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Case No. 2018-0300-JTL

IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

AKORN, INC.,	)	
	)	
Plaintiff and Counterclaim Defendant,	)	
	)	
v.	)	C.A. No. 2018–0300–JTL
	)	
FRESENIUS KABI AG,	)	
QUERCUS ACQUISITION, INC., and	)	
FRESENIUS SE & CO. KGAA,	)	
	)	
Defendants and Counterclaim Plaintiffs.	)	

MEMORANDUM OPINION

Date Submitted: September 25, 2018
Date Decided: October 1, 2018

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LASTER, V.C.

Pursuant to an agreement and plan of merger dated April 24, 2017 (the "Merger Agreement"), Fresenius Kabi AG agreed to acquire Akorn, Inc. In the Merger Agreement, Akorn made extensive representations about its compliance with applicable regulatory requirements and committed to use commercially reasonable efforts to operate in the ordinary course of business between signing and closing. Both Fresenius and Akorn committed to use their reasonable best efforts to complete the merger, and Fresenius committed to take all actions necessary to secure antitrust approval, without any efforts-based qualification. The parties agreed to a contractually defined "Outside Date" for closing, set initially at April 24, 2018. If the need for antitrust approval was the only condition to closing that had still not been met at that point, then the Outside Date would extend automatically to July 24, 2018.

If the merger closed, then each share of Akorn common stock would be converted into the right to receive $34 per share. Closing, however, was not a foregone conclusion. First, Fresenius's obligation to close was conditioned on Akorn's representations having been true and correct both at signing and at closing, except where the failure to be true and correct would not reasonably be expected to have a contractually defined "Material Adverse Effect." If this condition was not met and could not be cured by the Outside Date, then Fresenius could terminate the Merger Agreement. Fresenius could not exercise this termination right, however, if Fresenius was in material breach of its own obligations under the Merger Agreement.

Second, Fresenius's obligation to close was conditioned on Akorn having complied in all material respects with its obligations under the Merger Agreement. Once again, if

this condition was not met and could not be cured by the Outside Date, then Fresenius could terminate the Merger Agreement. Here too, Fresenius could not exercise the termination right if Fresenius was in material breach of its own obligations under the Merger Agreement.

Third, Fresenius's obligation to close was conditioned on Akorn not having suffered a Material Adverse Effect. The failure of this condition did not give Fresenius a right to terminate. Once the Outside Date passed, however, either Fresenius or Akorn could terminate, as long as the terminating party's own breach of the Merger Agreement had not been a principal cause of or resulted in the parties' failure to close before the Outside Date.

Akorn and Fresenius entered into the Merger Agreement shortly after announcing their results for the first quarter of 2017. During the second quarter of 2017, Akorn's business performance fell off a cliff, delivering results that fell materially below Akorn's prior-year performance on a year-over-year basis. The dismal results shocked Fresenius, because on the same date that the parties signed the Merger Agreement, Akorn had reaffirmed its full-year guidance for 2018 at Fresenius's request. Akorn's performance fell well below the guidance, forcing management to adjust Akorn's full-year guidance downward. Fresenius consulted with Akorn about the reasons for the sudden decline, which Akorn attributed to unexpected competition and the loss of a key contract.

Akorn's CEO reassured Fresenius that the downturn was temporary, but Akorn's performance continued to slide in July and again in August 2018. By September, Fresenius's management team had become concerned that Akorn had suffered a Material

Adverse Effect, although its legal counsel was not certain at that point that Fresenius could satisfy the high burden imposed by Delaware law.

In October 2017, Fresenius received a letter from an anonymous whistleblower who made disturbing allegations about Akorn's product development process failing to comply with regulatory requirements. In November 2017, Fresenius received a longer version of the letter that provided additional details and made equally disturbing allegations about Akorn's quality compliance programs. The letters called into question whether Akorn's representations regarding regulatory compliance were accurate and whether Akorn had been operating in the ordinary course of business.

Fresenius provided the letters to Akorn. Although Fresenius understood that Akorn would have to investigate the allegations in the ordinary course of business, Fresenius informed Akorn that Fresenius also needed to conduct its own investigation into the allegations. Under the Merger Agreement, Fresenius had bargained for a right of reasonable access to Akorn's officers, employees, and information so that Fresenius could evaluate Akorn's contractual compliance and determine whether the conditions to closing were met. Invoking this right, Fresenius had expert attorneys and advisors investigate the issues raised by the whistleblower letters.

Fresenius's investigation uncovered serious and pervasive data integrity problems that rendered Akorn's representations about its regulatory compliance sufficiently inaccurate that the deviation between Akorn's actual condition and its as-represented condition would reasonably be expected to result in a Material Adverse Effect. During the course of the investigation, tensions escalated between the parties. Matters came to a head

after Akorn downplayed its problems and oversold its remedial efforts in a presentation to its primary regulator, the United States Food and Drug Administration ("FDA"). As one of Akorn's own experts recognized at trial, Akorn was not fully transparent with the FDA. Put more bluntly, the presentation was misleading. From Fresenius's standpoint, Akorn was not conducting its operations in the ordinary course of business, providing an additional basis for termination.

During this same period, Akorn's business performance continued to deteriorate. In mid-April 2018, Fresenius sent Akorn a letter explaining why conditions to closing could not be met and identifying contractual bases for terminating the Merger Agreement. Fresenius nevertheless offered to extend the Outside Date if Akorn believed that further investigation would enable Akorn to resolve its difficulties. Akorn declined.

On April 22, 2018, Fresenius gave notice that it was terminating the Merger Agreement. Fresenius asserted that Akorn's representations regarding regulatory compliance were so incorrect that the deviation would reasonably be expected to result in a Material Adverse Effect. Fresenius also cited Akorn's failure to comply in all material respects with its contractual obligations under the Merger Agreement, including Akorn's obligation to use commercially reasonable efforts to operate in the ordinary course of business in all material respects. Fresenius also cited the section in the Merger Agreement that conditioned Fresenius's obligation to close on Akorn not having suffered a Material Adverse Effect.

Akorn responded by filing this action, which seeks a declaration that Fresenius's attempt to terminate the Merger Agreement was invalid and a decree of specific

performance compelling Fresenius to close. Fresenius answered and filed counterclaims, contending it validly terminated the Merger Agreement and is not required to close.

This post-trial decision rules in favor of Fresenius and against Akorn. First, Fresenius validly terminated the Merger Agreement because Akorn's representations regarding its compliance with regulatory requirements were not true and correct, and the magnitude of the inaccuracies would reasonably be expected to result in a Material Adverse Effect. Second, Fresenius validly terminated because Akorn materially breached its obligation to continue operating in the ordinary course of business between signing and closing. Third, Fresenius properly relied on the fact that Akorn has suffered a Material Adverse Effect as a basis for refusing to close.

If Fresenius had been in material breach of its own obligations under the Merger Agreement, then Fresenius could not have exercised either of the termination rights on which it relied. Akorn tried to prove that Fresenius failed to use its reasonable best efforts to complete the merger and breached its obligation to take all actions necessary to obtain antitrust approval. By piecing together bits of documents and testimony, Akorn's skilled counsel weaved a tale of buyer's remorse. I have taken this theory seriously, and there is some evidence to support it.

Having weighed the evidence and evaluated the credibility of the witnesses, I find that Fresenius fulfilled its contractual obligations. In prior cases, this court has correctly criticized buyers who agreed to acquisitions, only to have second thoughts after cyclical trends or industrywide effects negatively impacted their own businesses, and who then filed litigation in an effort to escape their agreements without consulting with the sellers.

In these cases, the buyers claimed that the sellers had suffered contractually defined material adverse effects under circumstances where the buyers themselves did not seem to believe their assertions.

This case is markedly different. Fresenius responded to a dramatic, unexpected, and company-specific downturn in Akorn's business that began in the quarter after signing. After consulting with Akorn about the reasons for the decline and receiving unconvincing answers, Fresenius appropriately began evaluating its contractual rights under the Merger Agreement. While doing so, Fresenius continued to move forward with the transaction. Later, Fresenius received whistleblower letters that made alarming allegations about data integrity issues at Akorn. Once again, Fresenius consulted with Akorn, then relied on an informational access covenant in the Merger Agreement to conduct an investigation. That too was proper, because buyers obtain informational rights so they can continue to evaluate the seller after signing and determine whether to close.

Akorn did prove that for approximately a one-week period during February 2018, Fresenius embarked on a strategy for achieving antitrust approval that would have breached its contractual obligation to take all steps necessary to satisfy that condition to closing. Fresenius promptly reversed course, and the parties were on the cusp of receiving antitrust approval when Fresenius terminated the Merger Agreement. If all other conditions to closing had been met on the initial Outside Date such that it would have extended automatically to June 24, 2018, then the parties easily would have obtained antitrust approval. Fresenius technically breached its contractual obligation, but it was not a material

breach sufficient to deprive Fresenius of its ability to exercise the termination rights on which it relied.

Any second thoughts that Fresenius had about the Merger Agreement were justified by unexpected events at Akorn. The parties agreed to provisions in the Merger Agreement that addressed those events, and Fresenius properly exercised its rights under those provisions. As a result, the Merger Agreement terminated on April 22, 2018.

I. FACTUAL BACKGROUND

A five-day trial took place on July 9–13, 2018. The parties introduced 1,892 exhibits into evidence and lodged fifty-four deposition transcripts—forty from fact witnesses and fourteen from experts. Nine fact witnesses and seven experts testified live at trial.

The parties prepared for trial during eleven weeks of highly expedited litigation. Despite the massive effort this entailed, the parties required assistance with only one significant discovery dispute, which involved contentious privilege issues. This case exemplifies how professionals can simultaneously advocate for their clients while cooperating as officers of the court. The parties were aided in this effort by a discovery facilitator who helped them craft and live by a detailed discovery plan.

My task is to make factual findings based on the record the parties generated. For that purpose, Fresenius bore the burden of proving by a preponderance of the evidence the facts supporting the exercise of its termination rights. Akorn bore the burden of proving by a preponderance of the evidence the facts necessary to establish its claim that Fresenius could not exercise those rights because Fresenius was in material breach of its own

obligations. Akorn bore the burden of proving by clear and convincing evidence the facts necessary to justify a decree of specific performance.

Fresenius would have borne the burden of proving the facts necessary to establish its affirmative defense of unclean hands. In this case, however, there was no meaningful distinction between its contractual arguments and its unclean hands defense. Fresenius simply repackaged its contractual arguments as an equitable theory. In my view, the Merger Agreement governs the parties' relationship. If there were issues or actions that could support a defense of unclean hands and which did not come within the analytical framework of the Merger Agreement, then I would have analyzed that defense. In this case, however, the facts fit neatly within the analytical framework of the Merger Agreement and point to a contract-based outcome. Under those circumstances, applying the doctrine of unclean hands would either duplicate the contractual outcome or create uncertainty by departing from the result that the parties sought to achieve for themselves. This decision therefore does not address the defense of unclean hands.

Based on these allocations of the burden of proof, the evidence supported the following findings of fact.

A. Fresenius

Defendant Fresenius Kabi AG is a pharmaceutical company headquartered in Germany.[1] It employs approximately 37,000 people worldwide, has seventy manufacturing

[1] PTO ¶ B.2. Citations in this form refer to stipulated facts in the pre-trial order. *See* Dkt. 165. Citations in the form "[Name] Tr." refer to witness testimony from the trial transcript. Citations in the form "[Name] Dep." refer to witness testimony from a

sites around the world, and is worth about €6.5 billion.[2] Its particular areas of focus lie in clinical nutrition, injectable drugs, IV solutions, and medical devices.[3] Fresenius Kabi is a signatory to the Merger Agreement.

Fresenius Kabi is the parent corporation of defendant Quercus Acquisition, Inc., a wholly owned acquisition subsidiary. Under the Merger Agreement, Quercus would merge with and into Akorn in a reverse triangular merger (the "Merger"). Although a necessary party for purposes of Akorn's request for specific performance, Quercus does not play a meaningful role in the dispute.

Fresenius Kabi is also the parent corporation of non-party Fresenius Kabi USA, LLC ("Fresenius USA"), another wholly owned subsidiary.[4] In the United States, Fresenius Kabi operates through Fresenius USA. Fresenius Kabi viewed the Merger as a way to expand its business in the United States, and personnel from Fresenius USA figure prominently in the record.

Fresenius Kabi is itself a wholly owned subsidiary of defendant Fresenius SE & Co. KGaA ("Fresenius Parent"), a German company whose shares trade publicly on the

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deposition transcript. Citations in the form "JX — at —" refer to a trial exhibit with the page designated by the last three digits of the control or JX number or, if the document lacked a control or JX number, by the internal page number. If a trial exhibit used paragraph numbers, then references are by paragraph.

[2] Henriksson Tr. 933, 1027; *see* PTO ¶ B.2.

[3] Henriksson Tr. 933–34.

[4] PTO ¶ C.2.

Frankfurt Stock Exchange.[5] Through various business segments, Fresenius Parent offers products and services for hospitals, dialysis, and outpatient treatment.[6] Fresenius Parent has been in existence for more than a century, operates in more than 100 countries, and employs approximately 277,000 people worldwide.[7] For its fiscal year 2017, Fresenius Parent had sales of approximately €34 billion and an operating profit of nearly €5 billion.[8] Fresenius Parent is a signatory to the Merger Agreement for the purpose of causing Fresenius Kabi to comply with its obligations.[9]

The resulting three-tiered corporate structure puts Fresenius Parent at the top, then Fresenius Kabi, then Fresenius USA. The corresponding human hierarchy starts with the Supervisory Board of Fresenius Parent, which plays the same role as the board of directors of a Delaware corporation. Because it is a German company, Fresenius Parent also has a Management Board, consisting of the senior executives of that entity. Since July 2016, Stephan Sturm has served as the top executive at Fresenius Parent and Chairman of the Management Board.[10] Since 2013, Mats Henriksson has served as CEO of Fresenius

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[5] *Id.* ¶¶ B.2–3.

[6] *Id.* ¶ B.3.

[7] Sturm Tr. 1171, 1195.

[8] *Id.* at 1171.

[9] JX 1 § 8.16.

[10] Sturm Tr. 1169–71.

Kabi.[11] He also serves as a member of the Management Board of Fresenius Parent.[12] For many years, John Ducker has served as President and CEO of Fresenius USA.[13]

Although critically important for many purposes, distinguishing among the Fresenius entities is generally not necessary in this decision. It therefore refers only to Fresenius, unless context requires a more specific referent.

B. Akorn

Plaintiff Akorn is a specialty generic pharmaceuticals company organized under the laws of the State of Louisiana and headquartered in Lake Forest, Illinois.[14] Akorn's stock trades publicly on NASDAQ under the symbol "AKRX."[15] Akorn is defined as the "Company" in the Merger Agreement, and this decision sometimes uses that term. During the events giving rise to this litigation, Raj Rai was its President and CEO.

Akorn's business model focuses on selectively targeting products with complex manufacturing processes or that are deliverable in alternative dose forms, such as

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[11] Henriksson Tr. 933–34.

[12] Sturm Tr. 1172.

[13] Henriksson Tr. 935–36; Bauersmith Tr. 575–76.

[14] PTO ¶ B.1. Attentive readers will have noted that none of the parties to the Merger Agreement is a Delaware entity. Even Quercus, the acquisition subsidiary, is a Louisiana corporation. The parties nevertheless chose Delaware law to govern the Merger Agreement (excluding internal affairs matters governed by Louisiana law) and selected the courts of this state as their exclusive forum for litigation. *See* JX 1 §§ 8.06 & 8.07.

[15] PTO ¶ B.1.

injectables, eye drops, oral liquids, inhalants, and nasal sprays.[16] Akorn's management team believes this strategy carries less risk and generates more consistent profit margins than other generic drug company strategies.[17] Akorn has manufacturing facilities in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; Hettlingen, Switzerland; and Paonta Sahib, India. Akorn has research and development centers in Vernon Hills, Illinois, and Cranbury, New Jersey.[18]

Akorn's primary regulator is the FDA.[19] Akorn's quality operations function is responsible for ensuring that Akorn's plants and R&D centers meet FDA requirements.[20] To carry out this function, Akorn's Global Quality Compliance ("GQC") team conducts periodic audits; Akorn also retains consultants who evaluate its sites and processes.[21]

Akorn's quality operations function is also responsible for ensuring that Akorn complies with FDA requirements when making submissions to the FDA, such as when filing an Abbreviated New Drug Application ("ANDA") to seek approval for a new generic

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[16] *See* Rai Tr. 455–56; PTO ¶ B.1.

[17] *See* Rai Tr. 456–57; *see also* Bauersmith Tr. 614; Bauersmith Dep. 111–12.

[18] Wasserkrug Tr. 7–8.

[19] *Id.* at 18–19.

[20] *Id.* at 8–9, 15–16.

[21] *See id.* at 14–15, 18; Pramik Tr. 219–220; Kaufman Tr. 272; Chesney Tr. 1240–41.

drug.[22] When reviewing an ANDA, the FDA relies on data submitted by the applicant. To ensure that data is reliable, the FDA imposes rigorous data integrity requirements on pharmaceutical companies.[23] From the FDA's standpoint, "ensuring data integrity is an important component of [the pharmaceutical] industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of [the] FDA's ability to protect the public health."[24]

The FDA's data integrity requirements place the burden on the pharmaceutical company to "prove the origin, transmission, and content of the company's data and that data is what it is purported to be."[25] "A properly designed and managed data integrity program strives to mitigate the risk of purposeful data manipulation or fraud by putting controls in place that limit to the greatest extent possible the opportunities to manipulate data . . . ."[26] To minimize those risks, the FDA's data integrity requirements impose strict requirements that data regarding testing and manufacturing be attributable, legible, contemporaneously recorded, original or a true copy, and accurate ("ALCOA"), as well as complete, consistent, enduring, and available.[27] The FDA's data integrity requirements are part of its current Good Manufacturing Practices ("cGMP"), which are designed to ensure

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[22] *See* Wasserkrug Tr. 22.

[23] JX 1251 ¶¶ 17–20.

[24] JX 112 at 1.

[25] JX 143 at 1; *accord* Kaufman Tr. 323; Kaufman Dep. 196; *see* Wasserkrug Tr. 9.

[26] JX 1252 ¶ 2.1.

[27] *See* JX 1247 ¶ 35; Wasserkrug Tr. 8–9, 22; Franke Dep. 33–36.

the systematic safety, quality, and reliability of drug products.[28] These requirements are set out in federal regulations and clarified by FDA guidance.[29]

A critical component of a modern data integrity system is the company's IT infrastructure.[30] The FDA requires that computer systems have adequate "access controls" that restrict who may access electronic data, as well as "change controls" designed to "ensure that no unnecessary changes are made, that all changes are documented, and that the possible effect of a change is evaluated prior to its implementation."[31] The FDA also requires that lab equipment have "audit trails" to document who uses the equipment, when, and for what purpose.[32]

Data integrity also requires ensuring the authenticity of entries in laboratory notebooks.[33] Notebooks contain original source data that should be contemporaneously recorded by chemists. Notebooks must be preserved, and missing notebooks are "an important data integrity issue" because "that data is no longer available" and cannot be

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[28] Wasserkrug Tr. 8, 12; JX 1251 ¶ 22; JX 1249 ¶ 26.

[29] *See, e.g.*, 21 C.F.R. Pt. 211. *See generally* Wasserkrug Tr. 12–13; JX 934 at 3; JX 1247 ¶¶ 34–35; JX 1251 ¶¶ 22–23.

[30] JX 439 at '436 (IT is a "core component of a 21st century quality control management structure"); *see* Pramik Dep. 26.

[31] JX 1249 ¶ 96 n.141; *see* 12 C.F.R. § 211.68(b); Pramik Dep. 27; JX 934 at 3.

[32] JX 1247 ¶ 36; *see* 12 C.F.R. § 211.192; Franke Dep. 56; JX 934 at 3.

[33] *See* 21 C.F.R. §§ 211.68(b) & 211.194(a); JX 934 at 3; JX 1251 ¶ 83; *see also* JX 1247 ¶¶ 39–40; Wasserkrug Tr. 22 (describing FDA site visits to inspect notebooks and batch records "to assure the ALCOA principles of that data").

verified.[34] At Akorn, each notebook is assigned to a particular individual; making unsigned entries in another analyst's notebook violates fundamental principles of data integrity.[35]

The FDA's data integrity rules require that all test data—both failing results and passing ones—be properly recorded.[36] The FDA forbids the practice of "testing into compliance," or running tests again and again until passing results are secured and recording only the passing results.[37]

FDA regulations require that potential data integrity violations be promptly investigated and remediated. FDA guidance calls for "potential data falsification" to be "fully investigated" by the firm's "quality system to determine the effect of the event on patient safety, product quality, and data reliability; to determine the root cause; and to ensure the necessary corrective actions are taken."[38]

The FDA is required to inspect manufacturing facilities on a risk-based schedule[39] and typically inspects Akorn's sites at least once a year.[40] The FDA may also conduct

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[34] Franke Dep. 51–52.

[35] Sherwani Dep. 54–57; Silverberg Dep. 54–55.

[36] Wasserkrug Dep. 86–87; *see* 21 C.F.R. § 211.194(a); JX 934 at 3.

[37] Wasserkrug Dep. 52–53, 86–87; JX 1252 at 3.

[38] JX 112 at 9–10 (citing 21 C.F.R. §§ 211.22(a), 211.125(c), 211.192, 211.198, 211.204); *see* Rai Dep. 26 (acknowledging that Akorn "absolutely" has "responsibilities to investigate and remediate data integrity problems").

[39] 21 U.S.C. § 360(h)(3).

[40] *See* Wasserkrug Tr. 20.

directed "for cause" inspections.[41] At the conclusion of an inspection, the FDA holds a close-out meeting and shares its observations.[42] The FDA may provide only oral observations, or it may document observations in a Form 483, which is a written report from the FDA documenting "observations [that] are intended to denote significant conditions that constitute violations of cGMPs."[43] The company has an obligation to respond to the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions ("CAPAs").[44] If the FDA determines that the company has proposed adequate CAPAs, it will typically classify the inspection as voluntary action indicated ("VAI").[45] If the FDA determines that the remedial measures are insufficient, it may classify the inspection as official action indicated ("OAI").[46] An OAI classification can lead to further regulatory action, such as follow-up inspections or the issuance of a Warning Letter.[47] After the issuance of a Warning Letter, the FDA typically will not approve new product applications from the facility until the

[41] JX 934 at 4; JX 1249 ¶ 55; Wasserkrug Tr. 23.

[42] Wasserkrug Tr. 24.

[43] JX 1249 ¶ 56; *see* JX 1247 ¶ 48; Wasserkrug Tr. 24.

[44] Wasserkrug Tr. 24–25; *see* JX 1249 ¶ 58.

[45] JX 1247 ¶ 52; Wasserkrug Tr. 25–26.

[46] JX 1247 ¶ 53; Wasserkrug Tr. 26.

[47] Wasserkrug Tr. 13, 25–28, 72; JX 1247 ¶ 53.

observations are remediated.[48] If the FDA has concerns about a company's data or a submission, it may send the company a Complete Response Letter ("CRL") which, as its name indicates, requires a complete response.[49]

Data integrity violations are particularly serious because they "break trust" between the offending company and the FDA.[50] The FDA may require the withdrawal of an ANDA if the FDA finds that it contains an untrue statement of material fact.[51] In cases of repeated, intentional submission of inaccurate data, the FDA may invoke its Application Integrity Policy ("AIP"), which "halts all ongoing scientific review of pending applications to the agency until specific milestones are accomplished by the company."[52] Exiting from the AIP is a time-consuming and expensive process that involves an independent investigation, corrective action plan, recall or retesting of products, and withdrawal and resubmission of applications.[53] If systemic issues remain uncorrected, the FDA may seek a court-enforced permanent injunction. In extreme cases, the FDA may bar a company from making

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[48] JX 1249 ¶ 61; Wasserkrug Tr. 28; *see also* JX 1247 ¶ 53; Chesney Dep. 149.

[49] Chesney Dep. 148–49.

[50] JX 1251 ¶ 19.

[51] *See* 21 U.S.C. § 355(e); JX 934 at 4.

[52] JX 1251 ¶ 33; *see* JX 1247 ¶ 53; JX 1355.

[53] JX 1251 ¶ 34.

submissions, exclude it from other federal programs, or refer matters for criminal prosecution.[54]

At the time the Merger Agreement was signed, Mark Silverberg was the head of Akorn's quality function, holding the title of Executive Vice President, Global Quality Affairs.[55] Silverberg had been Akorn's most senior quality official for over ten years. In that role, he reported directly to Rai, Akorn's CEO.

The record demonstrated that Silverberg was not a suitable individual to be responsible for Akorn's quality efforts. One year before the Merger Agreement was signed, Akorn's board of directors and Rai concluded that Silverberg was not up to task of carrying out his duties and needed to retire.[56] Silverberg nevertheless remained at his post until nearly one year after the signing of the Merger Agreement, on March 1, 2018, when Kim Wasserkrug, previously the head of quality at Akorn's Decatur site, took over the quality function. Silverberg was shifted to the role of "Quality Advisor."[57] His new role had no substantive responsibilities (other than to help with this litigation), came with a 20%

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[54] *See* JX 934 at 5; JX 1249 ¶ 61.

[55] *See* JX 204 at '056; Rai Tr. 498–99.

[56] *See* JX 115; JX 132; JX 137; *see also* JX 121; JX 890 at '274.

[57] JX 955 at '702.

diminution in pay, and was originally to last for the lesser of 90 days or until the Merger closed. It was a constructive termination for cause.[58]

Akorn took employment action against Silverberg only after learning that in August 2017, during the period between signing and closing, Silverberg submitted a response to a CRL that he had been told—and I believe knew—would result in the submission of fabricated data to the FDA.[59] If he had not signed off on the CRL, Akorn would have had to withdraw the ANDA, which would have been a red flag for Fresenius that could have put the Merger in jeopardy. In my judgment, Silverberg submitted the false CRL in an effort to avoid inviting any scrutiny of Akorn's data integrity deficiencies until after the Merger closed, when it would be Fresenius's problem.[60] Akorn ultimately withdrew the ANDA in March 2018.[61] But for an investigation that Fresenius was conducting into two whistleblower letters it received, Akorn would not have withdrawn the ANDA or taken

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[58] *See* Rai Tr. 496 ("Q. And, of course, as we all know, [Silverberg] was fired, right, by Akorn? A. Yes."); Wasserkrug Tr. 105 ("In my mind, he was fired, but yes.").

[59] *See* Wasserkrug Tr. 105 (agreeing that Silverberg was fired "because he failed to direct the withdrawal of an ANDA submitted to the FDA for the drug azithromycin after being told that the submission contained likely false or fabricated data" and "for knowingly resubmitting that inaccurate data, or highly likely inaccurate data, to the FDA in a CRL response back in August of 2017").

[60] In a submission made after post-trial argument, Akorn informed the court that the database of a stand-alone high accuracy liquid particle counter had been deleted at the Somerset site on August 22, 2018. Dkt 201 at 1. In a moment of brazen candor, Akorn argued that if Fresenius had not "repudiated the Merger Agreement itself, the deal would have closed months earlier and the risk of such an event would have fallen on Fresenius." Dkt. 209 at 7; *see also* Wasserkrug Dep. 157; Wasserkrug Tr. 139; JX 590 at '472.

[61] *See* JX 1070 at '771; Wasserkrug Tr. 43–44.

any action against Silverberg. After constructively firing Silverberg, Akorn did not use the opportunity to deliver any type of message to its employees about the importance of data integrity or its intolerance for inaccurate submissions to the FDA.[62]

During his ten years heading up the quality compliance function, Silverberg placed "a lot of pressure" on employees "to just get things done and get products out [the] door."[63] In an employee survey conducted in January 2016 that went to Rai and other members of senior management, a whistleblower submitted the following comment:

> Our current Executive Vice President of Quality Assurance is not fostering a willingness to change the current Akorn culture. Instead of acknowledging and embracing our compliance gaps and working collaboratively with other groups to change and mature our quality systems, he actively works to prevent collaboration and transparency. He has actually counselled his staff to not speak to Global Quality Compliance staff and to not share information with GQC. This is not in line with our new mission and values statement. He has also provided misleading information to regulatory bodies including the US FDA.[64]

The comment was exceptional both in its content and its source: it came from someone who worked in Akorn's headquarters in Lake Forest, where Silverberg himself worked along with Rai and the executive team. Yet Akorn did not investigate it. During the same period when the problems with the azithromycin CRL were unfolding, Silverberg instructed the head of quality at Akorn's Swiss site not to open an investigation into a

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[62] Rai Tr. 497, 502–03.

[63] JX 870 at '895 ("[T]here was a lot of pressure from Mark S to just get things done and get products out [the] door.").

[64] JX 246 at '573.

quality issue he reported, not to put Silverberg's response in any file relating to the matter, and not to put FDA-sensitive subjects in emails.[65]

On Silverberg's watch, Akorn did very little to address data integrity issues. In June 2016, Ron Johnson, an Akorn board member with FDA experience,[66] wrote to Silverberg to express concerns about Akorn's state of compliance:

> I continue to be concerned that our position always seems to be that FDA got it wrong and we are just fine. I do not think we are fine, I think there are signals that we are missing. As the leader of the quality function, I do not understand how you can tolerate the continued non-compliance by employees, supervisors and quality assurance staff. . . . We have dogged [sic] a bullet a number of times, but at some point, our number will be up unless we, once and for all, fix the underlying reasons why our people do not adhere to procedures. Why do we not see an effort to do this?[67]

Silverberg's initial response was "I think we should communicate live (on the phone)."[68] In December 2016, during a meeting of the board of directors' Quality Oversight

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[65] *See* JX 623 (Silverberg stating, "Please do not incorporate this correspondence into any related complaint investigations or files[,]" and instructing, "Please do not put FDA sensitive subjects into emails as such."); JX 667 (Silverberg: "Let's discuss by phone please at your earlier convenience."); JX 778 at '557 (Silverberg instructing Sherwani in connection with the azithromycin investigation, "No more emails."). Stuart testified that during Cravath's investigation into the azithromycin problems, discussed below, they determined that Silverberg subsequently ordered an investigation into the issue. Stuart Tr. 868–69.

[66] *See, e.g.*, JX 470 at 14 (April 2017 consultant report quoting unnamed FDA official: "Ron Johnson [a board member at Oak] is ex-FDA and highly respected. He gives the company excellent credibility.") (alteration in original).

[67] JX 1403 at '004.

[68] *Id.*

Committee, Johnson again "expressed his concern around the repetitiveness of issues between sites and across sites identified during audits & external inspections."[69]

Also in December 2016, Akorn received a "Compliance Gap Analysis Summary and Recommendation Report" for its Decatur facility from John Avellanet of Cerulean Associates LLC, who had inspected the facility during a four-day visit in September 2016.[70] The report was blunt: "Overall, the review found that the data integrity controls at . . . Akorn's Decatur, Illinois site . . . are insufficient to support compliance with current data integrity expectations and [FDA] regulatory requirements."[71] The report warned that "[a]s a result, Akorn currently shoulders significant regulatory and negative public perception risk."[72]

Cerulean identified seven critical, seven major, and at least five minor nonconformities at the Decatur site.[73] The report defined a critical nonconformity as one that is "reasonably likely to directly impact (e.g., either immediately cause, enable, or be a non-compliance) the regulatory compliance status of the organization."[74] The report warned that "[h]istorically, these findings have consistently resulted in public enforcement

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[69] JX 235 at '598; *see* Rai Tr. 515–16.

[70] *See* JX 231; Wasserkrug Tr. 31–32.

