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IN THE SUPREME COURT OF THE STATE OF DELAWARE

AKORN, INC., Plaintiff and Counterclaim Defendant Below, Appellant, v. FRESENIUS KABI AG, QUERCUS ACQUISITION, INC. AND FRESENIUS SE & CO. KGAA, Defendants and Counterclaim Plaintiffs Below, Appellees.	No. 535, 2018 Case Below: Court of Chancery of the State of Delaware C.A. No. 2018-0300-JTL

APPELLANT'S REPLY BRIEF

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PRELIMINARY STATEMENT[1]

As explained in Akorn's Opening Brief,[2] the Court rewrote MAE law to eliminate the "unknown events" test; announced a $900M impact from DI issues without evidentiary support; adopted a new legal standard for the ordinary course covenant; and created a "justified remorse" safe harbor to best efforts covenants. Fresenius's Answering Brief[3] largely recycles the Court's reasoning, and its arguments fail.

Fresenius does not deny regretting the Akorn deal; hiring advisors "to get [it] out of th[e] deal";[4] using them to develop litigation evidence under cover of a CIA; pushing them to portray Akorn as "liars and cheaters";[5] slow-walking antitrust approval; working to "stimulat[e]... an FDA investigation";[6] and using the results to "paint a portrait of horribles" in litigation.[7]

Fresenius succeeded at trial because the Court accepted Fresenius's "portrait of horribles" while uniformly discounting or ignoring contrary and

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[1] Unless indicated, names and defined terms are adopted from the Opinion and Akorn's Opening Brief, emphases are added and internal quotation marks omitted.

[2] "Open.__".

[3] "Ans.__".

[4] A4619/1214:6-10 (Sturm).

[5] A9045.

[6] A14431.

[7] A9749-50.

contextualizing evidence. It credited Fresenius's expert Chesney,[8] while discounting rebuttal expert Adams because he "did not testify at trial".[9] It credited a four-page report by Fresenius's expert Gokhale[10]—not a trial witness—while ignoring Gompers's 19-page rebuttal. It credited Avellanet (not a trial witness), a one-man operation[11] who spent only a few days at two Akorn sites,[12] while ignoring Toscano—the NSF lead who spent months at Akorn facilities—testifying he sees "these same types of issues throughout the industry"[13] and they are "not unique.... It is something that the entire industry is struggling with."[14] The Opinion quotes Avellanet's "Styrofoam cups" quip,[15] but ignores his testimony that DI remediation of Decatur would cost only $1.2M.[16] It credits Kaufman's statement that Akorn was not "fully transparent" in a meeting she did not attend,[17] but rejects her empirical analysis of hundreds of FDA 483s and Warning Letters

[8] Op.173-74.

[9] Op.174/n.701. In the pretrial conference, the Court and parties agreed "some of the expert folks can just come in through their reports". A4171-73; A4192-93.

[10] Op.183-84.

[11] A4213/32:11-17 (Wasserkrug).

[12] Op.26-27.

[13] A2844/324:11-325:11 (Toscano).

[14] *Id.*

[15] Op.27.

[16] A763/333:14-20 (Avellanet).

[17] Op.92.

because she "did not persuade me [of] her methodology".[18] It emphasizes 483s received by two Akorn facilities as evidence of an MAE,[19] ignoring the eight 483s received by 11 Fresenius sites inspected in 2017.[20] It tabulates NSF audit findings at Akorn facilities,[21] but ignores Toscano—who *made* those findings—explaining "[i]t is not atypical to see an inspection profile similar to what we have seen for the Akorn sites".[22] It tabulates NSF findings in ANDA reviews, again ignoring Toscano testifying the results are "about right" because "we are looking at data from typically eight to ten years ago, and we're applying the standard that you would be looking at today".[23] It notes "two critical deficiencies",[24] but not that they took place in 2012, a year *before* the Merger Agreement's warranty period,[25] and neither had any product impact.[26]

Fresenius points to a pile-on of post-Opinion law firm memos asserting the outcome was "not surprising given the facts" in the Opinion.[27] But

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[18] Op.175.

[19] Op.101-03, 108-12.

[20] A8890.

[21] Op.101.

[22] A2844/323:22-324:6 (Toscano).

[23] A2845/326:14-25 (Toscano).

[24] Op.104.

[25] A4729-31/§3.18.

[26] A4218-21/51:23-61:10 (Wasserkrug); A11583.

[27] Ans.1/n.1.

public reaction to the trial itself did *not* suggest investors had witnessed a first-ever MAE, much less one "far over the line".[28] By the end of post-trial briefing on August 20, Akorn traded at nearly $20/share—its highest point since termination. Analysts predicted a Fresenius loss.[29]

Reversal is necessary not just for the Court's selective view of the record, but because its ruling changes Delaware law concerning three near-universal merger terms: MAE provisions, and ordinary course and best efforts covenants.

[28] Ans.1/n.1.

[29] AR2 ("65% probability deal closes at... $34"); AR9 (Akorn "has a better than 50/50 probability of winning... according to approximately 90% of 32 respondents....").

ARGUMENT

I. THE COURT ERRED IN FINDING A GENERAL MAE.

Fresenius concluded in 2017 there was no Financial MAE,[30] and did not mention one in its termination notice[31] or its Counterclaims.[32] It has never genuinely believed Akorn's known, competition-driven decline established a termination right.[33]

A. Increased Competition for Akorn's Top Products Was Expected and Cannot Establish an MAE.

1. MAEs Are "Unknown Events".

The Court erred in finding MAE Carve-Outs replace *IBP*'s "unknown events" test.[34] Fresenius's primary response is to reiterate the Court's erroneous reasoning.[35] Fresenius notes a survey finding "28% of deals... involved an MAE carve-out for developments arising from facts disclosed to the buyer or in public filings".[36] But this minority effort to reduce ambiguity regarding what is

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[30] A844/107:15-25 (Empey); A4618-19/1210:20-1212:22 (Sturm).

