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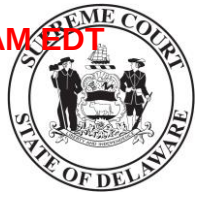


**IN THE SUPREME COURT OF THE STATE OF DELAWARE**

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

# APPELLANT'S OPENING BRIEF

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## TABLE OF CONTENTS

## TABLE OF CITATIONS

**Page(s)**

**Cases**

**Other Authorities**

## NATURE OF PROCEEDINGS[1]

This appeal is from a partial final judgment of the Court of Chancery (Laster, V.C.) (the "Court") and post-trial Memorandum Opinion dated October 1, 2018 (the "Opinion", Ex. A), denying Plaintiff-Appellant Akorn's request to order Defendants-Appellees Fresenius to specifically perform their obligations under an April 24, 2017 Merger Agreement. The Opinion found that Akorn suffered not one, but *two* independent MAEs; that Akorn materially breached its ordinary course covenant—under a "less onerous" materiality standard borrowed from securities law; and that Fresenius's actions to exit the merger were consistent with "reasonable best efforts" because its "[buyer's] remorse was justified". Each holding constitutes reversible error.

The parties are non-Delaware companies that signed a Merger Agreement governed by Delaware law. Recognizing there would be a gap between signing and closing, and wishing to maximize deal certainty, they included a no-shop provision; multiple voting agreements; a termination fee; a "hell-or-high-water" antitrust commitment; "reasonable best efforts" covenants; a "material adverse effect" qualification on the bring down for warranties; and a "material[ity]" qualification on the bring down for covenants.

After signing, increased competition in the generics industry caused

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

significant erosion in price and market share for Akorn's top products. Fresenius recognized this risk before signing and had unsuccessfully attempted to shift it to Akorn through CVRs linked to revenues.

By July 2017, however, Fresenius Parent CEO, Sturm, regarded the deal as "the most embarrassing personal or professional thing that ha[d] ever happened to him".[2] By August, Sturm retained litigation counsel at Paul Weiss to find a way out, which initially concluded Akorn's financial performance did not constitute an MAE. By September, Sturm told his executive team "we've got to build our legal case."[3] That took the form of a scorched-earth search for regulatory deficiencies and an effort to provoke FDA sanctions. Fresenius retained advisors to "get [it] out of [the] deal";[4] misled Akorn into believing it was not engaged in a "litigation exercise";[5] instructed its advisors to find a "smoking gun";[6] leaned on them to present Akorn as "liars and cheaters";[7] slow-walked antitrust clearance to "avoid[]... a... closing event before we have a more developed legal position";[8]

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[2] A7792.

[3] A8091.

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

[5] A4504/891:18-892:21 (Bonaccorsi).

[6] A8807.

[7] A9045.

[8] A9385.

conflicted Akorn's regular FDA counsel to "avoid the impression" of cooperation;[9] wrote letters to "stimulat[e]... an FDA investigation";[10] and secretly created a made-for-litigation model of data integrity ("DI") costs at litigation counsel's direction.[11] Fresenius actively sought to derail the deal while representing to Akorn and the public that Fresenius was working towards closing it.

On April 22, 2018, Fresenius purported to terminate the Merger Agreement. Akorn initiated this suit. Fresenius argued termination was permitted because (i) Akorn's financial performance constituted an MAE; (ii) Akorn breached regulatory warranties constituting another MAE; and (iii) Akorn materially breached its ordinary course obligation. Akorn argued Fresenius failed to carry its burden on each and that its brazen conduct in attempting to terminate materially breached its covenants.

On October 1, the Court ruled for Fresenius on each basis for termination and determined Fresenius did not materially breach.

To reach that outcome, the Court rewrote Delaware law. It found "[a]ny second thoughts... about the Merger Agreement were justified" and "[t]he parties agreed to provisions... that addressed those events".[12] Notwithstanding

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[9] A9743.

[10] A14431.

[11] A9020; A1408/179:18-180:16 (Bauersmith); A9012; A10676-707.

[12] Op.7.

numerous provisions designed to *maximize* deal certainty, the Court concluded the parties intended to: (i) loosen the traditional MAE standard by permitting known events to constitute an MAE; (ii) adopt a "less onerous" standard for material breach of a covenant; and (iii) authorize "reasonable" steps towards exiting the deal when a party's "remorse [i]s justified". These are reversible errors, which, if not corrected, will create a blueprint for future remorseful buyers.

## SUMMARY OF ARGUMENT

The Court erred by:

1. Holding Fresenius could declare an MAE based on known systemic risks; measuring an MAE solely from the seller's perspective; and failing to assess proportionality properly. (Argument §I.)

2. Finding regulatory issues at Akorn would cost $900M to address—an amount no party advanced—and that $900M was material based on "intuition and experience" rather than evidence. (Argument §II.)

3. Adopting a new, "less onerous" standard for material breach; making findings with no evidentiary support; and failing properly to assess whether Akorn cured its breaches. (Argument §III.)

4. Holding Fresenius had not materially breached on the grounds that "[i]n my view... [Fresenius's buyer's] remorse was justified". (Argument §IV.)

## STATEMENT OF FACTS[13]

Akorn is a generics pharmaceuticals company. In 2016, three products generated 34% of Akorn's revenues: ephedrine, clobetasol and lidocaine, with ephedrine alone accounting for 21%.[14]

In recent years, the generics industry has been exposed to significant price erosion from customer consolidation and accelerated FDA product approvals, among other things.[15] In February 2016, Akorn's Board discussed industry "conditions and trends" and decided to pursue strategic alternatives.[16] In late 2016, Akorn began discussions with Fresenius.[17]

Before signing, Fresenius identified risks to key Akorn products from increased competition. An October 2016 presentation by its financial advisor, Moelis, noted: "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".[18] Moelis modelled a downside case showing 62% and 51% declines in Akorn ephedrine

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[13] Hereinafter "SOF".

[14] A13349/¶33, A13383.

[15] A11956-66/¶¶53-67; A4349/457:11-458:12 (Rai); A1569/58:19-59:15 (Bowles).

[16] A4349/459:10-12 (Rai); Op.33.

[17] A4349/459:10-22 (Rai).

[18] Op.35 (quoting A4965).

revenues in 2017 and 2018, respectively.[19] In diligence, Fresenius's "red flag" findings noted "[r]isk to achieve forecasts due to stronger competition, especially for Ephedrine, Lidocaine ointment, [and] clobetasol".[20] Analysts warned of significant competitive risks to five of Akorn's top six products.[21]

Given these risks, Fresenius initially proposed to acquire Akorn for $30/share plus a CVR worth up to $5/share based on ephedrine sales.[22] Akorn declined. Fresenius then increased its offer to $32/share plus a $4/share CVR tied to all Akorn 2018 sales.[23] Akorn offered access to its data room on the condition that Fresenius remove the CVR.[24] Fresenius agreed.[25]

Following "detailed due diligence",[26] including access to at least two FDA officials,[27] Fresenius concluded that Akorn's quality system was not robust. In November 2016, Fresenius USA SVP for Portfolio/Marketing, Bauersmith, forwarded Fresenius USA CEO, Ducker, a Form 483 received by Akorn, noting

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[19] A5040.

[20] Op.41 (citing A5901).

[21] A13349/¶32, A13383.

[22] A5407.

[23] A4185/II.C.8.

[24] Op.40.

[25] Op.40.

[26] A7318; A7363; A4615/1197:8-1198:13 (Sturm). Fresenius did not request internal audit reports. A899/29:5-8 (Schreiner).

[27] A7227.

the risk of a Warning Letter.[28] Bauersmith testified he was concerned about possible DI issues[29] and management was ignoring his various warnings about the deal.[30] He began compiling a "CYA" file of correspondence.[31]

In diligence, Fresenius concluded Akorn's "[c]ommitment to quality" was "below average" or "poor" at three of four facilities reviewed.[32] Fresenius found "inconsistent and poor quality of product development"; "[f]ocus on speed and number of submissions"; "[f]ew formal processes to guide development"; "under-resourced" regulatory teams; "[p]oor quality of regulatory submissions"; "[n]umber of recalls quite high"; and "premises and equipment" deficiencies.[33]

Fresenius planned to address these issues through a $120M overhaul of Akorn's Amityville facility,[34] a $24M short-term investment in Decatur before divesting it, and closing Akorn's India facility in a $170M write-off.[35]

On March 23, Fresenius offered $33/share and eliminated the CVR.[36]

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[28] A5086-87; A4404-05/616:16-22, 617:5-21 (Bauersmith); A4994.

[29] A4405/617:5-20 (Bauersmith); A1370/27:22-28:7 (Bauersmith).

[30] A4406-07/623:22-628:19, A4409-10/635:12-637:24 (Bauersmith).

[31] A4409/636:12-637:22 (Bauersmith).

[32] A8842-48; A4528-29/990:17-991:10 (Henriksson).

[33] A6148-51.

[34] A1298/38:19-39:19 (Aldrian); A4529/991:8-992:10 (Henriksson).

[35] A6148-49; A902-04/42:5-49:23 (Schreiner).

[36] Op.42.

On April 2, it offered $34/share.[37] Akorn accepted. On April 24, the parties executed the Merger Agreement.[38]

Sturm told investors: "[W]e performed a detailed due diligence... Have we overlooked anything material? Possible, but unlikely."[39] In response to questions about Akorn's FDA compliance, Sturm said Fresenius itself "ha[d] received quite a number of form 483s also.... So I think we should be humble and avoid any form of arrogance."[40] He noted Fresenius has "more manufacturing scale and larger, better equipped quality systems... [to] bring to the party."[41]

Fresenius's integration planning demands were intense.[42] Akorn's interim CIO, Pramik, testified to over 50 meetings and calls with Fresenius counterparts.[43] Akorn reprioritized its IT Roadmap given these plans, pausing certain projects across functions.[44] Pramik's unrebutted testimony is that she discussed every paused project with Fresenius management.[45] While Pramik instructed employees not to move forward with IT projects unapproved by Akorn's

[37] Op.43.

[38] Op.45.

[39] Op.48.

[40] A7375.

[41] A7328.

[42] A4262/227:1-228:14 (Pramik).

[43] A4262/225:2-226:21 (Pramik); A4501/880:3-18 (Bonaccorsi).

[44] A4261-62/224:1-226:9-21, A4267/245:23-246:18 (Pramik).