[71] JX 231 at '062.

[72] *Id.*

[73] *Id.* at '062, '067.

[74] *Id.* at '067.

actions (e.g. FDA Warning Letter, product recall, etc.) and have been significant factors in product liability litigation."[75] The report also warned that "[r]epeat non-conformities . . . pose an increased risk because they are indicators that an organization did not take adequate corrective actions and thus may not treat its responsibilities as seriously as appropriate."[76]

The seven critical findings were:

- "Failure to exercise sufficient controls to prevent data loss."[77]
- "Insufficient data integrity controls (both procedural and technical) to prevent unauthorized changes to electronic data."[78]
- "Insufficient registered record archival controls and retention for records involved in drug product manufacture, testing and release, and quality records."[79]
- "Failure to have sufficient controls over computerized equipment used in regulated processes and used to create, manipulate, edit, [and] store . . . regulated data for drug product safety and quality testing and release."[80]
- "Inadequate validation of computerized systems to ensure the ongoing suitability of systems for Akorn processes, data, and personnel."[81]

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[75] *Id.*

[76] *Id.*

[77] *Id.* at '068.

[78] *Id.* at '069.

[79] *Id.* at '071.

[80] *Id.* at '072.

[81] *Id.* at '074.

- "Inadequate control over approved specifications for drug product and raw materials, and failure to ensure that product testing data is derived from compliance with established specifications and standards."[82]

- "Inadequate corrective action and preventative action and out-of-specification investigations, explanations, and corrective actions."[83]

Specific deficiencies included that *any* Akorn employee could add, delete, or modify electronic data, which undermined "all of the test data [and] all of the production data" at the Decatur site,[84] thereby "call[ing] into serious question the identity, strength, quality, safety, purity, and sterility of Akorn's drug products."[85] Cerulean also found that Akorn had failed to use an audit trail function that would have enabled Akorn to determine whether employees had exploited their unlimited access, which also "rais[ed] questions over the integrity of the laboratory's data since initial usage of the instruments."[86]

In January 2017, Cerulean conducted a similar assessment at the Somerset site. Cerulean was not able to complete its inspection because of inadequate IT support.[87] In

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[82] *Id.* at '075.

[83] *Id.* at '076.

[84] Avellanet Dep. 111–15.

[85] JX 231 at '075.

[86] *Id.* at '070. Avellanet also found that Akorn was claiming a clearly fraudulent number of hours for training on quality issues. *See id.* at '077 ("The Akorn Decatur site alone averages 7,000 trainings a month. Assuming each individual works 7 days a week, with no vacations or sick leave, that's 232 trainings a day."); Avellanet Dep. 120–24.

[87] Wasserkrug Tr. 131; Wasserkrug Dep. 156–57; Avellanet Dep. 142–45; *see* JX 439 at '430; JX 500; JX 504; JX 505; JX 509.

May 2017, Cerulean provided Akorn with a preliminary report on the Somerset facility, which identified three additional critical findings and three major findings.[88] This time, Avellanet believed that some of the violations were so severe that Akorn's senior management should be concerned about potential criminal liability under the *Park* doctrine.[89] Cerulean found that senior management had failed "to ensure an effective quality system" and that the IT department failed to "ensure the reliability of the controls around data used to make, test, [and] release" sterile drug products.[90] As at Decatur, Cerulean determined that the latter deficiency raised "serious questions about the reliability of any data integrity controls and thus the trustworthiness of any electronic information used throughout Akorn to make safety, efficacy and quality decisions."[91] Cerulean also identified additional "critical" computer access and audit trail deficiencies at Somerset similar to those it found at Decatur.[92]

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[88] JX 439 at '430.

[89] *Id.* at '435–36; *see United States v. Park*, 421 U.S. 658 (1975).

[90] JX 439 at '435–36.

[91] *Id.* at '436.

[92] *See id.* at '437 (citing Akorn's "[f]ailure to have sufficient controls over computerized systems . . . used to create, manipulate, edit, [and] store" data used for product testing); *id.* at '438 ("Audit trails appear to be inconsistently reviewed . . . ."); *see also* JX 564 at '352 (Somerset employee complaining in August 2017 that quality-tracking software's audit trails showed she had completed investigations for matters to which she was not even assigned: "It is alarming to me that in light of all the issues that we have presented with the Trackwise System, we are being told by IT that these issues do not warrant a re-validation of the system.").

Akorn made "no effort" to schedule a date for Cerulean to complete the inspection at the Somerset site.[93] Akorn cancelled Cerulean's previously scheduled assessment of its Amityville site.[94] Silverberg and other members of senior management identified the Merger as the reason for not having Cerulean do any more work.[95] I infer that they did not want Cerulean to identify any more data integrity gaps that could jeopardize their efforts to sell the Company. The only interest that Akorn's executives showed in the Cerulean report was a request by Joseph Bonaccorsi, Akorn's Executive Vice President, General Counsel, and Corporate Secretary, that Cerulean remove the reference to potential criminal liability for Akorn's executives.[96]

Avellanet testified that Akorn's data integrity issues were among the "top three worst" of the 120+ pharmaceutical companies that he has assessed,[97] a notorious status given that his practice only involves companies that "have problems."[98] Avellanet testified that some of Akorn's data integrity failures were so fundamental that he would not even

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[93] Wasserkrug Tr. 132; *see* Avellanet Dep. 139; *see also* JX 507 at '317 ("executive leadership" decided "that IT resources would not be engaged in the third party data integrity audit [Cerulean]").

[94] Avellanet Dep. 47; *see* JX 509 at '746.

[95] Wasserkrug Tr. 132.

[96] Avellanet Dep. 203–07. Gill voiced the request on Bonaccorsi's behalf. *See* Bonaccorsi Dep. 175–78, 196; Avellanet Dep. 203–05.

[97] Avellanet Dep. 172–73.

[98] Kaufman Tr. 317–19; *accord* Avellanet Dep. 301.

expect to see them "at a company that made Styrofoam cups," let alone a pharmaceutical company manufacturing sterile injectable drugs.[99] He believed that the "FDA would get extremely upset" about Akorn's lack of data integrity "because this literally calls into question every released product [Akorn has] done for however many years it's been this way."[100]

Roughly contemporaneously, in June 2016, Akorn's GQC team identified a critical data integrity failure at the Vernon Hills site that paralleled the problems identified by Cerulean: a failure to establish proper computer access controls and audit trials.[101] In December 2017 and January 2018, an investigation by Lachman Consulting Services, a

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[99] Avellanet Dep. 173; *see also id.* at 111–12 (testifying that he had never before seen a company where any employee could make changes to electronic data "willy-nilly with no traceability or accountability").

[100] *Id.* at 116–17. Avellanet's first report concerned Decatur, but the record evidence supports a finding that conditions at Decatur were representative of company-wide problems at Akorn. *See* JX 411 (Wasserkrug sending gap assessment to Sherwani: "I suspect you will have similar problems with your systems there."). Witnesses for Akorn also claimed that its IT problems did not matter because Akorn was a paper-based company. *See* Wasserkrug Tr. 66. As one of Fresenius's experts explained, that claim in itself is an alarming red flag, because in the current age, a company cannot operate compliantly using paper-based systems, and regardless, a company's computerized systems still must be in compliance. George Tr. 1146.

[101] JX 655 at '479 ("The program . . . is unable to record audit trails and cannot support accounts with unique user names and passwords for individual users. Analysts routinely log in as 'Admin' without a password."); *id.* at '472 ("[T]he audit observations together with the areas of risk identified within Data Integrity; require Akorn to take immediate action to mitigate said risk."); *see* Wasserkrug Tr. 109–12; *see also* JX 242 (GQC audit report on Amityville from October 2016 identifying "critical" deficiency related to data integrity).

consultant hired by Fresenius, identified similar issues at all of the sites that Lachman visited. Beginning in March 2018, an investigation conducted by NSF International, a consultant hired by Akorn, found extensive issues at the sites it examined.

Akorn did not do anything meaningful to address the issues raised by Cerulean until March 2018, after the investigation that Fresenius conducted into the whistleblower letters led to Akorn uncovering Silverberg's false CRL response, self-reporting to the FDA, and committing to address its data integrity problems. Until Fresenius's investigation forced its hand, Akorn was not devoting resources to data integrity. It is true that Silverberg facilitated the preparation of a data integrity plan for Decatur in August 2017, but he made clear in his contemporaneous communications that it was just so Akorn would have a document to show the FDA. When Akorn's IT department opposed the plan, Silverberg reassured them that it was not meant to be implemented. In his jargon, it "serves to represent to outside authorities our cognizance of the subject, without committing IT to any near term work or responsibility."[102] In late 2017, Patty Franke, Decatur's Quality Assurance Manager for Data Integrity and Compliance, [103] told Cerulean that Akorn was "making 0 progress on our DI remediation efforts" at Decatur, which she attributed to "the

[102] JX 590 at '472; *see* Wasserkrug Tr. 136–38, 142–43.

[103] Franke Dep. 25–26.

culture and the message from management."[104] Wasserkrug testified that she was told that "a lot of this stuff would wait until the Fresenius merger occurred," which was an excuse "we heard . . . actually quite often" in late 2017.[105]

To reiterate, Akorn only started making a concerted effort to address its data integrity issues in March 2018, after Fresenius had flagged Akorn's data integrity problems and prompted Akorn to uncover Silverberg's false CRL response, and after Akorn felt it had to try to get ahead of the problem by going to the FDA and committing to address its data integrity issues. At that point, Akorn formed an executive steering committee on data integrity remediation, which held its kickoff meeting on April 19, 2018.[106] It took until June 7, 2018 for Akorn to assemble a list of the hundreds of deficiencies it had accumulated, many of which went back years.[107] Over a year after receiving the Cerulean report, the Somerset facility had not taken any action to address the deficiencies it

[104] JX 754 at '740. Separate from the periodic audits conducted by GQC and the consultant assessments, Akorn's quality assurance personnel conduct ongoing site monitoring and represent "the eyes and ears" for each facility. *See* Wasserkrug Tr. 14.

[105] Wasserkrug Dep. 157–58.

[106] JX 1155; *see* Rai. Tr. 530.

[107] *See* JX 1885; Rai Tr. 531–34; Wasserkrug Dep. 27–28.

identified.[108] Decatur had only completed "32% of the corrective actions thus far."[109] By the time of trial, Akorn still did not have a remediation plan because it was still in the process of figuring out all of the deficiencies that the Company needed to address.[110]

In its post-trial briefs, Akorn attempted to paint a picture of compliance at Akorn that differed radically from what the evidence showed at trial. Notably absent from the witness list at trial was any representative from Akorn's quality function who could speak to Company-wide conditions before March 2018. Wasserkrug testified, but she took over the company-wide quality function from Silverberg in March 2018 and could not speak to matters preceding her tenure, except at the Decatur site where she had been the site quality director.[111] Silverberg was the obvious candidate, but neither he nor Jaspreet Gill, the head of Akorn's GQC team, nor any other senior member of the quality function testified at trial. Rai made claims about quality, but having considered his answers and evaluated his demeanor while he was being cross-examined about his commitment to quality, I am forced to conclude that he does not regard it as a priority.[112] Bonaccorsi gave testimony about the

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[108] JX 1077 at '065–66; *see* JX 1885 at '754; Wasserkrug Tr. 153–54 ("[I]n 2017, after getting the Somerset Cerulean report, no actions were taken in response.").

[109] JX 1094 at '623; *see* JX 1885 at '754; Wasserkrug Dep. 204–06; Franke Dep. 239. I do not credit Wasserkrug's contrary claim at trial that Decatur had completed 70–75% of the corrective actions. Wasserkrug Tr. 42, 148.

[110] *See* Rai Tr. 533–34 (Akorn's data remediation effort "does not have a timetable").

[111] Wasserkrug Tr. 106–07.

[112] *See* Rai Tr. 496–519. Another plausible and more alarming inference is that Rai consciously disregarded Akorn's quality issues, including its data integrity problems. Rai

overall structure of Akorn's quality function, but he is not a quality expert, nor is he part of the quality department.[113]

The evidence at trial demonstrated that Akorn took the steps necessary to establish the formal structure of a quality function. The evidence also revealed a gulf between appearance and reality.[114] The extensive and recurring quality and data integrity problems

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is the chair of Akorn's Quality Oversight Committee and its executive steering committee on data integrity remediation. Rai Dep. 33, 207. He receives Akorn's internal audit reports, but he does not read them. Rai Tr. 489; *see* Rai Dep. 201. Rai did not read the Cerulean reports either. Rai Dep. 40–41, 67; Rai Tr. 486. After being asked about these documents at his deposition, he made no effort to familiarize himself with them between his deposition and trial. *See* Rai Tr. 486–87; *see also id.* at 474. At his deposition, Rai could not recall whether he had ever seen the Decatur internal audit report that GQC sent him on March 23, 2018. Rai Dep. 200; *see* JX 1095. When asked for Akorn's timetable to address the critical findings in the Cerulean report and March 2018 GQC report, Rai said he would "go back and ask" for one. Rai Dep. 207–08. Rai made that decision at his deposition and only because opposing counsel showed him the GQC report. *See id.* at 208–09. At trial, Rai asserted that Akorn was "still assessing" a timetable for data remediation. Rai Tr. 534.

[113] *See* Bonaccorsi Tr. 872–77; *see also id.* at 923.

[114] *See, e.g.*, JX 50 at '885 (Akorn board's Quality Oversight Committee minutes from 2014 citing need for a "change of culture" around quality); JX 235 at '598 (December 2016 Quality Oversight Committee minutes in which director Ron Johnson "expressed his concern about the repetitiveness of issues between sites and across sites identified during audits & external inspections" and emphasized need for "corrective actions on a global basis[,]" and director Brian Tambi noted that "it appears that the implementation of corrective action is lacking or not timely"); Rai Tr. 514 ("Q. . . . [Y]ou were on a board committee [in November 2016] that was aware of significant and repeat problems that Akorn was having in its quality function; isn't that right? A. Yes."); *id.* at 518 (Rai agreeing that Akorn was having problems across all sites); *see also* JX 67 at '923 (discussion of problems with logbooks including use of post-it notes); JX 93 (discussion of missing logbooks and data); JX 104 (email discussing changing data and reporting only one set so that the FDA would not "point at the data for high impurities"); JX 105 (Franke being told that lack of password control and data insecurity were longstanding issues; Franke indicating that "[o]n all of the computerized systems within the [Amityville] lab, all users have the ability to change the PC time/date while logged in, which is used as a stamp on

at Akorn convinced me that Akorn did not have a well-functioning quality system and lacked a meaningful culture of compliance.

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the data file"); JX 106 (Franke noting concerns about Amityville facility that would require "a difficult explanation to any regulatory agency"); JX 107 (Franke expressing concern to Silverberg about "[l]ab data system administration" and "[l]ack of [a]ccountability for invalid or incomplete data sequences"); JX 116 (Gill calling it "too much to be a coincidence" where FDA's 2016 investigation of Somerset yielded multiple observations identical to those made in 2014); JX 126 (Franke noting data integrity problem with piece of equipment); JX 133 ("The Somerset findings suggest a step back to focus on remedial improvements before true quality advancement to current industry practices can be made."); JX 203 (email regarding investigation into "Falsification/Backdating of information"); JX 209 (Pramik emailing about competitor's Form 483 regarding computer controls and remarking, "From discussions with IT, I have the impression this is an area we haven't stayed on top of . . . . Impression is we also have instrumentation that is not validated."); JX 216 ("I wanted to make you aware of another documentation (back dating / falsification) issue identified this week. . . . Obviously, very concerning given this is the second issue in as many weeks."); JX 234 (Franke noting that the absence of a password for an Akorn backup server "does not meet industry data integrity and protection standards"); JX 241 at '113 (December 2016 Executive Leadership Overview on R&D / Quality / Compliance IT Systems: "There is FDA compliance risk & likely large remediation efforts, but not collective visibility to what we're dealing with"); JX 328 (Wasserkrug informing Silverberg and Franke about "a very serious data integrity issue" because of lack of access controls in TrackWise); JX 864 (Franke weighing in on quality issues from audit that remained unresolved); JX 377 at '206 (March 2017 presentation to Akorn Board Quality Committee: "Observations revealed a systemic breakdown in Quality system across functions, which included management responsibility, training, procedural deficiencies, qualification program weaknesses and 21 CFR Part 11 deficiencies."); JX 499 ("We have noticed multiple late entries/incomplete information in the log books in the lab."); JX 518; JX 526; JX 565; JX 566; JX 569; JX 870 at '895 ("If certain FDA inspectors come to Somerset, there will be problems there."); *cf.* Rai Tr. 484, 496 (Rai backing Silverberg and crediting his explanation for the false submission to the FDA); *id.* at 486–88 (Rai admitting that he never read the Cerulean reports and did not attend the training Cerulean was hired to give).

C. Akorn Explores Strategic Alternatives.

In February 2016, Akorn's board of directors consulted with management and J.P. Morgan Securities LLC about strategic opportunities.[115] The board decided that Akorn should explore strategic alternatives once it completed a restatement of its 2014 financial information and became current with its financial reporting.[116]

In July 2016, Akorn's then-Chairman of the Board and largest stockholder, John N. Kapoor, met with Rai and J.P. Morgan to develop a preliminary list of potential buyers.[117] During a meeting later in July, the board decided to "commence a process to solicit proposals to acquire the Company from potential strategic and financial counterparties."[118]

In August 2016, J.P. Morgan approached Alexander Dettmer, Head of Corporate Business Development/M&A and Senior Vice President of Fresenius Parent, to explore whether Akorn would be a good fit for Fresenius Kabi.[119] In early October 2016, Rai and J.P. Morgan met with Ducker and gave him a presentation about Akorn.[120] During the same

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[115] *See* JX 520 at '823.

[116] *Id.*

[117] *Id.* at '824.

[118] *Id.*

[119] JX 520 at '824; *see* PTO ¶ C.1; Rai Tr. 460.

[120] PTO ¶ C.2; JX 520 at '824.

period, J.P. Morgan approached other potential strategic acquirers and private equity funds.[121] At later points, other potential acquirers dipped in and out of the process.[122]

D. Fresenius's Initial Evaluation Of Akorn

After being approached by Akorn, Fresenius evaluated Akorn with assistance from Moelis & Company. A Moelis presentation identified positive attributes, including:

- "Attractive portfolio of niche, high-value generics focused primarily on ophthalmic and sterile injective products"[123]
- "[P]roduction expertise across difficult-to-manufacture alternative dosage forms (i.e., other than oral solid dose)"[124]
- "Deep pipeline of 85% filed ANDAs representing ~$9bn in brand revenue"[125]
- "Management expects 25 approvals (~$1bn in brand revenue) by March 2017"[126]
- "Management expects to file at least 20 ANDAs during 2017"[127]

At the same time, the Moelis presentation highlighted risks:

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[121] *See* JX 520 at '824–25.

[122] *See id.* at '828–29, '832. *See also* JX 224 at '339 (March 2017 draft J.P. Morgan presentation observing that "[s]ince May 2016, J.P. Morgan and [Akorn] have held discussions with 8 strategics and 5 financial sponsors").

[123] JX 180 at '879.

[124] *Id.*

[125] *Id.*

[126] *Id.*

[127] *Id.*

- "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 (e.g., Endo/Par) could emerge"[128]
- "Akorn's Ephedrine NDA has been impacted by Form 483 deficiencies at its Decatur, IL facility"[129]
- "However, 483 issues do not impact products outside of Ephedrine"[130]

An internal Fresenius assessment identified similar pros and cons.[131]

On November 4, 2016, Akorn announced its financial results for the third quarter.[132] Akorn management spoke about the threat of competition for ephedrine and said their market share and revenue remained stable.[133] Moelis sent Fresenius an updated presentation that provided additional detail on ephedrine, including by modeling base, downside, and upside cases for that product.[134] Fresenius also obtained and reviewed a

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[128] *Id.*

[129] *Id.*

[130] *Id.*

[131] *See* JX 188 at '007 (citing "[l]arge pipeline of pending ANDAs" but noting risk of "competition to Ephedrine" and "[c]ompliance status of manufacturing assets"). The Fresenius team also identified the risk posed by Kapoor's involvement with Akorn as Chairman of the Board and its largest stockholder. Kapoor previously had sold a company he took public, LyphoMed Inc., in a transaction that resulted in the buyer suing for fraud. *See* JX 183; *see also* JX 453 at '163; JX 470.

[132] *See* JX 194.

[133] *Id.* at '246.

[134] *See id.* at '246–47.

redacted version of a Form 483 for Decatur.[135] James Bauersmith, a Fresenius employee charged with evaluating Akorn's pipeline,[136] expressed concern about the Form 483, noting that it was the site where Akorn manufactured ephedrine.[137]

On November 8, 2016, Akorn and Fresenius USA entered into two confidentiality agreements, one covering due diligence generally and the second permitting a "clean team" to review competitively sensitive information that might have antitrust implications.[138] On November 11, Akorn management gave a lengthy presentation to representatives of Fresenius and provided them with a forecast.[139] Among other things, the presentation addressed Akorn's developmental pipeline,[140] the steps Akorn was taking to improve quality control at Decatur,[141] and the actions Akorn had taken to remediate its financial reporting and controls after its financial restatement.[142]

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[135] *See* JX 199.

[136] *See* JX 296 at '991.

[137] JX 202; *see* Bauersmith Tr. 591–94.

[138] PTO ¶ C.3; Bonaccorsi Tr. 878–79.

[139] PTO ¶ C.4; *see* JX 224 at '339; JX 204.

[140] *See* JX 204 at '073–79.

[141] *See id.* at '058–69.

[142] *See id.* at '082.

After the presentation, Fresenius looked more closely at the Form 483 for Decatur and two earlier Form 483's that Decatur received in 2013 and 2014.[143] A Fresenius executive reported that "[t]he 483 shows weaknesses in the quality system but it does not look [like] a not working quality system. . . . In summary the 483 does not indicate any topic which should lead to further regulatory measures."[144]

E. Fresenius's Initial Proposal

On November 23, 2016, Fresenius proposed to acquire Akorn for $30.00 per share plus a contingent value right ("CVR") that would pay up to $5.00 per share based on cumulative ephedrine sales over the next three years.[145] The proposal was conditioned on satisfactory due diligence and acceptable deal documents. On the day Fresenius made its proposal, Akorn's stock closed at $22.40 per share.[146]

On December 5, 2016, Rai met with Ducker, stressed the value of Akorn's pipeline and pending ANDAs, and told him that Fresenius's proposal was too low.[147] He said Fresenius would need to improve its bid to gain access to the data room.[148]

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[143] JX 207.

[144] *Id.* at '280.

[145] JX 222; PTO ¶ C.5.

[146] *See* JX 520 at '826.

[147] JX 230 at '809; *see* Rai Tr. 461.

[148] *See* JX 520 at '827.

F. Fresenius Improves Its Bid.

On January 9, 2017, Rai met with Sturm and reiterated the message about improving Fresenius's bid.[149] Ducker wanted to improve the bid,[150] but he encountered resistance internally: Bauersmith was heading up a group that was analyzing Akorn's pipeline,[151] and they questioned Akorn's ability to obtain FDA approval for as many new products as they planned, then launch those products as scheduled.[152] Bauersmith regarded Akorn's schedule for launching new products as "the definition of insanity."[153] Bauersmith and his team wanted to use more conservative assumptions.[154] Ducker disagreed, describing the more conservative assumptions as "a sure way to kill this project."[155]

On January 30, 2017, the FDA granted approval for a third competitor to sell ephedrine.[156] Akorn's stock price fell on the news, closing at $18.40 per share.[157] After this

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[149] JX 520 at '828; *see* PTO ¶ C.7.

[150] Bauersmith Tr. 621–23; *see id.* at 583–84.

[151] *See* JX 296 at '991; Bauersmith Tr. 574–75, 581.

[152] JX 245 at '314; Bauersmith Tr. 577, 581–82.

[153] *See* JX 261 at '424 (criticizing assumption of 113 launches over three years); *see also* JX 268 (Fresenius employee expressing view Akorn's "stated plan of about 25 products per year is unrealistic and not doable" and that a more realistic goal would be "10–12 products per year"); *see also* JX 278; JX 279; JX 280.

[154] *See* Bauersmith Tr. 584–85, 624; JX 260.

[155] JX 278 at '948; *see* JX 245 at '315–16.

[156] JX 264 at '690.

[157] JX 263; *see* JX 264.

development, Fresenius considered restructuring the proposed CVR to focus on revenue growth.[158] As Bauersmith explained, "We were buying an ephedrine company with a pipeline, now we are buying a pipeline company."[159] Bauersmith suggested a CVR that paid out if Akorn achieved its projections for FDA approvals in 2017.[160] Ducker agreed with a CVR tied to revenue, but wanted to base the improved bid on more optimistic assumptions than Bauersmith's group would endorse.[161] Over the years, Ducker had developed a high level of credibility with his superiors because he consistently beat his forecasts.[162] When push came to shove, the Management Board supported Ducker.

On February 3, 2017, Fresenius increased the cash component of its bid to $32.00 per share and modified the CVR to pay up to $4.00 per share based on Akorn's sales in 2018.[163] Ducker told Rai that the CVR would "mitigate the risk inherent in the ambitious

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[158] JX 281.

[159] *Id.* at '517–18; *see* Bauersmith Tr. 619–20, 627–28.

[160] JX 281 at '518 ("Specifically, something like a $5/share CVR based on achieving 25 approvals by the end of 2017."); *see also* JX 284 at '887 (Ducker agreeing with the idea of a "CVR link[ed] to approvals").

[161] *See* JX 283; JX 284; Bauersmith Tr. 586–87.

[162] *See* Sturm Tr. 1194; Henriksson Tr. 936 ("Internally in Fresenius Kabi, Mr. John Ducker is known as Mr. Sandbag. He is a person who has never made a budget or a forecast which has not overachieved."); *see, e.g.*, Sturm Tr. 1185 ("John 'Freight Train' Ducker had overdelivered relative to the expectations of ours and of the market.").

[163] PTO ¶ C.8; *see* JX 285.

product launch projections contained in [Akorn's] business plan."[164] On the day Fresenius made its proposal, Akorn's stock closed at $20.08 per share.[165]

After receiving guidance from Akorn's directors, Rai told Ducker on February 4, 2017 that Akorn would give Fresenius access to the data room, but with the expectation that Fresenius would improve its bid and drop the CVR.[166] Ducker agreed to proceed on those conditions.[167]

On February 13, 2017, Akorn gave Fresenius access to its data room.[168] Fresenius conducted detailed due diligence that included an examination of Akorn's product portfolio and regulatory issues.[169]

On March 1, 2017, Akorn announced its financial results for the quarter and fiscal year that ended on December 31, 2016.[170] Akorn also issued annual guidance for 2017.[171] On March 2, Akorn announced that it had received approval from the FDA for a new drug

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[164] JX 1601 at '759; *see* Rai Tr. 463.

[165] JX 520 at '828.

[166] *Id.* at '829; *see* JX 1601 at '760; Rai Tr. 460–62; JX 286 at '360.

[167] JX 1601 at '759; JX 520 at '829; *see* Rai Tr. 463; PTO ¶¶ C.9–10.

[168] PTO ¶ C.12.

[169] *See, e.g.*, JX 301; JX 303; JX 304; JX 313; JX 314; JX 319; JX 323; JX 325; JX 326; JX 327; JX 331; JX 332.

[170] JX 520 at '830.

[171] *See* JX 341; JX 342.

application involving ephedrine.[172] Later that day, Rai spoke with Ducker about the product, Akorn's guidance, and the regulatory and tax environment.[173]

By March 2, 2017, the Fresenius due diligence team had been working for just over two weeks. A presentation prepared as of that date identified a "preliminary red flag DD finding" under the heading of "Sales & Marketing": "Risk to achieve forecasts due to stronger competition, especially for Ephedrine, Lidocaine ointment, clobetasol, Fluticasone."[174] The presentation identified two "Preliminary red flag DD findings" under the heading of "I&D Regulatory": (i) "Regulatory Affairs organization appears to be under-resourced" and (ii) "2016 and 2017 R&D budgets do not substantiate the ambitious pipeline."[175] The presentation did not identify any data integrity issues. The presentation concluded: "So far, no deal breakers identified."[176] A Fresenius management presentation reported that "[t]he level of access being given/promised by [Akorn] is above average for a public company target."[177] Subsequent versions of the presentations largely offered the same assessments.[178]

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[172] JX 520 at '830.

[173] *See id.*

[174] JX 339 at 6.

[175] *Id.* at 6.

[176] *Id.* at 7.

[177] JX 343 at '073; *accord* JX 339 at 5.

[178] *See* JX 353; JX 357.

During this period, Fresenius developed its own projections for Akorn's product portfolio and pipeline. Once again, Ducker's team was more optimistic;[179] Bauersmith's group was more conservative.[180] Fresenius's final numbers were a mix of their views.[181]

Fresenius had largely finalized its due diligence by March 17, 2017.[182] During a meeting that same day, Ducker told Rai that Fresenius would increase its bid.[183] On March 20 and 21, Rai and Ducker had further discussions about Fresenius's due diligence and Akorn's financial results for the quarter ending March 31.[184] Fresenius reported that Akorn personnel indicated that "it was a 'solid' quarter; and they are on track to meet their full year expectations."[185]

On March 23, 2017, Fresenius increased its bid to $33 per share and eliminated the CVR. In its offer letter, Fresenius stated that it had largely completed its due diligence and was prepared to begin negotiating a merger agreement, but that senior management wanted to conduct site visits and that Fresenius would need additional information about the

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[179] *See, e.g.*, JX 350; JX 354.

[180] *See* JX 365; JX 366; JX 367.

[181] *See* JX 385; *see also* JX 395; Bauersmith Tr. 579–90.

[182] *See* JX 379; JX 390.

[183] JX 520 at '830.

[184] *Id.* at '830; *see generally* JX 433.

[185] *See* JX 433 at '619.

Company's efforts to comply with FDA serialization requirements.[186] On the day when Fresenius made its proposal, Akorn's stock closed at $22.30 per share.[187]

On March 25, 2017, Akorn's advisors posted a proposed merger agreement to the data room.[188] On March 30, Rai, Kapoor, Ducker, Henriksson, and Sturm met in person.[189] Rai said that the Akorn board needed Fresenius to increase its proposal. On March 31, Kapoor spoke with Sturm and reiterated the need for an improved proposal.[190]

On April 2, 2017, Fresenius increased its price to $34 per share and said this was the highest it would go.[191] On the day Fresenius made its proposal, Akorn's stock closed at $23.69 per share.[192] The Akorn board accepted the $34 per share price.[193]

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[186] PTO ¶ C.15; JX 403; *see also* JX 422 at '001 ("Implementation of serialization may not be performed in time at all [Akorn] sites, specifically Amityville and Decatur, resulting in the risk to not being able to sell prescription drugs until they are serialized. . . . However, Raj Rai assured John Ducker that Decatur facility status is NAI following December 2016 audit.").

[187] JX 520 at '830.

[188] *See* JX 413.

[189] JX 520 at '831.

[190] *Id.*

[191] *See* JX 520 at '831; *see also* JX 477 (Moelis analysis supporting offer of $34 per share); *id.* at '730 (finding price "in-line with the DCF [even] without synergies").

[192] JX 520 at '831.

[193] JX 441; *see* Rai Tr. 466.