[31] A10829-30.

[32] A186-332.

[33] *Mrs. Fields v. Interbake*, 2017 WL 2729860, at *24 (Del. Ch.) ("post-hoc nature of [Interbake's MAE] arguments bear on what it felt the contract meant").

[34] Open.30-36.

[35] Ans.31.

[36] Ans.31 (quoting Op.152/n.628).

"unknown" by scheduling certain events[37] does not eliminate the "unknown event" element of the MAE definition.[38]

Fresenius argues *IBP* and *Hexion* proceeded to analyze materiality rather than ending their discussion at knowledge.[39] That those cases considered all three prongs of the MAE test does not negate any one prong. Fresenius ignores *Interbake*, where the analysis *did* turn on knowledge,[40] and cites no case eliminating the "unknown event" element.

2. <u>These Events Were Known.</u>

Fresenius does not dispute that Akorn's decline was primarily driven by increased competition to ephedrine, clobetasol and lidocaine;[41] that ephedrine alone accounted for 21% of 2016 revenues and 15 percentage points of Akorn's

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[37] Kling & Nugent, *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* §11.04[9] ("Sellers sometimes try to limit the [MAE]... by excepting from it certain specific matters that [they] believe[] will, or are likely to, occur... [or] have occurred").

[38] *Id*. ("acquiror's pre-signing knowledge about trends and possible events... could diminish its ability to successfully claim [an MAE]"); Adams, *A Legal-Usage Analysis of 'Material Adverse Change' Provisions*, 10 Fordham J. Corp. & Fin. L. 9, 49 (2004) (buyers should "rely on an absolute MAC provision only in connection with disputes relating to matters that were not foreseeable").

[39] Ans.33.

[40] *Interbake*, 2017 WL 2729860, at *22; *see also Luxco v. Jim Beam*, 2016 WL 3136917, at *7 (N.D. Ill.) (summary judgment against MAE claim "[b]ecause undisputed evidence indicates that [buyer] had knowledge of the" cause).

[41] Open.36 (citing Op.144).

37% decline;[42] and that Akorn's performance without ephedrine was consistent with peers.[43] It claims "Akorn points to *no* evidence suggesting that Fresenius expected the events precipitating Akorn's collapse";[44] however, pre-signing evidence includes:

- Moelis warned: "Ephedrine challenges–Akorn is the sole supplier for an unapproved product that drives ~20% of revenues; however, Flamel has launched the first FDA-approved version and other entrants... could emerge";[45]
- Moelis warned of a possible 62% decline in ephedrine revenues in 2017 and a further 51% decline in 2018[46]—worse than actually materialized;[47]
- After a *third* competitor received FDA approval, Bauersmith warned: "We were buying an ephedrine company with a pipeline, now we are buying a pipeline company";[48]
- Fresenius's "red flag DD finding[s]" identified "[r]isk to achieve forecasts due to stronger competition, especially for Ephedrine, Lidocaine ointment, clobetasol";[49]
- Fresenius warned its Supervisory Board: "Sales are expected to decrease as Akorn's #1 product Ephedrine... is exposed to new

[42] Open.31-32.

[43] Open.32.

[44] Ans.34.

[45] Op.35 (quoting A4965).

[46] A5040.

[47] A11954-55/¶50.

[48] Op.39 (quoting A5769-70).

[49] Op.41 (quoting A5901).

market entrants", and "stronger competition" was expected for lidocaine and clobetasol;[50]

- Henriksson admitted Fresenius knew the likelihood of increased competition for all three products,[51] and predicted "ephedrine sales were going to decline substantially";[52] and

- Fresenius unsuccessfully sought CVRs linked to ephedrine revenues[53] or, alternatively, *all* sales.[54]

Fresenius argues MAEs are defined with reference to "events", not "risks", and "[i]f no event related to a *conceivable* risk could cause an MAE, MAE provisions would effectively mean nothing".[55] Whether discussed prospectively as "risks"[56] or retrospectively as "events", it is undisputed that, in 2017, Akorn's three largest products experienced increased competition; Fresenius expected this; it informed price negotiations;[57] and it became the "primary driver"[58] of the alleged MAE. This was a "risk" before signing and an "event" once it came to pass. It

[50] A6601; A6606.

[51] A4528/990:1-6 (Henriksson).

[52] A1635/44:5-19 (Henriksson).

[53] Op.37.

[54] Op.39.

[55] Ans.33-34.

[56] *See In re IBP S'holders Litig.*, 789 A.2d 14, 22 (Del. Ch. 2001) ("Tyson... was fully aware of the *risks* that attended... IBP's business"); *id*. at 30 (Tyson recognized "known *risks* that could compromise IBP's ability to deliver"); *see also* Op.153-54 (*IBP* and *Hexion* "held that buyers could not rely on the manifested consequences of widely known systematic *risks*").

[57] A1379-80/65:24-66:12 (Bauersmith); B256, 259-60.

[58] Op.144.

was not merely "conceivable"; it was known, and it impacted price.

Fresenius argues the parties did not anticipate the individual market entrants and contract losses that materialized.[59] But the identities of entrants and contracts are not relevant. Having knowingly purchased a business in a flood zone, Fresenius cannot complain that it did not anticipate the precise date, time or magnitude of subsequent flooding.

