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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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INTRODUCTION

Fortis agrees that the Merger Agreement's efforts provision was "highly customized" and that this Court should enforce the contract as written. AB41 (quoting Op.62). Yet, at every turn, Fortis urges this Court to rewrite the contract. On the implied covenant, Fortis opens with a demand to blue-line one of the most repeated phrases in the contract: "510(k) premarket notification." In doing so, it blows past four different limitations this Court has placed on that sort of extraordinary contractual revision.

Regarding the contract's efforts provision, Fortis interprets a contract that requires "commercially reasonable efforts" as prohibiting any consideration of what is commercially reasonable. Fortis affords no meaning to the ten factors that J&J was allowed to "tak[e] into account." It ignores that the provision assesses overall "efforts and resources," substituting instead a standard that flyspecks individual operational decisions. And Fortis rewrites the clause requiring that those efforts be "*consistent with* [J&J's] *usual* practice … with respect to priority medical device[s]," to find breaches wherever J&J made decisions that were not *identical* to those made for another device.

For the fraud claim, Fortis asks this Court to invalidate the plain text of the contract's exclusive-remedy provision, and flouts this Court's precedent requiring proof of active concealment.

These legal errors demand reversal without regard to any narrative or fact dispute. But Fortis repeats an assertion so often and so untethered from the record as to demand comment up front. Fortis's narrative is that J&J was *never* focused on developing iPlatform, but instead "cannibalized" iPlatform's parts for Verb "immediately after closing," AB1, and then seized on FDA's regulatory "change … as a pretext to abandon the milestones," AB3. That narrative is flatly inconsistent with the undisputed evidence—and several of the Court of Chancery's findings.

The undisputed evidence reflects that J&J stood to earn tens of billions from achieving the milestones and acted accordingly: It committed its most senior leaders to iPlatform's success, added hundreds of engineers, acquired two supporting companies, and—even by Fortis's stinting account—devoted at least $1.25 billion to develop iPlatform. AB54-55; *see* OB22-24, 44. Auris's own former CEO admitted at trial that no other project received "more resources or … more people or money." A1410. Even after FDA closed the 510(k) regulatory pathway to iPlatform, J&J doggedly pursued regulatory approval for iPlatform, not for a hybrid robot. A4307-11, A2186-88, A4224-27.

Despite all the resources J&J poured into overcoming iPlatform's existential technical and regulatory challenges, the robot never became safe enough to test on even a *single* live human for even the simplest of procedures. A1551, A1557, A2143, A4466. Fortis *conceded* below that it was not until years after the merger—long after

it became clear that iPlatform would be unable to achieve any of the milestones—that J&J attempted to mitigate its massive losses by combining elements of iPlatform with Verb. A0302, A0638 n.21. Fortis has never claimed that decision was a breach, and it cannot now backdate it to day one to obscure the legal errors that demand reversal.

ARGUMENT

I. The Implied Covenant Cannot Be Used To Override Explicit Contractual Language.

A. The court's use of the implied covenant to rewrite the contract violated four limits on the doctrine.

Fortis depicts the implied covenant as a free-roving power to line-edit contracts to "best reflect[] the parties' reasonable expectations at contracting." AB32. But this Court has stressed that the implied covenant is a "limited and extraordinary" remedy, not a tool for "re-writ[ing] the agreement between the parties." *Oxbow Carbon & Minerals Holdings v. Crestview-Oxbow Acquisition, LLC*, 202 A.3d 482, 507 (Del. 2019) (citations omitted). To enforce the doctrine's narrow scope, this Court has set strict limitations on its use. The Court of Chancery violated four of those limits, each of which independently warrants reversal. OB31-34. Fortis cannot defend any of the violations, let alone all four.

1. Contract addresses the issue. The implied covenant may not be used unless "the contract is truly silent concerning the matter at hand." *Oxbow*, 202 A.3d at 507 (cleaned up). The "matter at hand" here is what form of regulatory approval triggers J&J's milestone obligations. Fortis cannot deny that the contract is far from silent on that matter: As the Court of Chancery observed, it "expressly contemplates '510(k) premarket notification'" for every single regulatory milestone. Op.99. That is dispositive.

Fortis tries to avoid this conclusion by redefining the matter at hand as "what would occur if the 510(k) pathway were closed to iPlatform." AB31. But the silence requirement cannot be so easily evaded. A contract that explicitly imposes a condition on performance is not silent on that condition. Nor is a contract considered silent because it does not specify contingency plans for every potential scenario in which an explicit condition is not satisfied. This Court addressed exactly that situation in *Nemec v. Shrader* and held that the "absence of specific language contemplating" the specific scenario that occurred did not qualify as contractual silence or allow the court to infer "language that contradicts a clear exercise of an express contractual right." 991 A.2d 1120, 1126-27 (Del. 2010).

Nemec thus rejects Fortis's assertion that the contract is silent because it lacks a "term barring earnouts in the event of a[] … pathway change." AB31-32. Besides, the contract did have such a term: "[I]f any Milestone is not achieved"—here, by not obtaining 510(k) approval—"on or prior to the [deadline] … no Earnout Payment will be payable." A2842. It further recognized that the milestones might not be met for reasons "outside of the control of [J&J]," A2847—including regulatory change, *see* A2845.

