistent with Gorsky's earlier aspirations and the budget set" by the Ashley Challenge. Op.42.

Third, J&J continues its made-for-litigation narrative that Manhattan "yielded a decision to shelve Verb and devote all [J&J's] resources to iPlatform alone." AOB.46. But the Court found the contrary: Manhattan had "no upside for Auris," "did not advance iPlatform's development, provide it with resources, or bring it closer to regulatory approval," and "caused needless setbacks[,] … resource drains," and "delay[]." Op.70. Further, iPlatform's Manhattan win "did not mean

[18] The Court below rejected J&J's assertion that Auris wanted Project Manhattan. Op.40-41; *contra* AOB.45.

abandoning Verb," Op.46: The project "was a boon" for Verb and "iPlatform milestones were sacrificed to aid the Verb program." Op.71.

The breach holdings follow inexorably from these factual findings. Under any reading of the Merger Agreement, J&J's Project Manhattan—launched just *four days* after closing, Op.39—materially breached the "priority" CRE provision. By forcing iPlatform into a fight to survive, knowing it would impede achievement of the milestones, J&J did "the opposite" of "advanc[ing] iPlatform's development, provid[ing] it with resources, or bring[ing] it closer to regulatory approval." Op.70.

J&J now argues the contract "did not require J&J to prioritize iPlatform above Verb" on the purported ground that "Verb was another 'priority' medical device." AOB.46.[19] Because J&J asserted, confirmed, and reconfirmed below that *Velys*—not Verb—was the *only* comparator "priority" device, *supra* 10-11, this new argument is waived. It is also irrelevant to J&J's liability under the Merger Agreement: J&J's usual practice for "priority" devices, as confirmed by its treatment of Velys, was unequivocally *not* to pit one device against another in a zero-sum competition to determine which device would survive. Op.69-72; *see supra* 46.

[19] The Court below did *not* find that Verb was a "'priority' medical device" within the meaning of the Merger Agreement. Op.38; *contra* AOB.46. Instead, the Court found that, at closing, amidst the Ashley Challenge's self-imposed spending limit and with the Project Manhattan launch just days away, Shen instructed his team that "[d]elivering of *Verb* milestones is our No. 1 priority," Op.38 (emphasis added) (quoting B3395)—evidencing J&J's disregard of its obligation to achieve *iPlatform* milestones, *see* Op.65 n.362.

The CRE factors also support the Court below's holdings of breach. "[I]ssues of efficacy and safety," "risks inherent in … development," and "the likelihood and difficulty of obtaining FDA and other regulatory approval," A2845 § 2.07(e)(ii)(A)-(B), (E), counseled *against* a competition requiring the iPlatform team to resort to "the engineering and software equivalent of Band-Aids, duct tape, and baling wire" while "largely suspend[ing] [iPlatform's] development plan, MVP strategy, and beta version progress." Op.43. And iPlatform's commercial prospects, A2845 § 2.07(e)(ii)(B)-(C), (J), were likewise harmed by the resulting delay and "technical debt." Op.43, 70.

In short, the Court below correctly determined that J&J's wrongful conduct with Project Manhattan independently sufficed to support the holdings of breach and damage regarding iPlatform. Op.72, 74 n.392.

b. J&J's Refusal to Follow an MVP Development Approach Breached the Merger Agreement

As J&J's own robotics expert admitted, the structure and sequence of regulatory milestones in the Merger Agreement reflected *Auris's* proven MVP strategy for RASDs: Start simple and iterate to greater complexity and capability. Op.75-76; A2416; B415; *contra* AOB.47, 49. That MVP strategy likewise reflected *J&J's "usual practice" for priority medical devices*, as confirmed by Velys. J&J prioritized Velys's quick launch with a single indication when Velys still "lacked perfect performance statistics," was inferior to its rival, had money-losing

accessories, and needed further development for planned features. Op.67-68; B4348-49; A0830, A0849; A1701-02 (MVP is industry-standard); B4680-83; *contra* AOB.51 (incorrectly asserting Velys was "fully finished" at launch).[20]

After the delay and disruption caused by Project Manhattan, Moll sought this same MVP approach to achieve iPlatform's first 2021 regulatory milestone with a simple procedure. Op.76. Yet J&J blocked that strategy and instead demanded that iPlatform *first* try to achieve FDA approval for the far more difficult RYGB procedure that was not required until the 2023 milestone years later. Op.76-77.[21] The Court below correctly held J&J's refusal to allow Auris to use J&J's usual MVP strategy for priority devices breached the contract. Op.78.