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

Project Review Board ("PRB"),[46] Akorn continued to implement DI projects, including lab modernization and performing critical systems performance and reliability enhancements.[47]

Akorn also continued to address gaps identified by Cerulean—a third-party DI consultant voluntarily engaged to perform gap assessments—in 2016 and 2017.[48] By February 2018, the Decatur facility had completed 32% of Cerulean's recommended CAPAs and 59% of the Q4-targeted actions.[49] The Somerset facility had remediated seven of 17 Cerulean observations.[50]

Akorn also continued performing audits in the ordinary course. In April 2017, a regular FDA inspection required the Decatur manufacturing facility to reschedule its annual audit to February 2018,[51] completing a "verification audit" in the interim.[52] A distribution center and corporate headquarters also received

[46] A4263-64/232:19-233:12 (Pramik).

[47] A7693; A4256-57/204:20-208:5 (Pramik).

[48] A4213/31:14-32:3 (Wasserkrug). Cerulean applied a more stringent standard than FDA, and its recommendations are non-binding. A5417-18; A4209/15:21-16:21 (Wasserkrug). Akorn did not agree with all of Cerulean's findings. A1488-91/169:22-181:22 (Wasserkrug); A4214/34:19-35:5 (Wasserkrug).

[49] A10506.

[50] A9410-26.

[51] A2453/57:9-17 (Gill); A4210/17:24-18:1 (Wasserkrug).

[52] A2453-54/56:21-58:18 (Gill); A2454/59:14-20 (Gill).

verification audits in 2017.[53] A fourth facility, Somerset, received *both* full *and* verification audits in 2017.[54] Every Akorn manufacturing and R&D facility underwent a full-scale audit following signing.[55]

In Q2 2017, Akorn's financial performance declined. Q2 2017 net revenue was $199M, below a plan of $243M.[56] The results were attributed to: "[c]ustomer consortiums accelerating price erosion across industry"; "[l]imited [b]id/RFP opportunities, and increasing competitive responses"; and "[n]ew competitive entrants into higher value products", among other things.[57]

In response, Sturm told Rai Akorn's performance "[was] the most embarrassing personal or professional thing that ha[d] ever happened to him",[58] and asked the Fresenius team "if there was a way to cancel the deal".[59]

1. "[N]o basis for a termination"

Despite its obligations to use best efforts to close, Fresenius began searching for an exit shortly thereafter. It retained Paul Weiss, seeking advice on

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[53] A2453-54/56:21-58:18 (Gill).

[54] A7402-27; A8262; A7671.

[55] A2453/55:23-56:16 (Gill); A4210/17:24-18:12 (Wasserkrug); A8770; A10462-85.

[56] Op.53; A7729.

[57] A7729.

[58] A7792.

[59] A7776.

whether Fresenius could terminate based on Akorn's financial results.[60] Paul Weiss concluded that "there was no basis for a termination of the transaction".[61] The Opinion softens that, stating "Fresenius concluded that it did not have *clear* grounds for termination".[62] It reasoned lawyers "rarely... frame their legal advice in absolute terms"; and it was "confident" that testimony otherwise "oversimplifies matters".[63] The actual legal advice was withheld as privileged.

2. "[W]e've got to build our legal case."

In September 2017, Akorn reported more disappointing results, outraging Sturm: "I'm afraid we've got to build our legal case."[64]

Sturm "candidly admitted that at this point, he personally wanted to terminate the transaction",[65] but the Court chose not to draw an adverse inference: "Sturm... speaks English fluently, but it is not his native language, and I therefore do not draw the inference that by 'build our legal case,' he meant to manufacture one."[66] According to the Opinion, Sturm was only "focused on understanding

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[60] A4521/959:21-960:5 (Henriksson).

[61] A844/107:15-25 (Empey); A4618-19/1210:20-1212:22 (Sturm); A2382/218:22-219:25 (Ducker).

[62] Op.60.

[63] Op.60/n.279.

[64] Op.58; A8095.

[65] Op.58.

[66] Op.59.

Fresenius's rights under the Merger Agreement".[67]

Within two weeks, an anonymous letter sent to Ducker alleged DI issues at Akorn.[68] The letter urged "full due diligence" at Akorn facilities.[69] When Paul Weiss concluded the letter was too vague to take action,[70] a second, more detailed letter arrived.[71]

In the interim, Akorn reported disappointing Q3 results, attributed primarily to: "[i]ncreasing number of competitive approvals, in tandem with leverage from customer consortiums" and "[n]ew competitive entrants into higher value products".[72]

3. "[W]e'd be delighted to help.... develop a significant set of fraud on the FDA allegations."

Fresenius executives discussed the second letter on November 12, "decid[ing] that they did not want to proceed with the Merger as negotiated and would seek to terminate the Merger Agreement if they had a valid contractual basis".[73] The Court held "[t]hey had ample grounds to reach this conclusion".[74]

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[67] Op.230.

[68] A8159.

[69] A7467.

[70] A2379/207:9-11 (Ducker).

[71] A8314-15.

[72] A8214.

[73] Op.67.

[74] Op.67.

Before sharing the letters with Akorn, Fresenius contacted Sidley,[75] which was "delighted to help", noting its "significant experience litigating fraud on the FDA claims.... In one case... [o]ur interdisciplinary litigation team was... able to develop a significant set of fraud on the FDA allegations in discovery. This led to a very positive settlement...."[76] Fresenius brought Sidley on board.

4. "[Silhavy] told me not to take action."

When Akorn learned of the anonymous letters, Bonaccorsi, its GC, wanted to investigate.[77] However, Fresenius USA GC, Silhavy, "told [Bonaccorsi] not to take action... that Fresenius saw it as their responsibility and their prerogative to take charge of the investigation."[78] Silhavy never denied this statement, but the Court disregarded this unrebutted testimony, concluding Bonaccorsi "misremembered".[79]

5. "[P]lacing collateral pressure on Akorn by communicating concerns to the regulatory agency"

Meanwhile, Sidley got to work:

> "[W]e set out the various FDA regulatory consequences that could flow from these allegations, if substantiated. *This is a useful exercise* because... Kabi would have to

[75] A3039-40/66:15-70:22 (Silhavy); A8402-03; A8588; A8472-75; A8484; A4550/1077:15-1078:12 (Sheers); A2935-36/29:20-30:13 (Sheers).

[76] A8401.

[77] A8437; A4502/885:20-886:22 (Bonaccorsi).

[78] A4503/887:15-888:24 (Bonaccorsi); A3444/102:11-17 (Bonaccorsi).

[79] Op.70/n.321.

> demonstrate that the deficiencies identified are material *in order to employ those representations successfully in a litigation context*. This exercise also begins to help frame the possibility of *placing collateral pressure on Akorn by communicating concerns to the regulatory agency*."[80]

It researched "whether FDA outreach is allowed or prohibited under the terms of the [M]erger [A]greement".[81]

The Court dismissed this, reasoning "[o]nce [Fresenius's] investigation uncovered serious problems, Fresenius had good reason to be concerned that Akorn would present a misleading picture of its situation to the FDA".[82] However, Fresenius had not "uncovered serious problems" *before* starting its investigation.

6. "Q.... [You] hired Paul Weiss and Sidley and Lachman and Ernst & Young to try to get you out of this deal; true? A. True."

Fresenius also brought E&Y and Lachman on to its investigation team. Sturm admitted he "hired Paul Weiss and Sidley and Lachman and [E&Y] to try to get [him] out of this deal",[83] testimony not mentioned in the Opinion.

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[80] A8476.

[81] A8586-87.

[82] Op.231.

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

7. "I was assured by his statements that this was not a litigation exercise."

Fresenius also executed a common interest agreement ("CIA") stating the parties were "join[ing] in an investigation" and had a "mutual interest aris[ing] from and under the Merger Agreement",[84] an agreement Fresenius (unbeknownst to Akorn) wished to terminate. Internally, Sidley referred to Akorn as "our adversary".[85] However, Silhavy reassured Bonaccorsi "the goal here was to investigate... not litigation... I was assured... that this was not a litigation exercise. This was a joint investigation."[86]

The Court faulted Akorn for requesting the CIA at the outset of the joint investigation, characterizing it as an "unsuccessful attempt to secure the high ground... by including contractual provisions that could trip up... Fresenius".[87] It believed Akorn could not rely on the CIA, having "evidence[d] an understanding of the dual implications of Sidley's work".[88] Fresenius, on the other hand, was *not* "prevented from relying on a representation simply because [it] knew about a

[84] A8805.

[85] A8783; A4553/1088:2-10 (Sheers); A8777; A8755; A4552/1085:18-22 (Sheers).

[86] A4504/891:18-892:21 (Bonaccorsi).

[87] Op.71/n.326, 75.

[88] Op.71/n.326.

risk"[89]—an unreconciled inconsistency.

Relying on Fresenius's representations, Akorn provided Fresenius: five multi-day site visits and 50+ interviews of 48 Akorn employees (all attended by Cravath); data extraction from Akorn's servers; and millions of documents from 63 custodians.[90]

8. "Ron (the Lachman team lead) mentioned a search for 'a smoking gun'."

During his first and only site visit, Ron George—the Lachman lead subsequently offered as a litigation expert—referred to their search for "a smoking gun".[91] Sidley quickly instructed the team "to not make any editorial comments", as George was also "interrupting and his questioning suggested non-compliance".[92] George was thereafter reassigned to another project (but nevertheless testified about Akorn's compliance at sites he never visited).[93]

The Court concluded that "the details and context of th[e smoking gun] statement are too vague for me to draw any inferences",[94] though it "judge[d

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[89] Op.199.

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

[91] Op.76/n.346; A8807; A4562/1123:15-20 (George); A4569/1151:9-11 (George).

[92] A8807.

[93] A4562/1123:15-20 (George); A4569/1151:9-11 (George).

[94] Op.76/n.346.

George] to be among the most credible witnesses I have seen in Court"[95] and "not... capable of shading the truth".[96]

9. "The client thinks its sidley's fault that Lachman isn't calling these guys liars and cheaters."

Behind the scenes, Fresenius leaned on Sidley to develop the right record. Sidley's internal call notes explain:

> "Lachman needs to come away with a sense that these guys are liars and cheaters. If that's not coming across, then we need to not get off the call....
>
> The client thinks its sidley's fault that Lachman isn't calling these guys liars and cheaters. The client thinks we're not controlling them enough."[97]

The Opinion omits the text of these notes, but alludes to "evidence that Fresenius executives wanted Sidley and Lachman to be even more critical of Akorn than they were".[98]

10. "[T]he findings as disclosed so far from Akorn's work... [do] not get us close to the finish line."