Fresenius asserts the "events" were unknown because it inaccurately forecasted their impact.[60] As Sturm explained, "increased competition was generally anticipated, the impact has... unfortunately been greater than expected".[61] However, Fresenius cannot terminate simply because it misjudged the impact of a known event (while Moelis *over*-estimated the impact).[62] The onus was on Fresenius to negotiate contractual terms—through CVRs, closing conditions, etc.—to protect itself.[63]

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[59] Ans.32.

[60] Ans.34-35.

[61] Op.62 (quoting A8357).

[62] Op.151-52/n.626, 153-54.

[63] *Hexion v. Huntsman*, 965 A.2d 715, at 741-42 (Del. Ch. 2008); Greenberg & Haddad, *The Material Adverse Change Clause*, N.Y.L.J., Apr. 23, 2001 (recommending "employing a closing condition to address particularly important subjects.... [T]he more general MAC condition remains important to deal with contingencies that the parties *cannot anticipate*...."); Adams, 49 ("[Y]ou should ideally include... provisions addressing any topic that might conceivably... provide

B. Increased Competition Was Systemic, and the Court's Disproportionate Impact Analysis Was Flawed.

Increased competition by definition "generally affect[s]... the industry"[64] and cannot cause an MAE here.[65] Fresenius's response reiterates the Court's erroneous reasoning,[66] also arguing the issue is "moot" because the Court found Akorn's decline disproportionate to the industry.[67]

Fresenius offers no substantive defense of the Court's failure to consider "*incremental* disproportionate impact". It argues Akorn waived the issue by not using the word "incremental" below.[68] But Akorn explained that "Fresenius may point to an 'underlying cause' of any decline '*to the extent*' such underlying cause had 'a disproportionate adverse [e]ffect on [Akorn]'", citing the applicable contract provision.[69] The Court quoted that provision, stating "*incremental* disproportionate impact or impacts may be taken into account",[70] but failed to

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grounds to walk.... [R]ely on an absolute MAC provision only in connection with disputes that were *not foreseeable*....").

[64] A4767/§8.12.

[65] Open.37-39.

[66] Ans.27.

[67] Ans.28.

[68] Ans.28.

[69] A16035.

[70] Op.125-6 (quoting A4768/§8.12).

apply it. There is no waiver.[71]

Fresenius includes graphs showing analyst forecasts for Akorn, arguing "nothing in the MAE definition precludes consideration of" forecast evidence "*reflective of*... financial collapse".[72] But under subsection (B)(8) of the MAE Carve-Outs, failure to meet forecasts shall not "be taken into account in determining whether a[n] [MAE] has occurred";[73] there is no exception for forecasts "reflective of" poor performance. Fresenius's effort to distinguish *missed* forecasts from *revised* forecasts[74] is meaningless: analysts revised forecasts because they expected Akorn to miss them.

Fresenius also points to a decline in Akorn's stock price;[75] but, again, "decline[s] in the market price... of... shares" cannot be "taken into account".[76]

Fresenius attacks Akorn's challenge to analyst-forecast evidence as a "half-baked policy argument".[77] But it was *IBP* that noted its "dubious practical

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[71] *N. River Ins. v. Mine Safety Appliances*, 105 A.3d 369, 382-83 (Del. 2014); *Sergeson v. Del. Trust*, 413 A.2d 880, 881-82 (Del. 1980); *Reddy v. MBKS*, 945 A.2d 1080, 1086 (Del. 2008).

[72] Ans.30 (emphasis in original).

[73] A4768/§8.12.

[74] Ans.30.

[75] Ans.26.

[76] A4767/§8.12.

[77] Ans.31.

utility" and relied instead on "historical performance" as a basis of comparison.[78] Fresenius asserts "Akorn has never argued... the forecasts used here were irrational" or that its "fundamentals remain sound".[79] Fresenius's own figures show analysts overestimated performance industry-wide;[80] and, as Akorn explained, once the impact of a single product—ephedrine—is removed, Akorn's performance was consistent with peers.[81]

C. The Court Failed To Assess Materiality Properly.

Fresenius's materiality argument largely parrots the Court's reasoning[82] and fails for the reasons Akorn explained.[83] Fresenius argues consideration of synergies would make the "reasonable acquirer" test subjective. But the standard "must be read in the larger context in which the parties were transacting".[84] Just as a strategic acquirer should not be considered a "short-term speculator",[85] neither should it be treated as a financial buyer.[86] Fresenius

[78] *IBP*, 789 A.2d at 70 n.161, 71; *Hexion*, 965 A.2d at 742 (rejecting forecasts as benchmark).

[79] Ans.31.

[80] Ans.29-30.

[81] A11976/¶83; A12010-11.

[82] Ans.25-27.

[83] Open.40-42.

[84] *IBP*, 789 A.2d at 67.

[85] *Id*.

evaluated the loss in value with respect to anticipated synergies,[87] as did the buyer in *Hexion*,[88] as would any strategic buyer.[89] The *IBP* test requires a forward-looking assessment of "durational[] significan[ce]",[90] in a context where the parties contemplate a combined future. Fresenius's approach has the perverse result that courts measure MAEs differently from buyers. And while *IBP* and *Hexion* did not discuss synergies when assessing materiality,[91] neither case found it legally *prohibited*,[92] as the Opinion does.[93]

Fresenius denies believing the deal profitable, citing "losses in the first three years" and "risks and opportunity costs"; but it concedes the anticipated rate of return exceeds its cost of capital.[94] Fresenius Kabi's CFO testified the deal remains profitable.[95] The Court erred in refusing to give *any* weight to a factor *IBP*

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[86] Op.130/n.551 (suggesting durational significance might not apply to financial buyer); Adams, 25 (recommending clarifying that "reasonable acquirer" means "a reasonable person in the Buyer's position").