2. Parties could have drafted the contract to provide for the implied term. Fortis leaves unrebutted a key aspect of a second crucial limitation, which prohibits invoking the implied covenant if the parties "could easily have … drafted" the

contract "to expressly provide for" the implied term—here, alternative pathways for regulatory approval. *Oxbow*, 202 A.3d at 507 (citation omitted). Fortis does not dispute that the parties could have easily drafted the agreement to link the earnout payments to FDA approval under any pathway; the parties instead repeatedly specified the 510(k) pathway. OB32-33. That, too, is independently dispositive.

Fortis claims none of that matters, based on the false assertion that "[t]he Court below found … that the parties did not and *could not reasonably anticipate* the FDA's pathway change." AB29 (emphasis added). In truth, all the court found was that the parties considered 510(k) "logical," did not expect the shift, and "never … discussed" any other pathway. Op.99 & n.512. But the implied covenant does not apply to developments the parties "failed to consider"—only those "that *could not* be anticipated." *Nemec*, 991 A.2d at 1126 (emphasis added).

Fortis also has no response to the opening brief's showing that the regulatory shift could have been anticipated. First, as a general matter, regulated entities know that FDA can change past regulatory practices to impose additional requirements. OB16, 33. Second, the contract expressly contemplated that "developments from the FDA" could increase "the data required to obtain[] approval." A2845. Third, Auris knew FDA had raised doubts about iPlatform's 510(k) suitability before the merger. OB16.

Even if the court had found that the switch was unforeseeable, it would still have been improper to invoke the implied covenant to rewrite express contractual terms. That is evident from this Court's decision in *Cincinnati SMSA Ltd. Partnership v. Cincinnati Bell Cellular Systems*, 708 A.2d 989 (Del. 1998). There, a group of phone companies agreed to a noncompete provision for "Cellular Service," which the parties defined as services authorized under Part 22 of FCC regulations. *Id.* at 991. Later, FCC began licensing a new type of phone service, PCS, under a different regulation. *Id.* When one of the companies started offering PCS, the others sued. *Id.* This Court acknowledged that "the development and licensing of PCS was unfor[e]seen at the time the parties entered into the Agreement." *Id*. at 993. But this Court nevertheless held it was improper to use the implied covenant to rewrite the noncompete provision to include PCS, because doing so would conflict with "the unambiguous terms of the Agreement." *Id*.

So too here. Because the contract defines the type of regulatory approval required for milestone achievement "in precise terms" and "its meaning is confined" to the pathway specified in the contract, the court was "without room to include [regulatory] develop[ments]." *Id.* Arguments second-guessing that the contract should have included alternative regulatory pathways provide no justification "to vary the Agreement *ex post*." *Id.*

3. Not clear from the contract the parties would have agreed. Fortis's treatment of the next limitation revolves around another false assertion: that the court found "the parties would have agreed to the implied term had they considered the unforeseen development." AB34. What the court actually said was: "Had 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." Op.103. Obviously. But that is not enough. This factor is not satisfied unless "it is clear from the contract that the parties would have agreed" to the precise contract the court rewrote. *Nationwide Emerging Managers v. Northpointe Holdings*, 112 A.3d 878, 898 (Del. 2015) (cleaned up); OB33-34. That would require a finding that the parties would have agreed, at the time of contracting, to substitute De Novo approval for 510(k) clearance *and* still adhered to the same upfront payment, milestone deadlines, and earnout amounts. The court made no such finding, and nothing in the contract or record would support it. Fortis does not dispute that the only evidence addressing the topic is testimony from a J&J executive that switching to De Novo would have changed the company's entire calculus for the deal, because "anything beyond [510(k)] … would add time, investment, and it would impact the valuation." A1880; *see* OB34.

Fortis cannot fill the evidentiary gap by pointing to the court's finding that the regulatory shift turned out to have "an immaterial effect on the time and cost for

iPlatform to gain FDA clearance." AB33 (quoting Op.103). What matters is not how the consequences ultimately played out, but how the parties would have evaluated those factors "*at the time of contracting*," seven months earlier and before FDA explained what further data it would require. *Nemec*, 991 A.2d at 1126-27 (emphasis added). The court found, and Fortis admits, that "De Novo is 'generally more onerous' than 510(k)." AB22 (quoting Op.102) (alterations omitted). The court did not find—and there is no reason to believe—that the parties *upon signing the contract* would have been confident that iPlatform would be the outlier device for which substituting De Novo for 510(k) would have no material effect.

Moreover, "time and cost" are not the only factors parties consider in setting financial terms. Risk of failure is also key. Contrary to Fortis's repeated false contentions, the court never found that the change "had an 'immaterial' impact on … odds for approval." AB28; *see* AB3. Fortis does not dispute that De Novo approval odds are *half* those of 510(k) applications, A5455, A2311-12, and Fortis had no evidence showing that, at the time of contracting, the parties would have believed those odds to be any different for iPlatform specifically.