At Akorn's request, in December and January, Cravath investigated an instance of likely falsified data included in FDA filings for the drug

[95] Op.72.

[96] Op.173/n.697.

[97] A9045.

[98] Op.82/n.380.

azithromycin.[99]

Cravath determined that in 2012, an employee likely falsified particulate matter stability test data for azithromycin.[100] That data was included in the 2012 ANDA submission to FDA, a fact discovered by Akorn's head of Quality, Silverberg, in July 2016.[101] In January 2015, Akorn received a CRL from FDA requesting additional information about anti-microbial effectiveness ("AET") data[102]—not particulate data.[103] In August 2017, Silverberg authorized the submission of the CRL response,[104] which, when submitted, attached a table with the likely false data.[105]

Based on interviews with Silverberg and others and a review of Silverberg's emails,[106] Stuart, the lead Cravath investigator, determined that Silverberg had *not* known that the CRL response would contain the likely false data;[107] however, Stuart concluded "[t]hat did not excuse his submission of the

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[99] Op.77-81.

[100] Op.79.

[101] *Id.*; A15731; A2075/82:15-84:4 (Silverberg).

[102] A2087/130:22-25 (Silverberg); A7956; A7968-8043.

[103] A7956.

[104] A7968-8043.

[105] Op.80-81; A15740-41; A2078/94:21-95:14, A2078/96:6-20, A2085/122:25-123:5 (Silverberg).

[106] A4423/691:11-692:9 (Stuart); A4505/897:24-898:20 (Bonaccorsi).

[107] A4421-22/684:16-685:3, A4425/698:12-17, A4430/717:15-22 (Stuart).

CRL response, knowing that there was already problematic data on file.... conduct which I found unsatisfactory."[108]

Silverberg was removed from his role as head of Quality; and Akorn withdrew the azithromycin ANDA,[109] which was projected to generate no revenue.[110]

Cravath briefed Fresenius on its findings, which Silhavy characterized internally as "not earthshattering", though "interesting and may be helpful".[111] In response, Sturm scolded Silhavy.[112] Silhavy explained: "I did not mean to convey that the findings as disclosed so far from Akorn's work w[ere] not important, but only that by itself it did not get us close to the finish line."[113] Sturm warned Silhavy: "Given increasing Supervisory Board involvement we just need to be very closely aligned."[114]

11. "If [Sturm] is likely to go nuclear on the closing we should instruct the team to... avoid[] us having a potential closing event before we have a more developed legal position...."

At signing, Fresenius anticipated an FTC clearance process permitting

[108] A4430/717:15-22 (Stuart).

[109] A9822; A9493; A11585; A4505/895:3-15 (Bonaccorsi).

[110] A14463.

[111] A8924; A3062/158:7-16 (Silhavy); A4614/1191:3-16, A4620/1216:1-16, A4620/1218:2-24 (Sturm).

[112] A4620/1216:6-1218:1 (Sturm); A3062/158:7-21 (Silhavy); A9001.

[113] A9001.

[114] *Id.*

closing "towards the end of 2017".[115] However, Fresenius slow-walked the FTC-mandated divestiture agreement,[116] and stopped participating in antitrust calls, which its antitrust counsel could not explain.[117]

In mid-February, Fresenius considered "Option 2", which involved bundling the FTC-required divestiture of Fresenius products with an *unrequired* divestiture of Akorn's Decatur facility.[118] Fresenius chose to pursue this option because it "would likely delay close to June/July 2018":[119]

> "If [Sturm] is likely to go nuclear on the closing we should instruct the team to follow Option 2. This avoids us having a potential closing event before we have a more developed legal position on the investigation."[120]

The Court admitted this "technically breached" Fresenius's hell-or-high-water commitment, but excused it as immaterial.[121]

12. <u>"I sense a certain desperation on which we might capitalize."</u>

Around this time, Akorn began planning an FDA meeting to explain the withdrawal of the azithromycin ANDA. Sidley asked to participate in the

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[115] A4610/1175:3-8 (Sturm).

[116] A1587/130:2-132:19 (Bowles).

[117] A4510/916:22-917:13 (Bonaccorsi); A3473/218:3-219:20 (Bonaccorsi).

[118] A4402/605:4-606:21 (Bauersmith); A1403/158:12-160:16 (Bauersmith); A9366.

[119] A9366.

[120] Op.241; A9385.

[121] Op.242.

meeting,[122] hoping for a platform to raise alarm:

> "[E]ven if Akorn would not allow us to tell FDA that there are 13,000 trial injections we're looking into (which we would try to be able to do), just conveying that we are looking at trial injections... *will go a long way*."[123]

Sidley later resorted to threats: "We... conveyed that if Akorn declined our request to attend, we were prepared to contact FDA on our own...."[124]

Days before the FDA meeting, Sturm ordered Silhavy to assert a conflict as to Akorn's long-time FDA counsel, Robert Dormer, forcing the meeting to be postponed.[125] Dormer's firm had represented Fresenius, and Sturm felt "it would be difficult to avoid the impression of a joint investigation".[126] Bonaccorsi asked Silhavy to reconsider, prompting Silhavy to mull "capitaliz[ing]":

> "[W]e might trade for getting Sidley at the meeting.... *I sense a certain desperation on which we might capitalize*. I also wonder, when [Bonaccorsi] states that *we look like we're trying to have Akorn fail*, whether *for litigation defense purposes we could take that argument off the table* by granting this one-time and limited waiver in the trade - question for [Paul Weiss litigator Clayton]."[127]

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[122] A9733.

[123] A9743.

[124] A9733.

[125] A9735; A4428/710:9-21 (Stuart); A4506/901:24-902:4 (Bonaccorsi); A4622/1226:10-13 (Sturm). The Opinion incorrectly refers to Dormer as "newly retained", Op.87; in fact he had advised Akorn for years. A3434/64:22-24 (Bonaccorsi).

[126] A9743; A9735.

[127] A9746.

Fresenius ultimately refused, and Akorn did not invite Sidley to the meeting.[128]

The Court reasoned Fresenius simply "did not want any blowback... to hurt its own counsel's credibility."[129] The evidence shows that, in reality, Fresenius was concerned a "luke-warm response from FDA" might be used to "attack" its plans to "have an expert paint a portrait of horribles" in litigation.[130]

13. "[A] chance of stimulating the Agency to require a searching audit of Akorn and perhaps an FDA investigation of the company"

In the following weeks, Sidley sent letters to Akorn accusing it of misleading FDA in the meeting Sidley did not attend.[131] Sidley demanded that Akorn forward the letters directly to FDA—which Akorn did[132]—and threatened to contact the Agency directly.[133]

The letters were drafted with Paul Weiss's input and were intended "to... pique FDA's interest in contacting Fresenius".[134] Paul Weiss recommended cherry-picking language from some of the emails Akorn produced: "[Q]uoting the specific language showing that Akorn covered up FDA problems has a chance of

[128] A9740-42.

[129] Op.90.

[130] A9749-50.

[131] A10453-59; A14405-08; A14433-36; A4431/722:17-723:7 (Stuart); A14409-28; A14442-43.

[132] A2982/215:23-216:9 (Sheers); A4431-32/724:9-725:12 (Stuart).

[133] A10458; A14406; A14436.

[134] A14431-32.

stimulating the Agency to require a searching audit of Akorn and perhaps an FDA investigation of the company."[135]

Fresenius believed termination depended on "stimulating" FDA sanctions. In mid-March, Sturm informed the Supervisory Board that termination depended on "further findings from the still ongoing investigation, *the expected FDA sanctions and resulting consequences* for... Akorn".[136]

The Court concluded "Fresenius acted reasonably".[137]

14. "[B]egin the work on materiality"

FDA sanctions did not materialize, so Fresenius took matters into its own hands. In January, Silhavy "suggest[ed that] we, the lawyers, enlist [Bauersmith]'s support... [to] begin the work on materiality".[138] He explained that Clayton "confirmed that [Bauersmith]'s work, because it would be done at the request of us lawyers and for the benefit of possible litigation, would constitute 'Work Product' of the lawyers and would thus be shielded from Akorn's knowledge."[139] Silhavy later reported Bauersmith was "fully onboard.... [He] also

[135] A14431.

[136] A10596; A4623/1230:2-20 (Sturm).

[137] Op.231.

[138] A9020.

[139] *Id*.

now sees why we have not been pressing faster on some of the FTC issues."[140] Silhavy promised to "put [Bauersmith] in contact with Lew Clayton who will direct some of the analyses we'll need".[141]

The resulting project, codenamed "Cerafa", modelled a $1.9B valuation impact from DI issues at Akorn.[142] The Court explained: "[C]erafa fagacearum is a fungus that kills oak trees.... Fresenius's code name for the Akorn acquisition was Project Oak, and Akorn understandably infers from this name that Bauersmith had been instructed to come up with a way to kill Project Oak."[143] The Court, however, would not credit that inference.[144]

The Cerafa team consisted exclusively of Fresenius senior management, directed by litigation counsel. At least three members received Sturm's email to "build our legal case".[145] Four were on the November call[146] where they "decided that they did not want to proceed with the Merger... and would seek to terminate".[147] None of the team members participated in the Sidley

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[140] A9019.

[141] *Id*.

[142] Op.82/n.381; Op.179.

[143] Op.82/n.381.

[144] Op.82/n.381.

[145] A4532/1004:23-1005:15 (Henriksson); A8091.

[146] A4532/1004:23-1005:15 (Henriksson); A8382.

[147] Op.67.

site visits or had any direct knowledge of DI issues at Akorn.[148] They did not: consult third-party consultants; consult case studies of other pharmaceutical companies; look at any FDA presentations or guidance; rely on any conversations with FDA; or point to any literature in support of their assumptions.[149] Not one expert opined that the Cerafa assumptions are reasonable. Despite Sturm's comments to the Supervisory Board about an MAE turning on "FDA sanctions and... consequences", the actions modelled in Cerafa were not dependent on FDA sanctions—they were voluntary.[150] The Cerafa materials were withheld in discovery (over repeated requests) until three weeks before trial on the ground that they were prepared in anticipation of litigation.[151]

Courts have traditionally set aside such made-for-litigation analyses. *See Hexion Specialty Chems. v. Huntsman*, 965 A.2d 715, 727 (Del. Ch. 2008) (finding made-for-litigation insolvency opinion unreliable). Here, however, the Court deemed "[t]he views of Fresenius's management team on this subject... particularly credible",[152] notwithstanding the litigators' role: "I see no reason to criticize either side for consulting with top-flight law firms about the implications

[148] A4404/613:18-614:2 (Bauersmith); A1237/170:21-171:3, A1249/221:6-11 (Mahl); A2289/146:6-148:4 (Schulte-Noelle).