[87] A10699.

[88] *Hexion*, 965 A.2d at 725.

[89] A16041/n.607.

[90] 789 A.2d at 68.

[91] Ans.26.

[92] Op.139.

[93] Op.139-40.

[94] Ans.27.

[95] A2291/154:11-18 (Schulte-Noelle).

identified as "cast[ing] great doubt" on an MAE.[96]

Finally, Fresenius argues the deal is not profitable if one credits its $1.9B or the Court's $900M DI cost assertions;[97] but those cannot be credited, as explained in Akorn's Opening Brief and below.[98]

[96] *IBP*, 789 A.2d at 70.

[97] Ans.26-27.

[98] Open.25-26, 46-47.

II. THE COURT ERRED IN FINDING A REGULATORY MAE.

A. The Court's Erroneous Quantitative Findings.

Fresenius identifies no record evidence supporting the Court's $900M remediation figure.

Fresenius argues the Court "conservatively... did not accept Fresenius's *full* estimate",[99] attempting to reframe the $900M as a 53%, one-billion-dollar haircut. But the Court selected $900M because it "suspect[ed] the most credible outcome lies in the vicinity of the midpoint of the parties' competing submissions".[100] In other words, it split the baby.

Fresenius frames this as a "discretionary factual finding",[101] analogizing to a court "fail[ing] to endorse every cent of a damages claim".[102] *First*, factual findings—unlike damages awards—are not discretionary; they are reviewed for error.[103] *Second*, even under an abuse of discretion standard, the Court may not weigh economic evidence arbitrarily. *See DFC Glob. v. Muirfield Value Partners*, 172 A.3d 346, 388 (Del. 2017). *Third*, the discrepancy here is $1B—not "cent[s]".

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[99] Ans.40.

[100] Op.184.

[101] Ans.7.

[102] Ans.40.

[103] *Gotham Partners v. Hallwood Realty Partners*, 817 A.2d 160, 175 (Del. 2002).

Fresenius argues its experts opined that Cerafa was reasonable, citing an email consulting three potential experts.[104] None endorsed Cerafa:

- Horowitz: "There may well be information that would justify tossing all of the work done on the pipeline ANDAs.... *But generalized discomfort and lack of confidence, by itself, would probably not be sufficient* to argue that this course of action is necessary."[105]

- Taylor: "It could be that some should be withdrawn while in other cases there might be other data that obviates the need to withdraw the ANDAs."[106]

- Chesney: "If it came to a sworn declaration or a deposition, I would hedge at some of the time estimates since they are pretty loose from my perspective. If I were to testify along those lines I would need to either review or independently develop some data to back me up...."[107]

Only Chesney submitted a report, and it included no remediation plan.[108] Fresenius cites Klener; but he opined, "*if* Akorn were to identify any data-related issues, it would need to halt or withdraw the application for *the corresponding* product and redevelop *that* product."[109] (The Opinion cites Klener only once.[110]

[104] Ans.40-41 (citing A9810).

[105] A9809.

[106] *Id*.

[107] A9810.

[108] A13000-52.

[109] A12883.

[110] Op.176/n.715 (quoting A3634/80:14-15 (Klener)).

He has not worked in a quality role since 2005.[111]) No industry expert endorsed Fresenius's made-for-litigation assumptions.

Fresenius sidesteps its failure to prove that individual products must be withdrawn, arguing DI issues "raise questions about... *all* of [Akorn's] data".[112] But "questions" are not proof that an entire portfolio must be redeveloped.[113] Aside from Akorn's voluntary withdrawal of azithromycin, neither Fresenius nor the Court identifies a single product that must be withdrawn and/or redeveloped, nor has FDA required such action.

Fresenius argues Nicholson and Gompers only modelled "revenue impacts associated with a handful of drugs... and facilities".[114] Nicholson modelled revenue impacts "for the specific products implicated... in *each of the alleged improper activities and data integrity issues identified by Fresenius*".[115] Gompers modelled hypothetical two-year pipeline delays at each FDA-regulated manufacturing facility.[116] If the Court believed *every* on-market product specifically implicated by Fresenius's DI allegations needed to be pulled,

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[111] A4642/1306:7-10.

[112] Ans.41 (quoting Op.178, 182).

[113] A9809 ("generalized... lack of confidence" is not sufficient to "toss[] all of the work done").

[114] Ans.41.

[115] A12109; A14463-64.

[116] A13495-98.

Nicholson showed a $37M-$48M annual revenue impact.[117] If the Court believed both Decatur *and* Somerset (the two facilities to receive 483s in 2018) would experience two-year pipeline delays, Gompers's report showed a $34M-$51M combined present value impact.[118] The Opinion did not fail to "agree[] with" these unrebutted analyses;[119] it ignored them.

Fresenius asserts Gokhale's report "corroborates" the Court's analysis,[120] despite admitting he modelled "different assumptions".[121] Gokhale estimated $604M and $808M impacts for full-pipeline delays (an assumption the Court rejected[122]) of 1.5 and 2 years.[123] The Court selected the higher number *not* because it found a two-year delay more likely, but because the result was "close to" ($100M less than) the Court's own guess.[124] That self-justifying reasoning is not a "logical deductive process". *Nixon v. Blackwell*, 626 A.2d 1366, 1375 (Del. 1993).

Fresenius defends the Opinion's use of $4.3B as a denominator

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[117] A14463-64.

[118] A13495-98.

[119] Ans.41.

[120] Ans.42.

[121] Ans.42.

[122] Op.183-84.

[123] Op.183.