When the Supervisory Board of Fresenius Parent formally approved the bid, the final presentation they received from management cited Akorn's strengths as including "92 ANDAs under FDA review and over 75 additional ANDAs in various stages of development."[194] Management noted that Fresenius would need to integrate and modernize Akorn's production network, which would involve closing two Akorn plants and providing "supplementary capex investment to bring [Akorn] up to [Fresenius] standards while minimizing compliance risks."[195] In the "Key DD items summary," the presentation identified a high risk of a potential exposure of $100+ million from the postponement of product launches.[196] The presentation also cited high risk of a potential exposure of $100+ million from cGMP "deficiencies related to premises and equipment" in the Amityville and Decatur facilities.[197] The presentation projected a need for capital expenditures of $127 million for Amityville and $21 million for Decatur, with the Decatur facility to be closed

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[194] JX 428 at '643.

[195] *Id.*

[196] *Id.* at '673 (categorizing potential exposure as a "[o]ne-time effect"); *see* JX 422 at '001 ("Akorn has an aggressive product launch plan, which leads to risk of postponement for several products . . . and an estimated exposure above $100m. [Fresenius] prepared a bottom-up model for each molecule and adjusted the launch plan, R&D costs and revenues accordingly in the business plan.").

[197] JX 428 at '673; *see* JX 422 at '001 ("Site visit at Amityville and Decatur revealed [good manufacturing practice] deficiencies related to premises and equipment, which could result in negative outcome of regulator inspections and a mix of gross profit loss and capex need amounting to a maximum exposure over $100m. This finding is mitigated via the business plan.").

once products were transitioned to other sites.[198] The presentation did not identify a risk from data integrity issues.

G. The Merger Agreement

After the agreement on price, the parties negotiated the terms of the transaction documents.[199] On April 24, 2017, they executed the Merger Agreement.[200]

In the Merger Agreement, the parties allocated risks through detailed representations, warranties, covenants, and conditions:

- Akorn made extensive representations about its compliance with FDA regulations, including (i) "compliance with . . . all applicable Laws . . . relating to or promulgated by the" FDA,[201] (ii) "compliance with current good manufacturing practices[,]"[202] (iii) that all studies or tests had "been conducted in compliance with standard medical and scientific research procedures and applicable Law,"[203] (iv) that Akorn had not "made an untrue statement of a material fact or a fraudulent statement to the FDA,"[204] and (v) that all "ANDAs submitted by [Akorn] . . . are true, complete and correct,"[205] in each case except where failure of the representation to be true and correct would not reasonably be expected to have a Material Adverse Effect.

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[198] JX 428 at '712.

[199] *See* JX 520 at '831–32.

[200] PTO ¶ D.1.

[201] JX 1 § 3.18(a).

[202] *Id.* § 3.18(b).

[203] *Id.* § 3.18(c).

[204] *Id.* § 3.18(d).

[205] *Id.* § 3.18(g).

- Akorn committed to "use . . . commercially reasonable efforts to carry on its business in all material respects in the ordinary course of business" between signing and closing.[206]

- Akorn agreed to "afford to [Fresenius and Fresenius's representatives] reasonable access" to information about its business.[207]

- Fresenius agreed to take "all actions necessary" to secure antitrust clearance.[208]

- Fresenius had the right to terminate the Merger Agreement if any of Akorn's representations or warranties were not true and correct at signing or at closing, except, in the case of certain representations and warranties (including those at issue in this case), where "the failure to be true and correct would not individually or in the aggregate, reasonably be expected to have a Material Adverse Effect."[209]

- Fresenius had the right to terminate the Merger Agreement if Akorn "failed to perform any of its covenant or agreements" "in all material respects" and the breach was "incapable of being cured . . . ."[210]

- Fresenius could refuse to close the Merger if Akorn had suffered "any effect, change, event or occurrence that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect."[211]

- Fresenius could not exercise its termination right for an inaccurate representation or breach of covenant if Fresenius was "then in material breach of any of its representations, warranties, covenants or agreements" under the Merger Agreement.[212]

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[206] *Id.* § 5.01(a).

[207] *Id.* § 5.05.

[208] *Id.* § 5.03(c).

[209] *Id.* §§ 6.02(a) & 7.01(c)(i).

[210] *Id.* §§ 6.02(b) & 7.01(c)(i).

[211] *Id.* § 6.02(c).

[212] *Id.* § 7.01(c)(i).

- Both sides had the ability to terminate if the Merger was not completed by the Outside Date, defined initially as April 24, 2018, but if antitrust approval had not been received by April 24 and all other conditions to closing were met, then the Outside Date would extend automatically to July 24.[213]

This decision addresses the pertinent provisions in greater detail in the Legal Analysis.

After the close of trading on April 24, 2017, Akorn and Fresenius announced the Merger.[214] The total purchase price was $4.75 billion, comprising $4.3 billion in cash plus assumption of approximately $450 million in debt.[215] Fresenius stated in a press release that "Akorn brings to Fresenius Kabi specialized expertise in development, manufacturing and marketing of alternate dosage forms, as well as access to new customer segments like retail, ophthalmology and veterinary practices. Its pipeline is also impressive, with approximately 85 ANDAs filed and pending with the FDA and dozens more in development."[216]

When committing Fresenius to the transaction, Sturm asked Akorn to reaffirm its guidance for 2017. Sturm viewed guidance as a promise to the markets, and he felt a public reaffirmation would confirm that Akorn management had committed to its numbers and

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[213] *Id.* § 7.01(b)(i).

[214] JX 520 at '833.

[215] JX 481 at 1.

[216] *Id.*

would continue to perform post-signing.[217] As part of its announcement of the transaction, Akorn reaffirmed its full-year guidance, projecting $1,010–$1,060 million for revenue and $363–$401 million in EBITDA.[218]

Fresenius Parent held a conference call with its investors to discuss the Merger. During the call, Sturm described the due diligence process as follows:

> [W]e performed a detailed due diligence [with] access to a comprehensive data room, held countless expert sessions, and were able to address all our questions and concerns. Have we overlooked anything material? Possible, but unlikely. The due diligence also included plant visits, by me and much better qualified experts, as well as a detailed review of Akorn's product portfolio. That led to us building a solid bottom-up business plan, which formed then the basis of our decision to make a bid.[219]

Sturm stated that during due diligence, Fresenius found Akorn operating at a "generally good regulatory standard."[220] He noted that while Akorn had received a Form 483 for Decatur, Fresenius had "received quite a number of form 483s also in the past" and therefore "should be humble and avoid any form of arrogance" regarding regulatory issues."[221]

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[217] *See* Sturm Tr. 1176–77; *see also id.* at 1178 (explaining that guidance "where I'm coming from, is a promise"); *id.* at 1180 ("[A]t Fresenius, we consistently make our numbers. We view a guidance as a promise. We tend to keep promises.").

[218] JX 341; JX 481 at 2; Rai Tr. 538.

[219] JX 490 at '907.

[220] *Id.* at '918.

[221] *Id.* at '919; *see* Sturm Tr. 1199–1200.

During a special meeting on July 19, 2017, Akorn's stockholders approved the Merger by a wide margin.

H. Akorn Management Makes Changes In Response To The Merger.

Under the Merger Agreement, Akorn was required to continue operating in the ordinary course of business between signing and closing.[222] This obligation included, among other things, investigating and remediating quality issues and data integrity violations as they were identified.[223]

Instead of operating in the ordinary course, Akorn changed how its quality function and IT function approached their jobs.[224] Employees in these groups were told that "[p]riorities have been revised, and some 2017 initiatives will be stopped[,]" with the cited reason being the "implications of the pending Fresenius Kabi transaction."[225]

For the quality function, Akorn replaced certain regular internal audits scheduled for the end of 2017 with "verification" audits that would only assess Akorn's progress in

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[222] JX 1 § 5.01(a); *see* JX 488 at '574 (presentation to Akorn senior executives on interim operating covenants highlighting Akorn's obligation to "[c]arry on in the ordinary course"); Rai Tr. 521 (agreeing that Akorn was obligated "to operate as an independent business between the signing of the acquisition agreement and any closing of the deal"); *see also* JX 551 at '999 (announcement to all Akorn employees: "Until the transaction closes, it is business as usual and Akorn and Fresnius Kabi will continue to operate as two independent companies.").

[223] Rai Tr. 525; Kaufman Tr. 371.

[224] *See* JX 538; JX 539.

[225] JX 539 at '105; *see id.* at '106 ("2017 initiatives to be stopped" including "Quality Assurance overview" and "IT overview"); *id.* at '107 ("**STOP** - the identified 2017 projects and associated activities / spend"); JX 538 at '471 ("Reset 2017 Priorities").

addressing prior audit findings.[226] One of the sites that switched to verification audits was Decatur, the site Cerulean had visited.[227] The shift to verification audits meant that Akorn would not be identifying any new problems at those sites that might cause difficulties for the Merger. Akorn also used the Merger as grounds for stopping Cerulean's engagement.[228] Fresenius never gave approval for Akorn to change its audit and investigatory practices pending closing.[229]

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[226] Wasserkrug Tr. 17 ("[A]fter the merger was announced, it was decided that we would only do verification audits in the remaining facilities, which meant we were just going to look at the previous audits and the corrective actions that were applied from those previous audits to make sure that they were closed."); *accord id.* at 156–58; JX 532 at '276; JX 692; *see* Gill Dep. 60; Rai Dep. 42–43; JX 692; *see also* JX 1026 ("[T]he two are very different activities (audits vs. verifications). Verification is the last step in an audit lifecycle."); Rai Tr. 480–81 (explaining why certain audits "were not done deliberately"); *id.* at 525–26 (agreeing that Akorn only conducted verification audits for certain facilities because of the Merger). Wasserkrug recognized that Akorn had "a responsibility to continue with our audits[,]" and when the Merger did not close, Akorn resumed them. Wasserkrug Tr. 18.

[227] *See* Rai Tr. 551.

[228] *See* Wasserkrug Tr. 132.

[229] *See* Rai Tr. 527–28, 554–55. Wasserkrug suggested at trial that Fresenius supported the decision to move from regular audits to verification audits, but her testimony on this subject consisted of hearsay and was not reliable. Wasserkrug Tr. 165–67. The more persuasive evidence is that Akorn did not mention this change to Fresenius. *See* Gill Dep. 61–63; Rai Tr. 527–29. Rai asserted at trial that Akorn made the switch so that Akorn could give Fresenius a short document summarizing open audit findings. Rai Tr. 526; Rai Dep. 42–43; *see* Gill Dep. 63. Rai did not know whether Akorn ever prepared (or started) a report, and during discovery Akorn did not produce one. *See* Rai Tr. 526–27.

For the IT function, Wasserkrug testified at trial that "[a]ny [IT] projects that we wanted to put in place were deferred by the merger or had to be approved."[230] In light of the freeze, Akorn's IT department could not provide resources for data integrity projects.[231] In July 2017, Tammy Froberg, Executive Director of R&D and Quality Compliance Systems, told a quality manager at Vernon Hills that "we are not actioning any Data Integrity activities in 2017."[232] In August, Misbah Sherwani, the head of quality at Somerset, reported to Silverberg that even though Akorn was "on the cusp of the FK" merger, Somerset was "in a state of jeopardy as it relates to data integrity[,]" and IT was refusing to provide resources.[233] Also in August, Kathy Pramik, Akorn's acting Chief Information Officer, told Silverberg and other executives that she was "not authorizing" IT resources for Decatur's Data Integrity Site Master Compliance Plan, the first plan Akorn ever developed.[234] She admonished that it was "not appropriate" to "establish[] Data

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[230] Wasserkrug Tr. 141–42.

[231] *See* Pramik Tr. 223–24; *see also* JX 957 at '921 ("In July, we . . . reset 2017 priorities. . . . We also communicated that some 2017 priorities were being adjusted, per implications of the pending Fresenius Kabi transaction."). Ostensibly these projects were only put on hold until Silverberg assembled "an overall roadmap for data integrity," but the roadmap was never finalized. Pramik Tr. 234–36, 248.

[232] JX 891; *see* Kaster Dep. 118–20.

[233] JX 564 at '352.

[234] JX 589 at '192. Pramik is not an Akorn employee, but rather a consultant. She was retained in August 2016 to fill the CIO role while Akorn searched for a permanent hire. They never found one. *See* Pramik Tr. 191–92; JX 149. When she took the role, Pramik had no prior experience in how pharmaceutical companies handle data integrity issues. *See id.* at 242–45. To be fair to Pramik, it also appears that she inherited a bad situation. When she arrived, she found that "[t]here were foundational processes not in

Integrity Plans" because "Fresenius Kabi Quality & IT Leaders will drive any actions in this area."[235] That same month, Froberg refused a data integrity project, stating bluntly that "[e]xecutive leadership have discussed and aligned that data integrity changes are not actionable in 2017 in regards to adding responsibilities to cross functional teams."[236] In December 2017, Franke complained to another employee that "DI remediation activities

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place at Akorn[,]" including "no project governance" for IT. *Id.* at 196–97; *see* JX 150 (list of "IT Key Risks Identified By IA"); JX 223 (Rai in November 2016: "It seems like IT is a disaster across the company and out of control."). A significant motive for shutting down data integrity projects appears to have been her desire to focus her under-resourced department on senior management's priorities, which did not include data integrity. It nevertheless remains true that Pramik and her staff prevented any data integrity work that required IT resources from getting off the ground in 2017 and early 2018. This did not change until March 2018, when in response to Fresenius's investigation, Pramik rebranded an existing but dormant committee that had not met since early 2017. *See* Pramik Dep. 76–77 (formerly "R&D quality and compliance IT counsel"); Pramik Tr. 230–32 (now "data integrity steering committee"); JX 1082 (also referring to a "DI Oversight Committee"); *see also* Pramik Dep. 254–58 (agreeing that the rebranded committee is largely "the same governing body" as the executive steering committee Rai chaired a month later). Pramik gave much of her testimony in response to leading questions based on a demonstrative exhibit, resulting in my giving it diminished weight. *See* Pramik Tr. 199–224.

[235] JX 589 at '192–93.

[236] JX 596; *accord* JX 769 (Froberg writing in December 2017 that "[b]ased on a previous executive leadership directive, data integrity is not a 2017 approved project for cross functional teams [such as IT]. I wanted to . . . confirm IT resources will not be involved in [Franke's visit to the Cranbury site to discuss data integrity]."); JX 950 (Froberg reminding Pramik in February 2018 to draft an email from "executive leadership . . . to align all sites that we are not launching data integrity remediation initiatives at the sites at this time"); JX 957 at '921–22 (Pramik's draft email with Silverberg's comments: "With . . . the close of the acquisition transaction not occurring in fiscal 2017, unapproved project requests related to such things as Data Integrity are starting to arise again from the sites, and we need to alignment [sic] and focus on our priority initiatives, which are continuing in 2018 (e.g., Serialization, Somerset and Decatur lab modernizations / expansions, etc.).").

are not something that we are resourced to address at the moment."[237] There is no evidence that Fresenius ever gave approval for Akorn to stop working on data integrity projects.[238]

I. The Downturn In Akorn's Business

After the signing of the Merger Agreement, Akorn's business performance fell dramatically. On July 21, 2017, two days after Akorn's stockholders approved the Merger, Akorn gave Fresenius a preview of their second quarter results. The headline was revenue of $199 million, compared to a business plan of $243 million.[239] Management attributed $12 million of the miss to competition for ephedrine, but told Fresenius that "[m]arket share in Q2 is meeting expectations."[240] Management lowered its revenue forecast for the year from $1 billion to $930 million.[241] Management also reduced expectations for revenue from Akorn's pipeline, which fell to $24 million, down from the $80 million projected earlier in 2017.[242]

On July 31, 2017, Akorn publicly announced its results. The reported revenue number of $199 million represented a year-over-year decline of 29%. Akorn's reported

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[237] JX 832.

[238] *See* Pramik Tr. 249; Bowles Dep. 152–158.

[239] JX 547 at 1.

[240] *Id.* at 2.

[241] *Id.* at 15.

[242] JX 554.

operating income of $15 million represented a year-over-year decline of 84%. Akorn's reported earnings of $0.02 per share represented a year-over-year decline of 96%.[243]

Rai attributed the bad results to unexpected new market entrants who competed with Akorn's three top products—ephedrine, clobetasol, and lidocaine.[244] Akorn also faced a new competitor for Nembutal, another important product, which Akorn management had not foreseen.[245] As Rai testified, "There were way more than what [Akorn] had potentially projected in [its] forecast for 2017."[246] The new competition resulted in unexpected price erosion.[247] Akorn also unexpectedly lost a key contract to sell progesterone, resulting in a loss of revenue where Akorn had been forecasting growth.[248]

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[243] JX 1250 ¶ 8.

[244] Rai Tr. 542–44; Rai Dep. 237.

[245] Rai Tr. 545; Rai Dep. 238–39.

[246] Rai Tr. 545; Rai Dep. 238.

[247] Rai Tr. 542; *see* JX 693 at 35 (attributing poor performance to "more significant than expected declines in net revenue").

[248] Rai Tr. 546–47.

Ducker described the results bluntly, "Not very pretty I'm afraid."[249] Sturm was "very unhappy."[250] He asked his executive team whether they thought Fresenius "had been defrauded."[251] They did not think so. Sturm "also asked if there was a way to cancel the deal."[252] His team said "not at this point."[253]

Sturm and Henriksson flew to Lake Forest, Illinois to meet in person with Ducker and the Akorn executives.[254] Sturm told Rai that the "complete drop" in Akorn's business post-signing was "the most embarrassing personal or professional thing" that had happened to him.[255] Sturm could not understand how the parties had signed up a deal, only to have Akorn's results fall "off the cliff."[256] Rai told Sturm that "[m]any, if not most" of the

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[249] JX 547 at 1; *see* Sturm Tr. 1177 (describing performance as "dismal" and "well below our expectations and theirs"); Henriksson Tr. 952 (describing results as "very, very disappointing" with "a big miss, both on sales and profit, compared to the estimates that had been provided to us before"); Bauersmith Tr. 595 (describing Akorn's performance in the quarter after signing compared to is projections as "[a]bysmal"); *id.* at 596 (testifying that Akorn's performance was "even worse than what I thought, as the pessimist").

[250] Sturm Tr. at 1202; *see* Henriksson Tr. 952 ("Stephan was, rightfully, very, very upset.").

[251] JX 550 at '924.

[252] *Id.*

[253] *Id.*

[254] Sturm Tr. 1178.

[255] JX 554.

[256] Rai Tr. 468.

reasons for the poor performance were "temporary in nature."[257] Sturm was not satisfied. He felt that Akorn management exhibited "a complete lack of commitment" and that the guidance for 2017 "had been forgotten and was a thing of the very long past."[258] He did not perceive any sense of urgency to rectify the underperformance.[259]

After the meeting in Lake Forest, Sturm had his team analyze Fresenius's options. He tasked Henriksson and Ducker with finding new synergies and developing a business plan that would offset Akorn's problems.[260] Sturm also had his legal department look into whether Akorn's terrible financial performance qualified as a Material Adverse Effect.[261] Although Akorn has asserted that Fresenius decided at this point to find a way to terminate

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[257] Sturm Tr. 1178.

[258] *Id.*

[259] *Id.* at 1178–79.

[260] *See* Henriksson Tr. 956–58; Sturm Tr. 1179–80; JX 554 ("Our marching orders are to find a way so we can hold to guidance on EBITA and Top line for 2018."). Bauersmith, the primary skeptic about the deal, believed Fresenius needed to close the transaction quickly so that they could take control of Akorn and try to right the ship. *See* JX 554 ("The need to close fast is even more pressing as we can't really steer this wayward vessel until we are aboard."). Bauersmith couldn't resist an I-told-you-so, noting that "it is looking more and more like we should have pushed for a CVR on 2017 approvals as [I] suggested back in February." JX 549; *see* Bauersmith Tr. 600; *see also* JX 602; JX 603; JX 674. Other contemporaneous documents support the finding that closing remained a high priority within Fresenius. *See* JX 568 (Pramik reporting on Ducker making it a "very high priority" to plan IT integration); JX 572 (Fresenius executives exploring whether they could mitigate negative reactions by Fresenius Parent's stockholders by closing and then immediately stopping the reporting of separate results for Akorn); JX 575 (August 2017 Fresenius presentation regarding financial integration).

[261] *See* JX 581; JX 587.

the deal, I do not agree. Sturm testified credibly that he wanted "to get myself knowledgeable about my options under the merger agreement, but also my responsibility, my fiduciary duties in serving my shareholders, and hence I was asking my colleagues on the legal side to get us appropriate legal advice."[262]

As part of this process, the Fresenius team looked at precedent deals gone bad. One involved Abbott Laboratories's attempt to terminate its acquisition of Alere Inc. Paul, Weiss, Rifkind, Wharton & Garrison LLP had represented Alere, and Fresenius began consulting with Paul Weiss.[263]

Fresenius also began looking closely at Akorn's monthly results to determine whether the second quarter performance was an isolated occurrence, as Rai maintained, or the harbinger of deeper problems. Akorn's preliminary results for July did not show any improvement, but Rai claimed that Akorn was on track to deliver $80 million in sales in August.[264] If Akorn hit that figure and repeated the performance in September, then Akorn would meet its lowered forecast for the third quarter.[265]

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[262] Sturm Tr. 1183; *see id.* at 1209 (Sturm testifying that Paul Weiss was hired "[t]o make me acquainted with my rights and obligations").

[263] *See id.* at 1183–84.

[264] JX 592 at '100.

[265] *Id.*

In mid-September 2017, Fresenius heard that Akorn would fall short of its August revenue target.[266] Akorn later confirmed that it had achieved only $70 million.[267] Sturm was furious: "10m less within a few days? Without any sense of embarrassment? . . . These guys are shameless. I'm afraid we've got to build our legal case."[268] At trial, Sturm noted that over the same period, Fresenius USA exceeded expectations.[269]

Nor was the revenue miss Akorn's only bad news. The FDA issued a CRL for Difluprednate, a key pipeline product, and Akorn had to push back its launch from 2017 until 2019.[270]

Fixating on Sturm's email about "build[ing] our legal case," Akorn argues that Fresenius set out to manufacture a basis for termination. At trial, Sturm testified credibly to a more nuanced and responsible view. He candidly admitted that at this point, he personally wanted to terminate the transaction. He was "very unhappy" with Akorn's performance, believed that "the underperformance was more likely to be longer-lasting," and felt that Fresenius had overpaid.[271] At the same time, he knew that Fresenius had signed

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[266] *See* JX 636 at '891.

[267] *See* JX 646 at '654.

[268] JX 647 at '657.

[269] Sturm Tr. 1185.

[270] JX 610; JX 611 at 2; Sturm Tr. 1185; *see* JX 615 ("[A]korn got a deficiency letter from FDA regarding Difluprednate which is the biggest launch in 2018. The effect from this is 57 M.").

[271] Sturm Tr. 1186–88.

a contract, and "[t]he last thing [he] wanted to do was to . . . to go to court . . . without a valid case."[272] He also recognized that if Akorn had a stronger performance in the fourth quarter, then the situation would be different, although he was "not very optimistic."[273]

Sturm is a sophisticated international businessman. He 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. At trial, his testimony was direct and credible. I accept his explanation that in September 2017, he was "in an exploratory phase."[274] He no longer liked the deal, and he would seek to terminate it if Akorn's performance continued to deteriorate, but Fresenius also would live up to its obligations.

Consistent with this testimony, the contemporaneous evidence shows that Fresenius continued to assess how it could close the Merger and make the numbers work.[275] Fresenius also tasked a team with reviewing Akorn's most significant product launches to determine whether any of them could be accelerated to replace lost pipeline revenue.[276] Instead, Fresenius learned that three other launches would be delayed.[277] At the same time,

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[272] *Id.* at 1189.

[273] *See id.*

[274] *Id.*; *see id.* at 1206 ("Q. Okay. And you started looking for a way to get out of the transaction, did you not? A. No. I did not.").

[275] *See* JX 627 at '498; JX 657; JX 658; JX 661; JX 664; JX 670 at 20; JX 684 at '911.

[276] *See* JX 605; JX 619; JX 620.

[277] *See* JX 624.

Fresenius began examining whether there were grounds to assert a Material Adverse Effect.[278] Based on advice from Paul Weiss, Fresenius concluded that it did not have clear grounds for termination.[279] Given the Delaware precedent, this was hardly surprising.

J. Akorn's Third Quarter Results

On October 30, 2017, Akorn provided Fresenius with a presentation describing the quarterly results that Akorn expected to announce the next day.[280] Akorn would report revenue of $202 million, representing a miss from its reduced forecast of $225 million.[281] Akorn described the results as "[d]riven mostly by unanticipated supply interruptions and unfavorable impact from competition across [the] portfolio (Ephedrine, lack of new awards, unfavorable customer contract mix . . .)."[282] Akorn also noted that its "[a]verage product pricing [was] lower than expected due to [an] unfavorable customer/contract mix and price erosion [that was] not considered in our forecast."[283]

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[278] *See* JX 634; JX 635; JX 637.

[279] *See* Sturm Tr. 1211–12; Empey Dep. 106–08. In her deposition, the CFO of Fresenius Parent testified from memory about her understanding of these discussions, in which she did not personally participate. She stated the outcome in absolute terms: "[W]e concluded that there was no basis for a termination of the transaction." Empey Dep. 107. Based on Sturm's testimony, my knowledge about how rarely lawyers frame their legal advice in absolute terms, and the CFO's distance from the discussions, I am confident that this testimony oversimplifies matters and states the outcome too strongly.

[280] JX 688; *cf.* JX 732 (Ducker describing October 2016 results as "awful").

[281] JX 688 at '605.

[282] *Id.* at '606.

[283] *Id.* at '607.

On October 31, 2017, Akorn informed Fresenius that Kapoor had resigned from the Akorn board.[284] Five days earlier, federal law enforcement had arrested Kapoor and charged him with criminal fraud in connection with his leadership of another pharmaceutical company.[285]

On November 1, 2017, Akorn announced its financial results.[286] Akorn's reported revenue of $202 million represented a year-over-year decline of 29%. Akorn's operating income of $9 million represented a year-over-year decline of 89%. Akorn reported a loss of $0.02 per share, a year-over-year decline of 105%.[287]

In addition to another poor quarter, Akorn fell further behind in its product launches. Akorn had anticipated thirty-four launches in 2017; by mid-November it had launched only fourteen, with another six planned by year end. The fourteen launches netted only $3.3 million in sales. Akorn originally had projected $60 million from new product launches in 2017.[288] These results were far worse than what even Bauersmith, the biggest critic of

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[284] *See* JX 689.

[285] *See* JX 696 at '041; Press Release, District of Massachusetts, U.S. Attorney's Office, Department of Justice, Founder and Owner of Pharmaceutical Company Insys Arrested and Charged with Racketeering (Oct. 26, 2017), https://www.justice.gov/usao-ma/pr/founder-and-owner-pharmaceutical-company-insys-arrested-and-charged-racketeering.

[286] JX 693.

[287] JX 1250 ¶ 9.

[288] *See* JX 707 at '505.

Akorn's pipeline, had anticipated.[289] He viewed the performance of Akorn's launches as "almost comical," because it did not make commercial sense to launch a drug if that was the expected return.[290]

In spite of the bad news from Akorn, Sturm maintained a positive outlook about the Merger when speaking with Fresenius Parent's investors. He described Akorn's results as "for sure not what we had hoped for, but at least a sequential stabilization."[291] He also stated that "the reasons for the disappointing financial performance are broadly unchanged from the second quarter," citing three factors:

> A, more pronounced competition. Akorn continues to experience price pressure and market share losses on some of its key molecules. And while increased competition was generally anticipated, the impact has was [sic] unfortunately been greater than expected. . . .
>
> B, supply disruptions. And while some supply issues from the second quarter were resolved, new constraints have occurred, leading again to higher than normal backorders and inability to supply charges. Frankly, [we] can't wait to assume management control, so we can help with our expertise and our financial power.
>
> C, new product launches. And even though Akorn has launched a respectable 13 new products year-to-date, it had even higher expectations. So launch delays, including to some significant molecules, contributed to the shortfall versus projected revenues. We have reviewed these delays with Akorn's management, and we believe that the opportunities are essentially postponed rather than significantly diminished.[292]

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[289] Bauersmith Tr. 596.

[290] *Id.* at 598.

[291] JX 699 at '669.

[292] *Id.*

Notwithstanding these problems, Sturm said that Fresnius Parent would not revise its expectations for Akorn's performance in 2018, explaining:

> First, let me remind you that our 2018 expectations came[,] by our standards[,] extremely early and were based on the comprehensive but still outside[-]in due diligence process. Couple that with injectable generics, arguably Fresenius' most volatile business, and so we called it very consciously an expectation rather than a guidance. Now, in light of Akorn's year-to-date performance, it appears likely the 2017 base will be lower than assumed. And as a consequence, the stretch required to reach our 2018 expectations is clearly larger.
>
> But as I just said, this is a highly volatile business with limited visibility, notoriously hard to predict, and where you just cannot extrapolate from a quarterly run rate, where individual drugs and launches can make and have made a major difference. So I'm not ready to revise those expectations for next year. Please bear with us until February. By then, we will be Akorn's controlling owner and we'll provide you with a guidance of a reliability level that you're used to.[293]

My impression is that Sturm knew that expectations would have to be lowered, but he did not have numbers that he trusted and would not have them until his own people were running the Company.

After Akorn and Fresenius announced their third quarter results, Fresenius updated its business plan for Akorn. During a teleconference on November 12, 2017, Ducker presented the plan to the Management Board.[294]

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[293] *Id.*

[294] *See* JX 714 (Ducker circulating presentation to senior Fresenius Parent executives in advance of call).

Ducker's presentation noted that the "[s]trategic rationale for the Akorn acquisition remains compelling."[295] The compelling strategic rationale was Fresenius Kabi's desire to expand its North American footprint, which acquiring Akorn facilitated.[296]

The Akorn deal, by contrast, had become far from compelling. The presentation observed that Akorn's "2017 business performance has been disappointing and has fallen well short of guidance"[297] To partially address the shortfall, "[c]ost reduction opportunities well in excess of the deal model are now planned."[298] Even with these additions, the changes in the 2018 business plan were striking:

	Original Plan[299]	November Update	% Change
Revenue	$1,061	$783	(26%)
Gross Profit	$612	$414	(32%)
EBITDA	$397	$241	(39%)
EBIT	$239	$125	(47%)
Net Income	$33	$(38)	(215%)

[295] *Id.* at 2; *see* JX 730 at '832 ("The strategic rationale for the acquisition remains sound."). Fresenius made this same point in other presentations and in a call with its investors. *See* JX 743 at '306; JX 781 at '398; JX 874 at '779; JX 994 at 5, 15.

[296] *See* JX 994 at 5.

[297] JX 714 at 2.

[298] *Id.*

[299] In millions of dollars.

Akorn's performance was so bad, and the situation in such flux, that the Management Board excluded Akorn from their 2018 budget, which they presented to the Supervisory Board in December 2017.[300] The presentation explained the omission:

> Akorn is not included in the budget. We see some deviations to the original business plan and we are working on counter measures to mitigate these effects. This process will be ongoing until early February 2018. Until then we will also have better clarity about when closing will happen and we will only then seek for approval for the Akorn budget.[301]

This explanation is consistent with Sturm's earlier refusal to change his Akorn-related guidance to the market: the Management Board did not have any numbers they trusted for Akorn. I believe they also considered the possibility that Fresenius would terminate the Merger Agreement and either never own Akorn at all, or at least not own it during 2018, while the litigation over a broken deal would be ongoing.

Despite the senior management team's powerful internal misgivings, Fresenius did not change its public stance on the Merger. In roadshow materials dated November 27, 2017, Fresenius told investors the following:

- "[Akorn] Q3 performance below expectations."[302]
- "Achievement of 2018 expectation challenging."[303]

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[300] JX 716; *see* JX 744 at 4.

[301] JX 744 at 4.