[149] A4532/1005:16-1006:6, A4533-34/1010:20-1012:9 (Henriksson).

[150] A4524/973:2-974:6, A4534/1012:10-1013:3 (Henriksson).

[151] A9011-14; A14467; Op.98/n.457.

[152] Op.181.

of unfolding events for a high-profile deal."[153] The Court nevertheless rejected Cerafa's output of $1.9B in financial impact, finding it a "worst-case scenario"; that "only some of Akorn's products will require re-validation"; and that "disruption and delay will not be quite so extensive as Fresenius projects".[154]

* * *

On April 18, Paul Weiss sent a letter asserting Fresenius identified "clear and material breaches of Akorn's representations in the Merger Agreement" and asked to extend the outside date to permit further investigation.[155] Akorn declined. On April 22, Fresenius purported to terminate.[156] Akorn initiated suit the following day.

Trial was held July 9-13. On October 1, the Court issued an Opinion ruling against Akorn on all claims. Among other things, it credited testimony speculating that FDA would "halt the approval of Akorn's ANDAs"[157] and found "Akorn cannot currently prove the accuracy of its data".[158]

On October 9, Akorn received an ANDA approval from FDA stating that it "concluded that adequate information has been presented to demonstrate that

[153] Op.98/n.457.

[154] Op.183.

[155] A10708-09.

[156] A10832-33.

[157] Op.173-74.

[158] Op.180.

the drug is safe and effective for use".[159] Akorn moved to supplement the record; the Court denied Akorn's motion.[160] On October 26, Akorn received another ANDA approval—containing the same finding—for another product.[161]

[159] A16992-97.

[160] A16987-98; A16999-7006.

[161] A17011-15.

## ARGUMENT

## I. THE COURT ERRED IN FINDING A GENERAL MAE.

### A. Questions Presented

Did the Court err by eliminating the "unknown event" test from the settled MAE standard; failing to consider the *incremental* disproportionate impact of industrywide headwinds on Akorn's business; and assessing materiality from the perspective of the seller rather than the buyer? (A16013, A16033-043.)

### B. Scope of Review

This Court reviews legal conclusions *de novo*, *In re Peierls Charitable Lead Unitrust*, 77 A.3d 232, 235 (Del. 2013), and factual findings for clear error, *Smith v. Van Gorkom*, 488 A.2d 858, 871 (Del. 1985).

### C. Merits of Argument

Delaware courts have consistently held that an MAE refers to "[1] unknown events that [2] substantially threaten the overall earnings potential of the target [3] in a durationally-significant manner". *In re IBP, Inc. S'holders Litig.*, 789 A.2d 14, 68 (Del. Ch. 2001); *Frontier Oil v. Holly*, 2005 WL 1039027, at *34 (Del. Ch.); *Hexion*, 965 A.2d at 738; *Mrs. Fields Brand v. Interbake Foods*, 2017 WL 2729860, at *22 (Del. Ch.). These elements are "viewed from the longer-term perspective of a reasonable acquirer". *IBP*, 789 A.2d at 68. The Court disregarded these principles.

1. The Court Erred by Eliminating the "Unknown Events" Requirement.

The Court erroneously concluded that *IBP* and *Hexion*'s adoption of an "unknown event" test did not "prescribe[e] a standard that would govern all MAE clauses";[162] the "unknown events" test has been displaced by written "exceptions and exclusions" to the MAE definition;[163] in any event, the risks that led to Akorn's decline *were* unknown because Akorn underperformed Fresenius's projections;[164] and the cause of Akorn's decline was an endogenous, not exogenous, risk.[165]

i. *MAEs Are "Unknown Events"*.

In ruling that a *known* event could be an MAE,[166] the Court ignored Delaware precedent that was the backdrop for the parties' expectations. *See IBP*, 789 A.2d at 68 (MAE standard "protect[s] the acquiror from the occurrence of *unknown* events"); *Frontier*, 2005 WL 1039027, at *34 (MAE standard "protect[s] a merger partner from the existence of *unknown* (or undisclosed) factors that would justify an exit"). As Chancellor Bouchard explained:

> "Interbake could not reasonably have expected when it entered the License Agreement that it would be able to

[162] Op.153.

[163] Op.152-53.

[164] Op.154-56.

[165] Op.143-44.

[166] Op.150.

> terminate it on the basis of an adverse fact it knew about and yet ignored.... [I]f Interbake entered into the contract despite knowledge of an adverse fact, then it would be reasonable to assume it either considered the fact to be immaterial or decided to assume the risk."

*Interbake*, 2017 WL 2729860, at *22. The MAE closing condition provides protection only during the gap between signing and closing; the buyer assumes all long-term risk and must price *known* risks into the deal.[167] Permitting the buyer to terminate based on known risks undermines the deal struck by the parties.[168]

The Opinion, however, treats *every* downside risk—known or unknown—as a potential MAE unless expressly carved out of the MAE definition. That turns *caveat emptor* on its head. *See*, *e.g.*, *Hexion*, 965 A.2d at 740-41 (risk fell on buyer where seller disclaimed any warranty on a topic); *IBP*, 789 A.2d at 73.

Ephedrine—which alone accounted for 21% of Akorn's 2016 revenues—is a perfect example.[169] Fresenius knew of the risks posed by

[167] Kling & Nugent, *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* §14.11[5] (2018 ed.).

[168] Galil, *MAC Clauses in a Materially Adversely Changed Economy*, 2002 Colum. Bus. L. Rev. 846, 850 (2002) ("The impact of [a known] event should already be reflected in the agreed price; granting the buyer an option to break off the deal would be a reallocation of value contrary to what the parties originally bargained for.").

[169] A13357-58/¶¶55-56; A13383; A4405/619:1-620:7 (Bauersmith); A2335-36/32:9-34:11 (Ducker); A4994; A1311/90:16-20 (Aldrian).

competition on ephedrine. Moelis expressly warned of the risk,[170] and modelled a drop in ephedrine revenues even lower than actually materialized.[171]

Ephedrine accounted for 15 percentage points of Akorn's 37% 2017 revenue decline.[172] Akorn's expert economist Grabowski showed that when the impact of ephedrine is removed, Akorn's revenue decline was consistent with other comparable generics companies.[173]

Fresenius tried—unsuccessfully—to negotiate a CVR for ephedrine.[174] At trial, Sturm explained that Fresenius pushed for a CVR because "it transfers a bit of risk *from the acquirer to the seller*"[175]. By ignoring this negotiating history,[176] the Court gave Fresenius non-bargained-for insurance against a risk that Fresenius had already tried—and failed—to shift to Akorn. *See Chicago Bridge & Iron v. Westinghouse Elec.*, 166 A.3d 912, 927 (Del. 2017) ("*CB&I*") ("The basic business relationship between parties must be understood to give sensible life to any contract."). That was reversible error.

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[170] Op.34-35; A4965.

[171] *Compare* A5040, *with* A11954-55/¶50.

[172] A11976/¶83; A12010-11.

[173] *Id*.

[174] Op.37; A7466; A4184-85/II.C.5.

[175] A4609/1173:20-21 (Sturm).

[176] Op.117-56.

### ii. *MAE Carve-Outs Do Not Replace the "Unknown Events" Rule.*

The Court focused exclusively on "exceptions and exclusions" in the contract's MAE definition.[177] It reasoned that because the parties did not define an MAE as "unforeseeable effects, changes, events, or occurrences", they intended to replace the "unknown events" standard.[178] That fails.

MAE clauses include a general definition that allocates risk to the seller (the "General MAE Definition"), as well as "exceptions to reallocate specific categories of risk to the buyer" (the "MAE Carve-Outs").[179] The parties to the Merger Agreement "had the benefit of the doctrine developed in *IBP* and its progeny when they negotiated the text" of the General MAE Definition,[180] and the "same factors underlying its approach—*knowledge*, magnitude, and duration—are relevant". *Interbake*, 2017 WL 2729860, at *22. Because "material adverse effect" has a prevailing legal meaning, its use in the Merger Agreement should be interpreted as a reference to the background legal standard[181]—one limited to

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[177] Op.152.

[178] Op.152-53.

[179] Op.121, 126.

[180] The General MAE Definition closely tracks the language interpreted in *IBP*. *Compare IBP*, 789 A.2d at 65, *with* A4764-71/§8.12.

[181] *Penton Bus. Media Holdings v. Informa*, 2018 WL 3343495, *12 (Del. Ch.) (Laster, V.C.) ("[A] Court will presume that the parties intended to use the established legal meaning of the terms."); Restatement (Second) Contracts ("Restatement") §202(3).

"unknown events", *see IBP*, 789 A.2d at 68. If the parties intended otherwise, they would have said so.

The MAE Carve-Outs return some risk of "unknown events" to the buyer.[182] As the Court observed, many MAE Carve-Outs relate to exogenous, systemic risks as opposed to endogenous, business risks.[183] These reallocate to the buyer unknown, systemic risks that could otherwise be an MAE:

MAE Clause *Without* Carve-Outs

| Risk: | Known | Unknown |
|---|---|---|
| Exogenous/systemic | on Buyer | on Seller |
| Endogenous/business | on Buyer | on Seller |

MAE Clause *With* Carve-Outs

| Risk: | Known | Unknown |
|---|---|---|
| Exogenous/systemic | on Buyer | on Buyer |
| Endogenous/business | on Buyer | on Seller |

This narrows the universe of possible MAEs—shifting the risk of unknown, exogenous events from sellers to buyers.[184]

The Opinion, however, interprets these provisions as *replacing* the "unknown events" test, *expanding* the universe of possible MAEs to include

[182] A4764-71/§8.12.

[183] Op.121-22.