[124] Op.184.

because "Akorn and its financial advisor... valued the transaction on that basis".[125] But Akorn and JPMorgan included assumed debt.[126] Regardless, an MAE is measured from the perspective of the buyer.[127]

Fresenius argues "Akorn never suggested that the financial impact shown by Fresenius's plan was not material, so Fresenius could not... respond".[128] *First*, Fresenius bore the burden of proving materiality—not Akorn.[129] *Second*, Akorn had no chance to contest the materiality of Fresenius's plan because Fresenius withheld it as litigation work product until five days before rebuttal expert reports were due.[130] *Third*, the "financial impact shown by Fresenius' plan" was 37%,[131] not 21%. The Opinion rejected 37% and substituted 21% based on what made "intuitive sense to me".[132] *Fourth*, Akorn *does* contest that such a drop would be material.[133]

Finally, Fresenius concedes the Court's "'cross-checks'... were not

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[125] Ans.43.

[126] A7481.

[127] *IBP*, 789 A.2d at 68.

[128] Ans.43.

[129] Op.157.

[130] A9011-14; A14467.

[131] A15794-95.

[132] Op.184.

[133] *See Hexion*, 965 A.2d at 745 ("[I]t is... unconvincing... that 75% of Huntsman's business is fine, but that troubles in the other 25% materially changes the business as a whole.").

'directly on point'"; though it asserts it was "entirely appropriate for the [C]ourt to refer to [them]".[134] It does not explain why they support the Court's analysis. By supplying its own materiality threshold without any reliable support, the Court's MAE finding was arbitrary.

B. The Court's Erroneous Qualitative Findings.

Fresenius reiterates the Court's "qualitative significance" finding.[135] This "qualitative" notion is absent from *IBP* or *Hexion*—which measured materiality against "earnings potential".[136] It is mentioned once in *Frontier*; but even there, the analysis focused on litigation costs and damages awards.[137] The relationship between merger counterparties is economic; a buyer who cannot establish economic impact should not be permitted to terminate.[138]

Fresenius argues Akorn cannot "prove its data is reliable".[139] But FDA has granted Akorn four ANDA approvals post-Opinion, concluding in each case "adequate information has been presented to demonstrate that the drug is safe

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[134] Ans.43.

[135] Ans.36-38.

[136] *IBP*, 789 A.2d at 68; *Hexion*, 965 A.2d at 738.

[137] *Frontier Oil v. Holly*, 2005 WL 1039027, at *35-38 (Del. Ch.).

[138] *Cf. Hollinger Inc. v. Hollinger Int'l*, 858 A.2d 342, 384 (Del. Ch. 2004) ("qualitative element" of §271 inquiry "focuses on *economic* quality and... whether the transaction leaves the stockholders with an investment that *in economic terms* is qualitatively different").

[139] Ans.36.

and effective for use".[140]

Fresenius argues "[n]othing could be more material to an acquirer than the reliability of a drug company's test data, products and quality systems."[141] That is remarkable for an acquirer whose diligence found Akorn's manufacturing facilities below average in commitment to quality;[142] who opted not to request audits or ANDA filings in diligence;[143] and whose CEO—when asked about compliance at Akorn—effectively shrugged: "I think we should be humble and avoid any form of arrogance."[144] While Fresenius cites Sturm's testimony that "we thought we'd buy a house. We're buying a renovation project...",[145] it does not dispute that at signing it planned to close two Akorn facilities and invest hundreds of millions to fix issues at the others.[146]

Fresenius claims its DI problems only "affected one of more than 70 Fresenius sites",[147] but does not mention that only 13 of those sites are FDA-

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[140] *E.g.*, A16992-97; A17011-15.

[141] Ans.37.

[142] A8843-48.

[143] A4501/879:12-18 (Bonaccorsi); A899/29:5-8 (Schreiner); A613-14/33:2-34:13 (Ventrelli).

[144] A7328.

[145] Ans.37 (quoting A4615/1196:10-15).

[146] A4529/991:8-992:10 (Henriksson); A6148-49.

[147] Ans.40.

regulated.[148] In 2017, eight of those 13 facilities received 483s,[149] two received Warning Letters and one an Untitled Letter.[150]

C. The Court Erred by Ignoring Fresenius's Knowledge.

Fresenius claims it did not know of Akorn DI issues before signing. But its "red flag DD" report identified "severe data integrity issues (falsification of data)" at Akorn's India facility.[151] Fresenius read an FDA inspection report concerning trial injections in the data room, opting not to investigate.[152] Bauersmith warned of data manipulation; and Ducker noted a need to "check carefully" for DI issues.[153]

Fresenius asserts it "obtained representations from Akorn precisely because it could not fully diligence these issues".[154] But Fresenius had no trouble "fully diligenc[ing]" DI *after* it had buyer's remorse. Nothing prevented it from doing so before signing, as it did in a contemporaneous deal.[155] It argues *Cobalt*—which considered the elements of a breach claim, not an MAE-qualified closing

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[148] A9571.

[149] A8890.

[150] A14105-08; A14116-19; A9077-88.

[151] A6148; A6765.

[152] A915/91:22-94:12 (Schreiner).

[153] A4404/616:5-22 (Bauersmith); A4986; A2399/288:11-289:14 (Ducker).

[154] Ans.44.

[155] A899-900/30:15-23, 31:6-9 (Schreiner).

condition[156]—applies because the warranties in the Merger Agreement also "shift[ed] long-term risk to [Akorn]".[157] But the MAE-qualified warranties here supported no indemnification rights and offered no protection against post-closing events. Fresenius bore all long-term risk.