[302] JX 743 at '306.

[303] *Id.*

- "Strategic rationale unchanged: Deal offers offensive and defensive merits."[304]
- "Substantial cost and growth synergies paired with limited integration complexity."[305]
- "Accretive to Group net income from 2018."[306]

Fresenius described the Merger in similar terms in a presentation to investors at conferences in December 2017 and January 2018.[307]

K. The Whistleblower Letters

On October 5, 2017, Fresenius received an anonymous letter from a whistleblower who raised allegations about Akorn's product development processes at Vernon Hills, Decatur, and Somerset.[308] On November 2, Fresenius received a longer version of the letter that added more detail about the problems and included assertions about flaws in Akorn's quality control processes.[309]

During a teleconference on November 12, 2017, the senior executives of Fresenius Parent discussed the November letter. When circulating his presentation, Ducker noted that he had asked Jack Silhavy, the general counsel of Fresenius USA, "to join us for the first

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[304] *Id.*

[305] *Id.* at '307.

[306] *Id.*; *accord id.* at '308 ("Accretive [to EPS] in 2018 (excluding integration costs), from 2019 (including integration costs)").

[307] *See* JX 781 at '398–400; JX 874 at '779–81.

[308] *See* JX 789; *see also* JX 934 at 11.

[309] *See* JX 788; *see also* JX 934 at 11.

part of the call to brie[f] everyone on the letter just received from an Akorn employee, and the possible implications and next steps."[310] On November 13, the Fresenius executives had a call with Paul Weiss.[311] After the call, Fresenius personnel began looking into the information Akorn provided during due diligence about its R&D facilities and past FDA inspections.[312]

Having considered the evidence, I believe that during the teleconference on November 12, 2017, the Fresenius executives decided 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 for doing so. They had ample grounds to reach this conclusion. My sense is that they regarded Akorn's disastrous performance as falling within a businessperson's understanding of what should qualify as a material adverse effect, but their legal advisors were not confident that they could prove to the satisfaction of a court applying Delaware law that Akorn had suffered a Material Adverse Effect within the meaning of the Merger Agreement.

The whistleblower allegations about regulatory problems were yet another blow to the deal. The letters called into question the accuracy of Akorn's representations regarding regulatory compliance. They also called into question whether Akorn was operating in the

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[310] JX 714.

[311] JX 717.

[312] *See* JX 718; JX 720; JX 721.

ordinary course of business.[313] It was not clear yet whether the allegations were true, but the whistleblower letters gave Fresenius good cause to investigate.

In the Merger Agreement, Fresenius had bargained for a customary right of reasonable access to Akorn's "officers, employees, agents, properties, books, Contracts, and records."[314] The purpose of that covenant is to enable a buyer to investigate issues that arise between signing and closing. The Fresenius executives decided to use their information right for its intended purpose.

L. Fresenius Notifies Akorn.

On November 16, 2017, Ducker and Henriksson called Rai, informed him about the whistleblower letters, and conveyed Fresenius's view that both companies needed to investigate the allegations.[315] Ducker followed up with a formal notice letter, which stated:

> [P]ursuant to Section 5.05 of the [Merger Agreement] and for other reasons, Fresenius Kabi will be providing Akorn with requests for documents, information and access to potentially knowledgeable individuals regarding the allegations in these letters and related issues. We are in the process of identifying and retaining a team of third party experts with the skills and experience to properly investigate these matters expeditiously, and we ask that Akorn immediately take steps to begin to gather all related documentary material.[316]

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[313] *See* JX 1 §§ 6.02(a)(ii) & (b), 7.01(c)(i).

[314] *See id.* § 5.05.

[315] *See* JX 723 at '800–01.

[316] JX 724 at '204.

The letter closed by noting that Fresenius "reserve[d] all of our rights under the merger agreement."[317]

After receiving the whistleblower letters from Fresenius, Akorn shared them with its board members. Johnson, a director with substantial FDA experience, described them as "very worrisome," noting that "[i]f they were to get to FDA, we should expect an intensive investigation" and that "[m]ost data integrity issues are surfaced through whistleblowers going to FDA."[318] He advised that Akorn needed to conduct a "responsive and credible" investigation that "would require a review of named applications including product development files and lab notebooks" as well as "[i]nterviews of those involved, in any way, with the named submissions . . . ."[319] He advised that if the investigation uncovered problems, then "a much broader investigation following FDA guidance would be necessary."[320]

On November 17, 2017, Silhavy told Bonaccorsi that Fresenius could not simply rely on the investigation that he expected Akorn to conduct, but rather Fresenius would have to do its own investigation as well.[321] As it turned out, Akorn decided not to conduct

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[317] *Id.* at '205.

[318] JX 761.

[319] *Id.*

[320] *Id.*

[321] JX 726 at '084 (Silhavy reporting to Ducker about call with Bonaccorsi: "We then discussed how to proceed . . . . I told him I needed to be very clear that we needed to do our own investigation, not just rely on the one they needed also to do."); *see also* JX 723 at '801 (Fresenius anticipating that both companies would conduct investigations). In

its own investigation into the whistleblower letters because Akorn did not want to uncover anything that would jeopardize the Merger.

In the ordinary course of business, an FDA-regulated company confronted with a detailed whistleblower letter would conduct an investigation using counsel experienced in data integrity issues and knowledgeable about FDA compliance. Akorn chose to rely on its deal counsel, Cravath, Swaine & Moore LLP. Cravath's job was not to conduct an investigation, but rather to monitor Fresenius's investigation and head off any problems.[322]

David M. Stuart, a litigation partner, led the Cravath team.[323] Stuart previously worked for the SEC and had experience conducting internal investigations.[324] He is clearly a skilled and careful attorney, but he had never conducted a data integrity investigation for

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response to Fresenius's argument that Akorn breached its obligation to operate its business in the ordinary course by failing to conduct its own investigation, Bonaccorsi testified at trial that Silhavy instructed him over the phone that Akorn should not investigate. Bonaccorsi Tr. 887–88. Given the seriousness of the whistleblower allegations, that would not have been a viable position for Silhavy to take, and it would have contravened the ordinary course covenant in the Merger Agreement. The contemporaneous documents convince me that Bonaccorsi misremembered this conversation. Silhavy instead conveyed that Fresenius could not rely on Akorn's investigation and would also have to conduct its own investigation. *See* JX 723 at '801; JX 726 at '084.

[322] *See* Stuart Tr. 673 ("Q. So were you actually asked at that time to conduct an internal investigation for Akorn? A. I was asked to coordinate with Fresenius' counsel in conducting an investigation but not to do an independent investigation on my own."); *accord id.* at 728.

[323] *See id.* at 671.

[324] *See id.* at 671–72.

a pharmaceutical company, had never appeared before the FDA, and had no familiarity with FDA rules, regulations, or administrative guidance.[325]

Fresenius, by contrast, conducted a real investigation. Fresenius turned to the FDA Enforcement and Compliance Group at Sidley Austin LLP.[326] Nathan Sheers, a Sidley partner who specializes in FDA enforcement and compliance, led the team.[327] The Sidley

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[325] *Id.* at 688, 703, 730–31 ("Q. And prior to this moment in time [when Stuart was charged with leading the investigation], you weren't even familiar with the FDA rules, regulations, and guidance for the industry on data integrity and compliance. A. That's correct."); Stuart Dep. 30–40.

[326] *See* JX 719; Stuart Tr. 674 (testifying that Sidley "said that they had been hired to do an investigation to assess the validity of the allegations in these anonymous whistleblower letters"). Stuart claimed not to have known that Sidley's work could be used to evaluate whether Akorn was in compliance with its representations in the Merger Agreement and that he would have acted differently if he had known. *See* Stuart Tr. 675. I do not credit that testimony. Stuart is a sophisticated partner at one of the world's most sophisticated law firms. He certainly knew that if the whistleblower allegations were true, then they posed problems under the Merger Agreement. He also certainly knew that Fresenius would be assessing that issue when reviewing Sidley's work. Cravath's approach to the common interest agreement, discussed below, evidences an understanding of the dual implications of Sidley's work and an unsuccessful attempt to secure the high ground for Akorn by including contractual provisions that could trip up Sidley and Fresenius. Stuart also testified that if he had known that Sidley's work would be used to evaluate Akorn's compliance with the Merger Agreement, he would have prepared Akorn's witnesses before their interviews. Cravath did prepare Akorn's witnesses, although it was relatively "low-key prep." *See* JX 1443 at '130 (Stuart: "Similar to what we did in Somerset, I think a little low-key prep for each interviewer [sic] is important. We should let them know that while we have no reason to think there are concerns about operations in Decatur, Sidley will ask whether the interviewee is aware of any data integrity issues and, if the interviewee is, we should address that before the Sidley interview."); JX 1445 (Stuart directing Cravath associates on how to "instruct" Akorn employees during pre-interview "screening"); Sheers Tr. 1039–41 (describing his observations regarding Cravath's preparation of witnesses).

[327] Sheers Tr. 1029–30.

team also included Jeff Senger, the former acting chief counsel at the FDA.[328] Fresenius and Sidley determined that they needed technical expertise from a firm that could evaluate the integrity of the data Akorn used to support its drug applications.[329] For that task, they hired Lachman.[330] The Lachman team was led by Ron George, a scientist with over 40 years of experience in the pharmaceutical industry and who now specializes in data integrity audits and remediation.[331] Having heard George testify at trial, I judge him to be among the most credible witnesses I have seen in court.

Sidley started its investigation by examining the materials on regulatory compliance that Akorn posted to the virtual data room.[332] Before doing so, Sidley considered whether

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[328] Sheers Tr. 1035.

[329] *See* JX 776 at '758 (describing Lachman's role). Fresenius also needed a firm to extract the data for Lachman to analyze and retained Ernst & Young LLP for that purpose. *See id.*

[330] *See* Sheers Tr. 1035–36. Formally retaining Lachman took some time. Lachman told Fresenius that it had a conflict and would require waivers from both Fresenius and Akorn, but Lachman declined to disclose whether or not Akorn was or had been a client or to discuss the nature of any engagement. Silhavy worried about granting a blind waiver, noting that although it was unlikely, "Lachman could have worked for Akorn on the very topics that are at issue here." JX 734 at '192. *See id.* at '191 (noting that in the most extreme case, Lachman might have "evaluated the very data integrity issues that we want them to investigate, and opined to Akorn [that] those are not of a type or magnitude that would cause there to have been fraud on the FDA?"). After considerable effort, an agreement was reached with Lachman in early December. *See* JX 772. Akorn contends that Silhavy wanted an expert who would give him the answer he wanted, but I find that he correctly wanted a consultant who would take a fresh look at the issues, not one who had worked on the same issues for Akorn.

[331] George Tr. 1115–17.

[332] *See* JX 735.

anything in the confidentiality agreement between Fresenius and Akorn prevented them from using the information. After reviewing the agreement, Sidley concluded that they were "Representatives" of Fresenius who could receive the "Evaluation Material" in the virtual data room without prior written consent from Akorn. The Sidley attorneys noted that the Evaluation Material could be used "solely for the purpose of evaluating, negotiating, and executing" a transaction. Sidley concluded that their investigation was part of the process of executing (*i.e.*, carrying out) the transaction, and hence they could use the Evaluation Material in their investigation.[333] I agree with that interpretation.

Next, Fresenius provided Akorn with a request for access, information, and documents to conduct its investigation.[334] Demonstrating the importance of the investigation to Fresenius, Sturm and his fellow senior executives at Fresenius Parent were personally involved in reviewing and revising the requests.[335]

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[333] *See* JX 747; Sheers Tr. 1106. Sidley also noted that the confidentiality agreement foreclosed speaking with the FDA, or anyone else, about regulatory issues related to the Akorn transaction. *See* JX 748. Akorn has argued that executing the agreement only meant signing it, but the meanings of the verb include to carry out. Akorn also says that Fresenius could not have been seeking to carry out the Merger Agreement if it was considering terminating it, but carrying out the deal includes evaluating one's rights and obligations under the deal, including rights and obligations which turn on a counterparty's compliance with its obligations.

[334] JX 771; JX 776.

[335] *See* JX 767.

After receiving the requests, Cravath spoke with Sidley about how to proceed.[336] During these discussions, Sidley learned that Cravath would not be conducting its own investigation, but rather facilitating Fresenius's investigation, sitting in on interviews, and generally "shadowing" Sidley.[337] The lawyers also discussed "whether the interviews would be conducted under a 'common interest privilege.'"[338] Internally, Sidley expressed concern that "the only common interest at this point is the solicitation of information from the interviewees and to conduct a thorough investigation," but that how the resulting information was used "likely is outside the scope of any common interest."[339]

To support the common interest privilege, Cravath proposed a draft agreement which recited that Sidley and Cravath were conducting "a privileged joint investigation for the purpose of assisting our clients close the acquisition."[340] The draft elaborated that the

> mutual interest arises from the desire of both Fresenius and Akorn to consummate the pending merger between the two companies and prepare a defense for the surviving entity in anticipation of any litigation that might arise, including by the FDA, another interested government entity or private litigant, based on the substance or fact of the allegations in the anonymous communications.[341]

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[336] *See* JX 784.

[337] *See* Bonaccorsi Tr. 908; Stuart Tr. 728; Rai Tr. 509–11; JX 784; JX 793.

[338] JX 784; *see* Sheers Tr. 1085–86 ("Before they would permit us to interview anyone, they said we had to sign a common interest agreement.").

[339] JX 784.

[340] JX 793.

[341] JX 792 at '700.

Proposing this language was a clever way to try to box in Fresenius and prevent them from using any information to evaluate Akorn's compliance with its representations. For precisely this reason, the Fresenius executives reacted negatively to this language.[342]

The parties ended up agreeing to a modified version of the common interest agreement that struck the concept of a joint investigation and stated in its place that "[t]he investigation may include joint interviews, document collection and review and sharing of information related to Akorn's processes, procedures and controls."[343] The final agreement also changed the language on mutual interest to state that it "arises from and under the Merger Agreement dated April 24, 2017 between Fresenius (and certain affiliates) and Akorn, and additionally because of the possibility of claims made by third parties."[344] The final agreement stated expressly that "either party shall be free to use or disclose the fact of, and any and all information learned or obtained during, the referenced investigation, including information exchanged hereunder, in any dispute between them."[345] These changes put Akorn on notice that Fresenius could use the fruits of the investigation to

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[342] *See* JX 794 (Silhavy emailing Sheers: "Cravath's proposal has caused a stir in Germany. They would like a call tomorrow . . . and do not want us signing anything until after that call."); *see also* JX 798 at '812 (Sidley attorney referring to Akorn as "our adversary here").

[343] JX 804 at '988.

[344] *Id.* at '988.

[345] *Id.* at '989.

evaluate its rights and obligations under the Merger Agreement and not merely for the purpose of closing the Merger.

M. The Site Visits Begin.

Between December 11 and December 15, 2017, the Fresenius team visited Vernon Hills. Sidley interviewed nineteen employees, and Fresenius's consultants toured the laboratory and questioned employees about equipment, software, controls, processes, and procedures. The Fresenius team identified serious data integrity issues.[346]

Between December 18 and December 21, 2017, the Fresenius team visited Somerset and Cranbury. Sidley interviewed ten employees while the consultants toured the laboratory. The Fresenius team again identified serious data integrity issues.[347]

From January 2 until January 5, 2018, the Fresenius team visited Decatur. They interviewed eleven employees while the consultants toured the laboratory facilities. The Fresenius team again identified serious data integrity issues.[348]

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[346] *See* JX 809; JX 856 at '872–77; JX 934 at 14; Sheers Tr. 1092. Sidley and Lachman later had a follow-up visit at Vernon Hills. *See* Sheers Tr. 1094. Akorn has fixated on a comment that George made when visiting the Vernon Hills site about looking for "smoking gun[s]." Sheers Tr. 1090. The details and context of this statement are too vague for me to draw any inferences from it.

[347] *See* JX 828; JX 856 at '878–86; JX 934 at 14; Sheers Tr. 1093.

[348] *See* JX 934 at 14; JX 856 at '887–94; Sheers Tr. 1093. Sidley and Lachman later had a follow-up visit at Vernon Hills. *See* Sheers Tr. 1094–95.

On January 5, 2018, Fresenius received a third whistleblower letter, which alleged that Vernon Hills personnel had concealed information from Fresenius.[349] Fresenius sent the letter to Akorn.[350] Based on the letter's allegations and its own concerns, Fresenius questioned whether Akorn was providing Fresenius with reasonable access to information. Akorn provided a pointed and detailed response.[351]

On December 18, 2017, while the Fresenius team was starting its visit at the Somerset site, Cravath commenced the only investigatory work that it did on its own, in contrast to simply shadowing Sidley.[352] While preparing witnesses for their interviews, Cravath learned about problems with the data supporting Akorn's ANDA for azithromycin and about Silverberg's submission in August 2017 of a response to a CRL that relied on false data.[353] Cravath started investigating what had happened.[354]

Two days after Cravath started investigating, on December 20, 2017, Silverberg went to Misbah Sherwani, Executive Director of Quality at Somerset, to try to coordinate their stories. Sherwani immediately called an associate at Cravath, telling the associate that

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[349] JX 842 (alleging that personnel were instructed "not to cooperate with" Fresenius and "not to disclose any information" to Sidley); *see also* JX 934 at 12.

[350] *See* JX 848; JX 851.

[351] *See* JX 853.

[352] *See* Stuart Tr. 728.

[353] *See id.* at 679–80.

[354] *See id.* at 680–82; Sheers Tr. 1041–42.

> she is uncomfortable being in the same room with Mark right now because he is telling her to do things with respect to opening a [T]rackwise investigation that she is seriously concerned about (including inaccurate justifications for why an investigation was not opened earlier and telling her he will "eat" the drafts of the language about that).[355]

The associate called Stuart, who spoke by phone with Silverberg and Sherwani.[356]

Stuart claimed at trial that the phrase "eat the draft" did not mean anything to him.[357] It sounds to me like a fairly obvious reference to coordinating stories, documenting the coordinated story in Trackwise, the software Akorn uses to track quality issues and investigations, then concealing the evidence of the coordination. This is exactly how Sherwani understood it.[358] She said Silverberg told her that they should agree on a description of the investigation and then Silverberg would "get rid of" what they had drafted.[359] Stuart "very quickly" dismissed this as a "fleeting issue" by deciding that Silverberg and Sherwani simply had a miscommunication.[360]

Cravath's investigation took approximately four weeks. The resulting record supports the following findings:

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[355] JX 825.

[356] Stuart Tr. 767, 769.

[357] *Id.* at 690, 768.

[358] *See* Sherwani Dep. 114–116.

[359] Stuart Tr. 691, 718, 771.

[360] *Id.* at 690, 693, 769, 773–74.

- In 2012, Akorn began developing a topical ophthalmic form of azithromycin, a prescription antibiotic, at its Somerset site, but could not perform particulate matter stability testing due to its viscosity.[361]

- In September 2012, an Akorn lab supervisor at Somerset named Jim Burkert entered stability testing data into the lab notebook of an Akorn chemist. There is no evidence that he had the data; he seems to have made it up.[362]

- In December 2012, Akorn submitted to the FDA an ANDA for azithromycin which included the false data.[363]

- In fall 2014, the stability testing issue came up again, and the chemist discovered the entries in her notebook. She also noticed other entries in the same notebook and in two other notebooks that were not in her handwriting. She reported it to Burkert, who did not ask any questions or follow up. The chemist next brought the issue to the attention of a quality manager who instructed all scientists to review their notebooks. The review discovered numerous instances of altered and missing data. In addition, two of Burkert's notebooks were missing.[364]

- On December 30, 2014, Burkert resigned voluntarily.[365]

- In July 2016, Silverberg visited Somerset. He interviewed the chemist and told her to note in her notebooks where the writing was not hers. She identified six additional products where the writing was not hers. After learning about the missing notebooks, Silverberg instructed that going forward, all notebooks would be stored

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[361] *See* JX 890 at '268–69; JX 821 at '207; JX 1889 at 1; Stuart Tr. 682–83.

[362] *See* JX 890 at '268–69; JX 821 at '207; JX 1889 at 1; *see also* JX 914 at '087 ("In brief, Stuart admitted that the company submitted to FDA 'fabricated' stability data—i.e., data for which the company has no support—for the Azithromycin ANDA . . . ."); *id.* at '088 ("[T]he data was in fact 'fabricated.'"); Stuart Tr. 740–41 ("Q. . . . Cravath concluded that there was a high likelihood that the data was false; correct? A. Yes.").

[363] JX 890 at '269; JX 1889 at 2.

[364] JX 1889 at 2–4.

[365] JX 890 at '273; JX 1889 at 4.

in the quality manager's office and checked in and out. Employees expressed concern that Silverberg was not addressing the issues properly. [366]

- In August 2017, Somerset was attempting to respond to a CRL that asked questions about the stability testing for azithromycin, albeit not specifically the fabricated test. When preparing the response, Akorn personnel identified the problems with the data and brought them to Sherwani's attention. She and a colleague, Michael Stehn, concluded that Akorn would need to withdraw the ANDA, and they elevated the issue to Silverberg.[367]

- During Silverberg's discussion with Sherwani and Stehn, Silverberg was told that it was highly likely that there was false or fabricated data in the initial ANDA submitted to the FDA.[368]

- During a meeting on August 17, 2017, Silverberg told Sherwani and Stehn that Akorn would not withdraw the ANDA and should instead pull samples and test them to see if the samples passed the test.[369] Silverberg subsequently instructed Sherwani and Stehn to respond to the CRL, not to ask for an extension, and not to open an investigation in the data issues.[370]

- Sherwani believed it was essential to conduct an investigation and to obtain an extension from the FDA. Sherwani asked Silverberg whether he was "allowing Regulatory Affairs to continue to submit inaccurate information" to the FDA.[371] Silverberg argued that the FDA was asking about different data.[372]

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[366] *See* JX 821 at '208; JX 890 at '274–75; JX 1889 at 6–8; Stuart Tr. 683.

[367] *See* JX 853 at '545; JX 579; JX 821 at '209–10; JX 890 at '278; JX 1889 at 8–10; Stuart Tr. 683–84, 744–45.

[368] Stuart Tr. 741.

[369] *See* JX 591 (Silverberg describing request for extension as "stupid"); JX 821 at '210; JX 1889 at 10–11; Stuart Tr. 745.

[370] *See* JX 607 at '105–06; JX 821 at '210–11; JX 1887 at 2; JX 1888 at 1–2; Stuart Tr. 759–63.

[371] JX 607 at '103; JX 821 at '211; JX 1889 at 11.

[372] *See* JX 607 at '102–03; JX 821 at '211; JX 1889 at 11.

- Sherwani disagreed with Silverberg's positon and declined to sign the CRL.[373]
- Silverberg instructed Sherwani that there should be "[n]o more emails."[374]
- Silverberg signed the CRL on Sherwani's behalf while she was out of the office.[375]
- By signing off on the CRL, Silverberg validated the attachments, which were not yet attached to the form he signed. The attachments included the false stability data.[376] Sherwani had made clear to Silverberg that signing the CRL would constitute a resubmission of the false data.[377]

N. Cravath Reports To Sidley On Its Investigation.

On January 12, 2018, Stuart gave Sidley a preliminary report on Cravath's investigation.[378] At that point Cravath had interviewed twenty-four employees and reviewed 6,000 emails. Stuart told Sidley that the investigation would take another three to four weeks.[379]

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[373] *See* JX 777 at '221–22; *id.* at '216 (forwarding her exchange between Silverberg and herself to a colleague, Sherwani comments, "I'm not going to be his scapegoat"); JX 890 at '279.

[374] JX 778 at '557.

[375] *See* JX 821 at '211; JX 1889 at 12.

[376] *See* JX 873 at '320; Stuart Tr. 684–85, 786–89.

[377] JX 1425 at '102; Stuart Dep. 153; Sherwani Dep. 99–103; JX 1891 at 1, 3–5, 7; Stuart Tr. 802.

[378] *See* JX 873 at '320; Stuart Tr. 695; Sheers Tr. 1042–43.

[379] JX 873 at '323. *But see* Stuart Tr. 681 ("We were substantially complete by the middle of January"); *id.* at 697 (Stuart testifying that the investigation was "substantially complete" by January 22, 2018).

After receiving the preliminary report, Fresenius sent Akorn a letter identifying "extremely serious data integrity concerns."[380] Internally, Fresenius started a project to determine what it would cost to remediate the data integrity issues at Akorn so they could evaluate whether the issues constituted a Material Adverse Effect.[381]

On January 22, 2018, Stuart, Bonaccorsi, and members of the Cravath team gave a follow-up report to Silhavy and Sidley.[382] Stuart stated that Silverberg's explanations "were not satisfactory, they didn't hang together."[383] He also said that he would not be

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[380] JX 866; *see* Sheers Tr. 1037–39 (summarizing concerns). There is evidence that Fresenius executives wanted Sidley and Lachman to be even more critical of Akorn than they were. *See* JX 900; Sheers Tr. 1099–01. I find that Sidley and Lachman properly resisted this pressure and conducted appropriately professional investigations.

[381] *See* JX 887; JX 889; *see also* JX 888. Bauersmith handled the initial modeling and led the project team. In a bit of gallows humor, he labeled his draft presentations and some communications with the faux code name "Project CERAFA." *See, e.g.*, JX 978. Commonly known as oak rot, *cerafa fagacearum* is a fungus that kills oak trees. Baeursmith Tr. 609. 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. While this is one plausible interpretation of the evidence, I credit Bauersmith's testimony that he believed Akorn was already rotten, and that his job was to determine the extent of the rot. *Id.* ("[W]e thought that the tree was rotted."). Consistent with his testimony, Bauersmith had questioned Akorn's pipeline from the outset and been skeptical of its value. Bauersmith resigned effective May 4, 2018, and had no reason to shade his testimony to favor Fresenius. JX 1182; Bauersmith Tr. 573. In my judgment, he was a credible witness.

[382] JX 914.

[383] Stuart Tr. 700; *accord* JX 914 at '093; JX 1128; *see* Stuart Tr. 697 ("My assessment was that Mr. Silverberg's conduct was wholly unacceptable, that his explanations for his conduct were not satisfactory, and that we needed to take some action with respect to Mr. Silverberg."); *id.* at 748 ("Q. Okay. And in fact, you find [Silverberg's] explanation about this totally unsatisfactory. A. That's true."); Sheers Tr. 1044 ("[W]e asked Mr. Stuart whether he found [Silverberg's] statement credible, that explanation

relying on Silverberg's explanation "in an attempt to defend the [C]ompany before the FDA."[384] Although Stuart did not say this to the Fresenius team, he believed that there was "a high likelihood that [the FDA] would conclude, given the document trail that they'll conclude [Silverberg] did act with intent."[385] Stuart did not report on (or ever tell Sidley about) the incident between Silverberg and Sherwani in which Silverberg attempted to coordinate their stories and suggested he would "eat the draft" if necessary.[386]

Bonaccorsi and other senior executives at Akorn thought the situation was serious, and they worried that if they disclosed the azithromycin incident to the FDA and withdrew

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credible, and he told us specifically that he did not find his story satisfactory; that it did not hang together; and he told us that he wasn't going to defend it."). At trial, Stuart and his counsel spent a lot of time attempting to distinguish between finding Silverberg's explanation "not satisfactory" and finding it not credible. They did so in an attempt to justify the later presentation of Silverberg's explanations to the FDA as findings from Cravath's investigation. Based on the evidence, I do not perceive a meaningful distinction. Regardless of what adjective one uses, Akorn later presented the FDA with a finding from its investigation that parroted an explanation that the lead investigator did not find satisfactory.

[384] Stuart Tr. 700–01.

[385] JX 935 at '031.

[386] Sheers Tr. 1045–46. Based on Cravath's presentation, Silhavy did not initially regard Silverberg's findings as "earthshattering" or as providing a basis, standing alone, to terminate the Merger Agreement. Silhavy Dep. 158–60; *see* JX 878. Sturm scolded Silhavy for expressing this view before hearing from Fresenius's subject-matter experts. Sturm Tr. 1190–91, 1216–17; *see* Silhavy Dep. 158–60. Given this exchange and Sturm's candid testimony about his view of the Merger after Akorn's dismal performance, it is reasonable to infer that Sturm hoped the investigation would support a decision by Fresenius to terminate the Merger Agreement.

the ANDA, then the FDA would invoke the AIP.[387] To help them navigate dangerous waters, they decided to hire a law firm with specific FDA expertise. They selected Hyman, Phelps & McNamara, P.C., although this firm had also done work for Fresenius and therefore faced a potential conflict. They also decided to hire an outside consultant to conduct a review of Akorn's procedures and potentially tainted submissions. Akorn later chose NSF to conduct the investigation.[388]

After consulting with Hyman Phelps, Akorn decided that they should go to the FDA relatively soon, disclose the problems they had discovered, and explain how the false CRL came to be submitted.[389] Akorn also decided that Silverberg should no longer head up its quality function.[390] Effective March 1, 2018, they removed him from his position of Executive Vice President, Global Quality Affairs and placed him in the new role of "Quality Advisor."[391] His new position paid $250,000 per year, a reduction from his prior salary of $318,000, and he was not eligible for any bonus. The initial placement was for 90 days or until the Merger closed. He was "[n]ot to initiate <u>any contact</u> with Akorn employees

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[387] JX 884 at '068 ("They're going to invoke the application integrity policy."); *see* Stuart Tr. 854; *see also* JX 908 at '831 (discussing AIP); JX 1127 (same).

[388] JX 1078; *see* JX 932; JX 939; JX 951; JX 967; Stuart Tr. 707–08.

[389] *See* Stuart Tr. 703.

[390] Bonaccorsi Tr. 894–95.

[391] *See* JX 955 at '702; JX 961; JX 984.

at any level except for inquiries to the CHRO or General Counsel."[392] He was "[n]ot to have any contact with the U.S. FDA or other regulatory facilities."[393] He was "[n]ot to physically report to any Akorn location unless specifically requested or directed by his manager, CHRO or General Counsel."[394] Akorn took these steps with the understanding that the FDA would expect to see this type of disciplinary outcome in a case of "deliberate misconduct."[395] As of trial, Silverberg remained in his new role.

To fill the hole this created at the top of Akorn's quality function, Akorn promoted Wasserkrug to the position of Vice President, Quality Operations. Although historically the head of quality reported directly to the CEO, she would report to the head of pharmaceutical operations, where the entire quality assurance function would reside.[396]

Akorn also decided that it would be a good idea to start working on some data integrity projects. Bonaccorsi had Pramik start planning for IT to address some projects in this area.[397] The IT department also began responding to the issues raised in the Cerulean audits from December 2016 and May 2017.[398]

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[392] JX 955 at '702.

[393] *Id.*

[394] *Id.*

[395] Stuart Tr. 705.

[396] JX 955 at '703.

[397] JX 957 at '921.

[398] *See* JX 977.

O. Tensions Escalate.

By the second half of February 2018, tensions between the parties had escalated.[399] On February 16, Sidley sent Cravath a letter attaching an extensive list of FDA submissions where Lachman had not been able to locate the underlying data. Sidley asked for the data or, alternatively, an explanation for why it was missing.[400] Three days later, on February 19, Bonaccorsi sent Silhavy a lengthy email in which he accused Fresenius of foot-dragging before the FTC and failing to use its reasonable best efforts to obtain antitrust clearance.[401] Four days later, on February 23, Silhavy sent Bonaccorsi an email informing him that Fresenius would be making the following statement about the Merger on February 27, when Fresenius Parent held it earnings call:

> Fresenius is conducting an independent investigation, using external experts, into alleged breaches of FDA data integrity requirements relating to the product development at Akorn, Inc.
>
> In addition to FTC clearance, closing of the acquisition will now depend on the outcome of this investigation and the assessment of such outcome by the management and supervisory boards of Fresenius.[402]

Silhavy also sent Bonaccorsi an email complaining that Cravath had not yet provided Sidley with the emails from Cravath's investigation into the fabricated-data issues and expressing concern that "Akorn has not been and is not acting in good faith to fulfill its

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[399] *See* Stuart Tr. 709, 866.