Even as to "time and cost," Fortis relies entirely on a presentation that the court acknowledged was about *Verb*—a different robot, developed on a different trajectory and timeline, with a different clinical development plan that was further along at the time of the pathway change. Op.102 n.532 (citing B3452-67, a draft

Verb timeline presentation). Ignoring that caveat, Fortis fosters the false impression that the presentation concerned iPlatform. AB22, 33. This document does not prove that, *ex ante*, the parties would have considered a change in regulatory pathway so immaterial for iPlatform as to leave all other terms unaffected.

4. No arbitrary conduct. Fortis cannot quote a single sentence from the court's opinion finding that J&J "acted arbitrarily or unreasonably." *Nemec*, 991 A.2d at 1126; OB34. Instead, Fortis cobbles together snippets to attribute to the court findings it never made. For example, the court did not find that J&J "abandon[ed] efforts to achieve regulatory approval" right after the pathway change. AB27; *see* AB35. The undisputed evidence reflects that J&J kept striving toward iPlatform's regulatory approval after the shift. *E.g.*, A4307-11, A2186-88, A4224-27; *see supra* 2; OB23-34; A5801, A5790-800.

Even if Fortis's portrayal were accurate, it would not support invoking the implied covenant. Breach of the implied covenant cannot be based "on conduct authorized by the agreement." *Nemec*, 991 A.2d at 1125-26. Under the contract, J&J would have been within its rights to stop pursuing Milestone 1 once it became impossible to achieve due to the unavailability of 510(k). *See id.* at 1128 ("[A] party does not act in bad faith by relying on contract provisions … where doing so simply limits advantages to another party.").

Relatedly, what Fortis characterizes as an "unconscionable demand for a billion-dollar windfall," AB35, assumes a contractual guarantee of the earnout payments that does not exist. And it is particularly galling since Auris shareholders have pocketed $3.4 billion and seek to preserve a judgment giving them another $1 billion, all for a robot prototype that was never safe enough to test on a single live human for even the simplest procedure and that yielded a massive loss for J&J. *See* A1535, A1551, A1557, A2129, A2147-48.

Finally, Fortis drops a conclusory footnote asserting that if this Court reverses on implied covenant, it should "remand for consideration of Fortis's alternative specific performance claim." AB36 n.14. That claim sought to enforce a provision requiring the parties to "negotiate in good faith to modify this Agreement so as to effect the original intent of the parties" under specified circumstances. A2927. The court dismissed that claim as moot, Final Judgment ¶ 8, and Fortis did not cross-appeal that dismissal. An appellate court "may not alter a judgment" to remand on unappealed claims that are dismissed. *Worthen v. Fid. Nat'l Prop. & Cas. Ins. Co.*, 463 F. App'x 422, 428 (5th Cir. 2012) (quoting *Greenlaw v. United States*, 554 U.S. 237, 244-45 (2008)); *see generally Barker v. Huang*, 610 A.2d 1341, 1351 n.7 (Del. 1992). Fortis also waived this claim for extraordinary relief by failing to address the elements in its post-trial briefing, A0447, A0660-61—likely because the most this

claim could achieve is a pointless negotiation over positions solidified through years of litigation.

B. The court's error in applying the implied covenant requires reversal as to all iPlatform and GI regulatory milestones.

The opening brief explained why 510(k)'s unavailability for Milestone 1 warrants reversal on all the other regulatory milestones: The earnout amounts and timelines of all the milestones were keyed to the use of 510(k) approval for Milestone 1, with no requirement that J&J secure De Novo approval for Milestone 1 as a route to achieve the other milestones. The undisputed evidence showed that J&J would *not* have agreed to the same tiered deal with the same timing and payment terms if there had been any contractual obligation to use De Novo approval as a regulatory predicate to potentially unlock 510(k) clearance for the remaining regulatory milestones. OB35-37. Fortis does not directly address this critical problem when it asserts that FDA's shift "did not foreclose 510(k) clearance for later" milestones. AB37.

Nor does Fortis have an answer to *Exelon Generation Acquisitions v. Deere & Co.*, 176 A.3d 1262, 1270-71 (Del. 2017), which emphasizes that courts cannot assume a buyer like J&J would have "nonetheless [been] willing to commit" to all the same earnout provisions if a key term of those provisions were changed. *See* OB37. Fortis simply recycles its argument that FDA's switch to De Novo turned out to be "immaterial," AB37-38, which fails for the reasons explained above. *Supra* 8-

10. In particular, the question is not how the parties may have viewed things after the fact, but rather what the parties believed "at the time of contracting." *Nemec*, 991 A.2d at 1126-27.

Fortis then tries to dodge the issue by falsely claiming that J&J declined to appeal "*any* findings as to causation." AB38. Not so. The *only* causation finding J&J did not challenge on appeal is that the additional testing and data requirements FDA imposed simultaneously with the switch to De Novo did not, *by themselves*, cause Milestone 1 to be missed. OB19 n.3. J&J did not forgo any other causation arguments, and expressly appealed the ones relevant here. OB36-37.

As a fallback, Fortis drops a footnote claiming that "J&J's failure to appeal the Monarch GI rulings requires affirmance on liability and damages for that milestone." AB38 n.15. But there were no "Monarch GI rulings" to appeal because the court never found that Monarch would have met the GI milestone. Op.110-11 (finding that J&J's alleged breaches left "*iPlatform* unable to timely meet the GI milestone") (emphasis added).