[184] Zhou, *Material Adverse Effects as Buyer-Friendly Standard*, 91 N.Y.U. L. Rev. Online 171, 175 (2016) ("[C]ourts are more likely to rule for a buyer when alleged MAEs relate to unforeseeable events not connected to general economic trends, a result consistent with... ordinary principles of contractual interpretation.").

known, endogenous risks:[185]

Opinion: MAE Clause *With* Carve-Outs

| Risk: | Known | Unknown |
|---|---|---|
| Exogenous/systemic | on Buyer | on Buyer |
| Endogenous/business | on Seller | on Seller |

This approach deprives sellers who think they are bargaining for *more* protection, giving them less. The parties could easily have opted out of the *IBP* formulation by using the words "whether known or unknown".[186] They did not.

The Opinion concludes parties should draft MAE Carve-Outs to cover any "specific matters that [the seller] believes will, or are likely to, occur".[187] That is inconsistent with the MAE's role as a "backstop". *IBP*, 789 A.2d at 68. *IBP* rejected any requirement to exhaustively catalogue every known risk parties wish to allocate to the buyer, finding such a "rule will encourage the negotiation of extremely detailed 'MAC' clauses with numerous carve-outs or qualifiers." *Id*. n.155.

The Opinion also invokes the principle of *inclusio unius*, noting that

[185] Op.153-54.

[186] Kotran et al., *Material Adverse Change Provisions: Mergers and Acquisitions*, Practical Law Practice Note (2007-2009), Westlaw 9-386-4019 (parties should use the term "whether known or unknown" to overcome the unknown events presumption).

[187] Op.152 (quoting Kling & Nugent §11.04[9]).

the General MAE Definition does not mention unforeseeability.[188] The General MAE Definition also does not mention durational significance, but the Court nevertheless applied that element because it is a part of the background MAE standard.[189]

iii. *The Events That Caused Akorn's Performance Decline Were Known.*

Having found Fresenius's knowledge does not "change the result", the Opinion reasons that "the events that resulted in a General MAE at Akorn were unexpected" anyway.[190] This, too, was wrong.

The Court found that "[t]he primary driver of Akorn's dismal performance was unexpected new market entrants who competed with Akorn's three top products—ephedrine, clobetasol, and lidocaine."[191] These products generated 34% of its 2016 revenues.[192] In diligence, Fresenius flagged "[r]isk to achieve forecasts due to stronger competition, especially for Ephedrine, Lidocaine ointment, clobetasol...",[193] and Fresenius CEO, Henriksson, admitted knowing the

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[188] Op.153/n.629 (citing Schwartz, *A "Standard Clause Analysis" of the Frustration Doctrine and the Material Adverse Change Clause*, 57 UCLA L. Rev. 789, 834 (2010)).

[189] Restatement §202(3).

[190] Op.153.

[191] Op.144.

[192] A13349/¶33, A13383.

[193] Op.41 (quoting A5893-A5906).

risk posed by competition for all three products.[194] Having priced those risks into the deal, Fresenius cannot use them to terminate.

The Opinion reasons that the *impact* of these known risks proved worse than Fresenius projected.[195] *First*, with respect to ephedrine, that is incorrect, as Moelis's November 2016 ephedrine projections were worse than actually materialized.[196] *Second*, the MAE test asks whether the *events* are "unknown"—not their full impact. *Third*, this converts the MAE clause into a non-bargained-for warranty of financial projections. That the deal worked out worse than the buyer expected is not a basis to reapportion the bargained-for allocation of risk.[197]

iv. *The Events That Caused Akorn's Performance Decline Were Systemic Risks.*

Even if the Opinion's MAE Carve-Outs did replace the traditional "unknown element" test, the Opinion must still be reversed, as it misapplies its own test.

Competitive pressure on Akorn's top products was not bad luck; increased competition was an industry-wide trend[198] that Sturm said "was generally

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

[195] Op.155-56.

[196] *Compare* A5040, *with* A11954-55/¶50.

[197] Op.151/n.626.

[198] A11962-66/¶¶62-67; A4349/458:7-12 (Rai).

anticipated".[199] Fresenius understood this would harm Akorn as a small and undiversified generics company[200] and told investors:

> "[W]hat's happening to Akorn in Q2 and Q3 and the financial performance can even be viewed as a confirmation of our strategic rationale, our strategic hypothesis of what is going to happen to smaller players in that part of the business and that, therefore, consolidation and us becoming more—becoming broader and more powerful ourselves is the right strategy there.... [U]s joining forces will mitigate some of the headwinds that Akorn is facing right now."[201]

The Opinion characterizes this as endogenous "business risk" because it impacted specific Akorn products.[202] But competitors are, by definition, exogenous. Akorn is not "the cheaper cost avoider":[203] it cannot prevent new competition. By contrast, Sturm acknowledged that *Fresenius* was better positioned to cope in the long term.[204]

The Court distinguished *IBP* and *Hexion* because they "held that buyers could not rely on the manifested consequences of widely known systematic risks".[205] But that is the point. The impact of systemic forces will always be felt

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[199] Op.62.

[200] A13355-57/¶¶51-54; A8348.

[201] A8348.

[202] Op.144.

[203] Op.128.

[204] A8332.

[205] Op.153-54.

by specific products, facilities, etc. Just as Apollo could not rely on cyclicality and increased competition when those forces severely impacted Huntsman's titanium dioxide business, *Hexion*, 965 A.2d at 745-46, and Tyson could not rely on an "unexpectedly severe winter... causing a sharp increase in prices that hurt both the fresh meats business and Foodbrands [subsidiary]", *IBP*, 789 A.2d at 70, Fresenius cannot rely on the "manifested consequences" of increased industry-wide competition on Akorn's top products.

2. The Court Failed To Properly Assess Disproportionate Impact.

The Opinion rules that "[a]ssuming for the sake of argument... these *were* industry effects, they disproportionately affected Akorn" and therefore established an MAE.[206] This was error.

*First*, only the "*incremental* disproportionate impact or impacts may be taken into account" when assessing an MAE.[207] The Court did not analyze incremental disproportionate impact at all. *Second*, the proportionality analysis was based exclusively on third-party analyst forecasts. But subpart (B)(8) of the MAE Carve-Outs, states that "any failure to meet any... public projections, forecasts, guidance, estimates,... or published financial or operating predictions of revenue, earnings [or] cash flow" shall *not* "be taken into account in determining

[206] Op.145.

[207] A4764-72/§8.12.

whether a [MAE] has occurred".[208] *Third*, reliance on analysts makes the MAE determination hinge upon the accuracy of third-party predictions. Irrationally optimistic analysts could create an MAE even where the seller's underlying fundamentals remain sound. *IBP*, 789 A.2d at 70 n.161 (questioning reliance on analysts).

3. The Court Misapplied the Test for Materiality.

The Court excluded synergies—which account for approximately $660M of the deal's value to Fresenius[209]—from its assessment of materiality, reasoning that "[t]he MAE definition... focuses solely on the value of the seller".[210] Under *IBP*, however, value of the seller must be assessed from the "longer-term perspective of a reasonable acquirer". 789 A.2d at 68 & n.155. Any reasonable acquirer would consider the impact of synergies[211]—and Fresenius did.[212] *See RUS v. Bay Indus.*, 2004 WL 1240578, *19 n.22 (S.D.N.Y.) (no MAE from "short-term swings in profit" because buyer intended to "capitalize on... long-term synergies"); *Hexion*, 965 A.2d at 725 (buyer assessed MAE with reference to synergies).

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[208] *Id*.

[209] A10699.

[210] Op.140.

[211] A4663/1388:11-1389:20 (Shivdasani); A13474-77/¶¶17-23; A2650-51/13:10-17:5 (Gompers); A3264-65/66:15-68:11 (Shivdasani); A3888/34:7-13 (Gokhale).

[212] A7300; A2261/36:4-11 (Schulte-Noelle); A3888/34:14-22 (Gokhale).

The Opinion reasons that subpart (B)(2) of the MAE Carve-Outs excludes effects, such as synergies, arising from the Merger.[213] This turns that provision on its head. Per the Court:

> "The exception[] in subpart[] (B)(2)... identif[ies] agreement risks. Through th[is] exception[], *Fresenius assumes these risks*."[214]

Fresenius, having assumed "agreement risks", could not rely on synergies as establishing an MAE. That does not prevent *Akorn* from relying on them to establish an MAE's absence.

The Court also deemed it irrelevant that the deal remains profitable to Fresenius,[215] leading to the odd result that the first MAE in Delaware history is an acquisition the acquirer still thinks profitable.[216] The Court noted that "[t]he MAE definition does not include any language about... profitability".[217] But MAE interpretation is informed by case law, which holds that where a deal is "still within the range of fairness and a great long-term value" that "casts great doubt" on the existence of an MAE. *See IBP*, 789 A.2d at 70.

The Court thought profitability should be irrelevant because "the

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[213] Op.140.

[214] Op.127.

[215] Op.140-42.

[216] A10699.

[217] Op.140.

opportunity cost on a relative basis [c]ould [still] be quite high".[218] But Fresenius has conceded that the transaction's anticipated rate of return remains above its cost of capital.[219]

The Court assumed the MAE clause must be more permissive than the "doctrine of frustration of purpose [which] already operates to discharge a contracting party's obligations" when a deal becomes unprofitable.[220] But there is no evidence the parties' intent had anything to do with the frustration of purpose doctrine. Rather, as the Merger Agreement makes clear, their intent was to opt *in* to the Delaware MAE framework—which looks to profitability as a significant consideration, *see IBP*, 789 A.2d at 70.

[218] Op.141.

[219] A16106.

[220] Op.141.

## II. THE COURT ERRED IN FINDING A REGULATORY MAE.

### A. Question Presented

Did the Court err by assessing quantitative materiality based on its own "intuition and experience" rather than evidence in the record; assessing qualitative materiality based on warranties that were not made; and eliminating the "unknown event" requirement from the MAE standard? (A16013-033.)

### B. Scope of Review

*See* §I.B.

### C. Merits of Argument

#### 1. The Court Failed To Appropriately Assess Quantitative Materiality.

The Court's determination that DI issues at Akorn are financially material proceeds in four steps. The Court:

1. Rejected both parties' evidence of financial impact.[221]
2. Substituted its own "rough estimate" of $900M—an amount neither party advocated.[222]
3. Divided $900M by $4.3B—the cash merger consideration—to arrive at a 21% value figure.[223]
4. Determined based on its "intuition and experience" that amounts exceeding 20% constitute an MAE.[224]

[221] Op.179-84.

[222] Op.184.