[400] JX 970.

[401] JX 972.

[402] JX 983 at '002.

obligation to provide prompt and reasonable access to information under Section 5.05 of the Merger Agreement."[403]

The very next day, on February 24, 2018, a Cravath litigation partner sent a letter to Fresenius's outside deal counsel asserting that Fresenius had "made clear that it does not intend to perform its obligations under the Merger Agreement."[404] The letter cited Fresenius's positions regarding antitrust clearance and its planned disclosure about closing depending on the outcome of its investigation.[405]

Over the weekend, Cravath produced a portion of the emails to Sidley, and Bonaccorsi promised that the balance would be coming soon.[406] On February 26, 2018, Akorn's newly retained regulatory counsel at Hyman Phelps reached out to the FDA to advise them about the potential data integrity issues involving fabricated data.[407] The FDA agreed to a "listening only meeting" on March 7.[408]

P. The Earnings Calls

On February 27, 2018, Fresenius held its quarterly earnings call. Sturm announced that Fresenius was investigating "information which originated from an anonymous source

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[403] JX 991 at '948.

[404] JX 986 at '186.

[405] *Id.* at '187.

[406] JX 991 at '946.

[407] *See* JX 987; JX 988; Stuart Tr. 706.

[408] JX 1000 at '031.

alleging deficiencies and misconduct regarding the product development process for new drugs at Akorn."[409] He stated that during due diligence, Fresenius had "examined and audited [Akorn] as intensively, carefully, and conscientiously as possible," and he described the due diligence as "the most intensive and comprehensive that I have experienced during my time at Fresenius," but he added that "when you wish to acquire a competitor, there are restrictions," and "[t]here are areas where you simply are not allowed to look, including product development and drug approval processes."[410]

> So how do you protect yourself in these areas? You ask the seller for assurances, representations [and] warranties, to use the legal term, on certain key facts and issues. The task now is to verify whether these assurances provided by the seller actually hold true. . . . [S]hould the allegations prove to be of a nonmaterial nature, then we will complete the acquisition, as planned, and together make it a success . . . .
>
> If, however, the allegations are proved and prove to be so serious that we must question the very basis of the takeover agreement, then in the interest of our shareholders, we may use our rights to withdraw from the transaction.[411]

Akorn's stock price plummeted on the news.[412]

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[409] JX 994 at 5.

[410] *Id.*

[411] *Id.* Sturm "stress[ed] that the strategic rationale behind our offer for Akorn remains absolutely sound," and that Fresenius remained "determined to pursue the strategic goal of expanding our liquid pharmaceutical product offering in North America." *Id.*; *see also id.* at 15.

[412] *See* JX 992.

On February 29, 2018, Akorn reported its financial results for the final quarter of 2017, along with annual results for 2017.[413] For the quarter, Akorn reported revenue of $186 million, representing a year-over-year decline of 34%. Akorn reported operating income of negative $116 million, representing a year-over-year decline of 292%. Akorn reported a loss of $0.52 per share, representing a year-over-year decline of 300%.[414]

For 2017 as a whole, Akorn reported revenue of $841 million, representing a year-over-year decline of 25%. Akorn reported operating income of $18 million, representing a year-over-year decline of 105%. Akorn reported a loss of $0.20 per share, representing a year-over-year decline of 113%.[415] Akorn reported EBITDA of $64 million for 2017, down 86% from 2016, and adjusted EDBITA of $249 million, down 51% from 2016.[416] Akorn's actual revenue declined by 17% from the low end of the guidance of $1,010–$1,060 million that Akorn reaffirmed when announcing the Merger Agreement. Akorn's adjusted EBDITA declined by 31% from the low end of Akorn's reaffirmed guidance of $363–$401 million.[417]

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[413] JX 998.

[414] JX 1250 ¶ 11; *see* JX 941 at 5.

[415] JX 1250 ¶ 11; *see* JX 941 at 5.

[416] JX 1250 ¶ 11.

[417] *Id.* ¶ 22.

Q. The FDA Meeting

During the weeks leading up to Akorn's meeting with the FDA, Akorn withdrew the ANDA for azithromycin,[418] and the parties butted heads over several issues. When Fresenius realized that Hyman Phelps would be attending the meeting, they asserted a conflict based on Hyman Phelps's contemporaneous representation of Fresenius.[419] Akorn complained that Fresenius was trying to harm its ability to present its case to the FDA, but Fresenius had a legitimate concern that Akorn was going to whitewash its problems, and Hyman Phelps was contemporaneously appearing for Fresenius in matters before the FDA. Fresenius did not want any blowback from a misleading depiction to hurt its own counsel's credibility. Akorn replaced Hyman Phelps with Ropes & Gray LLP.[420] The meeting was rescheduled for March 16, and the change in counsel does not appear to have made any difference.

Akorn took similar stances towards Fresenius. When Sidley asked to attend the meeting, Akorn said no.[421] When Sidley asked to interview Avellanet, the author of the

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[418] *See* JX 1091.

[419] *See* JX 1003; JX 1006; JX 1017; Stuart Tr. 710; Bonaccorsi Tr. 901–02.

[420] Stuart Tr. 710–11.

[421] *See* JX 1013 at '486; Sheers Tr. 1049. At trial, Stuart cited three reasons. First, by conflicting out Hyman Phelps, Fresenius had taken the position that Akorn and Fresenius's interests were not aligned regarding the meeting. Second, "by that time, the relationship between Sidley and Cravath, as well as between Fresenius and Akorn, had grown to be hostile." Stuart Tr. 711. Third, Akorn feared that Sidley would try to sabotage the meeting. *Id.* at 711–12. All three seem to be variants on a theme: both sides' interests were becoming adverse.

Cerulean reports, Akorn again said no.[422] Akorn also instructed Sidley that they could not interview any former Akorn employees without Akorn's approval.[423] Akorn also instructed Sidley that no one other than Fresenius's outside consultants could review the documents Akorn was providing unless Akorn gave prior consent to provide specific documents to specific individuals.[424]

In advance of the in-person meeting on March 16, 2018, a lawyer from Ropes & Gray had a "sidebar" call with an FDA representative in which he denigrated Fresenius's motives and suggested that Fresenius would try to call Akorn's presentation into question.[425] During the subsequent in-person meeting, eight Akorn representatives, including Stuart and Bonaccorsi, met with sixteen FDA representatives, with four participating by phone.[426]

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[422] *See* JX 1023; JX 1032.

[423] JX 1037.

[424] JX 1038 at '447.

[425] JX 1066 at '893; *see* JX 1063 at '005; Stuart Tr. 840–44. Stuart failed to mention the criticisms of Fresenius when he described the sidebar call for Sidley. *See* JX 1071 at '707; Stuart Tr. 845–46. At trial, Sheers identified statements in the talking points for the sidebar call that did not accurately describe the state of the record. *See* Sheers Tr. 1055–58. Based on the trial record, Sheers's assessment appears correct. The sidebar call was thus another means by which misleading information reached the FDA.

[426] JX 1066 at '894.

As Akorn's expert conceded at trial, Akorn was "not fully transparent" with the FDA during the meeting.[427] First, Akorn presented the overall investigation into the whistleblower letters as one conducted jointly by Akorn and Fresenius.[428] In reality, Akorn did not conduct an investigation into the whistleblower letters. Fresenius expected Akorn to conduct an investigation, but Akorn chose to have Cravath shadow the Sidley investigation instead. Akorn's presentation cited investigatory work that Sidley and Lachman had performed in a manner that implied that Akorn had been responsible for it.[429] Akorn also described its production of emails to Sidley in a manner that implied it had happened months earlier, at the start of the investigation and as part of a joint effort,[430] when in fact the emails had been provided only three weeks before in response to pressure

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[427] Kaufman Tr. 378. Kaufman claimed that Akorn later became transparent by sending the FDA a letter containing Sidley's criticisms and the Cerulean reports. *Id.* at 402, 414. In fact, Akorn has never sent the FDA the Cerulean reports. Wasserkrug Tr. 40. Moreover, Akorn's regulatory counsel undermined the curative efficacy of sending the Sidley letter by priming the FDA not to give any credence to Sidley's concerns.

[428] *See* JX 1066 at '895 ("Dave Stuart presented briefly on . . . the whistleblower letters sent to Fresenius and the investigation conducted by Akorn and Fresenius as a result of those letters."); JX 1068 at '009 ("In response to anonymous letters, Akorn and Fresenius conduct investigation focused on data integrity controls."); JX 1068 at '038 ("Akorn has extensively investigated the concerns raised by the anonymous letters . . . ."). Stuart described the investigation differently when he reported on the meeting to Sidley. *See* JX 1071 at '707 (Stuart telling Sidley that they had told the FDA that "Fresenius, Sidley, Lachman, and EY had been given access to Akorn's sites, raw data, audit trails, emails and employees" and that "you were analyzing all of the information and data you had obtained").

[429] *See* JX 1068 at '009 (citing site visits, "65+ interviews of current and former Akorn personnel"; and "[l]ab walk-throughs")

[430] *See* JX 1066 at '895.

from Fresenius. Akorn likewise presented the investigation into the azithromycin ANDA as a joint investigation, when Cravath had conducted that investigation on its own.[431] Akorn also represented that Cravath's investigation into the azithromycin issue was "supported by Akorn GQC,"[432] without disclosing that Akorn GQC had been kept in a constrained and limited role.

Even more problematic, Akorn's presentation endorsed as valid Silverberg's claimed justification for signing the CRL with fabricated test results. Under the heading, "Investigative Findings," the presentation stated:

> Silverberg authorized submission of AET data without knowing stability table containing particulate matter data would be submitted because stability table not attached to CRL response Silverberg authorized for submission.[433]

This statement to the FDA adopted Silverberg's explanation for his actions. Stuart gave the presentation and called the FDA's attention to this statement during the meeting,[434] yet

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[431] *See* Stuart Tr. 728–29.

[432] JX 1068 at '009.

[433] JX 1068 at '014.

[434] Stuart Tr. 713. At trial, Stuart testified on direct that he "felt the FDA should know that that was [Silverberg's] position on the submission of the CRL response." *Id.* at 714. The presentation does not identify the statement as Silverberg's position. It identifies the statement as a finding from an Akorn internal investigation conducted by Cravath. *See* Stuart Tr. 794; Stuart Dep. 276. I empathize with Stuart, because I suspect that he was under a great deal of pressure to depict events in this way. I also give Stuart credit for testifying as directly as he did given the difficult position that his client had put him in. He appears to be an honest and conscientious person. The record shows that many lawyers revised and commented on the presentation, and their collective efforts to present Akorn to the FDA in the best light possible ultimately produced a misleading document. In the pressure of the moment, Stuart went along.

Stuart had said previously that "he did not find Silverberg's explanations satisfactory."[435] He also believed that there was "a high likelihood that [the FDA] would conclude, given the document trail that they'll conclude [Silverberg] did act with intent."[436] Most important, he had told the Sidley team that he would not be relying on Silverberg's explanation "in an attempt to defend the Company before the FDA."[437] Yet that is what the presentation did.

Finally, Akorn told the FDA that it had placed an "emphasis . . . on improving data integrity controls in the last few years,"[438] and the presentation cataloged a number of steps Akorn had taken. Akorn in fact historically prioritized other matters over data integrity and only began making a serious effort on data integrity after Sidley and Lachman identified pervasive problems. Moreover, while highlighting favorable information for the FDA, Akorn omitted the many deficiencies identified by Cerulean and Akorn's internal audit function. This approach resulted in a one-sided, overly sunny depiction. Akorn's witnesses have stressed that the FDA usually does not ask for or receive internal audit reports or

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[435] JX 914 at '093; *see* Stuart Tr. 697, 699–700.

[436] JX 935 at '031.

[437] Stuart Tr. 700–01.

[438] JX 1066 at '897; *see* JX 1068 at '016 (presentation representing (inaccurately based on the evidence in this case) that "Akorn management emphasizes the importance of data integrity and the data governance policy is endorsed at the highest levels of the organization"); *id.* at '017 (presentation representing (inaccurately based on the evidence in this case) that "[i]mprovement activities have been prioritized using a risk-based focus across all facilities").

consultant reports when it conducts an inspection,[439] but that is a different scenario than a company approaching the FDA voluntarily and purporting to come clean.[440]

After the meeting, Akorn provided Fresenius with a summary of the meeting and a copy of the presentation.[441] On March 22, 2018, Sidley sent Cravath a letter accusing Akorn of having given the FDA "false, incomplete and misleading information."[442] Sidley's leading criticism was the presentation's description of Silverberg's reason for approving the response to the CRL.[443] Although Sidley's language was strident, that was a fair criticism of the presentation. Sidley also criticized the presentation's portrayal of Akorn's "many supposed improvements in its data integrity practices."[444] The language was again quite strong, but the criticism was a fair one.[445]

Akorn's regulatory counsel at Ropes & Gray sent Sidley's letter to the FDA.[446] He also sent the FDA copies of letters from Sidley to Cravath in which Sidley identified

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[439] *See* Wasserkrug Tr. 19; Kaufman Tr. 275.

[440] *See* Kaufman Tr. 399 (agreeing that self-disclosure is different than an audit).

[441] *See* JX 1073.

[442] JX 1084 at '171; *see* Sheers Tr. 1050–54 (describing Sidley's concerns).

[443] JX 1084 at '171–72.

[444] *Id.* at '173.

[445] *See* Wasserkrug Tr. 167–72 (Wasserkrug on cross-examination agreeing that Akorn did not disclose numerous problems with the data integrity accomplishments it touted to the FDA).

[446] *See* JX 1105.

various data integrity issues, along with Cravath's response to those letters. He followed up with a call with an FDA representative, during which he sought to undermine Fresenius's criticisms.[447] He correctly noted that "the heated tone of the correspondence was somewhat embarrassing."[448]

R. Fresenius Terminates The Merger Agreement.

On March 16, 2018, Sturm raised with the Supervisory Board of Fresenius Parent the possibility of terminating the Merger Agreement. He cited the results of Fresenius's data integrity investigation, which he noted was still ongoing, but which had revealed evidence of breaches of representations in the Merger Agreement.[449] He told the Supervisory Board that they did not yet have to make a decision.[450]

On April 13, 2018, the senior executives at Fresenius Kabi decided to recommend terminating the Merger Agreement to their superiors at Fresenius Parent. They based their decision on the data integrity problems at Akorn, the costs of remediation, and the decline in Akorn's business performance.[451]

On April 17, 2018, the Supervisory Board met. Management gave the directors a presentation that detailed (i) the downward revisions in the business plan for Akorn made

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[447] *See* JX 1106.

[448] *Id.*

[449] JX 1143 at '975–76.

[450] *Id.* at '976.

[451] JX 1142 at '496.

necessary by Akorn's dismal business performance, (ii) the cost of data integrity remediation, and (iii) the lost value from suspending sales of existing products and delaying production of pipeline products until data could be verified.

- For 2018, Akorn's projected EBIT fell from $239 million in the signing case to $14 million in the updated case. Of the total, a decline of $221 million was attributable to on-market products and a decline of $127 million to pipeline products, with these declines partially offset by deal-related factors.[452]

- For 2018, data integrity remediation would cost another $48 million, with a decline in EBIT of $272 million attributable to suspending on-market products pending data verification. With these effects, Akorn's adjusted EBIT in 2018 would be negative $313 million.[453]

- Over a ten-year period, Akorn would incur $254 million in direct costs to redevelop the twenty-four most commercially valuable Akorn products.[454]

- The biggest valuation hit to Akorn would come from suspending on-market products and pushing out pipeline products while data was verified. Depending on the assumptions used, the loss in value from the deferral could reach $1.6 billion, excluding the direct remediation costs.[455]

- Taking into account both the direct remediation costs and the lost value from product suspensions and deferrals, Akorn's value fell from $5.236 billion at the time of the Merger to $3.307 billion, representing a decline of 37%.[456]

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[452] JX 1152 at 17.

[453] *Id.* at 18.

[454] *Id.* at 19; *see* Henriksson Tr. 979, 1009.

[455] JX 1152 at 25.

[456] *Id.*

The estimates were developed by a team of Fresenius personnel that included senior executives and staff who had first-hand experience based on Fresenius's efforts to remediate data integrity issues at one of its sites in India.[457]

Although Sturm and his colleagues were prepared to terminate the Merger Agreement, they recommended that Fresenius offer Akorn the choice of extending the outside date for the Merger to the end of August to facilitate further investigation into the data integrity issues, including the investigations by NSF that Akorn had pledged to the FDA to conduct. In a letter dated April 18, 2018, Paul Weiss surfaced for the first time and communicated this offer. The letter asserted that Akorn had breached various provisions in the Merger Agreement, including its representations regarding regulatory compliance. The letter noted that "[i]f Akorn believes Fresenius is mistaken in its assessment of the facts and that Akorn's own investigation, when complete, would support its position, then extending the Outside Date could be advantageous to both parties."[458] Akorn declined.

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[457] *See* Henriksson Tr. 1005, 1022–23. Given that litigation was on the horizon, Fresenius also consulted with lawyers from Paul Weiss. Akorn has stressed this point and observes that Fresenius initially designated the analysis as privileged. *See* Henriksson Tr. 1002. The fact is that both sides involved lawyers extensively and labeled many internal documents and analyses privileged. The major difference is that Fresenius used three firms: Allen & Overy for deal work, Sidley for regulatory work, and Paul Weiss for litigation. Akorn only used Cravath. It is therefore easier for Akorn to track when Paul Weiss became involved. I suspect that Akorn took similar steps to consult with Cravath after its disastrous post-deal performance. Akorn used Cravath litigators to address the whistleblower letters and had other Cravath litigators involved by February 2018. *See* JX 986; JX 1337 at '405. I see no reason to criticize either side for consulting with top-flight law firms about the implications of unfolding events for a high-profile deal.

[458] JX 1153 at '553.

On April 22, 2018, Fresenius gave notice that it was terminating the Merger Agreement. Fresenius cited its right to terminate under Section 7.01(c)(i) based on (i) Akorn's breaches of representations and warranties, including those related to regulatory compliance, and (ii) Akorn's breaches of its covenants, including its obligation to operate in the ordinary course of business. Fresenius also cited its right not to close under Section 6.02(c) because Akorn had suffered a General MAE, which would give rise to a right to terminate two days later, on April 24, 2018, when the initial Outside Date in the Merger Agreement was reached.[459]

S. This Litigation

On April 23, 2018, Akorn filed this action. Fresenius answered and asserted counterclaims. Akorn sought an expedited trial on or before July 24, 2018.[460] Over Fresenius's opposition, I granted the request and scheduled trial for July 9–13.[461]

While the litigation was ongoing, factual developments continued apace. On May 2, 2018, Akorn announced its financial results for the first quarter of 2018. Akorn reported revenue of $184 million, representing a year-over-year decline of 27%. Akorn reported operating income of negative $25 million, representing a year-over-year decline of 134%.

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[459] JX 1165.

[460] Dkt. 22.

[461] Dkt. 171.

Akorn reported a loss of $0.23 per share, a year-over-year decline of 170%. Akorn reported EBITDA of negative $6 million and Adjusted EBITDA of $24 million.[462]

While the parties litigated, NSF moved forward with its investigation. The original plan consisted of (i) conducting data integrity audits at six facilities (but not Somerset), (ii) reviewing both the ANDAs where Burkert had some involvement and the ANDAs generated at Somerset since 2006, (iii) examining any lab notebooks to which Burkert had access and sampling other notebooks at Somerset, and (iv) reviewing sample manufacturing data for thirty-two products manufactured at Somerset.[463]

By the time Fresenius issued its termination notice, NSF had only delivered its data integrity audit for one site (Vernon Hills). By the time of trial, NSF had completed its audits at four of the five other sites. NSF's inspection of the Decatur facility was postponed due to an FDA inspection that began on April 9, 2018, lasted through trial, and eventually ended on July 23. As noted, NSF did not plan to conduct a data integrity audit at Somerset.

The following table identifies the facilities reports that NSF had conducted by the time of trial, along with the number and types of findings made by NSF.

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[462] JX 1250 ¶ 19.

[463] *See* JX 1078 at '886.

Site	Date of Report	Major Findings	Minor Findings	Exhibit
Vernon Hills	April 13, 2018	7	7	JX 1141
Amityville	April 29, 2018	9	3	JX 1178
Lake Forest	May 7, 2018	2	7	JX 1189
Cranbury	May 9, 2018	10	8	JX 1190
Hettlingen	May 10, 2018	6	9	JX 1192

As the table shows, NSF found major data integrity deficiencies at each site.

Importantly, NSF's definition of a major deficiency resembled Cerulean's definition of a critical deficiency. For NSF, a major finding

> documents a systematic failure of a regulatory requirement, correlates to product defects, and/or represents uncorrected repeat findings cited by FDA in previous inspections. These findings would appear on a form FDA 483 and may provide the basis for further enforcement action.[464]

For NSF, a critical finding was more extreme: a "condition which has produced or leads to a significant risk of producing an unsafe or hazardous product which may be harmful and puts the consumer at risk of serious injury or death."[465] Minor findings were regulatory violations that fell short of these standards. A minor finding "would most likely appear on a Form FDA 483, but would not be a basis for further enforcement action unless it represents a repeated finding . . . ."[466]

On May 16, 2018, part way through its investigation of Decatur, the FDA issued a twenty-four page Form 483 for that facility which identified thirteen categories of

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[464] JX 1141 at 7.

[465] *Id.*

[466] *Id.*

deficiencies.[467] Two of the categories addressed the types of data integrity problems that Fresenius had cited: one identified a "[f]ailure to maintain complete data derived from all testing and to ensure compliance with established specifications and standards pertaining to data retention and management;"[468] another identified a failure "to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed."[469] The former category included five specific deficiencies; the latter included ten specific deficiencies, including "[r]epeat observation[s] from 11/2004, 9/2006, 8/2007, 6/2009, 5/2013, 6/2016."[470] This was not the only instance of repeat observations that the Form 483 raised. Another category of deficiencies identified "[r]epeat observations from 11/2004, 9/2006, 8/2007, 6/2009 & 2017."[471] Still another identified a "[r]epeat observation from 11/2004."[472] Based on the Form 483, Wasserkrug testified at trial to her belief that the FDA had placed Decatur on OAI status and that Akorn will not receive any product approvals

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[467] JX 1198.

[468] *Id.* at '973.

[469] *Id.* at '975.

[470] *Id.* at '980.

[471] *Id.* at '966.

[472] *Id.* at '969.

until Decatur is cleared.[473] The two prior times when an Akorn facility was on OAI status, it took six months to a year to clear the facility.[474]

In May 2018, while the FDA inspection at Decatur was ongoing, the FDA approved two of Akorn's pending ANDAs.[475] Akorn has cited these approvals to suggest that the FDA had no concerns about Akorn's facilities, but the more persuasive interpretation is that the ANDAs had been in the FDA pipeline for some time and were ready for approval when Akorn's issues arose. Consistent with the latter interpretation, the FDA subsequently declined to approve two other ANDAs, citing quality issues at Decatur.[476] Akorn also has received two CRLs for products that would be manufactured at Decatur.[477]

In addition to the data integrity audits, NSF reviewed ANDAs from the Somerset facility. NSF was only able to review two ANDAs before Fresenius terminated the Merger Agreement. In the first, NSF found thirty-six major deficiencies and twenty-nine minor deficiencies.[478] In the second, NSF found eleven major deficiencies and three minor deficiencies.[479] After receiving the reports, the most Cravath felt it could say to Akorn's

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[473] Wasserkrug Tr. 72–73, 77.

[474] *Id.* at 73–74.

[475] *See* JX 1187; JX 1188.

[476] JX 1223; JX 1226.

[477] Wasserkrug Tr. 71–72.

[478] *See* JX 1156 (Azelastine Hydrochloride Opthalmic Solution (0.05%)).

[479] *See* JX 1157 (Moxifloxacin HCI Ophthalmic Solution, 0.5%).

directors was that they did not believe that the approval of either product was in "immediate jeopardy," but that the process was still unfolding.[480] At the time, NSF still planned on reviewing another twenty-eight ANDAs.[481] Notably, Akorn was not planning to address the broader universe of products that Silverberg oversaw, precisely because it was everything the Company had produced during the preceding decade.

By the time of trial, NSF had reviewed another six ANDAs. The following table summarizes the results:

Product	Critical	Major	Minor	Exhibit
Cyclopentolate Hydrochloride Ophthalmic Solution	1	34	8	JX 1185
Gentamicin Sulfate Opthalmic Ointment	0	30	5	JX 1196
Neomycin and Polymxin B Sulfate and Bacitracin Zinc Ophthalmic Ointment Sterile (Veterinary)	0	17	15	JX 1201
Epinastine HCI Opthalmic Solution 0.5%	0	22	19	JX 1204
Olopatadine Hydrochloride Opthalmic Solution	0	26	18	JX 1221
Olopatadine Ophtalmic Solution	1	34	23	JX 1224

The two critical deficiencies involved data fabrication. One involved an employee from Vernon Hills who engaged in a deliberate act to force a passing result for cyclopentolate.[482] The other involved an employee from Cranbury who engaged in the practice of testing into

[480] JX 1159 at '389.

[481] *See* JX 1177 at '229–31.

[482] Wasserkrug Tr. 176–77.

compliance for olopatadine.[483] NSF's findings meant that the total number of individuals at Akorn involved in data fabrication had increased to four: Silverberg, Burkert, and the two additional employees. It also meant that the number of ANDAs that Akorn had submitted to the FDA based on false or misleading data had risen to three: azithromycin, cyclopentolate, and olopatadine.[484] NSF expanded its investigation based on its findings.

During its investigation, NSF also found extensive evidence of Akorn employees performing trial injections, a prohibited practice.[485] In response to these findings, on April 5, 2018, Stuart expressed concern about the risk that the FDA would impose the AIP:

> [G]iven how prevalent this bad practice was, the FDA is likely to have a very negative reaction to our report. . . . Potential FDA reactions include (1) suspension of review of all pending submissions; (2) mandating review by a third party of product released for the market; and—the worst—(3) "AIP" (Application Integrity Policy), which requires a third-party monitor to oversee all activity at Akorn's sites.[486]

During a conference call the following day, Akorn's regulatory counsel expressed concern that "[i]f audit reports make it look like there are similar issues across the company, FDA might see need to get whole company under decree."[487] At trial, Wasserkrug testified that

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[483] Wasserkrug Tr. 179.

[484] *Id.* at 179–80. In addition to inspecting facilities and auditing ANDAs, NSF conducted employee interviews. The one interview memorandum in the record, dated April 16, 2018, provides striking insight into the absence of a well-functioning quality system at Akorn and the lack of a top-down culture of compliance. *See* JX 1149.

[485] Wasserkrug Tr. 181–85.

[486] JX 1127.

[487] JX 1496 at '055; *see id.* at '056 ("Sheer number of issues across all sites audited by NSF . . . could raise concern."); JX 1493 ("[A]s other audit reports roll out," it may

Akorn still had not yet been able to resolve fifty instances of trial injections involving approximately twenty analysts and multiple products.[488]

Through the remediation process that Akorn initiated after its meeting with the FDA, Akorn identified so many open deficiencies from past internal audits and received so many new deficiencies flagged by NSF that it retained PricewaterhouseCoopers LLP as a program manager to keep track of them. PwC's task was to organize all of the findings so that they could be evaluated and addressed.[489] Before April 2018, no one had ever tried to create and maintain a master list of deficiencies at Akorn.[490]

At trial, Akorn asserted that fully remediating its data integrity problems would take approximately three years.[491] Akorn estimated the cost at $44 million.[492] The estimate assumed that Akorn would not uncover any additional problems with data, that no other ANDAs would be withdrawn, that no products would be recalled, and that there would not be any effect on Akorn's pipeline.[493]

"look[] like multiple sites are having similar issues" and the FDA "may see it as the whole corporation/multiple sites under decree.").

[488] Wasserkrug Tr. 63, 87, 182–83.

[489] *Id.* at 67–68, 94–95.

[490] *Id.* at 116–17.

[491] *Id.* at 69.

[492] JX 1318.003. Wasserkrug read the $44 million figure of the page, but she did not have any personal knowledge about how it was derived. Wasserkrug Tr. 95, 115–16.

[493] *See* Wasserkrug Tr. 69, 77–78.

T. Post-Trial Events

On July 23, 2018, the FDA initiated an inspection at Akorn's Somerset facility. Between July 23 and August 30, 2018, the FDA spent a total of twenty-one days inspecting the site.[494]

By letter dated August 3, 2018, Akorn reported to the FDA about NSF's expanded investigation into the work performed by the miscreant Vernon Hills employee. As part of this work, NSF found an additional critical deficiency involving fabricated data, this time for palonosetron hydrochloride.[495] NSF also identified major deficiencies related to data falsification involving six other products.[496] NSF found that the fabrication of data by the Vernon Hills employee was "not isolated but more systemic in nature" and "call[ed] into question the reliability of data" he had generated.[497] As a result, NSF concluded that "a further comprehensive assessment of [his] work and the work produced by the Vernon Hills facility in support of GMP activities" was necessary to determine "potential impact to marketed product, regulatory findings, and submission supporting data."[498] NSF also

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[494] Dkts. 199–200.

[495] *See* Dkt. 191, Ex. A at '826.

[496] *See* Dkt. 191, Ex. B at '098.

[497] *Id.* at '098.

[498] *Id.*

determined that it would need to sample "all GMP testing . . . conducted by the Cranbury R&D organization, since its relocation [from Somerset] in October, 2016."[499]

By letter dated August 9, 2018, the FDA sent Akorn a letter formally classifying the Decatur facility as OAI.[500] The August 9 letter stated:

> Based on [the FDA's] inspection, this facility is considered to be in an unacceptable state of compliance with regards to current good manufacturing practice (CGMP). The facility may be subject to a CGMP regulatory or enforcement action based on this inspection, and FDA may withhold approval of any pending applications or supplements in which this facility is listed.[501]

The letter thus not only informed Akorn of Decatur's OIA status, but also noted the possibility of "regulatory or enforcement action."

On August 30, 2018, the FDA issued a twenty-two page Form 483 for the Somerset site that detailed serious regulatory deficiencies, many of which echoed the evidence presented at trial.[502] The violations included the following:

- Akorn distributed batches of adulterated sterile eye drops that failed four separate stability tests. Akorn could not provide data for the batches at the beginning of the FDA's inspection, and the inspectors later witnessed Akorn employees retrospectively modifying the relevant laboratory notebooks.[503]

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[499] *See* Dkt. 191, Ex. C at '047.

[500] Dkt. 191, Ex. D ("FDA has determined that the inspection classification of this facility is 'official action indicated' ('OAI').").

[501] Dkt. 191, Ex. D.

[502] Dkt. 204, Ex. A.

[503] *Id.* at '516–17.