J&J erroneously contends the Court below ignored what it describes as its framework for MVPs to be (1) safe and efficacious; (2) commercially viable; and (3) architecturally sound. AOB.51. But the Court determined, in unappealed factual findings, that: (1) as to safety and efficacy, iPlatform would have achieved FDA

[20] Gorsky also directed J&J to follow such an MVP strategy for Verb. Op.80; B2200 ("Alex has asked us to … make sure we hit the goals and deliver the first general 'minimally viable project.'"); A2624 (targeting just "1 indication" for a "[r]educed program scope"); *contra* AOB.51.

[21] J&J's commentary about Auris's "'shift' in strategy" for the first iPlatform milestone, AOB.47, is inapposite: The requested focus on simpler indications was (1) caused by Manhattan and J&J's subsequent Verb-iPlatform combination, Op.76, and (2) consistent with the heavily negotiated sequence of the milestones, Op.75-76; *see also* A2840-42 § 2.07(a); A1436; B3061 (Auris anticipating doing simple "procedures … to gain clearance[] in quick fashion").

approval, and thus would be "clinical[ly] safe[] and effective[]," Op.94, but for J&J's conduct, Op.96, 104; (2) as to commercial viability, Velys "was not superior (or even equivalent) to its market-leading rival upon launch," Op.67-68; and (3) as to platform architecture, iPlatform had "the capability to safely and effectively complete procedures," Op.97; *see also* Op.95-96, 105-09.[22] The CRE Factors likewise "were promoted through an MVP approach." Op.78-79; *see also* B416-18.[23] Even if the CRE Factors granted J&J some flexibility in balancing speed of regulatory approval with competing interests, they cannot justify J&J's insistence on first satisfying a complex *2023* milestone indication when doing so "impeded the achievement of the 2021 milestone." Op.78. On these facts, J&J "did not provide 'efforts and resources … consistent with the usual practice of [J&J] with respect to [a] priority device.'" Op.78.

c. J&J's Decision to Combine iPlatform and Verb Breached the Merger Agreement

The Court below further held that J&J's decision to "mesh" iPlatform and Verb breached *both* J&J's priority efforts obligation, A2845 § 2.07(e)(i)-(ii), *and* its obligation not to take actions "based on taking into account the cost of making any

[22] The Court below found an MVP iPlatform "would have 'plenty of differentiation' … to drive adoption" in the market. Op.79.

[23] Rather than "confirm[] … J&J's approach was consistent" with the CRE Factors, AOB.49, the Court below found that, while J&J might "believe[]" the CRE Factors supported a more complex procedure, Op.77, they did not, Op.78-79.

Earnout Payment(s)," A2845-46 § 2.07(e)(iii); Op.72-75; *see also* B400. As J&J knew and intended, its combination plan and related delay prevented achievement of iPlatform's milestones. After McEvoy told Gorsky the valuation of the "combined scenario" improved "when you consider what will also happen with the contingent payment"—"meaning the earnout"—Gorsky gave the "green light" to combine. Op.47; A4030-31.

J&J disputes the findings of the Court below as clear error, contending the record "showed only that J&J was considering this strategy" (and that it did not "actually combine[]" the robots until later). AOB.52. The record proves otherwise. Gorsky secured approval for major Verb funding from J&J's Board on the promise of a meshed iPlatform-Verb robot. Op.49. J&J then publicly represented its robot launch was delayed because it was working to "incorporate elements from … both Verb and Auris" in a combination robot. B4036; B3960. J&J conceded post-trial that it had decided to pursue the combination by October 2019. *See* A0514-15. When J&J *completed* the combination is irrelevant: Gorsky's *decision* to combine, knowing it would doom the milestones, alone sufficed to breach the CRE provisions and Section 2.07(e)(iii). Op.72-74; *see also* B405-06; Final Judgment 7.[24]

[24] J&J does not appeal the ruling it breached Section 2.07(e)(iii). AOB.27 n.4. J&J wrongly asserts "this breach finding does not support any liability," *id.*; on the contrary, the Court below dismissed Fortis's Count IV as moot "without prejudice" because it viewed that breach as "part and parcel" of the other breaches, obviating

Once again, the CRE Factors do not insulate J&J from liability, *contra* AOB.53. As the Court below found, "[a] 'priority' device would not have its system, technology, and team diluted to fix another device's problems." Op.75.[25] That finding was confirmed by J&J's practice for its one comparator, Velys, which was never "enmeshed" with another device. Op.82. The combination's purpose was not to improve iPlatform, much less achieve the Milestones, but rather to salvage Verb and create a "good overall value case" by avoiding earnouts; no "priority" device would be subjected to that. Op.46-47, 73; *contra* AOB.53.[26]

J&J also asserts the "employee integration" of Verb engineers into the iPlatform team did not contribute to the breach. AOB.53-54. But J&J again ignores the factual findings. The integration created a "calamity of … redundancy" and "[h]ostility … between the two factions, which had just faced off in Project Manhattan for the survival of their respective projects." Op.50; B3973. "Within a year of the integration, every engineer from legacy Auris's iPlatform clinical

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the need to "assess separate damages." Final Judgment 7. If this Court reverses the CRE claims, it should remand to allow that damages assessment.