Fresenius asserts without citation "Akorn went to extraordinary lengths to conceal [DI] issues" in diligence.[158] Akorn provided a "well populated" data room and "above-average" access for a public target;[159] permitted Fresenius to "address all [its] questions and concerns";[160] and Fresenius represented that it received "access to such [information]... which it... desired or requested to review" and "conducted, to its satisfaction, its own independent investigation of [Akorn]".[161] Fresenius *chose* not to request audits.[162]

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[156] *Cobalt Operating v. James Crystal Enters.*, 2007 WL 2142926, at *27 (Del. Ch.).

[157] Ans.44 (quoting Open.51).

[158] Ans.44.

[159] A5900; A11810-26/¶¶170-220.

[160] A7318.

[161] A4735/§4.07; A11808-10/¶¶165-69.

[162] A899/29:5-8 (Schreiner).

III. THE COURT ERRED IN FINDING A MATERIAL BREACH OF AKORN'S ORDINARY COURSE COVENANT.

The Opinion treats the ordinary course covenant as an overarching duty to comply with all other duties,[163] measuring conduct against industry "obligat[ions]"[164] rather than operations.[165] It then loosens the materiality standard to a "total mix" test.[166] The result is a hair-trigger termination right: a buyer need only identify a duty (whether under FDA rules, environmental regulation, securities law or otherwise) and argue that a company operating in the ordinary course is obligated to comply. A court will review the seller's conduct *de novo*—ignoring comparative evidence—and decide whether any non-compliance altered the "total mix" of information. If the answer is yes, the buyer may terminate.

A. The Court Applied the Wrong Standard of Conduct.

The Court observed in pretrial proceedings that "you would assess ordinary course in the industry by looking at multiple different companies or wider practices"[167]—a standard it failed to apply in the Opinion. As Subramanian

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[163] Open.56-65.

[164] Op.216.

[165] Op.216-20.

[166] Open.53-55.

[167] A474/70:7-11. *See also Rudnitsky v. Rudnitsky*, 2000 WL 1724234, at *6 (Del. Ch.) (considering "prior 'custom or course of dealing' and 'the general custom' of analogous" actors); *Ivize of Milwaukee v. Compex Litig. Support*, 2009 WL 1111179, at *8 (Del. Ch.); *Novipax Holdings v. Sealed Air*, 2017 WL 5713307, at *2 (Del. Super.).

explained, the ordinary course covenant is designed to protect buyers from the moral hazard problem arising after signing,[168] not to authorize courts to act as an uber-regulator. It grants seller's management operating flexibility.[169] By contrast, the Opinion goes beyond what would be permitted even in a fiduciary duty claim—exercising plenary oversight over internal audits,[170] allocation of IT resources,[171] conduct of internal investigations[172] and individual bullets in regulatory presentations.[173]

This application of the wrong standard of conduct was legal error, requiring reversal. Even apart from that error, however, the Court's factual findings were clearly erroneous.

Audits: Fresenius does not dispute that only *one* manufacturing or R&D facility received a verification audit in place of a full audit,[174] and it has since undergone two full-scale audits.[175] Fresenius cites no evidence comparing this to practice in the industry. It notes "FDA guidance recommends that firms conduct

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[168] A11891-93/¶¶39-41.

[169] A11894-95/¶43.

[170] Op.216.

[171] Op.217.

[172] Op.218.

[173] Op.219.

[174] Ans.15-16, 48; Open.60; A2453-54/56:21-58:18 (Gill).

[175] A10463-84; A16436-37.

internal audits",[176] but does not dispute Akorn has done so.

DI "Freeze"/Remediation: Fresenius has no answer to Pramik's unrebutted testimony that "there were several data integrity projects... we continued to work on throughout" 2017[177] and that she discussed "all" paused projects with Fresenius.[178] Contrary to Fresenius's assertion that "no proposal to fix issues was ever presented to the PRB",[179] Pramik testified to numerous such projects.[180] Fresenius argues the Court "refused to credit" a February 2018 DI Chronological Overview.[181] But the Court said no such thing; it cited the document for other propositions.[182] Fresenius does not dispute that by February 2018, Akorn completed 32% of Cerulean-recommended Decatur CAPAs and addressed 41% of Somerset observations, but claims the "vast majority" were not remediated.[183] Fresenius points to nothing suggesting Akorn's pace in addressing findings from a voluntary, third-party assessment was outside the

[176] Ans.48 (quoting Open.59/n.296).

[177] A4264/233:3-6 (Pramik).

[178] A4262/225:2-226:24 (Pramik).

[179] Ans.49.

[180] A4256-57/204:20-208:5, A4264/233:3-6 (Pramik).

[181] Ans.47.

[182] Op.85/n.398.

[183] Ans.48.

ordinary course of practice. Akorn had no obligation to retain Cerulean *at all*.[184]

The Opinion's true complaint was that "Akorn should have prioritized the remediation of its [DI] systems" differently.[185] Neither Fresenius nor the Court identifies evidence that Akorn's resource allocation was outside of the ordinary for the industry.[186]

Investigation: Upon learning that Akorn intended to investigate DI, Ducker wrote that "the presumption... that Akorn will investigate... is unacceptable", instructing Silhavy to work with litigators to respond.[187] Fresenius nevertheless claims it "ma[de] clear... that, of course, [Akorn] should do whatever investigation they wanted".[188] That is deeply disingenuous. Fresenius never claims it "ma[de] clear" it would regard a joint investigation as a material breach. And it knew it would make no sense to do simultaneous investigations into the same allegations, witnesses, data, documents, etc.—a wasteful strain on Akorn's facilities[189] months before the parties were to combine.[190] It was reasonable for

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[184] A4213/31:14-32:3 (Wasserkrug).

[185] Op.220.

[186] Fresenius insinuates Akorn is under DOJ investigation. Ans.23. Akorn was a victim of a crime, reported it to DOJ and is cooperating with DOJ's effort to identify the perpetrator(s).