- Akorn conducted trial injections as a "widespread practice" dating back to 2015, and "[n]o corrective measures to prevent this practice were implemented until" May 2018. Akorn's prior investigation was inadequate and, as a result, "there is limited assurance in the reliability of data submitted to the Agency and generated for commercial batches."[504]

- Akorn failed to exercise "[a]ppropriate controls . . . over computers or related systems to assure that changes in master production and control records are instituted only by authorized personnel."[505]

- Akorn "invalidated" negative test results in more than 70% of cases between January 2017 and July 2017 "without adequately supporting [the reasons for invalidation] with scientific evidence," and the investigations into these failing results did not "determine why the [issues] . . . kept on recurring nor were there effective CAPAs implemented to minimize these incidents going forward."[506]

- Akorn delayed investigating quality issues for months "without adequate justification."[507]

- Akorn failed to review laboratory notebook testing data for months, and an Akorn employee informed the FDA that "due to personnel resource issue[s], they could not review the notebooks in a timely manner."[508]

By letter dated September 3, 2018, Akorn reported to the court that on August 22, during the later stages of the FDA's investigation, the database for a high accuracy liquid particle counter had been deleted along with the local backup file and the associated

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[504] *Id.* at '518–19.

[505] *Id.* at '527.

[506] *Id.* at '518–20.

[507] *Id.* at '525–26.

[508] *Id.* at '526.

electronic security logs.[509] These databases contained all of Somerset's data for the relevant testing, which is designed to ensure that sterile intravenous products do not contain excessive amounts of undisclosed solids. Akorn's preliminary investigation suggested that the files were deleted intentionally using an electronic shredding utility.[510] Given the timing of the deletion, it is reasonable to infer that the perpetrator may have been trying to hide information from the FDA, or from personnel who would follow up on the deficiencies that the FDA identified in its Form 483.

By letter dated September 21, 2018, Akorn submitted its response to the Somerset Form 483.[511] The response is lengthy, spanning seventy-three pages, and makes expansive claims about Akorn's commitment to quality and the steps it has taken or will take to address the problems that the FDA identified. In light of the record presented at trial, including my evaluation of the credibility of Akorn's witnesses, it is difficult to put much faith in Akorn's claims about its commitment to quality. Having seen the divergence between Akorn's representations to the FDA during the March 2018 meeting and what Akorn's internal documents and witness testimony showed, it is equally difficult to have confidence that Akorn is being fully transparent in describing the corrective actions that it

[509] Dkt. 199.

[510] Dkt. 201.

[511] *See* Dkt. 234, Exs. A & B.

has taken or will take. It would require an additional round of discovery and another merits hearing to assess the accuracy of Akorn's claims.

Even taking Akorn's response at face value, the document evidences the deep and pervasive nature of Akorn's quality problems are at Akorn. In an effort to respond to the FDA's concerns, Akorn took a barrage of actions, including:

- Stripping the Head of Quality at Somerset of daily oversight responsibilities and assigning those duties to PwC;
- Stripping the Quality Control Laboratory Director at Somerset of daily oversight responsibilities responsibility and assigning those duties to NSF;
- Engaging NSF to provide supplemental oversight of the daily operation of the quality Control laboratory;
- Engaging NSF personnel to act as mentors for the Somerset Quality Control laboratory supervisory team;
- Engaging NSF to oversee Akorn's process for reviewing its laboratory data and to provide mentoring for Akorn's staff;
- Committing to retrain and certify all of its quality control laboratory personal, all data reviewers, and all investigators;
- Committing to review and revise all of its laboratory procedures including for titration, chromatography, and notebook handling;
- Committing to review all of its analytical testing methods;
- Recalling its Azelastine HCl Ophthalmic Solution and Gentamicin Ophthalmic Solution based on confirmed stability failures;
- Recalling its Ciprofloxacin Ophthalmic Solution based on concerns expressed by the FDA;
- Committing to investigate the use of trial injections at all Akorn sites;
- Committing to re-investigate all Out-of-Specification results generated in the past three years at all of its sites;

- Committing to address backlogs in reviewing and approving data in notebooks and procedures for handling notebook retention and storage;
- Committing to review user level access across all laboratory and manufacturing equipment;
- Committing to review each piece of Somerset laboratory equipment and the data associated with the equipment;
- Committing to conduct a complete review of all unsigned data and to investigate any instances that fail to meet acceptance criteria; and
- Recognizing that all of its sites would need to be assessed based on the issues identified at Somerset.

After hearing the evidence at trial, I did not have any confidence that Akorn would be able to support its data if the FDA called upon Akorn to do so. Based on developments since trial, Akorn's situation has grown even worse.

II. LEGAL ANALYSIS

The disputes in this case are primarily contractual. Fresenius contends that it terminated the Merger Agreement in accordance with its terms. Akorn contends that Fresenius did not validly terminate the Merger Agreement and seeks an order of specific performance to compel Fresenius to close the Merger. Both parties are highly sophisticated and crafted the Merger Agreement with the assistance of expert counsel. The pertinent provisions are dense and complex.

The analysis turns on three conditions that Akorn must meet before Fresenius is obligated to close the Merger:

- Under Section 6.02(a)(ii), Akorn's representations must be true and correct as of the Closing Date, except "where the failure to be true and correct would not, individually

or in the aggregate, reasonably be expected to have a Material Adverse Effect" (the "Bring-Down Condition").[512]

- Under Section 6.02(b), Akorn must have "complied with or performed in all material respects its obligations required to be complied with or performed by it at or prior to the Effective Time" (the "Covenant Compliance Condition").[513]

- Under Section 6.02(c), Akorn must not have suffered a Material Adverse Effect (the "General MAE Condition").[514]

The failure of either the Bring-Down Condition or the Covenant Compliance Condition

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[512] JX 1 § 6.02(a)(ii). *See generally* Lou R. Kling & Eileen T. Nugent, *Negotiated Acquisitions of Companies, Subsidiaries and Divisions* § 1.05[2], at 1-41 (2018 ed.) (describing "the critical 'bringdown' condition"); *id.* § 1.05[4], at 1-41 ("[O]ne critical condition almost always found is that the other party's representations and warranties be true at closing. If this is not the case, the party need not close.") (footnote omitted); *id.* § 14.02, at 14-9 ("From a business point of view, the condition that the other party's representations and warranties be true and correct at closing is generally the most significant condition for Buyers.").

[513] JX 1 § 6.02(b). *See generally* Kling & Nugent, *supra*, § 1.05[3], at 1-41 (explaining that the actions that parties commit to take in a transaction agreement are described as covenants and identifying three general categories); *id.* § 14.02[7], at 14-16 to -17 (discussing customary condition requiring "that the parties have performed and complied with all of their obligations and agreements in the acquisition agreement required to be performed and complied with prior to the closing"); Simon M. Lorne & Joy Marlene Bryan, *Acquisitions & Mergers: Negotiated and Contested Transactions* § 3:59 (2018 ed.) ("The principal conditions to a closing under an acquisition agreement usually include . . . confirming compliance with all covenants that have been made.").

[514] In the Merger Agreement, the General MAE Condition appears as a formal condition to closing. Sometimes, a seller may represent that no General MAE has occurred. When that representation has been made, the bring-down condition also operates as a General MAE Condition. *See* Kling & Nugent, *supra*, § 11.04[9], at 11-57 to -58 (discussing forms of representation); *In re IBP, Inc. S'holders Litig.*, 789 A.2d 14, 42–43 (Del. Ch. 2001) (Strine, V.C.) (analyzing seller's representation that "since the Balance Sheet Date," there had not been "any event, occurrence or development of a state of circumstances or facts which has had or reasonably could be expected to have a Material Adverse Effect").

gives Fresenius a right to terminate the Merger Agreement, but only if (i) the breach that would give rise to the failure of the condition is incapable of being cured by the Outside Date and (ii) Fresenius is not "then in material breach of any of its representations, warranties, covenants, or agreements."[515] The failure of the General MAE Condition does not give Fresenius an independent right to terminate the Merger Agreement, but it does give Fresenius the right to refuse to close.[516]

To establish a failure of the Bring-Down Condition, Fresenius relies on Section 3.18 of the Merger Agreement, where (in overly simplistic terms) Akorn represented that it was in full compliance with all of its regulatory obligations (the "Regulatory Compliance Representations").[517] To establish a failure of the Covenant Compliance Condition, Fresenius relies on Akorn's obligation to "use its . . . commercially reasonable efforts to carry on its business in all material respects in the ordinary course of business" (the "Ordinary Course Covenant").[518]

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[515] JX 1 § 7.01(c)(i).

[516] With the passage of time, however, the failure to close ripens into a termination right, because under Section 7.01(b)(i) of the Merger Agreement, either side can terminate once the Outside Date has passed, assuming that the party exercising the termination right has not itself breached the Merger Agreement in a manner that was a principal cause of the Merger not closing by the Outside Date. Fresenius terminated the Merger Agreement before the Outside Date.

[517] JX 1 § 3.18.

[518] *Id.* § 5.01(a). Fresenius also contends that Akorn breached its obligation to provide Fresenius with "reasonable access . . . to the Company's officers, employees, agents, properties, books, Contacts and records." *Id.* § 5.05. This decision does not reach the alleged breach of that covenant.

To establish a failure of the Covenant Compliance Condition, Akorn relies on each party's agreement to "cooperate with the other parties and use . . . their respective reasonable best efforts . . . to cause the conditions to Closing to be satisfied as promptly as reasonably practicable and to consummate" the Merger (the "Reasonable Best Efforts Covenant").[519] Akorn also relies on Fresenius's specific commitment to "take all actions necessary" to secure antitrust clearance, which the Merger Agreement states shall require efforts that "shall be unconditional and shall not be qualified in any manner."[520] This level of commitment is generally called a "Hell-or-High-Water Covenant."

Like many transaction agreements, the Merger Agreement deploys the concept of a Material Adverse Effect in multiple locations, including (i) in the General MAE Condition, (ii) in various representations for purposes of evaluating any inaccuracies in those representations at the time of signing, and (iii) in the Bring-Down Condition for purposes of evaluating any inaccuracies in Akorn's representations when determining whether Fresenius is obligated to close.[521] The General MAE Condition is not tied to a particular representation about a particular issue, leading this decision to describe the resulting event

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[519] *Id.* § 5.03(a).

[520] *Id.* § 5.03(c).

[521] *See* Kenneth A. Adams, *A Legal-Usage Analysis of "Material Adverse Change" Provisions*, 10 Fordham J. Corp. & Fin. L. 9, 10–11 (2004) [hereinafter, Legal-Usage Analysis] ("MAC provisions are used in different parts of a contract. They occur most commonly in representations" but can "also occur in closing conditions."). In their discussion of material adverse change provisions, Kling and Nugent cite this article with approval. *See, e.g.*, Kling & Nugent, *supra*, § 11.04[9], at 11-59 n.100.

as a "General MAE." The Bring-Down Condition examines the inaccuracy of specific representations and uses as its measuring stick whether the deviation between the as-represented condition and the actual condition would reasonably be expected to constitute a Material Adverse Effect. The critical representations for this case are the Regulatory Compliance Representations, and this decision refers to a sufficient inaccuracy in those representations as a "Regulatory MAE."[522]

Working through the pertinent provisions requires determining whether Akorn has suffered either a General MAE or a Regulatory MAE, whether Akorn complied in all material respects with the Ordinary Course Covenant, whether Akorn could cure, and whether Fresenius itself was in material breach of the Reasonable Best Efforts Covenant or the Hell-or-High-Water Covenant. This decision makes the following findings:

- The sudden and sustained drop in Akorn's business performance constituted a General MAE.
- Akorn's Regulatory Compliance Representations were not true and correct, and the deviation between Akorn's as-represented condition and its actual condition would reasonably be expected to result in a Regulatory MAE.
- Akorn materially breached the Ordinary Course Covenant.

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[522] Commentators have used different terms for the two types of MAEs. Adams refers to an "absolute MAC" and a "modifying MAC." Legal-Usage Analysis, *supra*, at 10–11, 15–17, 50. In its annotated model merger agreement, the Mergers and Acquisitions Committee of the American Bar Association distinguishes between a "MAC condition," and a "back-door MAC." *See* ABA Mergers and Acquisitions Committee, *Model Merger Agreement for the Acquisition of a Public Company* 233, 243–44 (2011) [hereinafter, Model Merger Agreement].

- None of Akorn's breaches could be cured by the Outside Date, which remained April 24, 2018.
- Fresenius did not breach the Reasonable Best Efforts Covenant.
- Fresenius breached the Hell-or-High-Water Covenant, but the breach was not material.

Based on these findings, Fresenius validly terminated the Merger Agreement under Section 7.01(c)(i) because of (i) a non-curable failure of the Bring-Down Condition and (ii) a non-curable failure of the Covenant Compliance Condition. Fresenius could validly exercise its termination rights because it was not in material breach of its obligations. Regardless, Akorn has suffered a General MAE, so Fresenius cannot be forced to close.

A. The Failure Of The General MAE Condition

From the standpoint of contract interpretation, the most straightforward issue is whether Akorn suffered a General MAE. Starting with this issue is also helpful because much of the commentary on MAE clauses has focused on General MAEs. Because Fresenius seeks to establish a General MAE to excuse its performance under the Merger Agreement, Fresenius bore the burden of proving that a General MAE had occurred.[523] This decision concludes that Akorn suffered a General MAE.

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[523] *See Hexion Specialty Chems., Inc. v. Huntsman Corp.*, 965 A.2d 715, 739 (Del. Ch. 2008) ("[A]bsent clear language to the contrary, the burden of proof with respect to a material adverse effect rests on the party seeking to excuse its performance under the contract."); *Frontier Oil Corp. v. Holly Corp.*, 2005 WL 1039027, at *35 (Del. Ch. Apr. 29, 2005) ("[T]he expectation of the parties, as reflected in the Merger Agreement and as informed by the case law, was that the burden of demonstrating that the Beverly Hills Litigation would have (or would not reasonably be expected to have [sic]) an MAE falls on Holly [the buyer who was asserting breach]."); *IBP*, 789 A.2d at 53 ("Under both New

In any M&A transaction, a significant deterioration in the selling company's business between signing and closing may threaten the fundamentals of the deal. "Merger agreements typically address this problem through complex and highly-negotiated 'material adverse change' or 'MAC' clauses, which provide that, if a party has suffered a MAC within the meaning of the agreement, the counterparty can costlessly cancel the deal."[524]

Despite the attention that contracting parties give to these provisions, MAE clauses

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York and Delaware law, a defendant seeking to avoid performance of a contract because of the plaintiff's breach of warranty must assert that breach as an affirmative defense.").

[524] Robert T. Miller, *The Economics of Deal Risk: Allocating Risk Through MAC Clauses in Business Combination Agreements*, 50 Wm. & Mary L. Rev. 2007, 2012 (2009) (footnote omitted); *accord* Andrew A. Schwartz, *A "Standard Clause Analysis" of the Frustration Doctrine and the Material Adverse Change Clause*, 57 UCLA L. Rev. 789, 820 (2010) ("[T]he MAC clause allows the acquirer to costlessly avoid closing the deal if the target's business suffers a sufficiently adverse change during the executory period."); *see* Jeffrey Manns & Robert Anderson IV, *The Merger Agreement Myth*, 98 Cornell L. Rev. 1143, 1153 (2013) ("The MAC/MAE Clause gives teeth to the closing conditions in specifying what type of events would entitle the acquiring company to call the deal off if events occur between signing and closing that make the deal less advantageous than expected.").

"Although the phrase 'material adverse effect' (MAE) is more commonly used in merger agreements, MAC and MAE are generally understood to be synonymous." Miller, *supra*, at 2012 n.2; *see* Ronald J. Gilson & Alan Schwartz, *Understanding MACs: Moral Hazard in Acquisitions*, 21 J.L. Econ. & Org. 330, 331 (2005) (characterizing an MAE clause as the "equivalent" of a MAC clause). This decision uses the terms interchangeably. That said, one commentator has argued (in my view, persuasively) that the "material adverse change" formulation facilitates greater drafting clarity. *See* Legal-Usage Analysis, *supra*, at 17–20.

typically do not define what is "material."[525] Commentators have argued that parties find it efficient to leave the term undefined because the resulting uncertainty generates productive opportunities for renegotiation.[526] Parties also risk creating more problems

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[525] *See Frontier Oil*, 2005 WL 1039027, at *33 ("It would be neither original nor perceptive to observe that defining a 'Material Adverse Effect' as a 'material adverse effect' is not especially helpful."); Y. Carson Zhou, Essay, *Material Adverse Effects as Buyer–Friendly Standard*, 91 N.Y.U. L. Rev. Online 171, 173 (2016) (noting that in the typical MAE provision, the core concept of materiality is "left undefined"), http://www.nyulawreview.org/sites/default/files/NYULawReviewOnline-91-Zhou.pdf; Steven M. Davidoff & Kristen Baiardi, *Accredited Home Lenders v. Lone Star Funds: A MAC Case Study* 17 (Wayne State Univ. Law Sch. Legal Studies Research Paper Series, Paper No. 08-16, 2008), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1092115 ("MAC clauses are typically defined in qualitative terms and do not describe a MAC in quantitative terms."); Albert Choi & George Triantis, *Strategic Vagueness in Contract Design: The Case of Corporate Acquisitions*, 119 Yale L.J. 848, 854 (2010) ("[T]he typical MAC provision is not quantitative and remains remarkably vague."); Schwartz, *supra*, at 826 ("A few MAC clauses include a quantitative definition of materiality, but the overwhelming majority offer no definition for the key term 'material.'") (footnote omitted); Kenneth A. Adams, *A Manual of Style for Contract Drafting* 229 (4th ed. 2017) [hereinafter, Contract Drafting] ("[Q]uantitative guidelines are little used."). One commentator sees no reason to criticize the MAE definition for its self-referential quality. *See* Legal-Usage Analysis, *supra*, at 22 ("It has been suggested that there is some circularity or tautology involved in using the phrase material adverse change in the definition of MAC. . . . [I]n contracts it is routine, and entirely appropriate, for a definition to include the term being defined.") (footnotes omitted); Contract Drafting, *supra*, at 169 ("Dictionaries shouldn't use in a definition the term being defined, as that constitutes a form of circular definition. . . . In a contract, a defined term simply serves as a convenient substitute for the definition, and only for that contract. So repeating a contract defined term in the definition is unobjectionable.").

[526] *See* Choi & Triantis, *supra*, at 888–892 (arguing that vague MAE clauses are efficient partly because uncertainty facilitates renegotiation); Eric L. Talley, *On Uncertainty, Ambiguity, and Contractual Conditions*, 34 Del. J. Corp. L. 755, 788 (2009) ("A number of practitioners . . . suggested that, in addition to concerns about uncertainty, one of the key reasons for a MAC/MAE provision is to provide a backdrop for possible deal restructuring should market conditions change."); ABA Mergers and Acquisitions Committee, *Model Stock Purchase Agreement with Commentary* 268 (2d ed. 2010) [hereinafter, Model Stock Purchase Agreement] (explaining that a buyer may prefer a price

when they attempt to include specific quantitative thresholds, both during the negotiations[527] and for purposes of subsequent litigation.[528] "What constitutes an MAE, then, is a question that arises only when the clause is invoked and must be answered by the presiding court."[529]

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renegotiation rather than engaging in costly litigation over a "subjective" and "vague" MAE clause); *see also* Davidoff & Baiardi, *supra*, at 19 (reasoning that if a buyer credibly asserts an MAE, then both parties have incentives to renegotiate to a lower price to avoid an all-or-nothing litigation outcome); Katherine Ashton et al., *MAC Clauses in the U.K. and U.S.: Much Ado About Nothing?*, The M&A Lawyer (LegalWorks), Mar. 2014 ("[T]he lack of clear standards for determining whether a material adverse change has occurred may inure to [the buyer's] benefit . . . as the ambiguity might allow the buyer to use the threat of litigation concerning the MAC clause . . . to pressure the seller to renegotiate the deal.").

[527] *See* Claire A. Hill, *Bargaining in the Shadow of the Lawsuit: A Social Norms Theory of Incomplete Contracts*, 34 Del. J. Corp. L. 191, 198 (2010) ("[A]chieving clarity [in an MAE clause] may simply be exceedingly difficult: as a practical, and perhaps, theoretical, matter, defining ex ante such a change in a manner that commands assent by the parties and applies cleanly to a significant number of circumstances may be impossible."); Kling & Nugent, *supra*, § 11.04[9], at 11-66.2 ("The problem is that it is very difficult in most cases for the parties to reach agreement on a particular percentage or dollar decrease in sales, earnings or net worth."); Contract Drafting, *supra*, at 228 ("[E]stablishing one or more numerical thresholds for materiality can complicate the negotiation process."). That said, achieving agreement on a specific metric is not impossible. *See, e.g.*, *Nip v. Checkpoint Sys, Inc.*, 154 S.W.3d 767, 769–70 (Tex. App. 2004) (enforcing MAE clause that set monetary threshold for materiality; affirming jury determination that target suffered an MAE when its second-largest customer attempted to cancel all orders from target's Far East factories).

[528] Contract Drafting, *supra*, at 228 ("Setting a [quantitative] threshold for all possible [adverse changes] would seem impractical, and addressing only a limited number could be arbitrary."); *id.* ("[I]f the quantitative indicia are illustrative rather than exclusive, adding them to the definition of MAC would increase the risk that a court wouldn't consider to be a MAC a change that doesn't resemble the examples.").

[529] Zhou, *supra*, at 173; *see Frontier Oil*, 2005 WL 1039027, at *34 ("The parties chose to use the term 'Material Adverse Effect' and it is the Court's function to discern

Rather than devoting resources to defining more specific tests for materiality, the current practice is for parties to negotiate exceptions and exclusions from exceptions that allocate categories of MAE risk.[530] "The typical MAE clause allocates general market or industry risk to the buyer, and company-specific risks to the seller."[531] From a drafting perspective, the MAE provision accomplishes this by placing the general risk of an MAE on the seller, then using exceptions to reallocate specific categories of risk to the buyer.[532]

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what they intended. . . . The notion of an MAE is imprecise and varies both with the context of the transaction and its parties and with the words chosen by the parties."); Choi & Triantis, *supra*, at 876–77 ("The definition of material adverse event and the related material adverse change condition leave broad interpretive discretion to the court. For example, the definitions leave open the scope of changes that affect 'business' or 'operations.'").

[530] *See* Miller, *supra*, at 2013 n.7 ("There is virtually universal agreement, among both practitioners and academics, that MAC clauses allocate risk between the parties."); Gilson & Schwartz, *supra*, at 339–54 (analyzing how MAE clauses allocate risk).

[531] Zhou, *supra*, at 173; *accord* Choi & Triantis, *supra*, at 867 ("The principal purpose of carve outs from the definition of material adverse events or changes seems to be to remove systemic or industry risk from the MAC condition, as well as risks that are known by both parties at the time of the agreement."). "A possible rationale" for this allocation "is that the seller should not have to bear general and possibly undiversifiable risk that it cannot control and the buyer would likely be subject to no matter its investment." Davidoff & Baiardi, *supra*, at 15; *see also* Gilson & Schwartz, *supra*, at 339 (arguing that "an efficient acquisition agreement will impose endogenous risk on the seller and exogenous risk on the buyer"). As with any general statement, exceptions exist, and "different agreements will select different exogenous risks to shift to the counterparty, and in stock-for-stock and cash-and-stock deals, parties may shift different exogenous risks to each other." Miller, *supra*, at 2070.

[532] *See* Miller, *supra*, at 2073 ("Because of the drafting conventions used in MAC Definitions—all the risks are on the party except for those shifted to the counterparty by the MAC Exceptions—this class of risks would, strictly speaking, probably be best defined negatively."); Schwartz, *supra*, at 822 ("[T]he risk of a target MAC resulting from a carved-out cause is allocated to the acquirer, while the risk of a target MAC resulting from

Exclusions from the exceptions therefore return risks to the seller. A standard exclusion from the buyer's acceptance of general market or industry risk returns the risk to the seller when the seller's business is uniquely affected. To accomplish the reallocation, the relevant exceptions are "qualified by a concept of disproportionate effect."[533] "For example, a buyer might revise the carve-out relating to industry conditions to exclude changes that disproportionately affect the target as compared to other companies in the industries in which such target operates."[534]

A more nuanced analysis of the types of issues addressed by MAE provisions reveals four categories of risk: systematic risks, indicator risks, agreement risks, and business risks.[535]

- Systematic risks are "beyond the control of all parties (even though one or both parties may be able to take steps to cushion the effects of such risks) and . . . will generally affect firms beyond the parties to the transaction."[536]

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any other cause is allocated to the target."). *See generally Hexion*, 965 A.2d at 737 ("The plain meaning of the carve-outs found in [the MAE clause's] proviso is to prevent certain occurrences which would *otherwise* be MAE's being found to be so.").

[533] Model Merger Agreement, *supra*, at 242.

[534] Model Merger Agreement, *supra*, at 242; *accord* Miller, *supra*, at 2048; *see* Choi & Triantis, *supra*, at 867 ("The most common carve outs remove from the MAC definition changes in the general economic, legal, or political environment, and conditions in the target's industry, except to the extent that they have 'disproportionate' effects on the target.").

[535] *See generally* Miller, *supra*, at 2071–91.

[536] *Id.* at 2071; *see* Richard A. Brealey & Stewart C. Myers, *Principles of Corporate Finance* 168 & n.22 (7th ed. 2003) (explaining that market risk, also known as systematic

- Indicator risks signal that an MAE may have occurred. For example, a drop in the seller's stock price, a credit rating downgrade, or a failure to meet a financial projection is not itself an adverse change, but rather evidence of such a change.[537]

- "Agreement risks include all risks arising from the public announcement of the merger agreement and the taking of actions contemplated thereunder by the parties."[538] Agreement risks include endogenous risks related to the cost of getting from signing to closing, *e.g.*, potential employee flight.[539]

- Business risks are those "arising from the ordinary operations of the party's business (other than systematic risks), and over such risks the party itself usually has significant control."[540] "The most obvious" business risks are those "associated with the ordinary business operations of the party—the kinds of negative events that, in the ordinary course of operating the business, can be expected to occur from time to time, including those that, although known, are remote."[541]

Generally speaking, the seller retains the business risk. The buyer assumes the other risks.[542]

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risk, "stems from the fact that there are . . . economywide perils that threaten all businesses").

[537] Miller, *supra*, at 2072, 2082–83.

[538] *Id.* at 2087.

[539] *Id.*

[540] *Id.* at 2073.

[541] *Id.* at 2089.

[542] *See, e.g.*, *id.* at 2073 (explaining that "(a) systematic risks and agreement risks are usually, but not always, shifted to the counterparty, (b) indicator risks are so shifted in a significant minority of cases, and (c) business risks are virtually always assigned to the party itself").

In this case, as a condition to Fresenius's obligation to close, Akorn must not have suffered a General MAE. Section 6.02 of the Merger Agreement, titled "Conditions to the Obligations of [Fresenius Kabi] and Merger Sub," states:

> The obligations of [Fresenius Kabi] and Merger Sub to effect the Merger shall be subject to the satisfaction (or written waiver by [Fresenius Kabi], if permissible under applicable law) on or prior to the Closing Date of the following conditions:
>
> * * *
>
> (c) No Material Adverse Effect. Since the date of this Agreement there shall not have occurred and be continuing any effect, change, event or occurrence that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.

The effect of this condition is to place the general risk of an MAE on Akorn.

The Merger Agreement defines the concept of a "Material Adverse Effect" in customary albeit complex and convoluted prose. The following reproduction of the definition adds formatting to enhance legibility:

> "Material Adverse Effect" means any effect, change, event or occurrence that, individually or in the aggregate
>
> (i) would prevent or materially delay, interfere with, impair or hinder the consummation of the [Merger] or the compliance by the Company with its obligations under this Agreement or
>
> (ii) has a material adverse effect on the business, results of operations or financial condition of the Company and its Subsidiaries, taken as a whole;
>
> provided, however, that none of the following, and no effect, change, event or occurrence arising out of, or resulting from, the following, shall constitute or be taken into account in determining whether a Material Adverse Effect has occurred, is continuing or would reasonably be expected to occur: any effect, change, event or occurrence
>
> (A) generally affecting (1) the industry in which the Company and its Subsidiaries operate or (2) the economy, credit or financial or capital

markets, in the United States or elsewhere in the world, including changes in interest or exchange rates, monetary policy or inflation, or

(B) to the extent arising out of, resulting from or attributable to

(1) changes or prospective changes in Law or in GAAP or in accounting standards, or any changes or prospective changes in the interpretation or enforcement of any of the foregoing, or any changes or prospective changes in general legal, regulatory, political or social conditions,

(2) the negotiation, execution, announcement or performance of this Agreement or the consummation of the [Merger] (other than for purposes of any representation or warranty contained in Sections 3.03(c) and 3.04), including the impact thereof on relationships, contractual or otherwise, with customers, suppliers, distributors, partners, employees or regulators, or any litigation arising from allegations of breach of fiduciary duty or violation of Law relating to this Agreement or the [Merger],

(3) acts of war (whether or not declared), military activity, sabotage, civil disobedience or terrorism, or any escalation or worsening of any such acts of war (whether or not declared), military activity, sabotage, civil disobedience or terrorism,

(4) pandemics, earthquakes, floods, hurricanes, tornados or other natural disasters, weather-related events, force majeure events or other comparable events,

(5) any action taken by the Company or its Subsidiaries that is required by this Agreement or at [Fresenius Kabi's] written request,

(6) any change or prospective change in the Company's credit ratings,

(7) any decline in the market price, or change in trading volume, of the shares of the Company or

(8) any failure to meet any internal or public projections, forecasts, guidance, estimates, milestones, budgets or internal or published financial or operating predictions of revenue, earnings, cash flow or cash position

(it being understood that the exceptions in clauses (6), (7) and (8) shall not prevent or otherwise affect a determination that the underlying cause of any such change, decline or failure referred to therein (if not otherwise falling within any of the exceptions provided by clause (A) and clauses (B)(1) through (8) hereof) is a Material Adverse Effect);

> provided further, however, that any effect, change, event or occurrence referred to in clause (A) or clauses (B)(3) or (4) may be taken into account in determining whether there has been, or would reasonably be expected to be, a Material Adverse Effect to the extent such effect, change, event or occurrence has a disproportionate adverse affect [sic] on the Company and its Subsidiaries, taken as a whole, as compared to other participants in the industry in which the Company and its Subsidiaries operate (in which case the incremental disproportionate impact or impacts may be taken into account in determining whether there has been, or would reasonably be expected to be, a Material Adverse Effect).[543]

As is common, the definition starts with a general statement of what constitutes an MAE. It next carves out certain types of events that otherwise could give rise to an MAE. It then creates two broad exceptions to the carve-outs. One is that while the carve-outs confirm that certain evidentiary indicators of an MAE will not themselves constitute an MAE, such as a decline in the seller's market price or an adverse change in its credit rating, those carve-outs do not foreclose the underlying cause of the negative events from being used to establish an MAE, unless it otherwise falls within a different carve-out. The other is that four of the identified carve-outs will give rise to an MAE if the effect, change, event or occurrence has had a disproportionately adverse effect on the Company.

Fresenius relies on subpart (ii) of the MAE definition, which establishes (subject to the carve-outs and their exceptions) that an MAE means "any effect, change, event or occurrence that, individually or in the aggregate that . . . (ii) has a material adverse effect on the business, results of operations or financial condition of the Company and its Subsidiaries, taken as a whole." This aspect of the MAE definition adheres to the general

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[543] JX 1 at 58.

practice and defines "Material Adverse Effect" self-referentially as something that "has a material adverse effect."