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

Fortis has almost nothing to say in defense of the court's decision to base damages for each milestone on each party's pre-merger estimates of the probabilities of success, without accounting for how those estimates would have changed had the parties known that De Novo approval would be required for at least Milestone 1.

OB37-38. On the merits, Fortis makes only two points, both of which are refuted above. First, Fortis repeats its baseless claim that J&J did not appeal *any* causation rulings, AB39, which is wrong because J&J's point about causation was much narrower and limited to Milestone 1, *see supra* 13. The second is the assertion that "the odds of achieving approval were materially unchanged," AB39, which is wrong because the court made no such finding as to "odds" and the undisputed evidence was to the contrary, *see supra* 9.

That leaves only Fortis's baseless contention that this argument is unpreserved. AB39. It was Fortis's burden to prove all three elements of its breach of contract claim, including that it suffered damages caused by the claimed breach. *LaPoint v. AmerisourceBergen Corp.*, 2007 WL 2565709, at *9 (Del. Ch. Sept. 4, 2007). J&J repeatedly emphasized the drastically lower odds of success for De Novo applications in addressing what damages, if any, were caused by the alleged breach. *See, e.g.*, A2311-12, A5424; B672. Further, J&J's cross of Fortis's damages expert highlighted that his damages model failed to account for the change to De Novo. A2038-39. And after trial, J&J underscored the difference in approval rates specifically in connection with damages. AR0459-62. That is more than sufficient to "fairly present[]" the argument. *N. River Ins. Co. v. Mine Safety Appliances Co.*, 105 A.3d 369, 382-83 (Del. 2014).

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

J&J agreed to use "commercially reasonable" "efforts and resources," measured against its usual practice for "priority" devices, to achieve the iPlatform milestones. J&J did not commit to blindly pursue the milestones at all costs or to allow a court to second-guess every single business decision related to iPlatform. J&J instead bargained for the right to "tak[e] into account" a range of business considerations when calibrating its efforts to achieve the milestones. Acquiring companies in J&J's position must be able to rely on courts to enforce such explicit terms preserving business judgments. The Court of Chancery failed to honor these contractual protections when it supplanted J&J's bargained-for discretion to calibrate its efforts to achieve the milestones with the court's own views about how J&J should have run its business. § II.A. Every breach finding flowed from the court's interpretive errors. § II.B.

A. The court legally erred in interpreting J&J's efforts obligation.

The dispute over the meaning of J&J's efforts obligation boils down to two related questions: (1) what is the consequence of the language requiring the "expenditure of efforts and resources" toward achieving the milestones "consistent with [J&J's] usual practice … with respect to [similar] priority medical device[s]"; and (2) what is the relationship between that commitment and the ten enumerated factors that J&J is contractually entitled to "tak[e] into account"?

As J&J has shown, the efforts provision requires a court to assess overall "efforts and resources," not to flyspeck individual strategic business decisions. OB44. Fortis disputes the total amount that J&J spent on iPlatform, but even using Fortis's own math, J&J spent at least $1.25 billion directly on developing the robot. AB54-55; Op.82. Fortis cites no contract provision that justifies ignoring both that direct investment and all the other resources J&J dedicated to iPlatform. OB22-24, 44.

Instead, at every turn, Fortis interprets the efforts provision as if it required J&J to treat iPlatform exactly the same as one specific priority device, Velys—such that J&J was in breach whenever it took *any* action with respect to iPlatform that did not identically correspond to its actions for Velys. Nothing in this "'highly customized' CRE term" authorized that sort of decision-by-decision comparison. *Contra* AB42 (quoting Op.62). The contract requires only efforts "consistent with" J&J's "usual practice" for priority devices, and expressly qualifies that obligation by allowing J&J to "tak[e] into account" the ten factors. A2845. This express reservation of discretion means that, for iPlatform, J&J was allowed to tailor its priority device efforts in light of iPlatform-specific factors like "risks inherent in … [iPlatform's] commercialization," market "competitiveness," feedback from FDA, the likelihood or difficulty of obtaining regulatory approval, and expected

"profitability." A2845. In other words, different treatment can still be "consistent" when justified by different circumstances.

Which brings us to the second critical interpretive question. Everyone agrees that the ten factors must have some meaning. AB43. Yet, Fortis has no answer for how J&J is allowed to "tak[e]" all those factors "into account" if they can never override the imperative to achieve a milestone. Without an answer to that question, Fortis impermissibly reduces the entire litany to surplusage.

Suppose J&J determined that it would cost $10 billion to secure FDA approval for iPlatform, but that the resulting product would be so inferior that it would not make a penny. It would obviously not be commercially reasonable—under any assessment of the factors—to pursue development. Yet, Fortis's position is that J&J would nevertheless have a contractual obligation to pursue the milestones. That would be absurd. No business would agree to that obligation, and J&J most certainly did not. The court was simply wrong in concluding that "J&J was not … permitted to prioritize" any combination of the ten factors "at the expense of achieving the milestones," Op.78—and in declining to even consider those factors in assessing J&J's iPlatform "efforts and resources." OB41-43.