[187] A8431.

[188] Ans.51 (quoting A3037/58:25-59:7 (Silhavy)).

[189] A10571 ("That facility simply does not have the resources to respond to two overlapping audits simultaneously.").

Akorn to "join in an investigation" with its acquirer.[191]

FDA Meeting: Fresenius reiterates the Court's erroneous reasoning regarding the FDA meeting,[192] which fails for reasons explained in Akorn's Opening Brief.[193] Stuart testified he provided FDA in person with the very clarifications the Court urges should have been included in the presentation deck.[194] FDA was "appreciative[] that [Akorn] brought the information to their... attention".[195]

Azithromycin: Fresenius asserts Silverberg's azithromycin submission was a breach by Akorn.[196] But Akorn's response was entirely appropriate: it investigated, removed Silverberg, withdrew the ANDA and reported the issue to FDA.[197] And while Akorn provides FDA with voluntary monthly updates, Fresenius does the same for its own DI problems.[198]

Having set out to manufacture "fraud on the FDA allegations" for

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[190] A7241; A4610/1175:3-8 (Sturm).

[191] A8805.

[192] Ans.51-53.

[193] Open.62-65.

[194] A4429-30/713:22-715:12, 717:15-22 (Stuart); Open.64-65.

[195] A2147/54:18-19 (Levine).

[196] Ans.50.

[197] Op.78-81, 84; A10460; A9822.

[198] A9575.

purposes of this litigation,[199] Fresenius falsely accuses Akorn of a "scheme to defraud Fresenius and the FDA".[200] This is categorically false. "Akorn largely complied" with Fresenius's "broad requests",[201] executing a CIA with Fresenius and providing five multi-day site visits, 49+ employee interviews, direct extraction of laboratory data and millions of documents from 63 custodians.[202] It also proactively informed FDA that it had identified likely false data, withdrew the offending ANDA, voluntarily shared reams of information regarding Akorn's DI work, and disclosed Fresenius's accusations[203] despite regarding them as "irresponsible and offensive".[204]

B. The Court Applied the Wrong Materiality Standard.

The term "material" has different meanings in different contexts.[205] Where, as here, the term governs excusal of contractual performance, Delaware law applies a "root or essence" standard.[206]

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[199] A8401; A8458.

[200] Ans.47; *see also* Ans.6.

[201] Op.231.

[202] Op.74; A14059-64; A10532-44; A10571-72; A4555/1096:3-1098:19 (Sheers); A4420/677:17-679:15 (Stuart); A8780-81.

[203] A2982/215:22-216:9 (Sheers); A4431-32/724:9-725:12 (Stuart); A14550-66; A14567-75; A14576-5569.

[204] A4432/727:3-5 (Stuart).

[205] *E.g.*, *Brehm v. Eisner*, 746 A.2d 244, 259 n.49 (Del. 2000).

[206] Open.54/n.268; *see also* Restatement (Second) Contracts ("Restatement") §241.

Fresenius cites no authority applying its "total mix" standard to "in all material respects" language in a closing condition. *Frontier* interpreted a warranty that "no contracts... are material to the business", but does not analyze compliance with a covenant closing condition "in all material respects".[207] Moreover, although *Frontier* references the "total mix" standard, it does not apply it.[208] *Wiesemann* never states that it is applying the "total mix" standard, it merely quotes Black's Law's definition of "material".[209]

Fresenius's arguments that a material breach standard would "do violence to" the Merger Agreement fail.[210] *First*, the standard would not "equate 'in all material respects' with an MAE".[211] The tests are "analytically distinct, even though their *application* may be influenced by the same factors". *Frontier*, 2005 WL 1039027, at *38.[212]

Second, Fresenius argues the use of the term "in all material respects" in the Merger Agreement's SEC compliance warranty "could not possibly mean a common law material breach".[213] But that language has nothing to do with

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[207] *Frontier*, 2005 WL 1039027, at *37-38.

[208] Open.55.

[209] 237 F. Supp. 3d 192, 213 (D. Del. 2017).

[210] Ans.55-56.

[211] Ans.55.

[212] *Compare IBP*, 789 A.2d at 68, *with* Restatement §241.

[213] Ans.55.

termination.[214] The warranty is subject to an MAE-qualified bring down.[215] Moreover, why would the parties permit termination based on an SEC-filings issue insufficiently serious to reach the essence of the agreement?

Third, Fresenius notes that the Agreement uses both "in all material respects" and "material breach".[216] But those terms are commonly used interchangeably,[217] reflecting an affirmative and negative formulation. A party that does not comply "in all material respects" is in "material breach".

Fourth, Fresenius points to the individual subsections of the ordinary course covenant, such as recruitment and capital expenditures.[218] These provisions *support* Akorn's argument, as they prohibit fundamental corporate changes, such as to capital structure,[219] debt levels,[220] accounting methods[221] or capital expenditures.[222] But the Court found no such changes by Akorn. Instead, it

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[214] A4720/§3.05.

[215] A4756/§6.02(a).

[216] Ans.55.

[217] Open.54.

[218] Ans.55-56. Fresenius misleadingly asserts Akorn could not hire employees earning more than $250,000. *Id*. In fact, the Agreement permits such hiring so long as it "is consistent with the past practice... in similar positions". A4739/§5.01(b)(vi).

[219] A4737/§5.01(b)(i).

[220] A4737-38/§5.01(b)(ii).

[221] A4739/§5.01(b)(vii)

[222] A4738/§5.01(b)(iii).

criticized the timing of regulatory audits, the pace of DI work, the handling of an investigation and a bullet point in a regulatory presentation.