The subsequent exceptions to the definition and exclusions from the exceptions implement a standard risk allocation between buyer and seller. Through the exceptions in subparts (A)(1) and (A)(2), Fresenius accepted the systematic risks related to Akorn's industry and "the economy, credit or financial or capital markets, in the United States or elsewhere in the world, including changes in interest or exchange rates, monetary policy or inflation."[544] Through the exceptions in subparts (B)(3) and (B)(4), Fresenius also accepted the systematic risks related to acts of war, violence, pandemics, disasters, and other *force majeure* events. Each of these allocations is subject to a disproportionate-effect exclusion that returns the risk to Akorn to the extent that an event falling into one of these categories disproportionately affects Akorn "as compared to other participants in the industry."[545] Under subpart (B)(1), Fresenius also assumes the systematic risk relating to changes in GAAP or applicable law. This exception is not subject to a disproportionate-effect exclusion and therefore would remain with Fresenius in any event.

The exceptions in subparts (B)(2) and (B)(5) identify agreement risks. Through these exceptions, Fresenius assumes these risks.

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[544] *Id.*

[545] *Id.*

The exceptions in subparts (B)(6), (B)(7), and (B)(8) identify indicator risks. The MAE definition explicitly treats these risks as indicators, first by excluding them through the exceptions, then by confirming that although these indicators would not independently give rise to an MAE, the underlying cause of a change in the indicators could give rise to an MAE.

What remains is business risk, which Akorn retains. Scholars view this outcome as economically efficient because the seller "is better placed to prevent such risks (i.e., is the cheaper cost avoider) and has superior knowledge about the likelihood of the materializations of such risks that cannot be prevented (i.e., is the superior risk bearer)."[546]

1. Whether The Magnitude Of The Effect Was Material

The first step in analyzing whether a General MAE has occurred is to determine whether the magnitude of the downward deviation in the affected company's performance is material: "[U]nless the court concludes that the company has suffered an MAE as defined in the language coming before the proviso, the court need not consider the application of

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[546] Miller, *supra*, at 2091; *see also id.* (arguing that it "would be ludicrous to suggest, for example, that the [buyer] would be a cheaper risk avoider or superior risk bearer with respect to, say, design or manufacturing defects in the [seller's] products or with respect to hidden liabilities resulting from the [seller's] operations long ago"); Gilson & Schwartz, *supra*, at 357 (arguing that an MAE definition with carve-outs "allocates transaction risks to the party that can most efficiently bear them").

the . . . carve-outs."[547] Whether the party asserting the existence of an MAE has adduced sufficient evidence to carry its burden of proof is a question of fact.[548]

"A buyer faces a heavy burden when it attempts to invoke a material adverse effect clause in order to avoid its obligation to close."[549] "A short-term hiccup in earnings should not suffice; rather the Material Adverse Effect should be material when viewed from the longer-term perspective of a reasonable acquiror."[550] "In the absence of evidence to the

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[547] *Hexion*, 965 A.2d at 737.

[548] *See ChyronHego Corp. v. Wight*, 2018 WL 3642132, at *9 (Del. Ch. July 31, 2018) ("At this pleading stage, the Plaintiffs have met their burden to allege a knowingly false representation of the absence of an MAE, the proof of which is inherently fact-intensive."); *Osram Sylvania Inc. v. Townsend Ventures, LLC*, 2013 WL 6199554, at *7 (Del. Ch. Nov. 19, 2013) (finding it reasonably conceivable that the defendants' "alleged practice of billing and shipping excess product, without applying the proper credits or discount, could have a materially adverse effect on the financial condition of the Company when the excess product is returned and revenues are reduced."); *H–M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 144 (Del. Ch. 2003) ("If Wexford's allegations are accepted as true, then it could show that there was a material adverse change in Encorp's financial position between the Balance Sheet Date and the date the Purchase Agreement was executed."); *see also Pine State Creamery Co. v. Land-O-Sun Dairies, Inc.*, 201 F.3d 437, 1999 WL 1082539, at *3–6 (4th Cir. 1999) (per curiam) (TABLE) (holding that whether severe operating losses over a two-month period constituted an MAE was a question of fact for the jury where there was evidence that the business was seasonal and that downturns were expected each fall); *RUS, Inc. v. Bay Indus, Inc.*, 322 F. Supp. 2d 302, 314 (S.D.N.Y. 2003) ("[M]aterial issues of fact exist as to whether the need for the Phase II investigation, when considered in light of the transaction as a whole and the nature of the environmental issues involved, constituted a material adverse effect that caused the representations in § 4.8 to be untrue.").

[549] *Hexion*, 965 A.2d at 738; *see also* Kling & Nugent, *supra*, § 11.04[9], at 11-69 ("[I]t is much tougher to prove the existence of a material adverse effect than clients realize.").

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

contrary, a corporate acquirer may be assumed to be purchasing the target as part of a long-term strategy."[551] "The important consideration therefore is whether there has been an adverse change in the target's business that is consequential to the company's long-term earnings power over a commercially reasonable period, which one would expect to be measured in years rather than months."[552]

> This, of course, is not to say that evidence of a significant decline in earnings by the target corporation during the period after signing but prior to the time appointed for closing is irrelevant. Rather, it means that for such a decline to constitute a material adverse effect, poor earnings results must be expected to persist significantly into the future.[553]

Put differently, the effect should "substantially threaten the overall earnings potential of the target in a durationally-significant manner."[554]

The *Hexion* decision teaches that when evaluating the magnitude of a decline, a company's performance generally should be evaluated against its results during the same quarter of the prior year, which minimizes the effect of seasonal fluctuations.[555] The *Hexion*

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[551] *Hexion*, 965 A.2d at 738. Commentators have suggested that "the requirement of durational significance may not apply when the buyer is a financial investor with an eye to a short-term gain." Choi & Triantis, *supra*, at 877; *see Genesco, Inc. v. The Finish Line, Inc.*, 2007 WL 4698244, at *19 (Tenn. Ch. Dec. 27, 2007) (finding that two quarters of bad performance would be material to a buyer in a highly leveraged acquisition).

[552] *Hexion*, 965 A.2d at 738.

[553] *Id.*

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

[555] *Hexion*, 965 A.2d at 742 ("The proper benchmark . . . (and the analysis the court adopted here) is to examine each year and quarter and compare it to the prior year's equivalent period.").

court declined to find an MAE where the seller's 2007 EBITDA was only 3% below its 2006 EBITDA, and where according to its management forecasts, its 2008 EBITDA would be only 7% below its 2007 EBITDA. Even using the buyer's more conservative forecasts, the seller's 2008 EBTIDA would still be only 11% below its 2007 EBITDA.[556] The average of analyst estimates for the seller's 2009 EBITDA was only 3.6% below the seller's average results during the prior three years. The court noted that the buyer had contemplated scenarios consistent with these results.[557]

In their influential treatise, Lou R. Kling and Eileen T. Nugent observe that most courts which have considered decreases in profits in the 40% or higher range found a material adverse effect to have occurred.[558] Chancellor Allen posited that a decline in

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[556] *Id.*

[557] *Id.* at 743.

[558] Kling & Nugent, *supra*, § 11.04[9], at 11-66. Both the Delaware Supreme Court and this court regularly rely on this treatise as an authoritative source on M&A practice. *See, e.g.*, *Chicago Bridge & Iron Co. N.V. v. Westinghouse Elec. Co.*, 166 A.3d 912, 921 & nn.32, 34 (Del. 2017) (citing Kling & Nugent as authority on post-closing indemnification); *ev3, Inc. v. Lesh*, 114 A.3d 527, 530–31 & nn.6, 8 (Del. 2014) (citing Kling and Nugent as authority on letters of intent); *Martin Marietta Materials, Inc. v. Vulcan Materials Co.*, 68 A.3d 1208, 1219 & n.45 (Del. 2012) (citing Kling & Nugent as authority on NDAs); *Ford v. VMWare, Inc.*, 2017 WL 1684089, at *13 & n.8 (Del. Ch. May 2, 2017) (citing Kling & Nugent as authority on the purpose of representations and warranties); *Alliance Data Sys. Corp. v. Blackstone Capital P'rs V L.P.*, 963 A.2d 746, 763 n.60 (Del. Ch.) (Strine, V.C.) (citing Kling & Nugent as authority on best efforts covenants), *aff'd*, 976 A.2d 170 (Del. 2009) (TABLE); *ABRY P'rs V, L.P. v. F & W Acq. LLC*, 891 A.2d 1032, 1042, 1044 & nn.9, 14 (Del. Ch. 2006) (Strine, V.C.) (citing Kling & Nugent as authority on representations regarding financial statements and bring-downs). *See generally GRT, Inc. v. Marathon GTF Tech., Ltd.*, 2011 WL 2682898, at *12 (Del. Ch. July 11, 2011) (Strine, C.) ("[Y]oung lawyers are now often pointed to the sections of *Negotiated Acquisitions of Companies, Subsidiaries and Divisions,* by Lou R. Kling and

earnings of 50% over two consecutive quarters would likely be an MAE.[559] Courts in other jurisdictions have reached similar conclusions.[560] These precedents do not foreclose the possibility that a buyer could show that percentage changes of a lesser magnitude constituted an MAE. Nor does it exclude the possibility that a buyer might fail to prove that percentage changes of a greater magnitude constituted an MAE.

An example of the latter scenario is *IBP*, where Chief Justice Strine held while serving as a Vice Chancellor that a 64% drop in quarterly earnings did not constitute a material adverse effect. There, a major producer of beef suffered a large quarterly decline

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Eileen T. Nugent, which address in even more depth than Freund, just how complex acquisition agreements work."); *id.* at *12–13 (describing Kling & Nugent as among the "leading works" and "most incisive learned commentary" on M&A practice).

[559] *Raskin v. Birmingham Steel Corp.*, 1990 WL 193326, at *5 (Del. Ch. Dec. 4, 1990) (Allen, C.) ("While it is possible that on a full record and placed in a larger context one might conclude that a reported 50% decline in earnings over two consecutive quarters might not be held to constitute a material adverse development, it is . . . unlikely to think that that might happen.").

[560] *See Allegheny Energy v. DQE, Inc.*, 74 F. Supp. 2d 482, 518 (W.D. Pa. 1999) (finding an MAE and permitting termination of merger agreement where write-off exceeded company's annual net income and regulatory action denied company "a large stream of guaranteed future revenues that it had been receiving prior to deregulation"), *aff'd*, 216 F.3d 1075 (3d. Cir. 2000) (TABLE); *Peoria Sav. & Loan Ass'n v. Am. Sav. Ass'n*, 441 N.E.2d 853, 854–55, 858–59 (Ill. App. Ct. 1982) (affirming trial court decision finding an MAE and preliminarily enjoining merger where after signing counterparty acquired two troubled savings and loan associations but failed to obtain expected federal financial assistance); *Genesco*, 2007 WL 4698244, at *16–20 (in the context of highly leveraged transaction where short-term losses were durationally significant, finding that weak performance in consecutive quarters would have constituted an MAE if not for carve-out for materially adverse effects that are not "materially disproportionate" to those suffered by similarly situated industry participants).

in performance primarily due to widely known cycles in the meat industry, exacerbated by a harsh winter that also affected the buyer.[561] After the bad quarter and the onset of spring, "IBP began to perform more in line with its recent year results."[562] The Chief Justice concluded that "IBP remain[ed] what the baseline evidence suggests it was—a consistently but erratically profitable company struggling to implement a strategy that will reduce the cyclicality of its earnings."[563] The Chief Justice nevertheless noted that "the question of whether IBP has suffered a Material Adverse Effect remains a close one"[564] and that he was "confessedly torn about the correct outcome."[565] He further posited that

> [i]f IBP had continued to perform on a straight-line basis using its first quarter 2001 performance, it would generate earnings from operations of around $200 million. This sort of annual performance would be consequential to a reasonable acquiror and would deviate materially from the range in which IBP had performed during the recent past [thus giving rise to an MAE].[566]

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[561] *IBP*, 789 A.2d at 22 ("During the winter and spring of 2001, Tyson's own business performance was dismal. Meanwhile, IBP was struggling through a poor first quarter. Both companies' problems were due in large measure to a severe winter, which adversely affected livestock supplies and vitality. As these struggles deepened, Tyson's desire to buy IBP weakened.").

[562] *Id.* at 70.

[563] *Id.* at 71.

[564] *Id.* at 68.

[565] *Id.* at 71; *accord id.* ("I admit to reaching this conclusion [that no MAE occurred] with less than the optimal amount of confidence.").

[566] *Id.* at 69.

IBP's prior year earnings from operations during the preceding five years were $528 million (1999), $374 million (1998), $227 million (1997), $323 million (1996), and $480 million (1995).[567] An annual performance of $200 million would have represented a 52% decline from IBP's five-year average of $386 million. The Chief Justice also noted that the buyer's arguments were "unaccompanied by expert evidence that identifies the diminution in [the seller's] value or earnings potential as a result of its first quarter performance" and observed that "[t]he absence of such proof is significant."[568]

In this case, Fresenius made the showing necessary to establish a General MAE. At trial, Professor Daniel Fischel testified credibly and persuasively that Akorn's financial performance has declined materially since the signing of the Merger Agreement and that the underlying causes of the decline were durationally significant.[569] The factual record supports Fischel's opinions.

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[567] *Id.* at 66.

[568] *Id.* at 69–70.

[569] *See* Fischel Tr. 1352 (describing the "collapse in Akorn's stand-alone value from the time of the signing of the merger agreement to the termination and collapse that's expected to continue into the future"). In contrast to Fischel's testimony, I did not find the testimony of Akorn's rebuttal witness, Professor Anil Shivdasani, to be helpful or, in some instances, credible. In one telling example, Shivdasani would not even agree that Akorn's share price at the time of trial was supported to some degree by the possibility of the transaction closing. Shivdasani Tr. 1412.

As contemplated by *Hexion*, the following table depicts the year-over-year declines that Akorn suffered during each of the three quarters of FY 2017 that took place after signing, plus full-year results for FY 2017, plus first quarter results for FY 2018:

Year-Over-Year Change In Akorn's Performance[570]					
	Q2 2017	Q3 2017	Q4 2017	FY 2017	Q1 2018
Revenue	(29%)	(29%)	(34%)	(25%)	(27%)
Operating Income	(84%)	(89%)	(292%)	(105%)	(134%)
EPS	(96%)	(105%)	(300%)	(113%)	(170%)

Akorn did not report EDBITA or adjusted EBITDA figures on a quarterly basis for 2017.[571] It reported full-year EBITDA of $64 million, a year-over-year decline of 86%. Akorn reported full-year adjusted EBITDA of $241 million, a year-over-year decline of 51%.[572] As these figures show, Akorn's performance declined dramatically, year over year, with positive operating income and positive earnings per share turning to losses.

In addition to representing a dramatic decline on a year-over-year basis, Akorn's performance in FY 2017 represented a departure from its historical trend. Over the five-year span that began in 2012 and ended in 2016, Akorn grew consistently, year over year, when measured by revenue, EBITDA, EBIT, and EPS.[573] During 2017, Akorn's

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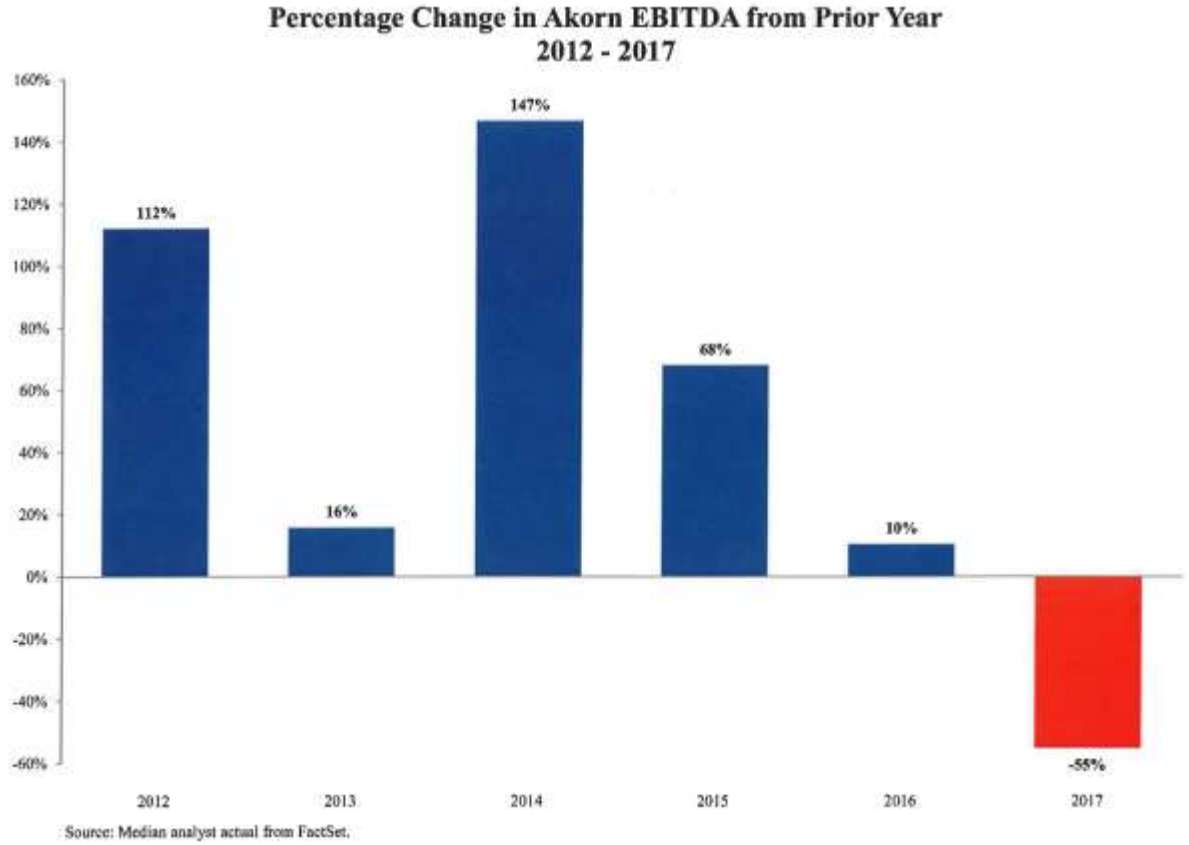
[570] *See* JX 1250 ¶¶ 8–9, 11, 19. To be clear, quarterly declines are measured against performance in the same quarter the previous year.

[571] *Id.* ¶ 11 n.17.

[572] *Id.* ¶ 11.

[573] Fischel Tr. 1353–55; JX 1250 ¶¶ 26–30, Exs. 1–4.

performance fell dramatically when measured by each metric.[574] For example, Akorn's EBITDA and EBIT grew each year from 2012 to 2016, but in 2017, fell by 55% and 62%, respectively.[575] Fischel prepared the following chart that illustrates the percentage change from year to year in Akorn's EBITDA.



Notably, Akorn's performance during the first quarter of 2017—before the Merger Agreement was signed—did not exhibit the downturn that the ensuing three quarters did.[576]

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[574] *See* Fischel Tr. 1354; JX 1250 Exs. 1–4.

[575] Fischel Tr. 1354; JX 1250 ¶¶ 28–29, Exs. 2 & 3.

[576] JX 1250 ¶ 26 & n.44.

But immediately after the signing of the Merger Agreement, Akorn's performance dropped off a cliff.

Akorn's dramatic downturn in performance is durationally significant. It has already persisted for a full year and shows no sign of abating.[577] More importantly, Akorn's management team has provided reasons for the decline that can reasonably be expected to have durationally significant effects.[578] When reporting on Akorn's bad results during the second quarter of FY 2017, Rai attributed Akorn's poor performance to unexpected new market entrants who competed with Akorn's three top products—ephedrine, clobetasol, and lidocaine.[579] He noted that Akorn also faced a new competitor for Nembutal, another important product, which Akorn management had not foreseen.[580] As Rai testified, "There were way more [competitors] than what [Akorn] had potentially projected in [its] forecast for 2017,"[581] and the new competition resulted in unexpected price erosion.[582] Akorn also unexpectedly lost a key contract to sell progesterone, resulting in a loss of revenue where

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[577] *See* Rai Tr. 545–46 (agreeing that he has no reason to think that any of Akorn's unexpected competitors will withdraw); Portwood Dep. 64–65 (Akorn's CFO testifying that he was not aware of any factors indicative of an "uptick").

[578] *See* JX 1250 ¶ 23.

[579] Rai Tr. 542–44.

[580] *Id.* at 545.

[581] *Id.*

[582] *Id.* at 542; *see* JX 693 at 35 (attributing poor performance to "more significant than expected declines in net revenue").

Akorn had been forecasting growth.[583] When explaining its third quarter results, Akorn described its poor performance as "[d]riven mostly by unanticipated supply interruptions and unfavorable impact from competition across [the] portfolio."[584] Akorn also noted that its "[a]verage product pricing [was] lower than expected due to [an] unfavorable customer/contract mix and price erosion [that was] not considered in our forecast."[585] There is every reason to think that the additional competition will persist and no reason to believe that Akorn will recapture its lost contract.

Additional support for the collapse in Akorn's value and its durational significance can be found in recent analyst valuations. In connection with the Akorn board's approval of the Merger, the board's financial advisor, J.P. Morgan, submitted a discounted cash flow valuation for Akorn with a midpoint of $32.13 per share.[586] Based on Akorn's post-signing performance, analysts have estimated that Akorn's standalone value is between $5.00 and $12.00 per share.[587] Analysts also have dramatically reduced their forward-looking estimates for Akorn.[588] For example, as of the date of termination, analysts' estimates for Akorn's 2018, 2019, and 2020 EBITDA were lower than their estimates at signing by

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[583] Rai Tr. 546–47.

[584] JX 688 at '606.

[585] *Id.* at '607.

[586] *See* JX 520 at '841.

[587] *See* Fischel Tr. 1352–53; JX 1505; JX 1508; JX 1250 ¶ 45.

[588] *See* Fischel Tr. 1362–65.

62.6%, 63.9%, and 66.9% respectively.[589] Analysts' estimates for Akorn's peers have declined by only 11%, 15.3%, and 15%, respectively, for those years.[590] Analysts thus perceive that Akorn's difficulties are durationally significant.[591]

To contest this powerful evidence of a Material Adverse Effect, Akorn contends that any assessment of the decline in Akorn's value should be measured not against its performance as a standalone entity, but rather against its value to Fresenius as a synergistic buyer.[592] In my view, the plain language of the definition of an MAE makes clear that any MAE must be evaluated on a standalone basis. First, the broad definition of an MAE refers to any "material adverse effect on the business, results of operations or financial condition *of the Company and its Subsidiaries*, taken as a whole." If the parties had contemplated a

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[589] *See id.* at 1363–1365; JX 1250 ¶ 39, Ex. 7.

[590] *See* Fischel Tr. 1364–65; JX 1250 ¶ 39, Ex.7.

[591] *See* Fischel Tr. 1365–66 ("[I]f there was an expectation of a big reversal, the stand-alone values wouldn't be what they are."). Akorn misleadingly argues that the mean of analyst consensus forecasts for Akorn's EPS from 2018 to 2020 is 46% higher than the mean of Akorn's historical EPS from 2011 to 2013. Dkt. 186 at 123. This comparison leaves out four years of results: 2014, 2015, 2016, and 2017. Akorn attempts to justify its cherry-picking by claiming that Akorn should be compared to a prior period when it struggled, but the record does not support a finding that Akorn struggled during this period, only that it was a smaller company. What is necessary is to evaluate a company's performance over a meaningful time horizon to take into account trends, such as cyclicality. *See IBP*, 789 A.2d at 71 (noting that analyst EPS forecasts for the seller "for the next two years would not be out of line with its historical performance during troughs"). Here, Akorn's performance improved steadily over the past five years across all of the metrics that Fischel examined, only to reverse dramatically after the parties signed the Merger Agreement.

[592] *See* Dkt. 186 at 122–23 n.607.

synergistic approach, the definition would have referred to the surviving corporation or the combined company. Second, subpart (B)(2) of the definition carves out any effects resulting from "the negotiation, execution, announcement or performance of this Agreement or the consummation of the [Merger,]" and the generation of synergies is an effect that results from the consummation of the Merger. A review of precedent does not reveal any support for Akorn's argument; every prior decision has looked at changes in value relative to the seller as a standalone company.[593] Akorn's desire to include synergies is understandable—it increases the denominator for purposes of any percentage-based comparison—but it is not supported by the Merger Agreement or the law.

Akorn also argues that as long as Fresenius can make a profit from the acquisition, an MAE cannot have occurred.[594] The MAE definition does not include any language about the profitability of the deal to the buyer; it focuses solely on the value of the seller. Assessing whether Fresenius can make a profit would introduce a different, non-contractual standard. It would effectively require that Fresenius show a goodwill impairment before it could prove the existence of an MAE. The parties could have bargained for that standard, but they did not. Requiring a loss before a buyer could show

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[593] *See Hexion*, 965 A.2d at 740–42 (analyzing quarter-over-quarter and year-over-year changes in EBITDA without referring to synergies); *id.* at 745 ("[U]nder the terms of the merger agreement, an MAE is to be determined based on an examination of Huntsman [the seller] taken as a whole."); *IBP*, 789 A.2d at 66 (comparing IBP as it existed as of December 25, 1999, and as portrayed in the merger agreement, with IBP's later condition).

[594] *See* Dkt. 186 at 122.

an MAE also would ignore the fact that acquirers evaluate rates of return when choosing among competing projects, including acquisitions. A buyer might make money on an absolute basis, but the opportunity cost on a relative basis would be quite high.

More broadly, the black-letter doctrine of frustration of purpose already operates to discharge a contracting party's obligations when his "principal purpose is substantially frustrated without his fault by the occurrence of an event the non-occurrence of which was a basic assumption on which the contract was made."[595] This common law doctrine "provides an escape for an acquirer if the target experiences a catastrophe during the executory period."[596] "It is not reasonable to conclude that sophisticated parties to merger agreements, who expend considerable resources drafting and negotiating MAC clauses, intend them to do nothing more than restate the default rule."[597] In lieu of the default rule that performance may be excused only where a contract's principal purpose is completely

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[595] *Wal–Mart Stores, Inc. v. AIG Life Ins. Co.*, 901 A.2d 106, 113 (Del. 2006) (quoting Restatement (Second) of Contracts § 265 (Am. Law Inst. 1981)); *see also* 14 *Corbin on Contracts* § 77.1, at 242 (2001 ed.) ("If a frustration of both parties' respective purposes were necessary to invoke the [frustration of purpose] doctrine, discharge would be rare."); *id.* § 77.10, at 286 ("The frustration of a contractor's purpose may be either complete or only partial. A partial frustration by subsequent events is less likely to discharge a contractor from its duties.").

[596] Schwartz, *supra*, at 828.

[597] *Id.*; *see id.* at 829 ("Although the standard required to invoke a MAC clause is 'a high one, the test does not require the offeror to demonstrate frustration in the legal sense.'" (quoting Takeover Panel, *Practice Statement No. 15: Note 2 on Rule 13 – Invocation of Conditions* 3 (Apr. 28, 2004), http://www.thetakeoverpanel.org.uk/wp-content/uploads/2008/12/2004-13.pdf.)).

or nearly completely frustrated,[598] a contract could "lower this bar to an achievable level by providing for excuse when the value of counterperformance has 'materially' (or 'considerably' or 'significantly') diminished."[599] That is what the parties did in this case. It should not be necessary for Fresenius to show a loss on the deal before it can rely on the contractual exit right it negotiated.

The record in this case established the existence of a sustained decline in business performance that is durationally significant and which would be material to a reasonable buyer. Akorn suffered a General MAE.[600]

2. Whether The Reason For The Effect Falls Within An Exception

Akorn's litigation counsel attributes Akorn's dismal performance to "industry headwinds" that have affected the generic pharmaceutical industry since 2013.[601] One

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[598] *Wal–Mart Stores, Inc. v. AIG Life Ins. Co.*, 872 A.2d 611, 621 (Del. Ch. 2005), *aff'd in part, rev'd in part on other grounds*, 901 A.2d 106 (Del. 2006).

[599] Schwartz, *supra*, at 807; *see, e.g.*, Gilson & Schwartz, *supra*, at 336 (arguing that when a merger agreement "has a traditional MAC, the acquirer . . . no longer commits to purchase the bottom half of a probability distribution, but instead only commits to purchase if the realized value is close to the negotiated price"); *id.* at 331 n.5 ("We define a MAC as 'traditional' if the acquisition agreement omits setting out explicit exceptions to the acquirer's right to cancel in the event of a material adverse change or effect.").

[600] In substance, Akorn and its expert do not contest that Akorn suffered a General MAE on a standalone basis. Instead, they try to sidestep that reality by arguing that (i) Akorn's value should be measured with synergies and (ii) Akorn's decline in value was not disproportionate to its peers. For reasons discussed elsewhere, neither of those arguments succeeds. This outcome leaves Fischel's opinion that Akorn suffered a General MAE on a standalone basis effectively uncontested.

[601] *See* Dkt. 186 at 8–9, 123–24.

headwind has been a "consolidation of buyer power," which has "led to large price reductions."[602] Another headwind has been the FDA's efforts to approve generic drugs, "leading to increasing numbers of new entrants and resultant additional price erosion."[603] Akorn's lawyers also cite "legislative attempts to reduce drug prices" and the FDA's requirement that every product have a unique serial number, called serialization.[604] According to Akorn, "Fresenius and the market were well aware of these challenges at the time [Fresenius] agreed to buy Akorn—and that if the headwinds were greater than expected, Akorn would likely underperform relative to its competitors."[605] Akorn claims that Fresenius cannot claim the existence of an MAE because everyone, including Fresenius, knew about these "industry headwinds."[606]

Consistent with standard practice in the M&A industry, the plain language of the Merger Agreement's definition of a Material Adverse Effect generally allocates the risk of endogenous, business-specific events to Akorn and exogenous, systematic risks to Fresenius. The definition accomplishes this by placing the general risk of an MAE on Akorn, using exceptions to reallocate specific categories of risk to Fresenius, then using

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[602] *Id.* at 8.

[603] *Id.*

[604] *Id.* at 8–9.

[605] *Id.* at 9.

[606] *Id.* at 120 (arguing that "[t]he *risks* of industry headwinds that ultimately caused Akorn to underperform were known before signing").

exclusions from the exceptions to return risks to the Akorn. Through the exceptions in subpart (A)(1), Fresenius accepted the systematic risks "generally affecting (1) the industry in which the Company and its Subsidiaries operate."[607] But this allocation was subject to a disproportionate-effect exclusion that returned the risk to Akorn to the extent that an event falling into one of these categories disproportionately affects Akorn "as compared to other participants in the industry."[608]

Under the risk allocation established by the Merger Agreement, Akorn's argument about "industry headwinds" fails because the causes of Akorn's adverse performance were actually business risks allocated to Akorn. The primary driver of Akorn's dismal performance was unexpected new market entrants who competed with Akorn's three top products—ephedrine, clobetasol, and lidocaine.[609] Akorn also unexpectedly lost a key contract to sell progesterone.[610] These were problems specific to Akorn based on its product mix. Although Akorn has tried to transform its business-specific problems into "industry headwinds" by describing them at a greater level of generality, the problems were endogenous risks specific to Akorn's business.

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[607] JX 1 at 58.

[608] *Id.*

[609] Rai Tr. 542–44.

[610] *Id.* at 546–47.

Assuming for the sake of argument that these were industry effects, they disproportionately affected Akorn. As a result, under the structure of the contractual definition of a Material Adverse Effect, these risks were allocated to Akorn.