[25] J&J mischaracterizes the Court below as endorsing its position that the combination "ma[de] all the sense in the world," AOB.53; instead, the Court simply acknowledged J&J's spin. Op.46, 49.

[26] J&J speculates the combination was not a breach because the definition of "iPlatform Products" includes derivatives of iPlatform. AOB.53. This new argument is, again, both waived and wrong: J&J knew a combination plan would cause iPlatform (and any derivatives) to miss the milestones. Op.72 n.388.

engineering team left the company—a 'devastating' loss for the program." Op.50. "A 'priority' device would not have its … team diluted to fix another device's problems," and Velys never had to integrate a rival team. Op.75 & n.400.

d. J&J's Incompatible New Employee Incentives Breached the Merger Agreement

J&J complains it is faulted for offering "employees more money" for success. AOB.55. In fact, the Court below correctly found the new incentives redirected employees *away from* the Regulatory Milestones toward incompatible goals. Op.81-82. Although J&J could reasonably calibrate CRE, it could not rewrite or deprioritize the milestones themselves. The Court relatedly found (again, unappealed) that the new incentives were different in kind from those for Velys, which were aimed at "achiev[ing] rapid FDA clearance." Op.68.

e. J&J's Spending Did Not Excuse Its Breaches

The Court below rejected J&J's facile argument that it could not have breached because it spent large sums on robotics. Op.82-83; *see* A0554-56. The Court found, and J&J does not appeal, that its *general* spend on robotics (which, for J&J, included Verb, instruments, and this very litigation) is a misleading "oversimplification." Op.82-83. The spend was not directed to *achievement of the*

milestones; indeed, approximately $1 billion was not even directed to *iPlatform*. *Id.*[27] Under the Merger Agreement, that cannot satisfy J&J's duties. *Id.*

[27] Spending alone is never dispositive. The Court below found J&J's efforts on Monarch endourology were commercially *reasonable* even though endourology was "underfunded." Op.88.

III. THE COURT BELOW CORRECTLY FOUND J&J COMMITTED FRAUD

A. Questions Presented

1. Whether the Court below had a proper factual basis to find J&J actively and knowingly concealed material information when it represented to Auris the ablation milestone had such "high certainty" of success that it was "'effective' up-front consideration," while concealing a patient death and government investigation into J&J that placed the milestone at risk. Preserved at Op.30-33, 124-26; A0349-53; A0406-12.

2. Whether the Court below correctly held the Merger Agreement does not foreclose Fortis's fraud claim where the contract expressly disclaims only reliance by J&J—not Auris—upon extracontractual representations. Preserved at AOB Ex. A ("MTD.Op.") 21-29; B38-48.

B. Scope of Review

This Court reviews whether the fraud judgment has "any factual basis," AOB.62, under "the deferential 'clearly erroneous' standard." *CDX Hldgs., Inc. v. Fox*, 141 A.3d 1037, 1041 (Del. 2016). Legal conclusions are reviewed *de novo*. *Smith v. Mahoney*, 150 A.3d 1200, 1204-05 (Del. 2016).

C. Merits of Argument

Fraud may occur through "overt misrepresentations," "deliberate concealment of material facts," or "silence in the face of a duty to speak." *Stephenson v. Capano*

Dev., Inc., 462 A.2d 1069, 1074 (Del. 1983). Concealment may include oral misrepresentations. *Nicolet, Inc. v. Nutt*, 525 A.2d 146, 149 (Del. 1987).

1. Extensive Evidence Supports the Court's Factual Finding of Fraud

The Court below did not find fraud lightly. It rejected "most" of Fortis's fraud claims, Op.4, despite finding J&J made numerous misleading statements. *E.g.*, Op.42, 120, 122 (J&J misrepresented it "planned to launch both iPlatform and Verb" when it had already "capped the robotics budget" at a level that would "not support" parallel development); Op.18-19 (Gorsky told the market Verb was "on track" while knowing it was "significantly behind schedule").