Tellingly, Fortis never disputes that one thing a court *cannot* do is ignore the factors entirely in deciding whether a particular decision breached the provision. But it never refutes the point that the court did exactly that when assessing each of the

asserted iPlatform-related breaches. OB42. All Fortis says is that the court "gave effect to J&J's ability to balance other concerns" when it analyzed "J&J's efforts on the *Monarch* milestones," which are not at issue on appeal. AB43-44 (emphasis added). Fortis's inability to cite *any* instance in which the court "gave effect" to J&J's right to balance the ten factors with respect to *iPlatform* speaks volumes.

Nor does Fortis offer any persuasive rationale for demoting the ten-factor provision to oblivion. It asserts that the ten factors are "grammatically subordinate" to the "priority" clause. AB45. But just because they come second does not make them "subordinate." The ten factors expressly qualify the priority language: J&J is allowed to tailor its efforts by "taking into account" each of the ten factors. A2845. That makes sense. Having spent billions to acquire Auris's robots, of course J&J would insist on some degree of latitude over their development strategy. This natural reading does not mean J&J's "discretion" was "bereft of limits." *Contra* AB43. If the overall "efforts and resources" J&J devoted to iPlatform were less than the efforts and resources J&J generally devotes to priority devices and unreasonable in light of the economics, challenges, and risks, then they would not be "commercially reasonable."

All that remains is Fortis's meritless preservation argument. AB44. Fortis does not dispute that J&J specifically and repeatedly argued that the court was required to consider each alleged breach under the ten factors and that those factors

justified each decision. A0492, A0559, A0561, A0563, A2441; B313, B327, B637, B640-45, B666-67. The problem here was not that the court failed "to assess every possible permutation of CRE Factors," AB44, but that the court disregarded them all as categorically irrelevant, OB42-43.

B. The court also erred in finding that J&J breached its efforts obligation.

Even if Fortis's decision-by-decision approach were permissible, none of the court's breach findings can be sustained under a proper reading of the contract.

1. Project Manhattan. Both the court's disregard of the ten factors and its erroneous cookie-cutter approach to Velys are exemplified in its finding that J&J breached its efforts obligation by conducting Project Manhattan—an assessment of iPlatform and Verb that J&J conducted shortly after the merger.

As much as Fortis tries to portray the debate here as factual, J&J's position does not depend on challenging any disputed fact. The legal error is evident even accepting Fortis's most aggressive depiction of the facts: that Project Manhattan was a showdown between Verb and iPlatform that distracted the Auris team for a few months and thereby set them back somewhat from achieving the milestones. AB46-48. Fortis cannot point to anything in the contract prohibiting any of this if Project Manhattan was otherwise reasonable, taking into account the ten factors. Regardless of Fortis's view of what Project Manhattan was "designed to achieve," AB47, the court found that, "[t]hrough the assessment, J&J identified synergies between the

robots," Op.71, which is a contractually permissible objective. The court also found that "further technical due diligence" was required after the merger. Op.29. While insisting that Project Manhattan was not the exact "technology audit" the parties discussed pre-merger, AB46, Fortis cannot contest that Project Manhattan supplied more technical information about iPlatform. Nor does Fortis dispute that an exercise like this could yield important information on contractually authorized considerations, including "issues of efficacy and safety," "risks inherent in [iPlatform's] development and commercialization," and expected "competitiveness" of the robot. A2845. Nothing in the contract gives a court the authority to micromanage the ways in which J&J gathered information it needed to assess the explicitly authorized considerations or required J&J to forgo these useful steps just to avoid any possible short-term delay.

Fortis also asserts that Project Manhattan was "something Velys … did not endure." AB46. That is a good example of Fortis's cookie-cutter fallacy of reading the contract to require efforts *identical* to any other device rather than "consistent" with its usual practice in light of the unique circumstances of iPlatform's development. Velys was differently situated, because J&J did not own another orthopedic robot like Velys with which to assess synergies.

That leaves only Fortis's argument that some of the contractual factors supposedly counseled against Project Manhattan. AB49. Fortis never made those

arguments below. And having ignored the factors entirely, the court never made any such findings. In any event, the question is not whether it is possible to spin the factors against a particular decision, but whether J&J's assessment of the factors was reasonable. Fortis fails to refute J&J's showing it was.

2. MVP. Fortis does not dispute that Auris, J&J, and FDA all agreed with the plan to meet Milestone 1 by performing a gastric bypass surgery (RYGB) that would use at least five robotic arms. AB50 n.21. The breach finding was based on J&J's decision not to shift almost immediately to a watered-down strategy that Fortis now calls "MVP." That "strategy" would have required J&J to develop, purely for the purpose of securing initial regulatory approval, a "basic pre-commercial" stripped-down prototype, A0327, that would likely "never even" get to market, A3504-05. OB47. Fortis has no real defense of its paradoxical proposition that the only commercially reasonable approach was to seek approval for a robot that was not intended to be commercially viable.