Fresenius argues, alternatively, that Akorn's conduct satisfied the correct test because it "increase[d] the likelihood and severity of regulatory action".[223] However, an "increase[d]... likelihood"[224] of harm is not alone material. *Frontier*, 2005 WL 1039027, at *38 ("risk" of mass tort liability "too uncertain to be material"). Nowhere in the Opinion did the Court find FDA sanctions likely;[225] and Fresenius points to no evidence of economic harm.

Fresenius's pre-signing conduct eliminates any argument it viewed such issues as material. Fresenius did not request audit reports or ANDA filings in diligence.[226] Nor did it engage a third-party auditor or follow up on mentions of trial injections in the data room.[227] Afterwards, Fresenius announced it was "unlikely" it overlooked anything "material"[228]—an assessment it changed only after developing buyer's remorse.[229]

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[223] Ans.56-57.

[224] Ans.56-57.

[225] *Cf.* A4634/1271:5-15 (Chesney) ("would be premature to even opine on whether the FDA may invoke the AIP").

[226] A4501/879:12-18 (Bonaccorsi).

[227] A915/91:22-94:12 (Schreiner).

[228] Op.48.

[229] Op.67.

C. The Court's Cure Analysis Was Erroneous.

Every purported breach was cured. Fresenius does not dispute:

- Audits: Every manufacturing and R&D facility has received a full-scale audit since signing;[230]
- Investigation: Cravath began its investigation within a week of Sidley[231] and NSF began DI audits in March;[232]
- FDA Meeting: FDA has been informed of Fresenius's assertions;[233] and
- Azithromycin: Akorn withdrew the ANDA, removed Silverberg and reported the issue to FDA.[234]

Fresenius argues that curing the DI "freeze" is impossible because "Akorn cannot ever regain the entire year... it lost".[235] *First*, neither Fresenius nor the Court quantifies any economic harm as a result of a one-year DI remediation delay[236] or explains why it would go to the "root or essence" of the $4.8B deal. Fresenius already planned to close two facilities and invest hundreds of millions in

[230] A2453/55:23-56:16 (Gill); A4210/17:24-18:12 (Wasserkrug).

[231] Op.76-77.

[232] Op.28, 101.

[233] A4431-32/724:9-725:12 (Stuart); A2982/215:22-216:9 (Sheers); A14550-66; A14567-75; A14576-5569. Although Fresenius asserts Akorn "primed" FDA to discount Sidley's criticisms, Ans.60, which is false, Open.62/n.312, it fails to explain how this would disable FDA from objectively evaluating the situation.

[234] Op.78-81, 84; A10460; A9822.

[235] Ans.57.

[236] *See Frontier*, 2005 WL 1039027, at *38.

others.[237]

Second, this assertion is premised on the idea that at signing Akorn had to "embark[] on the steps that Fresenius [now] contends are necessary".[238] But Fresenius does not explain how its $1.9B Cerafa plan could possibly be "ordinary course" given the covenant's limitations on hiring, capital expenditures, etc.[239]

[237] A6148-49; A902-04/42:5-49:23 (Schreiner); Op.44-45.

[238] Op.220-21.

[239] Ans.55-56.

IV. THE COURT ERRED IN FINDING FRESENIUS COMPLIED WITH ITS EFFORTS COVENANTS.

Fresenius does not dispute Sturm instructed his team to "build [a] legal case" to terminate,[240] or that Fresenius subsequently:

- retained advisors to "get [it] out of th[e] deal"[241] by "develop[ing]... fraud on the FDA allegations"[242] and "search[ing] for 'a smoking gun'";[243]
- pushed Sidley to make Lachman view Akorn as "liars and cheaters";[244]
- "instruct[ed]" its team to drag its feet on antitrust to "avoid[]... having a potential closing event before [it] ha[d] a more developed legal position";[245]
- "plac[ed] collateral pressure on Akorn"[246] though letters designed by litigators to "stimulat[e]... an FDA investigation";[247] and
- created a "worst-case scenario"[248] remediation plan at the direction of Paul Weiss.[249]

In finding this undisputed conduct to be "reasonable best efforts" to

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[240] A8095.

[241] A4619/1214:6-10 (Sturm).

[242] A8401.

[243] A8807.

[244] A9045.

[245] A9385.

[246] A8476.

[247] A14431.

[248] Op.183.

[249] A9020.

close, the Court committed error. The Opinion characterizes this as "legitimate investigation" and "evaluating... rights and obligations".[250] But "investigat[ing]" and "evaluating" do not require misleading Akorn, leaning on advisors, provoking regulatory action or manufacturing "materiality" evidence out of whole cloth. Nowhere did the Court consider actions Fresenius *failed* to take, like sharing investigatory findings,[251] engaging in remediation dialogue, leveraging its "larger, better equipped quality systems"[252] or presenting a united front to FDA. Akorn believed it bargained for an enthusiastic and cooperative partner. The Court allowed Fresenius to behave like the opposite.

Fresenius asserts "Akorn fails to identify any action by Fresenius that could have caused the failure of closing conditions".[253] That burden is on Fresenius.[254] But, as just an example, Akorn's DI investigation and FDA meeting would have been very different had Fresenius not actively exploited those events, seeking to drive a wedge between Akorn and FDA.

The Court's decision to reward such conduct should be reversed.

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[250] Op.73/n.333, 75-76, 230.

[251] A4428/709:23-710:8 (Stuart).

[252] A7328.

[253] Ans.61.

[254] *Williams Cos. v. Energy Transfer Equity*, 159 A.3d 264, 273 (Del. 2017).

CONCLUSION

The Opinion should be vacated and partial final judgment reversed.

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