The Court below ruled for Fortis on a single fraud claim, finding J&J actively concealed material information when Gorsky falsely assured Moll the ablation milestone was "high certainty" and "'effective' up front consideration," while concealing that a patient death, and related FDA investigation, rendered the milestone "not remotely certain to be met." Op.124-25 & n.635. J&J improperly asks this Court to "re-weigh the evidence and come to different conclusions." *In re Tesla Motors, Inc. S'holder Litig.*, 298 A.3d 667, 678 (Del. 2023).

First, J&J cannot show clear error in the finding that J&J engaged in "active concealment of material facts." Op.125. "Gorsky's statement" to Moll was "undoubtedly" an affirmative act to conceal the death and investigation. Op.125; *contra* AOB.60. J&J was "working to convince Auris to sell" on J&J's terms,

Op.124, and could not afford questions about FLEX's regulatory status. Gorsky therefore assured Moll the milestone was a "certainty." *Id.* "Gorsky's statement was intended to induce Auris to agree to a contingent payment," and it worked. Op.125. J&J has no basis to substitute a contrary finding about Gorsky's possible "belie[f]" in the milestone's probability, AOB.58, particularly after Gorsky's "[u]nfortunate[]" refusal to testify. Op.73 n.389.

J&J cannot and does not dispute the death and investigation were "material" because "a reasonable person would attach importance to [such facts] in determining his choice of action in the transaction.'" *Harper v. Russell*, 836 A.2d 513, at *2 (Del. 2003) (cleaned up). Auris never would have accepted the ablation milestone knowing the true facts, which "[d]estroy[ed] the value of the milestone," Op.126; B3450.

J&J's compulsory reporting of the death *to the FDA*, A5429, did not satisfy its duties *to Auris*, Op.126 n.643; *contra* AOB.60. The Court below found the record did not show whether the death became public pre-merger, as the FDA's time to publish incident reports is unpredictable. Op.126 n.643; A2014; *contra* AOB.60. Further, "Auris would have had no reason to search the FDA's website" after receiving Gorsky's false assurance. Op.126 n.643; A1679. Regardless, J&J's report

of the death to the FDA did not mention the *investigation*, A2694-98, which was independently material because it "risked substantial delay," Op.125.[28]

Second, the Court below properly found J&J had the requisite knowledge for fraud. Op.124-25. The question is not whether "J&J knew Gorsky's statement to be false," AOB.60, but whether it knew it was "materially misleading" to represent the milestone as a "certainty" while concealing the death and investigation, *Lock v. Schreppler*, 426 A.2d 856, 862 (Del. Super. Ct. 1981); *Stephenson*, 462 A.2d at 1074 (citing *Lock* for "concealment" standard).

J&J knew the death and investigation "risked substantial delay," Op.125 & n.641 (citing B2440 (J&J discussing "push[ing] out" ablation launch by "years")); *see also* B2417, and "suspected that the FDA would place the [NeuWave] study on hold," Op.31. The very team members that "guided" Gorsky to represent the milestone as a "high certainty" were focused on what "will be required for the FDA approval" in light of the death and investigation. Op.32, 124. The Court below clearly found J&J's knowledge of the risks meant it knew Gorsky's statement of

[28] J&J's cases are inapposite. *Bovay v. H.M. Byllesby & Co.*, 38 A.2d 808 (Del. 1944) merely summarizes *Jones Mining Co. v. Cardiff Mining & Milling Co.*, 191 P. 426 (Utah 1920), which did not address fraudulent concealment and this Court found "not … convincing," *Bovay*, 38 A.2d at 817. *Garner v. Global Plasma Solutions, Inc.* supports Fortis, recognizing that fraud could occur through "burying" even publicly available facts. 590 F. Supp. 3d 738, 745 (D. Del. 2022) (applying Maryland law). The concealment claim there failed for lack of an "affirmative action," *id.* at 747—which Fortis proved—not because the concealed information was "public," *contra* AOB.60.

"certainty" was false and materially misleading. Op.124-25; *Tesla*, 298 A.3d at 716 (opinion below must be "fairly read"); *contra* AOB.60.