Fortis does not dispute that the court said the original RYGB strategy was "ideal," Op.76, and that iPlatform's "'competitiveness'" and "'profitability' would be furthered" by the strategy J&J pursued. Op.77-78. Even though the court made these statements in declarative sentences, Fortis argues that they were not actually findings, but only the court's acknowledgments of J&J's argument. AB51 n.23. Regardless, the court nowhere suggested J&J's assessment of those contractual

factors was unreasonable. It found a breach based solely on the ground that "J&J was not … permitted to prioritize" the ten factors "at the expense of achieving the milestones." Op.78. That was erroneous for reasons already discussed. *Supra* 17-18.

Properly read, the contract did not require J&J to abandon its "ideal" strategy. Fortis cannot change that by recasting the court's observation that the contract "reflected an MVP strategy, albeit not explicitly." Op.75. The contract did not *require* an MVP strategy of any sort, let alone "*Auris's* … MVP strategy" of seeking regulatory approval for a prototype without regard to its commercial viability. AB49. Fortis has conceded the milestones "leave freedom to choose among multiple procedures" and "do not require specific features, numbers of arms, or architecture." A0183-84; OB49-50.

Fortis also cannot support the breach finding by repeating the court's fallacy that some of the ten factors "were promoted through an MVP approach." AB51 (quoting Op.78). It has no response to the point that that would just mean that pursuing that approach was *a* permissible option, not the *only* option consistent with the contract. OB49-50.

Nor can Fortis support the breach finding with its assertion that J&J applied an MVP approach for Velys. AB49-50. The MVP criteria are context dependent. The contract does not require J&J to reach the same result in applying those criteria to two very different devices. Fortis does not dispute that J&J's definition of MVP

has three strict requirements: a device must be (1) "safe and efficacious," (2) "commercially viable," and (3) architecturally sound. A1752, A0814; OB50-51. While Fortis emphasizes what those criteria do *not* require (such as "superior[ity] … to [the device's] market-leading rival"), AB51, it does not dispute that Velys met them. In contrast, the proposal for a stripped-down three-armed iPlatform robot would not have satisfied them all. For example, Fortis does not even have an argument that the stripped-down iPlatform would have met the requirement that there be "no architectural change" for later iterations. OB51. Instead, it offers a non-sequitur—that the stripped-down robot would "safely and effectively complete procedures," AB51—which would, if true, only address the first criterion. Under a contract that measured the required efforts by J&J's own practices, it was not a breach for J&J to decline to pursue a development strategy that undisputedly failed its own standards.

3. Proposed combination. The finding that J&J "meshed" iPlatform "with Verb components" in late 2019 or early 2020, Op.72, was clearly erroneous—and highly consequential. The court repeated it 15 times. And it drove not just this one specific breach finding, but the court's entire conception that J&J turned iPlatform into a "parts shop for Verb" right from the start. Op.3. That, in turn, was the only basis for other findings, such as the court's conclusion that Project Manhattan

afforded iPlatform no benefit even though it yielded a decision to "prioritize iPlatform." Op.45.

For such a consequential finding, one would expect robust support. But Fortis fails to support it at all. Nor could it, since Fortis *conceded* below that "J&J ultimately chose not to incorporate Verb components into iPlatform" (the "iPlatform+" proposal). A0638 n.21. The undisputed record reflects what Fortis acknowledged: J&J did not "pivot to a combination system" until "Dec[ember] 2021," A0302, after J&J concluded that no version of iPlatform (not even a commercially unviable one) could receive FDA approval until long after the milestone deadlines. OB25; A5076, A5291-92. Only then did J&J "shelv[e] iPlatform," A0646, and begin developing the "new" "Apollo" robot, a hybrid robot that includes elements of both Verb and iPlatform. A0211; *see* OB25. Fortis has never argued the Apollo combination was a breach.

Despite Fortis's concession below, Fortis *now* asserts that the "record proves" that J&J actually did mesh Verb components into iPlatform. AB52. But there is no record support for this. Fortis cites two documents that it claims show that J&J, in early 2020, "publicly represented its robot launch was delayed because it was working to 'incorporate elements from … both Verb and Auris.'" AB52. False. Those documents state only that J&J contemplated that it "*will* incorporate elements from Verb and Auris" in the future, B4036 (emphasis added), and that benefits could

flow from that, B3960. They say nothing about current meshing work—there was not any—nor do they attribute delay to the abandoned iPlatform+ plan. Beyond that, Fortis offers nothing but an assertion that "J&J conceded post-trial that it had decided to pursue the combination by October 2019." AB52 (citing A0514-15). All J&J conceded was that it was *considering* the iPlatform+ combination at that time. But J&J was always clear—and the record clearly shows—that "[u]ltimately, J&J chose not to incorporate any elements of Verb's hardware into iPlatform." A0516; *see* A1531, A2131-32, A2161, A4227.

Unable to defend the court's clearly erroneous finding, Fortis quickly shifts to asserting that the court's basis of decision "is irrelevant," because a "*decision* to combine," even if not effectuated in the relevant time period, breached J&J's efforts obligation. AB52. But the breach finding cannot be sustained on a ground the court did not adopt. And that ground is irrational anyway. The "commercially reasonable efforts" clause is about "efforts." It does not make J&J liable for thoughts or unexecuted decisions.