[223] Op.184.

[224] Op.185-86.

This contains at least six errors.

*First*, Step 1 established a failure of proof that should have been dispositive. The Court rejected Fresenius's $1.9B Cerafa estimate as a "worst-case scenario in which every product at Akorn has to be fixed" and found it "more likely... that only some of Akorn's products will require revalidation and that the level of disruption and delay will not be quite so extensive as Fresenius projects".[225] Fresenius bore the burden of proof;[226] its failure to submit reliable evidence of *actual* financial impact should have been fatal. *See Frontier*, 2005 WL 1039027, at *36 (no MAE because asserting party "simply has not provided that foundation").

*Second*, the Court rejected Akorn's financial impact evidence at Step 1 by entirely ignoring two of Akorn's expert economists. Akorn submitted three types of financial impact evidence:

- **<u>On-market products</u>**: An unrebutted analysis by Nicholson[227] modelled the revenue impact if Akorn were forced to withdraw each on-market drug with potential DI concerns at the time of trial—concluding the impact would not exceed $47.7M (or 4.5%) of revenues in any year.[228]

[225] Op.183.

[226] Op.157.

[227] A12089-132, A14463-464; A3979, A3982-84, A3993; A16020.

[228] A12089-132, A14463-464.

- **Pipeline products**: An unrebutted analysis by Gompers[229] modelled the valuation impact of hypothetical 2-year delays of pipeline products at each facility[230]—concluding the combined impact of a delay at both Decatur and Somerset (the facilities mentioned in the Opinion as receiving adverse FDA inspections results[231]) would be a loss of $33.5M to $51.2M of Akorn's present value.[232]

- **Remediation outlays**: An analysis by Akorn management forecasted DI remediation outlays of roughly $44M[233]—or roughly 0.4% to 0.6% of enterprise value—over three years.[234]

Focusing exclusively on the third category, the Court found "Akorn's estimate contemplates direct outlays of $44M *with no other effect on Akorn's value*".[235] But the Court ignored the "other effect on Akorn's value" modelled by Nicholson and Gompers. Had Fresenius carried its burden of identifying products to be withdrawn or facilities that would suffer delays, the Court could have consulted these analyses by respected economists to accurately assess financial impact, rather than "suspect[ing]" it was "the vicinity of the midpoint of the parties' competing submissions".[236] Fresenius did not carry that burden—nowhere

[229] A13466-520; A16032-33.

[230] A13466-520.

[231] Op.100-02, 108-09.

[232] A13495-98.

[233] A11740.

[234] A12044-46/¶¶100-06.

[235] Op.179.

[236] Op.184.

does the Opinion identify a single product that must be redeveloped.

*Third*, at Step 2, the Opinion's selection of a $900M figure for which no party advocated was not "the product of an orderly and logical deductive process". *Nixon v. Blackwell*, 626 A.2d 1366, 1375 (Del. 1993).

As Henriksson acknowledged, Fresenius's $1.9B estimate assumed they "have to throw out everything that's ever been done by way of research and development at Akorn and essentially start a new company".[237] The Court rejected that "worst case scenario",[238] but its solution of simply dividing it in half is no more reliable. *See DFC Glob. v. Muirfield Value Partners*, 172 A.3d 346, 388 (Del. 2017) (court abused its discretion by failing to "explain[], with reference to the economic facts..., why it is according a certain weight to a certain indicator of value").

There is no evidence that $900M accurately measures the cost of the Akorn products, facilities or systems that need "to be fixed" or the time horizon necessary to fix them.[239] It is a guess based on what "makes intuitive sense to" the Court.[240] *See Frontier*, 2005 WL 1039027, at *39 ("Holly asked the Court to

[237] A4533/1007:21-23 (Henriksson).

[238] Op.183.

[239] Cerulean believed its entire remediation plan for Decatur would cost only $1.1-1.2M, A763/333:8-20 (Avellanet), a figure ignored by the Court.

[240] Op.184.

assign a... speculative, [damages] number. The Court declines Holly's invitation to guess.").

The Opinion's effort to bolster its estimate by referring to the four-page expert report submitted by Gokhale fails.[241] The Court rejected Cerafa on the grounds that "only some of Akorn's products will require revalidation".[242] Yet Gokhale's $800M estimate assumes a two-year delay into perpetuity of "every product" in Akorn's pipeline (including those not yet identified for development)—not "only some".[243] If anything, Gokhale's projection that a delay of "every product" would cost $800M *undercuts* the Court's hypothesis that a delay of "only some" products would cost $900M. The Opinion further ignores Gompers's rebuttal report, which explained that the sensitivity of Gokhale's methodology's to extreme assumptions renders it unreliable.[244] That Gokhale's estimate of $800M is within $100M of the Court's "mid-point" guess is coincidence, not evidence of reliability.

*Fourth*, at Step 3, the Court selected an artificially low denominator that did not reflect Fresenius's *actual* estimate of Akorn's value. Had the Court

[241] Op.183-84.

[242] Op.183.

[243] A3891/48:19-25 (Gokhale).

[244] A13474-84/¶¶17-52.

included the $450M in assumption of debt[245] in its denominator, it would have derived a decline of 19%—less than the 20% threshold the Court deemed material. Had it used $5.572B (Fresenius's calculation of enterprise value without synergies and one-time costs)[246] the decline would be 16%. And had it used Fresenius's own $6.234B estimate of Akorn's enterprise value at signing,[247] the decline would be 14%, underscoring the arbitrariness of the analysis.

*Fifth*, at Step 4 the Court found another failure of proof:

> "[T]he parties have not provided much assistance in determining whether remediation costs equal to approximately 20% of... value would constitute an amount that would 'be material when viewed from the longer-term perspective of a reasonable acquiror.'... It would have been helpful to have access to expert testimony or studies.... No one addressed these issues."[248]

That was Fresenius's failure, one the Court attempted to remedy by substituting its "own intuition and experience (admittedly as a lawyer and judge rather than as a buyer or seller of businesses)".[249] But "[t]he court's decision should not be the product solely of subjective, reflexive impressions based primarily on suspicion or what has sometimes been called the 'smell test.'" *See Nixon*, 626 A.2d at 1378.

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[245] A7287-90.

[246] A10653.

[247] *Id.*

[248] Op.185.

[249] Op.185-86.

*Sixth*, to bolster its intuition, the Court relied on irrelevant comparisons:

- **Bear markets**:[250] A market-wide loss of 20% indicates a fundamental problem in the economy, not "a broad cultural sense" that 20% is a material number. Individual stocks (Fresenius's included) experience drops of 20% with some frequency.

- **Renegotiated deals**:[251] The "[o]ne unpublished study" on which the Court relies uses MAE criteria far looser than the legal definition—asserting that "MAEs are common" and appear in "9% of... sample acquisitions".[252] The fact that buyers settle for renegotiation where there has been a >15% value decline suggests that 15% is *not* enough to prove an MAE.

- **Stock collars**:[253] Even if a 10% change in the value of stock-based merger consideration is sufficiently material to require that "deal consideration be[] handled differently",[254] it says nothing of what change in the seller's fundamental value is so material as to permit a party to terminate.[255] That collar provisions appear in deals that *also* have MAE clauses shows that collars apply to changes insufficient to trigger an MAE.

- **Reverse termination fees**:[256] These are typically used in private equity deals, and the articles the Court cites focus on private equity transactions. That financial buyers sometimes negotiate for a

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[250] Op.187.

[251] Op.187-88.

[252] Denis & Macias, *Material Adverse Change Clauses and Acquisition Dynamics*, 48 J. Fin. & Quantitative Analysis, No. 3 819, 819-20 (2013) (published version).

[253] Op.188-89.

[254] Op.189.

[255] *See* Adams, *A Manual of Style for Contract Drafting*, §§9.3-9.4 (4th ed. 2017).

[256] Op.190.

> termination option in exchange for 3% to 6% of transaction value says nothing of the value decrease sufficient to justify a *strategic* buyer in walking away from a deal that *lacks* a bargained-for option.

2. The Court Failed To Appropriately Assess Qualitative Materiality.

The Court's assessment of "qualitative" materiality focuses on the "deviation between Akorn's as-represented condition and its actual condition",[257] incorrectly concluding that "Akorn has gone from representing itself as an FDA-compliant company... to a company in persistent, serious violation of FDA requirements".[258]

In reality, each warranty cited in the Opinion includes a carve-out for non-compliance that would not reach the level of an MAE—language omitted from the warranty excerpts in the Opinion.[259] Akorn never "represent[ed] itself as an FDA-compliant company". No generics company, including Fresenius (which received two Warning Letters in 2017 and is under criminal investigation[260]), could warrant absolute compliance. In reality, Fresenius assumed the risk of any regulatory non-compliance falling short of an MAE. By measuring qualitative materiality against absolute compliance, the Court based its analysis on a straw

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[257] Op.161.

[258] *Id*. 178.

[259] *Compare* Op.160-61, *with* A4729-31/§3.18.

[260] A14105-08; A14116-19; A14352; A4536/1019:3-15 (Henriksson).

man.[261]

3. The Court Failed to Assess "Unknown Events".

Finally, for the reasons explained in §I.C.1, the Court erroneously concluded that the MAE standard, when qualifying a warranty, loses the "unknown event" element and merely "stands in for a specific dollar figure".[262]

To permit Fresenius to terminate the deal based on issues it identified in diligence and planned to address through its business plan would amount to a unilateral termination right. *See Interbake*, 2017 WL 2729860, at *22. As discussed above, Fresenius's diligence identified significant regulatory concerns, including Akorn's facilities, equipment, regulatory submissions and "[c]ommitment to quality".[263] (*See* SOF.) It planned to address those concerns by making hundreds of millions of capital expenditures and closing or divesting facilities.[264] The Opinion's reliance on *Cobalt Operating v. James Crystal Enterprises,* 2007 WL 2142926 (Del. Ch.), and similar cases[265] is inapposite. Those warranties supported bargained-for indemnification rights, consciously shifting long-term risk to the seller. The warranties here were MAE-qualified and

[261] The same flaw dooms the Court's cure analysis. Op.201-03. Cure does not mean full compliance—only sufficient compliance to avoid an MAE.

[262] Op.195-96.

[263] A6148-51; A8842-48; A4528-29/990:17-991:10 (Henriksson).

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

[265] Op.192/n.756.

supported no indemnification protections. Permitting Fresenius to terminate based on long-term risks that it recognized and assumed undermines the parties' bargain.