The Court below considered J&J's evidence, including its original estimate that the ablation milestone was 85% likely to succeed, Op.136; *contra* AOB.60-61, but found it unpersuasive. J&J's original estimate presumed achievement over a year before expiration. B2486. Subsequently, Gorsky's team—"mindful" of FDA risks, Op.32—told J&J's bankers to move the achievement date to right before expiration, A2724. Significantly, J&J offered no banker testimony at trial, and no witness asserted the 85% probability was reexamined after the milestone lost all buffer because of the death and investigation.[29]

J&J's evasive discovery conduct buttresses the Court below's findings. J&J initially withheld the FDA's letter requiring a new clinical study not only from Fortis but from its own expert. B1392-93. After belatedly producing that letter at Fortis's demand, J&J still refused to produce the pre-merger inspection report referenced therein. Fortis sought sanctions, which the Court never reached because the evidence of fraud, even with J&J's selective withholding, was overwhelming. B380-81; Op.124-26.

[29] J&J's arguments about the "proximate cause" of the death and the timing of the FDA's conclusions, AOB.61, are inapposite. Leaving aside that the ultimate FDA findings were undisputedly "adverse," *id.*, the investigation itself imperiled the milestone, predictably causing delay, Op.31-32, 125-26.

2. The Merger Agreement Does Not Bar Fortis's Fraud Claim

The Court below correctly held the Merger Agreement does not immunize J&J from liability for its fraud. Op.115-16. Delaware's "distaste for immunizing fraud" means "a contracting party cannot, as a matter of public policy, 'limit … exposure for its own conscious participation in the communication of lies to the [other party.]'" *Express Scripts, Inc. v. Bracket Hldgs. Corp.*, 248 A.3d 824, 830 (Del. 2021) (quoting *Abry P'rs, V LP v. F & W Acq. LLC*, 891 A.2d 1032, 1061, 1064 (Del. Ch. 2006)). Absent "unambiguous anti-reliance language," parties will not "escape responsibility" for extracontractual fraud. *Abry*, 891 A.2d at 1059. As J&J conceded below, "anti-reliance language is needed to stand as a contractual bar to an extra-contractual fraud claim based on factual misrepresentations." B325.

It is uncontested that the Merger Agreement contains no anti-reliance language as to Auris. AOB.63. That should end the inquiry. *Abry*, 891 A.2d at 1059, 1064. But, more, the contract contains a one-sided anti-reliance provision barring *J&J's* reliance on extracontractual representations. A2877 § 4.08; B2714 (Auris inserting draft clause). That unusual, asymmetric provision confirms that the parties (1) knew how to draft anti-reliance provisions following *Abry*, and

(2) intended to bar only J&J, and not Auris, from asserting extracontractual fraud claims. MTD.Op.29.[30]

The Merger Agreement's separate "exclusive remedy" provision (applicable to both parties), A2903 § 8.05(b), cannot be read to bar all extracontractual fraud claims, or the anti-reliance provision on this subject would be surplusage, *contra* AOB.62. Further, no case holds that exclusive remedy terms *without* anti-reliance language can immunize deliberate fraud. J&J points to *Express Scripts* (which it never cited below), which enforced an exclusive remedies provision that respected the *Abry* line of cases by "carv[ing] out deliberate fraud." *Express Scripts*, 248 A.3d at 830-31 (reversing Superior Court). Here, by contrast, (1) the subject of extracontractual fraud is instead addressed in the distinct anti-reliance provision—which runs against J&J alone; (2) the exclusive remedy provision does *not* exclude deliberate fraud; and (3) J&J invokes the exclusive remedy provision to escape liability for "active concealment of material facts" (Op.125), which is inherently "deliberate," *see Stephenson*, 462 A.2d at 1074 (cited at Op.114 n.589); *Transdigm Inc. v. Alcoa Glob. Fasteners, Inc.*, 2013 WL 2326881, at *6 (Del. Ch. May 29, 2013) ("active concealment" means action "designed or intended" to hide facts). Immunizing such fraud without anti-reliance terms would not "[f]ollow[] Delaware

[30] This made sense: Auris, unlike J&J, made extensive representations in the Merger Agreement itself.

law." *Express Scripts*, 248 A.3d at 831; *accord Abry*, 891 A.2d at 1064; *New Enter. Assocs. 14, L.P. v. Rich*, 295 A.3d 520, 531-32 (Del. Ch. 2023) (anti-reliance provisions are the "only … situation where Delaware law" has "held that a provision restricting tort liability for intentional harm was not facially invalid").[31] That J&J's fraud was extracontractual does not make "the law's traditional abhorrence of fraud" less applicable. *Abry*, 891 A.2d at 1058.

[31] Anti-reliance provisions are unique because they promote Delaware's policy against fraud by preventing misrepresentations about reliance. *Abry*, 891 A.2d at 1058; *contra* AOB.63.

CONCLUSION

As set forth above, this Court should affirm the judgment.

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