Fortis also has no satisfactory response to the legal point that meshing the two robots would not have been a breach anyway. Fortis does not dispute that several of the ten factors would have supported "augment[ing]" iPlatform with Verb components. B3794; *see* OB53; A2917. Given that, it does not matter whether the "purpose" of the proposed combination was to "improve iPlatform." AB53. Nor

does Fortis dispute that the contract expressly anticipates the milestones can be satisfied with "enhancements" to or "derivates" of iPlatform. OB53; A2917.[1] Fortis's only other argument—that Velys was not "enmeshed" with another device, AB53—fails for the reasons already discussed. *Supra* 16-17.[2]

4. Employee Integration. Fortis does not dispute that it was reasonable for J&J to view integrating Verb engineers into the iPlatform team as necessary to fill critical resource gaps in the Auris team and avoid long-term resource drain. OB23-24, 53-54. Fortis responds with the false accusation that J&J "ignores … factual findings" about the consequences of the integration. AB53. Fortis overlooks the entire paragraph J&J devoted to those findings. OB54. Fortis also re-ups its cookie-cutter argument, noting that Velys never "had to integrate a rival team." AB54. But iPlatform faced a staffing crisis that Velys did not. OB53-54; *see* AR0036. The

[1] Fortis argues J&J did not cite the specific contract provision below. AB53 n.26. But it does not dispute that J&J argued the "broader" point that any combination was not a breach. *N. River*, 105 A.3d at 383. The contract term is "merely an additional reason in support of" that broader point. *Mundy v. Holden*, 204 A.2d 83, 87 (Del. 1964).

[2] As a fallback, Fortis asks for a remand to assess whether Fortis is entitled to any damages on its related § 2.07(e)(iii) breach claim. AB52 n.24. But Fortis is not entitled to a remand on this unappealed dismissed claim. *Supra* 11. Moreover, there are no damages to support a breach since J&J never implemented the contemplated combination, making remand "futile." *In re Peierls Fam. Testamentary Trs.*, 77 A.3d 223, 231 (Del. 2013).

contract did not prohibit J&J from fixing a problem unique to iPlatform. *Supra* 16-17.

5. Employee Incentives. Fortis achieves nothing with its four-sentence defense of the court's conclusion that J&J breached by offering its employees *additional* financial incentives on top of the original, milestone-focused incentives. AB54. Three of those sentences repeat points that J&J rebutted, without addressing those rebuttals. OB54-55. The fourth is an extreme version of Fortis's cookie-cutter theme: that the extra incentives "were different in kind from those for Velys." AB54. Of course they were: iPlatform encountered regulatory and development challenges that Velys did not. AR0259-60; A0896.

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

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

Fortis cannot support the court's finding of fraud based on Gorsky's opinion that Milestone 7 was "highly likely" to be achieved.

1. No proof that J&J "actively concealed" any material fact. Fortis fails to plug a gaping hole in its fraud case—the lack of any active concealment. Instead of pointing to an affirmative act, as required, Fortis points to nothing but the statement itself, arguing: "'Gorsky's statement' to Moll was 'undoubtedly' an affirmative act to conceal the death and investigation." AB57 (quoting Op.125). That is insufficient to sustain a fraudulent concealment claim. The statement is not actionable unless Fortis proved that J&J committed an *additional* "'action affirmative[ly] … designed … to prevent … the discovery'" of the patient death. OB60 (quoting *Metro Commc'n Corp. BVI v. Advanced Mobilecomm Techs. Inc.*, 854 A.2d 121, 150 (Del. Ch. 2004)). By asserting that the statement itself *is* the act of concealment, Fortis negates the active-concealment requirement.

Fortis also fails to overcome an independent flaw: A claim of active concealment cannot be sustained where the defendant made the fact "a matter of public record." *Bovay v. H. M. Byllesby & Co.*, 38 A.2d 808, 818 (Del. 1944); *see* OB60. Fortis does not deny there is such a rule, but simply declares those cases "inapposite." AB59 n.28. But *Bovay* recognized public disclosure was inconsistent

with an active concealment claim, and distinguished *Jones Mining Co. v. Cardiff Mining & Milling Co.*, 191 P. 426 (Utah 1920), on that basis. 38 A.2d at 818, 820. And in *Garner v. Global Plasma Solutions, Inc.*, the court found no "affirmative action" to conceal precisely because the alleged "action" had made the relevant facts a "matter[] of public record." 590 F.Supp.3d 738, 747 (D. Del. 2022).

In applying the rule, Fortis misses the point in arguing that "Auris would have had no reason to search the FDA's website." AB58 (quoting Op.126 n.643). The legal principle is based on the premise that public disclosure is fundamentally inconsistent with a finding of active concealment; it does not depend on proof that Auris stayed abreast of regulatory developments.

Fortis next quibbles over the exact date "the report was posted" on FDA's public website. AB58 (quoting Op.126 n.643). But it is undisputed that FDA publishes these reports monthly, AR0269, and that FDA recorded J&J's report of the death by December 21, 2018, A2691, A1367—more than *four months before closing*. Thus, the undisputed evidence shows J&J's report became public before closing.

2. No proof that J&J did not believe Gorsky's assessment. On intent to defraud, Fortis leaves several more holes. To start, Fortis fails to point to any finding that J&J or Gorsky knew achieving Milestone 7 was not "highly certain" when Gorsky made the statement. OB60-62. That alone warrants reversal.