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

### A. Question Presented

Did the Court err in creating a new standard for material breach; finding breaches of the ordinary course covenant without empirical basis; and holding ordinary course breaches could be cured only by remediating all DI issues "dat[ing] back years"? (A16043-052.)

### B. Scope of Review

*See* §I.B.

### C. Merits of Argument

1. The Court Applied the Incorrect Materiality Standard.

Rather than apply the well-established standard for material breach, the Court imported a materiality standard from securities law, encompassing "breaches [that] are not severe enough to excuse a counterparty's performance under a common law analysis".[266] It reasoned that by using the common phrase "in all material respects", the parties intended to replace the material breach standard with a "total mix" test.[267] That conclusion has no legal or factual basis.

A "material" breach that excuses performance goes "to the root or essence of the agreement between the parties, or... defeats the object of the parties

[266] Op.212.

[267] Op.211-12.

in entering into the contract". *Interbake*, 2017 WL 2729860, at *28.[268] The Agreement was drafted against the background law defining "material[ity]" in the context of excusal of performance.[269] Authorities generally use the phrase "in all material respects" (and similar language) interchangeably with "material breach". *Ameristar Casinos v. Resorts Int'l Holdings*, 2010 WL 1875631, at *3 (Del. Ch.); *In re Sugarhouse Realty*, 192 B.R. 355, 378 (Bankr. E.D. Pa. 1996); Kling & Nugent §11.03[1], [3].

The Court cited no evidence the parties intended to create a new materiality standard; there is none. The Opinion reasons that treatises on M&A agreements "suggest" that the phrase "in all material respects" in a closing condition is intended to "eliminate the possibility that an immaterial issue could enable a party to claim breach or the failure of a condition".[270] None of those authorities suggests the phrase "in all material respects" is meant to relax the background standard.[271]

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[268] *2009 Caiola Family Trust v. PWA*, 2015 WL 6007596, at *18 (Del. Ch.); *BioLife Sols. v. Endocare*, 838 A.2d 268, 278 (Del. Ch. 2003); *In re Mobileactive Media*, 2013 WL 297950, at *13 (Del. Ch.); *Preferred Invs. Servs. v. T&H Bail Bonds*, 2013 WL 3934992, at *11 (Del. Ch.); Restatement §241.

[269] Kling & Nugent §14.01/n.3 (citing material breach standard of Restatement §241 as governing issues of materiality).

[270] Op.2019-10.

[271] Kling & Nugent §§14.02[3], 14.02[7]; Adams, *Manual of Style* at 213 ("In an M&A context... material refers to information that would have caused the buyer not to enter into the agreement....").

The only case cited for this lower materiality threshold is *Frontier*,[272] which, although it mentions the "total mix" standard (in the context of a warranty, not a covenant), applies a more demanding test. The warranty in *Frontier* was breached by information that, according to that court, would have caused the buyer "not [to] have entered into the Merger Agreement", meaning it necessarily changed the "total mix" of information. 2005 WL 1039027, at *38 & n.236. However, the Court focused on the "potential adverse consequences" of the information—noting that although materiality and an MAE are "analytically distinct", "their application may be influenced by the same factors"—and found the information *not* material because any adverse financial impact was too speculative. *Id*. at *38.

Finally, the Court's ruling makes no sense in the context of the Merger Agreement. "[C]ourts must read the specific provisions of the contract in light of the entire contract." *CB&I*, 166 A.3d at 913-14. The Agreement contains extensive protections to provide both parties with deal certainty. Having bargained for these protections, why would the parties want to make it *easier* to walk away from the deal?[273] And if they did, why not say so expressly?

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[272] Op.211. *Cooper Tire & Rubber v. Apollo (Mauritius) Holdings*, also cited by the Court, *see* Op.211/n.786, never states which standard it applied. *See* 2014 WL 5654305, at *13-17.

[273] Op.212.

2. The Court's Conclusion That Akorn Breached Is Unsupported by Evidence.

"[O]rdinary course of business" means the "normal routine in managing a trade of business". *Ivize of Milwaukee v. Compex Litig. Support*, 2009 WL 1111179, at *8 (Del. Ch.). It calls for an empirical assessment of how businesses *actually* behave within the industry; not how a Court thinks they should.

The record contained two sets of data in this regard: (i) Fresenius's own extensive history of DI issues; and (ii) a comparative analysis by Akorn's expert Kaufman of hundreds of FDA Warning Letters and Forms 483. No Fresenius expert conducted any empirical analysis.[274] The Court disregarded Akorn's evidence and engaged in no comparative analysis to support its ordinary course conclusions.

i. *Akorn Continued DI Work.*

The Court ruled that a generics company "operating in the ordinary course of business is obligated to maintain a DI system that enables the company to prove" the accuracy of its data.[275] It did not consider the actual state of industry compliance. Kaufman identified 166 Forms 483 and 188 FDA Warning Letters issued for DI problems.[276] In 2017 alone, Fresenius received two Warning Letters

[274] A4643-44/1310:24-1311:3 (Klener); A3805/84:15-18 (George); A2707/129:25-130:7 (Chesney); A4634-35/1272:9-1275:4 (Chesney).

[275] Op.217.

[276] A12197/¶149; A7701-22.

and one Untitled Letter for DI deficiencies at three different facilities.[277]

The Court found Akorn violated the ordinary course standard because "Akorn senior management instructed its IT department not to devote any resources to DI projects" and "prevented any DI work that required IT resources from getting off the ground".[278] That was error.

The Court ignored extensive trial evidence concerning the parties' integration planning process.[279] This involved resetting IT priorities and pausing some projects;[280] it did *not* involve devoting *no* resources to DI.[281] Akorn employees "were directed not to work on DI projects *that were not approved by the PRB*".[282] However, "there were several DI projects that *were* approved by PRB that [Akorn] continued to work on throughout that year".[283] For example, A9391-450, a February 2018 "DI Chronological Overview" lists extensive DI improvement steps undertaken throughout 2017.

The Court found "*no evidence* that Fresenius ever gave approval for

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[277] A4536/1019:3-10 (Henriksson); A14105-08; A14116-19; A9077-88; A946/217:19-218:5 (Schreiner).

[278] Op.52/n.234, 217.

[279] A15953-57.

[280] A4261/224:1-19 (Pramik); A1916-17/245:24-246:20 (Pramik).

[281] A4263-64/232:19-233:12 (Pramik); A9391-450.

[282] A4263-64/232:19-233:12 (Pramik).

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

Akorn to stop working on DI projects".[284] In reality, there was quite strong evidence. Pramik testified that she discussed *all* PRB-paused DI project with Fresenius over the course of more than 50 calls and meetings.[285] The Court dismissed Pramik's unrebutted testimony in its entirety—not because it found her to be non-credible, but because she "gave much of her testimony in response to leading questions based on a demonstrative exhibit".[286] But the testimony on integration planning refers to no demonstrative exhibit, and the questions were not leading.[287]

The Court found Akorn "did not begin to address its DI issues until March 2018", when Akorn also "*began* responding to the issues raised in the Cerulean audits".[288] In reality, Akorn continued work on numerous DI initiatives in 2017, including:

- addressing priority DI issues at Decatur;[289]
- implementing OpenLab chromatography software at two locations;[290] and

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[284] Op.53.

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

[286] Op.51-52/n.234.

[287] A4262/225:2-226:24 (Pramik); A4259/215:23-216:1 (Pramik) (overruling leading objection).

[288] Op.51-52/n.234, 85, 217.

[289] A9403.

[290] A4258-59/212:19-214:21 (Pramik).

- upgrading computers and laboratory software.[291]

As of February 2018, Akorn had completed 32% of Cerulean's recommended CAPAs[292] and remediated seven of 17 Cerulean observations[293] at the Decatur and Somerset facilities, respectively.

The Court's true complaint is not that *no* resources were devoted to DI, rather that it felt those resources were inadequate.[294] But allocation of finite resources is precisely what companies do in the ordinary course—particularly during integration. Fresenius submitted no empirical evidence that Akorn's level of DI resourcing was different from similarly situated companies.

ii. *Akorn's Audits Were Ordinary Course.*

The Court found that "a generic pharmaceutical company operating in the ordinary course of business is obligated to conduct regular audits".[295] It cited no FDA guidance or empirical evidence concerning companies' audit practices.[296] It still found that "Akorn departed from this aspect of ordinary course operations...

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[291] A9402; A4257/207:1-11 (Pramik).

[292] A10506.

[293] A9410-26.

[294] Op.51-52/n.234.

[295] Op.216.

[296] FDA guidance recommends that firms conduct internal audits, but does not prescribe a frequency or approach. *See* FDA, *Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations*, 21-22 (Sept. 2006), https://www.fda.gov/downloads/Drugs/Guidances/UCM070337.pdf.

by cancelling regular audits at four sites in favor of verification audits".[297] This was error.

As noted above (*see* SOF), every one of Akorn's five manufacturing facilities has undergone a full-scale, ordinary course audit since signing.[298] Only one manufacturing facility (due to a scheduling conflict with an FDA inspection) and two non-manufacturing, non-R&D facilities conducted verification audits instead of regular audits in 2017.[299] A fourth site did not cancel audits—it received an extra one.[300]

There is no record evidence as to whether this is consistent or inconsistent with industry practices. The Court made no effort to assess that question.

iii. *Akorn's Investigation and FDA Presentation Were Appropriate.*

The Court concluded that Akorn chose not to investigate the anonymous letters;[301] chose instead to have Cravath "front run" the Sidley

[297] Op.216.

[298] A2453/55:23-56:16 (Gill); A4210/17:24-18:12 (Wasserkrug); A8771; A10462-85.

[299] A24543-54/56:21-58:18 (Gill); A4210/17:24-18:12 (Wasserkrug).

[300] A7402-27 (full audit); A8793-804 (verification audit); A8262.

[301] Op.69-70/n.321.

investigation;[302] and gave a misleading presentation to FDA.[303] Each is unsupported.