Moreover, Fortis neither points to evidence that would have supported such a conclusion nor refutes the undisputed evidence undermining it. As to J&J's legitimate belief at the time that the patient death would not affect Milestone 7, Fortis does not dispute that two independent investigations concluded the Flex device was *not* the "proximate cause" of the death. A2690; *see* AR0175; OB58, 61. Fortis also does not dispute that J&J contemporaneously calculated an 85% likelihood of achieving the milestone. A4242. Fortis's only response is that "no *witness* asserted the 85% probability was reexamined after the … death." AB60 (emphasis added). But J&J witnesses testified that they "did not believe there was any impact due to the patient death." A1884-85; A2192. And Fortis acknowledges (AB60) that additional non-testimonial evidence showed J&J *did* assess the likelihood of achieving the milestone after the death, B2440-41, in correspondence with its bankers, A2724-28, and continued to maintain its confidence that the milestone would be achieved.

Without evidence that J&J did not actually maintain its confidence in Milestone 7, Fortis points only to evidence suggesting that J&J knew there could be an FDA investigation, which could cause *some* delay. AB59-60. From there, Fortis leaps to the conclusion that J&J knew that "the investigation itself imperiled the milestone." AB60 n.29. But even assuming J&J knew of the pending investigation, it remained confident in the milestone—at 85% certainty. Notably, Fortis concedes

that "J&J's original estimate presumed achievement over a year before expiration," and, accounting for the death, J&J told its bankers that it would still achieve the milestone "right before expiration." AB60 (citing A2724). There is no evidence suggesting that J&J did not believe what it told its bankers, nor even that it believed the delay diminished its "high certainty" of achieving the milestone.

In the end, there was a regulatory delay that contributed to the milestone's failure: FDA's unexpected decision to require J&J to seek an IDE and conduct further clinical testing. OB58-59. But Fortis does not dispute that this change occurred *after* closing, that FDA cited reasons having nothing to do with the patient death, and that J&J had no way of anticipating this change when Gorsky expressed his confidence. OB61-62. Just because subsequent developments thwarted Gorsky's prediction does not mean his statement was false or intentionally misleading when made.

Fortis tries to plug this evidentiary hole with irrelevancies. First, it asserts that J&J engaged in "evasive discovery conduct" regarding an FDA letter and inspection report. AB60. But the court did not even mention this in its fraud finding, for good reason. The documents in question were not responsive to any discovery request, and indeed, Fortis did not inject this active-concealment claim into the case until July 2023, A1368, long *after* discovery had closed in March 2023, AR0001. That

explains why the court did not grant Fortis's request for an adverse inference. *See* AR0007-09.

Second, Fortis points out that Gorsky declined to come out of retirement to testify at trial. AB58. The court did not rely on that either, and Fortis does not explain its relevance. Moreover, Gorsky *did* testify—extensively. His eight-plus hour deposition is in the trial record. AR0272-0404. Fortis had the burden of proving Gorsky's knowledge that the statement was false. Yet, it points to nothing in his testimony supporting its fraud claim, and Fortis did not even ask any questions about his confidence in Milestone 7.

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

The effect of the exclusive-remedy provision, § 8.05(b), depends on two disputed legal questions. First, if § 8.05(b) were the only relevant provision in the contract, would it bar Fortis's claim? The answer is plainly yes. OB62-63. Fortis does not dispute that its claims fall within the literal terms of § 8.05(b), as the court recognized. MTD-Op.24.

Fortis's only response is that the literal language cannot control. Fortis asserts that J&J "conceded" fraud claims must survive unless a contract uses specific "anti-reliance language." AB61 (citing B325). Fortis ignores the portion of the quoted sentence stating that different language may suffice in different scenarios. B325. And Fortis does not dispute that *this* Court has never embraced any such magic-

words approach. OB63. Indeed, this Court enforced a contractual bar to a fraud claim without anti-reliance language in *Express Scripts, Inc. v. Bracket Holdings Corp.*, 248 A.3d 824, 830-33 (Del. 2021). *See* OB63. Fortis responds that its claim would proceed under *Express Scripts* because that provision carved out "deliberate fraud," and, unlike here, the contract lacked a countervailing "distinct anti-reliance provision." AB62. But those distinctions only confirm that the objective, in all these cases, is to read the plain language of the relevant provisions. Neither that case nor any other applies different rules to waiver provisions depending on whether they waive deliberate fraud or reckless fraud.

The second question is whether the separate anti-reliance clause somehow changes § 8.05(b)'s plain meaning or effect. On that, Fortis argues only that faithful application of § 8.05(b) would render the anti-reliance provision surplusage. AB62. But the two provisions are not co-extensive: The exclusive-remedy provision applies only after closing, whereas the anti-reliance provision is not so time-limited. Each serves a distinct purpose and is properly enforced. *Cf. Perik v. Student Res. Ctr., LLC*, 2024 WL 181848, *4 (Del. Ch. Jan. 17, 2024) (distinguishing between claims that arose upon contract execution and those that arose upon closing). It was perfectly rational, and hardly superfluous, for the parties to impose stricter limits on claims available against one another once merged.

CONCLUSION

This Court should reverse.

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