After receiving the anonymous letters, Bonaccorsi intended to begin investigating immediately.[304] This alarmed Ducker, who viewed an Akorn investigation as "unacceptable".[305] Bonaccorsi testified that in a phone call shortly thereafter:

> "*[Silhavy] told me not to take action*; that, in fact, due to the issues raised in the letters, due to the fact that the letters were sent to Fresenius and not to Akorn, that Fresenius *saw it as their responsibility and their prerogative to take charge of the investigation*.
>
> ...
>
> I was a bit surprised. I did comment that I'm obligated to investigate, as these matters relate to Akorn.
>
> He acknowledged that *but asked me to not take any action* until they decided what the next steps would be...."[306]

Fresenius has never argued Bonaccorsi's recollection of the conversation was inaccurate, and Silhavy did not testify otherwise. Nor was it unreasonable for Akorn in November to permit Fresenius to take the lead in investigating; it

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[302] Op.218.

[303] Op.219.

[304] A8432-33.

[305] A8431.

[306] A4503/887:13-889:7 (Bonaccorsi); A3444/102:12-17 (Bonaccorsi).

believed Fresenius would own it within months.[307]

Although the Court asserts Akorn had Cravath "front run the investigation... and head off any problems",[308] the facts surrounding one of the central DI issues at trial—the azithromycin incident—were discovered and developed *by Cravath*.[309] Rather than "head off problems", Cravath affirmatively brought the issue to Fresenius's attention, understanding that the parties had "join[ed] in an investigation".[310]

The Court ruled Akorn and its counsel "ma[de] a misleading presentation to the FDA" during the March meeting.[311] It criticized the lawyers present for "a one-sided, overly sunny depiction" that "present[ed] Akorn to the FDA in the best light possible"[312]—faulting them for the ordinary course activity of advocating for positive regulatory outcomes on behalf of a client. The Court

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[307] A4610/1175:3-8 (Sturm).

[308] Op.218.

[309] Op.78-81.

[310] A8805-06.

[311] Op.219.

[312] Op.93/n.434, 94. The Court also criticized Akorn's regulatory counsel for a sidebar call before the meeting, Op.92/n.427, relying on the assessment by Sidley (who was not on the call) of produced talking points, Op.91/n.425. Akorn's regulatory counsel gave unrebutted testimony that he did not make the statements Sidley alleged were misleading. *Compare* A4545/1055:12-1058:19 (Sheers), *with* A2194-96/245:4-250:8 (Levine).

faulted Akorn for presenting the investigation as "one conducted jointly".[313] But Akorn believed it *was* a joint investigation and executed a CIA saying so.[314] The Court faults Akorn for suggesting that it was involved in "65+ interviews of current and former Akorn personnel" and "lab walk-throughs", but Cravath *was* present for those interviews and walk-throughs.[315] It faults Akorn for representing that the investigation was "supported by Akorn GQC".[316] But it was.[317]

In particular, the Court faulted Akorn for a single bullet in the 38-page presentation stating: "Silverberg authorized submission of AET data without knowing stability table containing particulate matter data would be submitted"[318]—a conclusion with which the Court disagreed. Stuart testified:

> "I explained to [FDA] that... *Silverberg was on notice that there was a pending ANDA at the time that he authorized submission of the CRL that had a problematic data point* in it because those tests had probably not been performed; and that his submission or *his authorization of the submission of the CRL response, knowing that fact, was wholly inexcusable*; and that, for that reason, among others... he had been removed from his role.
>
> I *also* stated that... at the time that Mr. Silverberg authorized submission... the CRL response that he

[313] Op.92.

[314] A8805-06; A4432/728:12-24 (Stuart).

[315] Op.74; A8780-81; A10537; A3287/14:11-15:19 (Stuart).

[316] Op.93.

[317] A4422/686:12-688:12 (Stuart).

[318] Op.93.

> received did not contain that problematic data. And he told us in his interview that that was his view. And we verified that by doing a forensic look at his e-mail."[319]

The Court concluded the presentation was misleading to FDA because Stuart previously characterized Silverberg's explanation as "not satisfactory".[320] Again, at trial Stuart distinguished between two issues: he believed Silverberg "absolutely did not want false data to be submitted to the FDA in the CRL response"; but "[t]hat did not excuse his submission of the CRL response, knowing that there was already problematic data on file.... *conduct* which I found unsatisfactory."[321]

The Court reached its own view of Silverberg's mental state based on a review of the documentary record.[322] (Silverberg did not testify at trial.) It substituted its own judgment for Stuart's—focusing exclusively on the written bullet to the exclusion of Stuart's trial testimony—to find Akorn misled FDA. FDA was informed of the alleged misrepresentation through Sidley's letters,[323] but has never asked about the issue or expressed the view that it was misled.[324]

The Court cites cross-examination testimony by Kaufman, Akorn's

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[319] A4429/714:2-715:1 (Stuart).

[320] Op.82, 94.

[321] A4430/717:15-22 (Stuart).

[322] Op.19, 81.

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

[324] A4432/725:13-18 (Stuart).

litigation expert, that Akorn was "not fully transparent" during the FDA meeting (not that it misled FDA).[325] Kaufman was not at the FDA meeting; testified before Stuart and did not hear his testimony; never read Stuart's deposition transcript; and never spoke to Stuart or Silverberg.[326] She was prepared to assess whether Akorn's DI status is consistent with the industry—not statements made in an FDA meeting she did not attend.

3. Akorn Cured Any Supposed Breaches.

The Court held that Akorn's ordinary course breach was incurable because the alleged DI deficiencies "dated back years".[327] But, by the Court's own admission, "Akorn's [ordinary course] obligation only began in April 2017".[328] To cure any supposed breach, Akorn was obligated to resume ordinary operation[329]—as the Court recognized in finding Fresenius cured its hell-or-high-water breach when it "changed course... and returned" to compliant conduct.[330]

Each of the supposed breaches has been cured. Akorn's IT function has always been willing to invest resources into DI projects, and many new

[325] Op.219.

[326] A3141/50:9-17 (Kaufman).

[327] Op.222.

[328] Op.220.

[329] A4736-41/§5.01.

[330] Op.242.

remedial projects are ongoing.[331] Each of Akorn's facilities has received a full scale audit since signing.[332] And Akorn provided Sidley and Fresenius's allegations to FDA, curing any supposedly misleading statements in the March meeting.[333] The Court itself found that after Akorn's meeting with FDA it "start[ed] acting like a generic pharmaceutical company operating in the ordinary course of business".[334]

[331] A10548-68; A10710-26; A15701-10; A11736-45; A13839-14048; A4234/115:13-16 (Wasserkrug).

[332] A2454/58:16-18, 59:14-60:23 (Gill); A10462-85; A11039-328.

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

[334] Op.219.

## IV. THE COURT ERRED IN FINDING THAT FRESENIUS'S CONDUCT COMPORTED WITH ITS EFFORTS COVENANTS.

### A. Question Presented

Did the Court err in concluding Fresenius could take steps to cause the failure of the Merger Agreement so long as its "remorse was justified"?[335] (A16002-012.)

### B. Scope of Review

*See* §I.B.

### C. Merits of Argument

The Merger Agreement obligates Fresenius to "cooperate" and use "reasonable best efforts" to take "all actions... necessary, proper or advisable" to close the deal.[336] This imposed not only a negative duty not to "'obstruct', 'derail' [or] 'delay'" the close, *In re Oxbow Carbon Unitholder Litig.*, 2018 WL 818760, at *68 (Del. Ch.), but also an affirmative one "to take all reasonable steps to solve problems and consummate the transaction", *Williams Cos. v. Energy Transfer Equity*, 159 A.3d 264, 272 (Del. 2017). It required Fresenius to be transparent and cooperative when obstacles arose. *WaveDivision Holdings v. Millennium Dig. Media*, 2010 WL 3706624, at *18 (Del. Ch.); *Hexion*, 965 A.2d at 749-50.

Fresenius breached the negative duty by spending "most of [its]

[335] Op.229.

[336] A4745/§5.03(a).

energy and resources trying to design ways to thwart" the deal, rather than close it. *Oxbow*, 2018 WL 818760, at *68. As discussed above (*see* SOF), it assembled an advisory team to create a record for termination; executed a CIA falsely representing that the parties had a "mutual interest arising under the Merger Agreement" that Fresenius wanted to terminate; falsely assured Akorn that "this was not a litigation exercise"; instructed advisors to find a "smoking gun"; pressured them to "call[] these guys liars and cheaters"; dragged its feet on antitrust approval; conflicted Akorn's FDA counsel; attempted to "stimulate" FDA sanctions; and developed a secret made-for-litigation "materiality" model at litigators' direction. The Court deemed this "reasonable", distinguishing *IBP* and *Hexion* on the grounds that Fresenius's "remorse was justified".[337]

The standard of conduct is not that of a buyer with "justified remorse". It is that of an "enthusiastic partner" taking "*all reasonable steps* to solve problems and consummate the transaction". *Williams*, 159 A.3d at 272-73. There is no "justifiable remorse" carve-out to the covenant.[338] The Court did not consider whether Fresenius:

- took "all reasonable steps" to try to close, *Williams*, 159 A.3d at 272;

[337] Op.229-32.

[338] Op.151-52/n.626.

- acted as promptly as reasonably practicable, A4745-46/§§5.03(a), (c);
- was transparent about its intentions, *WaveDivision*, 2010 WL 3706624, at *18; or
- sought to cooperate and problem solve on DI issues, *Hexion*, 965 A.2d at 749-50.

To the contrary, it recognized that "Fresenius did not want to go the extra mile",[339] and believed the Merger Agreement "did not require a single-minded drive to closing".[340]

In essence, the Court concluded that Fresenius had no best-efforts obligation once it experienced "justified" buyer's remorse. That is not the law. Even if Fresenius believed it had a good faith reason to investigate, it still had an obligation to conduct that investigation in a way that did not deceive Akorn, stall the deal, or exacerbate any financial or regulatory challenges.

The Court compounded this error by not shifting the burden to Fresenius to prove that its breaches did not materially contribute to the failure of the relevant closing conditions. *Williams*, 159 A.3d at 273. Viewed through this lens, Fresenius cannot prove that its failure to work aggressively towards antitrust approval, conduct a true joint investigation, be upfront about its concerns, exchange findings and methodologies, have an open dialogue about remediation,

[339] Op.232.

[340] Op.231.

leverage its "larger, better equipped quality systems" and present a united front to the FDA did not materially contribute to the deal's failure to close before the outside date.[341]

The Court's failure to consider this question was error. By endorsing Fresenius's conduct, the Opinion created a new blueprint for remorseful buyers to exit Delaware merger agreements.

[341] A16390.

## CONCLUSION

The Opinion should be vacated and partial final judgment reversed.

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