The record evidence shows that Akorn's business has suffered a decline that is disproportionate to its industry peers.[611] Ironically, Akorn concedes the point by asserting that "Akorn was particularly exposed to the risk of these [industry] headwinds."[612] Regardless, to analyze the relative effects of industry-wide conditions, Fischel compared Akorn's performance against the performance of the industry peers selected by J.P. Morgan, Akorn's financial advisor, when preparing its fairness opinion.[613] In each case, Fischel looked at Q2 2017, Q3 2017, Q4 2017, FY 2017, and Q1 2018 results and compared Akorn's actual performance relative to consensus analyst estimates with the actual performance of the peer companies relative to their consensus analyst estimates. For revenue, EBITDA, EBIT, and EPS, Akorn's underperformance in each period was

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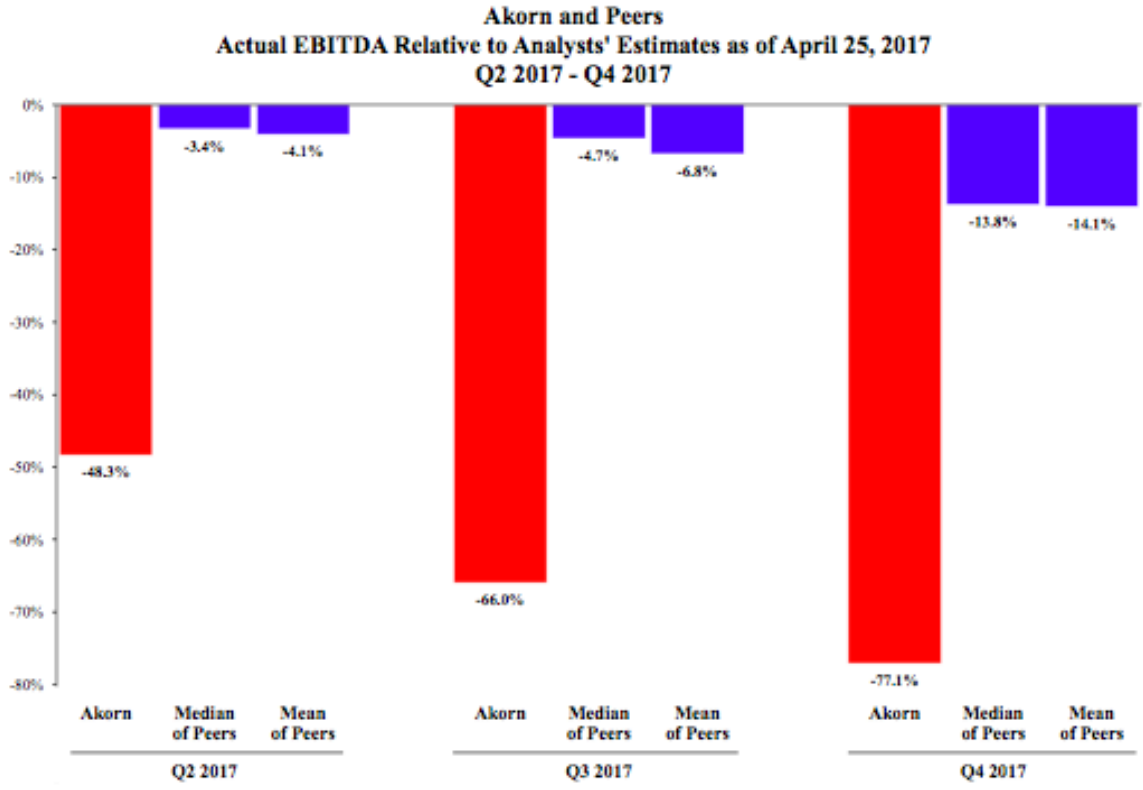
[611] *See Hexion*, 965 A.2d at 737 (noting that the seller performed "significantly worse than the mean, and in most, in the bottom decile" when compared to two sets of benchmark companies in the industry and that "[t]his potentially would be compelling evidence if it was necessary to reach the carve-outs").

[612] Dkt. 186 at 9.

[613] Akorn used the same peer group when crafting the allegations of its complaint. *See* Dkt. 1 ¶ 6. Shivdasani did not propose any different peer companies. Shivdasani Tr. 1402.

substantially worse than the median and mean of its peers.[614] Fischel prepared the following chart to illustrate the divergence in EBTDA performance:



Fischel also compared the changes in analysts' forward-looking estimates for Akorn with the changes in analysts' forward-looking estimates for the peer companies used by J.P. Morgan. He found that analyst estimates of Akorn's revenue, EBITDA, EBIT, and EPS for 2018, 2019, and 2020 have declined disproportionately more than their estimates for Akorn's peers.[615] Fischel prepared the following chart to illustrate the divergence in EBTDA estimates:

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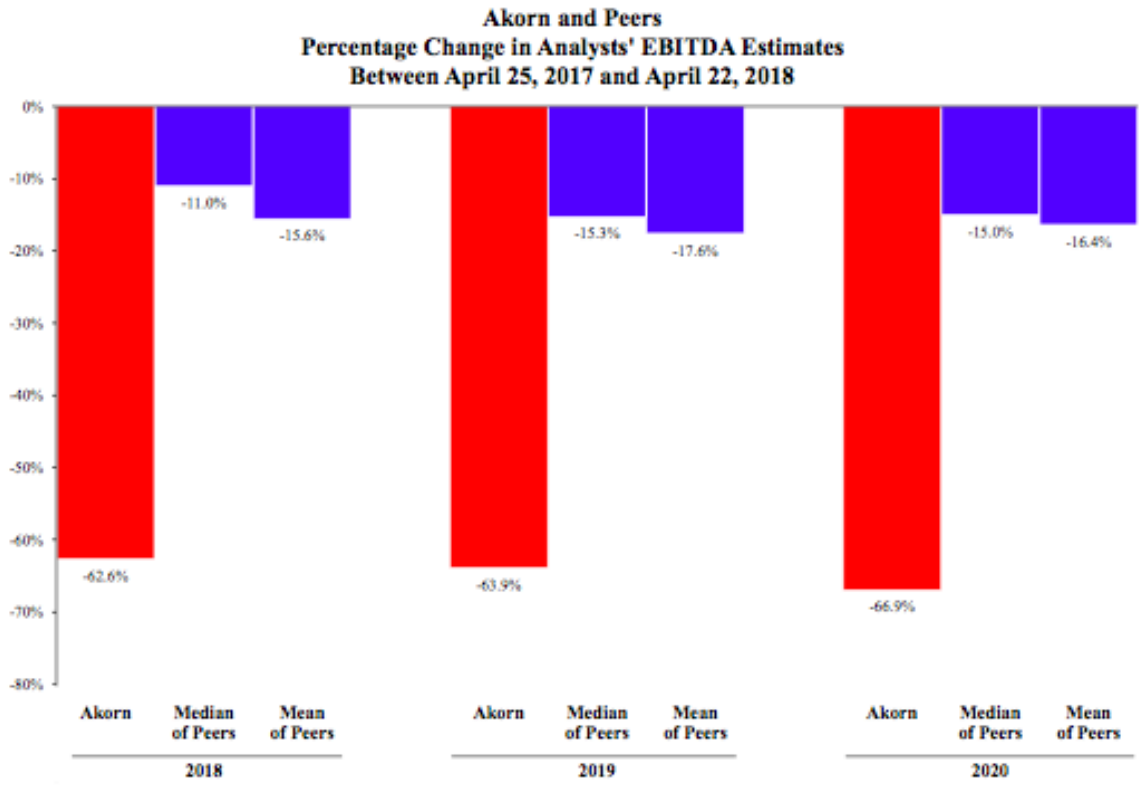
[614] JX 1250 ¶¶ 33–36.

[615] JX 1250 ¶¶ 37–41, Exs. 7 & 8.



Based on his analysis, Fischel testified that with "one or two minor exceptions, Akorn not only vastly underperform[ed] the median and the mean of comparable firms, but it underperform[ed] every single one of the comparable firms on all time periods, on all metrics, which is really dramatic underperformance."[616] Akorn's expert recognized that Akorn underperformed the generics industry generally and its peers.[617] He offered no opinion on whether the performance was disproportionate.[618]

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[616] Fischel Tr. 1361.

[617] Shivdasani Tr. 1400; *see* Grabowski Dep. 59–60.

[618] Shivdasani Tr. 1400.

This decision finds that Akorn's dismal performance resulted from Company-specific factors, not industry-wide effects. Assuming for the sake of analysis that the causes were industry-wide effects, this decision credits Fischel's analysis and finds that Akorn was disproportionately affected by the industry-wide effects.[619] For these two independent reasons, Akorn's "industry headwinds" argument fails.

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[619] For purposes of the analysis in this section, I have assumed that Fresenius bore the burden of proof as part of the general allocation to Fresenius of the burden to establish a General MAE. In my view, a preferable and more nuanced allocation would require Fresenius to bear the burden of showing a material decline in Akorn's performance. At that point, Akorn would have the burden of proving that the cause of the decline fell into one of the exceptions in the MAE definition. *See* 29 Am. Jur. 2d *Evidence* § 176 ("A party seeking to take advantage of an exception to a contract is charged with the burden of proving facts necessary to come within the exception."); *accord Westlake Vinyls, Inc. v. Goodrich Corp.*, 518 F. Supp. 2d 947, 951–52 (W.D. Ky. 2007) (collecting cases); *Zebrowski & Assocs., Inc. v. City of Indianapolis*, 457 N.E.2d 259, 262 (Ind. Ct. App. 1983) ("[A] common rule of contract and insurance law states that when performance is promised in general terms, followed by specific exceptions and limitations, the obligor has the burden of proving that the case falls with the exception."); *see, e.g.*, *Hollinger Int'l, Inc. v. Black*, 844 A.2d 1022, 1070 (Del. Ch. 2004) (Strine, V.C.) ("Black bears the burden to establish that this contractual exception applies."); *see also, e.g.*, *E.I. du Pont de Nemours & Co. v. Admiral Ins. Co.*, 1996 WL 111133, at *1 (Del. Super. Feb. 22, 1996) ("The undisputed application of Delaware law in an insurance coverage suit requires the insured . . . to prove initially . . . that the loss is within a policy's coverage provisions. Once the insured meets that burden, the burden shifts to the insurer to establish a policy exclusion applies."); *E.I. du Pont de Nemours & Co. v. Admiral Ins. Co.*, 711 A.2d 45, 53–54 (Del. Super. 1995) (placing burden of proof on insured to prove exception to exclusion from coverage; noting that the insured had better access to information about whether the exception to the exclusion applied and was better positioned to prevent events that might trigger coverage); Restatement of the Law of Liability Insurance § 32 cmt. e (Am. Law. Inst. 2018) ("It is the insurer that has identified the excluded classes of claims and will benefit from being able to place a specific claim into an excluded class. Thus, assigning the insurer the burden of proving that the claim fits into the exclusion is appropriate."). If Akorn met its burden, then the same authorities would support placing the burden on Fresenius to show that Akorn's performance was disproportionate to its peers, bringing the case within an exclusion from the exception.

Akorn has also argued that its poor performance resulted from the restrictions that the Merger Agreement imposed on its ability to continue growing through acquisitions. In subpart (B)(2), the definition of Material Adverse Effect excludes effects resulting from "the . . . performance of this Agreement." In other words, the definition allocates agreement-related risks to Fresenius. As Akorn sees it, Fresenius cannot criticize its poor results when the Merger Agreement prevented Akorn from buying other companies.

This argument fails for multiple reasons. First, Akorn suffered a Material Adverse Effect because of the sharp downturn in its existing business. It was the performance of that business that fell off a cliff shortly after the parties signed the Merger Agreement. The question is not whether Akorn might have been able to hide that downturn and post overall growth by buying other companies. The problem is what happened to the business that Fresenius agreed to buy. Second, the downturn happened so quickly as to defeat the suggestion that it was caused by the Merger Agreement's restrictions on acquisitions. Acquisitions take time. It was Akorn's legacy business that took a nosedive. Third, Akorn has not only grown through acquisitions. Akorn historically grew both organically and through acquisitions.[620] Fourth, if Akorn wanted to pursue an acquisition, it could have sought consent from Fresenius. Akorn has not pointed to any acquisition that Fresenius blocked. The no-acquisitions argument does not bring Akorn within an exception to the definition of a Material Adverse Effect.

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[620] *See* Rai Tr. 455; JX 38 at '428-30, '444-50; JX 98 at '035, '040; JX 188 at 9, 11; JX 204 at '021-24.

3. Whether Fresenius Knowingly Accepted The Risks That Led To The General MAE.

Akorn contends most vigorously that Fresenius cannot claim an MAE based on any risks that Fresenius (i) learned about in due diligence or (ii) generally was on notice about because of its industry knowledge and did not thoroughly investigate in due diligence. Akorn relies for its position on Chief Justice Strine's observation in *IBP* that "[m]erger contracts are heavily negotiated and cover a large number of specific risks explicitly," and that consequently, even a "broadly written" MAE provision "is best read as a backstop protecting the acquiror from the occurrence of *unknown events* that substantially threaten the overall earnings potential of the target in a durationally-significant manner."[621] In my view, Akorn goes too far by transforming "unknown events" into "known or potentially contemplated risks." The legal regime that Akorn argues for would replace the enforcement of a bargained-for contractual provision with a tort-like concept of assumption of risk, where the outcome would turn not on the contractual language, but on an ex-post sifting of what the buyer learned or could have learned in due diligence.

The "strong American tradition of freedom of contract . . . is especially strong in our State, which prides itself on having commercial laws that are efficient."[622] "Delaware courts seek to ensure freedom of contract and promote clarity in the law in order to facilitate

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[621] *IBP*, 789 A.2d at 68 (emphasis added); *accord Hexion*, 965 A.2d at 738.

[622] *ABRY*, 891 A.2d at 1059–60; *see GRT, Inc.*, 2011 WL 2682898, at *12 ("Under Delaware law, which is more contractarian than that of many other states, parties' contractual choices are respected . . . .").

commerce."[623] "When parties have ordered their affairs voluntarily through a binding contract, Delaware law is strongly inclined to respect their agreement, and will only interfere upon a strong showing that dishonoring the contract is required to vindicate a public policy interest even stronger than freedom of contract."[624] Requiring parties to live with "the language of the contracts they negotiate holds even greater force when, as here, the parties are sophisticated entities that bargained at arm's length."[625] "The proper way to allocate risks in a contract is through bargaining between parties. It is not the court's role to rewrite the contract between sophisticated market participants, allocating the risk of an agreement after the fact, to suit the court's sense of equity or fairness."[626]

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[623] *ev3, Inc.*, 114 A.3d at 529 n.3; *see Aspen Advisors LLC v. United Artists Theatre Co.*, 843 A.2d 697, 712 (observing "Delaware law's goal of promoting reliable and efficient corporate and commercial laws") (Del. Ch. 2004) (Strine, V.C.), *aff'd*, 861 A.2d 1251 (Del. 2004); *see, e.g.*, *Elliott Assocs. L.P. v. Avatex Corp.*, 715 A.2d 843, 854 (Del. 1998) (commending a "coherent and rational approach to corporate finance" and "uniformity in the corporation law").

[624] *Libeau v. Fox*, 880 A.2d 1049, 1056 (Del. Ch. 2005) (Strine, V.C.), *aff'd in pertinent part*, 892 A.2d 1068 (Del. 2006); *see also Related Westpac LLC v. JER Snowmass LLC*, 2010 WL 2929708, at *6 (Del. Ch. July 23, 2010) (Strine, V.C.) ("Delaware law respects the freedom of parties in commerce to strike bargains and honors and enforces those bargains as plainly written."); *NACCO Indus., Inc. v. Applica Inc.*, 997 A.2d 1, 35 (Del. Ch. 2009) ("Delaware upholds the freedom of contract and enforces as a matter of fundamental public policy the voluntary agreements of sophisticated parties."); *Personnel Decisions, Inc. v. Bus. Planning Sys., Inc.*, 2008 WL 1932404, at *6 (Del. Ch. May 5, 2008) (Strine, V.C.) ("Delaware is a freedom of contract state, with a policy of enforcing the voluntary agreements of sophisticated parties in commerce.").

[625] *Progressive Int'l Corp. v. E.I. Du Pont de Nemours & Co.*, 2002 WL 1558382, at *7 (Del. Ch. July 9, 2002) (Strine, V.C.).

[626] *Wal–Mart Stores*, 872 A.2d at 624; *see Nemec v. Shrader*, 991 A.2d 1120, 1126 (Del. 2010) ("[W]e must . . . not rewrite the contract to appease a party who later wishes

The MAE definition in this case uses exceptions and exclusions to allocate risks between the parties. The MAE definition could have gone further and excluded "certain specific matters that [the seller] believes will, or are likely to, occur during the anticipated pendency of the agreement,"[627] or matters disclosed during due diligence, or even risks identified in public filings.[628] Or the parties could have defined an MAE as including only

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to rewrite a contract he now believes to have been a bad deal. Parties have a right to enter into good and bad contracts, the law enforces both.") (footnote omitted); *Allied Capital Corp. v. GC–Sun Hldgs., L.P.*, 910 A.2d 1020, 1030 (Del. Ch. 2006) (Strine, V.C.) (explaining that Delaware courts "will not distort or twist contract language" because "[b]y such judicial action, the reliability of written contracts is undermined, thus diminishing the wealth-creating potential of voluntary agreements"); *DeLucca v. KKAT Mgmt., L.L.C.*, 2006 WL 224058, at *2 (Del. Ch. Jan. 23, 2006) (Strine, V.C.) ("[I]t is not the job of a court to relieve sophisticated parties of the burdens of contracts they wish they had drafted differently but in fact did not. Rather, it is the court's job to enforce the clear terms of contracts."). *See generally* 11 *Williston on Contracts* § 31:5 (4th ed. 2003) ("A contract is not a non-binding statement of the parties' preferences; rather, it is an attempt by market participants to allocate risks and opportunities. [The court's role] is not to redistribute these risks and opportunities as [it sees] fit, but to enforce the allocation the parties have agreed upon.") (alterations in original).

[627] Kling & Nugent, *supra*, § 11.04[9], at 11-59 to -60 (identifying examples such as "the loss or anticipated loss of a significant customer, specific operational problems, change in government regulation, a favorable contract that won't survive the closing, write-downs of assets or adverse business trends").

[628] According to a survey of merger, stock purchase, and asset agreements executed between June 1, 2016 and May 31, 2017, 28% of deals valued at $1 billion or more involved an MAE carve-out for developments arising from facts disclosed to the buyer or in public filings. *See* Nixon Peabody LLP, *NP 2017 MAC Survey* 5, 13, https://www.nixonpeabody.com/-/media/Files/PDF-Others/mac-survey-2017-nixon-peabody.ashx; *cf.* Talley, *supra*, at 789 (opining that Nixon Peabody's annual MAC survey's methodology "has become sufficiently consistent to be usable in empirical investigations").

unforeseeable effects, changes, events, or occurrences.[629] They did none of these things. Instead, for purposes of a General MAE, they agreed upon a condition that turned on whether an effect, change, event, or occurrence occurred after signing and constituted or would reasonably be expected to constitute an MAE.[630] The contractual language is forward-looking and focuses on events. It does not look backwards at the due diligence process and focus on risks.

As discussed later in this decision, the evidence shows that the events that resulted in a General MAE at Akorn were unexpected. But assuming for the sake of argument that Akorn was correct and Fresenius had foreseen them, I do not believe that would change the result given the allocation of risk under the definition of a Material Adverse Effect set forth in the Merger Agreement. The *IBP* decision interpreted a broad MAE clause that did not contain lengthy lists of exceptions and exclusions, and then-Vice Chancellor Strine did not suggest that he was prescribing a standard that would govern all MAE clauses, regardless of what the parties specifically bargained for in the contract. Nor did *Hexion*, which adhered closely to *IBP* on this point. Instead, both cases held that buyers could not

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[629] *See* Schwartz, *supra*, at 834 ("[T]he MAC clause says nothing about foreseeability. It includes other characteristics of the change—"material" and "adverse"—but does not mention unforseeability. *Inclusio unius est exclusio alterius*—the expression of one thing is the exclusion of another."); *see also id.* (providing additional arguments why MAE provisions should not be interpreted to contain an implied foreseeability term).

[630] *See* JX 1 § 6.02(c) ("*Since the date of this Agreement* there shall not have occurred and be continuing any effect, change, event or occurrence that, individually or in the aggregate, has had or would reasonably be expected to have a Material Adverse Effect.") (emphasis added).

rely on the manifested consequences of widely known systematic risks. In *IBP*, the financial performance of the seller (a beef producer) suffered due to cyclical effects in the meat industry, exacerbated by a harsh winter that put even greater pressure on the performance of the buyer (a chicken producer).[631] In *Hexion*, the performance of the seller (a chemical company) suffered due to macroeconomic challenges, including "rapidly increased crude oil and natural gas prices and unfavorable foreign exchange rates."[632] Although the decisions framed the analysis in terms of known versus unknown risks, both cases actually allocated systemic risks to the buyers, consistent with general contracting practice and the clause at issue in this case.

Assuming for the sake of argument that *IBP* and *Hexion* did establish an overarching standard for analyzing every MAE, those decisions speak in terms of "unknown events," not contemplated risks.[633] As Akorn's management admitted, the events that gave rise to

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[631] *See IBP*, 789 A.2d at 22 ("During the winter and spring of 2001, Tyson's own business performance was dismal. Meanwhile, IBP was struggling through a poor first quarter. Both companies' problems were due in large measure to a severe winter, which adversely affected livestock supplies and vitality. As these struggles deepened, Tyson's desire to buy IBP weakened."); *id.* at 26 ("Cattle and hog supplies go through cycles that can be tracked with some general precision using information from the United States Department of Agriculture. . . . Livestock supply is also heavily weather driven."); *id.* at 45 (citing public statements by acquirer acknowledging the cyclical factors that affect commodity meat products); *id.* at 47–48 ("Tyson's anxiety was heightened by problems it and IBP were experiencing in the first part of 2001. A severe winter had hurt both beef and chicken supplies, with chickens suffering more than cows.").

[632] *Hexion*, 965 A.2d at 743.

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

Akorn's dismal performance were unexpected.[634] Indeed, when announcing the Merger Agreement on April 24, 2017, Akorn reaffirmed the sales and earnings guidance that management had provided on March 1, 2017, which projected revenue of $1,010-$1,060 million and adjusted EBITDA of $363-$401 million.[635] Akorn underperformed the low end of its revenue guidance by 17% and the low end of its EBITDA guidance by 31%. If Akorn management had anticipated the competition and price erosion that was on the horizon, they would not have reaffirmed their guidance.

Finally, Fresenius did not know about the specific events that resulted in Akorn's collapse. Fresenius expected that Akorn would not meet its internal projections and adopted lower forecasts of its own, but Akorn dramatically underperformed Fresenius's less

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[634] *See* Rai Tr. 467 (citing "more competition than [Akorn] had projected"); *id.* at 542 (citing "price erosion [for ephedrine] that we had not factored in"); *id.* at 544 ("Q. Okay. Now, in fact, you had unexpected competition in 2017 for all of your top three products, and the competition was way more than what you had projected; isn't that right? A. That is correct."); *id.* at 545 ("The[re] were way more [competitors] than what [Akorn] had potentially projected in [its] forecast for 2017."); *id.* at 546–47 (discussing the unexpected loss of a key contract to sell progesterone); JX 688 at '606 (Akorn presentation describing its poor performance as "[d]riven mostly by unanticipated supply interruptions and unfavorable impact from competition across [the] portfolio"); *id.* at '607 ("Average product pricing [was] lower than expected due to [an] unfavorable customer/contract mix and price erosion [that was] not considered in our forecast."); JX 693 at 35 (Akorn's Form 10-Q for Q3 2017 discussing "more significant than expected declines in net revenue").

[635] *See* JX 341; JX 481.

optimistic estimates.[636] Bauersmith was the resident pessimist on the Fresenius deal team, and Akorn even performed worse than he anticipated.[637]

In my view, Fresenius did not assume the risk of the problems that resulted in a General MAE at Akorn. Instead, the General MAE Condition allocated those risks to Akorn.

4. The Finding Regarding A General MAE

Fresenius proved that Akorn suffered a General MAE. Fresenius carried its heavy burden and showed that the decline in Akorn's performance is material when viewed from the longer-term perspective of a reasonable acquirer, which is measured in years. Fresenius also showed that Akorn's poor performance resulted from Company-specific problems, rather than industry-wide conditions. Nevertheless, assuming for the sake of argument that the results could be attributed to industry-wide conditions, those conditions affected Akorn disproportionately. Neither Akorn nor Fresenius knew about the events that caused Akorn's problems, which were unforeseen. Because Akorn suffered a General MAE, the condition in Section 6.02(c) has not been met, and Fresenius cannot be forced to close.

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[636] Bauersmith Tr. 595–596 (explaining that Akorn's performance was "much, much worse" than Fresenius's projections); Henriksson Tr. 953 ("[T]he [ephedrine] decline was bigger than what we had in the original plan.").

[637] Bauersmith Tr. 596 (describing Akorn's performance as "even worse than what [he personally] had thought").

B. The Failure Of The Bring-Down Condition

The next question is whether Fresenius validly terminated the Merger Agreement under Section 7.01(c)(i) because the Bring-Down Condition could not be met. The Bring-Down Condition permits Fresenius to refuse to close if Akorn's representations are not true at closing, except where the deviation from Akorn's as-represented condition would not reasonably be expected to constitute a Material Adverse Effect. To defeat the Bring-Down Condition, Fresenius relies on the Regulatory Compliance Representations, so the analysis boils down to whether Akorn would reasonably be expected to suffer a Regulatory MAE. Once again, because Fresenius sought to excuse its performance under the Merger Agreement, Fresenius bore the burden of proof.[638]

In a public-company acquisition, it is standard practice to require that the seller's representations be true at signing and to condition the buyer's obligation to close on the seller's representations also being true at closing.[639] "From a business point of view, the condition that the other party's representations and warranties be true and correct at closing is generally the most significant condition for Buyers . . . . This is what protects each party

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[638] *See Hexion*, 965 A.2d at 739; *Frontier Oil*, 2005 WL 1039027, at *35; *IBP*, 789 A.2d at 53.

[639] *See* Kling & Nugent, *supra*, § 1.05[2], at 1-40.2 to -41; Legal-Usage Analysis, *supra*, at 10–12.

from the other's business changing or additional, unforeseen risks arising before closing."[640]

Section 7.01(c)(i) gives Fresenius the right to terminate if the Bring-Down Condition cannot be met. Formatted for greater legibility, Section 7.01(c)(i) states:

> This Agreement may be terminated and the [Merger] abandoned at any time prior to the Effective Time (except as otherwise expressly noted), whether before or after receipt of the Company Shareholder Approval: . . .
>
> (c) by [Fresenius Kabi]: (i) if the Company shall have breached any of its representations or warranties . . ., which breach . . .
>
> (A) would give rise to the failure of a condition set forth in Section 6.02(a) [the Bring-Down Condition] . . . and
>
> (B) is incapable of being cured . . . by the Outside Date . . .
>
> provided that [Fresenius Kabi] shall not have the right to terminate this Agreement pursuant to this Section 7.01(c)(i) if [Fresenius Kabi] or Merger Sub is then in material breach of any of its representations, warranties, covenants or agreements hereunder . . . .

Whether Fresenius could terminate the Merger Agreement pursuant to Section 7.01(c)(i) therefore turns on three questions: (i) whether Akorn breached a representation in a manner that would cause the Bring-Down Condition to fail, (ii) whether the breach could be cured by the Outside Date, and (iii) whether Fresenius was otherwise in material breach of its obligations under the Merger Agreement. The answer to the third question also determines

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[640] Kling & Nugent, *supra*, § 14.02[1], at 14-9; *accord id.* § 1.05[2], at 1-41; § 1.05[4], at 1-41.

whether Fresenius may terminate based on the failure of the Covenant Compliance Condition, so this decision addresses it separately.

1. The Operation Of The Bring-Down Condition

Section 6.02(a) is the Bring-Down Condition. Formatted for greater legibility, it states:

> The obligations of [Fresenius Kabi] and Merger Sub to effect the Merger shall be subject to the satisfaction (or written waiver by [Fresenius Kabi], if permissible under applicable law) on or prior to the Closing Date of the following conditions:
>
> (a) Representations and Warranties. The representations and warranties of the Company
>
> (i) set forth in Section 3.01(a), Section 3.02(a), Section 3.02(b), Section 3.03(a)-(c), Section 3.14 and Section 3.20 shall be true and correct in all material respects as of the date hereof and as of the Closing Date, with the same effect as though made as of such date (except to the extent expressly made as of an earlier date, in which case as of such earlier date) and
>
> (ii) set forth in this Agreement, other than in those Sections specifically identified in clause (i) of this paragraph, shall be true and correct (disregarding all qualifications or limitations as to "materiality", "Material Adverse Effect" and words of similar import set forth therein) as of the date hereof and as of the Closing Date with the same effect as though made as of such date (except to the extent expressly made as of an earlier date, in which case as of such earlier date), except, in the case of this clause (ii), where the failure to be true and correct would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. . . .

The Bring-Down Condition in the Merger Agreement thus requires Akorn's representations to have been true "as of the date hereof," *viz*., at signing, and "as of the Closing Date."

In this case, Fresenius asserts that Akorn breached the Regulatory Compliance Representations found in Section 3.18 of the Merger Agreement. In that section, Akorn

made extensive representations regarding its compliance with regulatory requirements. Each of the relevant representations contained specific materiality or MAE qualifiers that applied for purposes of evaluating the accuracy of those representations in their own right, such as if Fresenius had asserted a fraud claim. For purposes of testing the Bring-Down Condition, the language of the condition scrapes away those specific qualifiers in favor of an aggregate MAE qualifier.[641] Formatted for greater legibility, the following reproduction of the Regulatory Compliance Representations omits the specific qualifiers and the portions that are not at issue in this case:

> (a) The Company and its Subsidiaries are and, to the Knowledge of the Company, since July 1, 2013, (1) have been in compliance with
>
> > (A) all applicable Laws (including all rules, regulations, guidance and policies) relating to or promulgated by the U.S. Food and Drug Administration (the "FDA"), DEA, EMEA and other Healthcare Regulatory Authorities and
> >
> > (B) all Healthcare Regulatory Authorizations, including all requirements of the FDA, DEA, the EMEA and all other Healthcare Regulatory Authorities, in each case that are applicable to the Company and its Subsidiaries, or by which any property, product, filing, submission, registration, declaration, approval, practice (including without limitation, manufacturing) or other asset of the Company and its Subsidiaries is bound, governed or affected . . . .
>
> (b) All . . . reports, documents, claims and notices required or requested to be filed, maintained, or furnished to any Healthcare Regulatory Authority by the Company and its Subsidiaries since July 1, 2013, have been so filed, maintained or furnished and, to the Knowledge of the Company, were complete and correct . . . on the date filed (or were corrected in or supplemented by a subsequent filing) . . . .

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[641] *See* Kling & Nugent, *supra*, § 14.02[3], at 14-12 to -13 (discussing materiality scrape as a solution to the double materiality problem).

> The Company and its Subsidiaries are and have been, since July 1, 2013, in compliance with current good manufacturing practices and have maintained appropriate mechanisms, policies, procedures and practices to ensure the prompt collection and reporting of adverse event or any other safety or efficacy data, notifications, corrections, recalls and other actions required by Law related to their products . . . .
>
> * * *
>
> (d) Since July 1, 2013, neither the Company nor any of its Subsidiaries (i) have made an untrue statement of . . . fact or fraudulent statement to the FDA or any other Governmental Authority, (ii) have failed to disclose a . . . fact required to be disclosed to the FDA or other Governmental Authority, (iii) have committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy or (iv) have been the subject of any investigation by the FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy . . . .

When Section 3.18 and the Bring-Down Condition are read together, the operative question becomes whether Fresenius proved by a preponderance of the evidence that (i) the Regulatory Compliance Representations were inaccurate and (ii) the deviation between Akorn's as-represented condition and its actual condition was so great that it would reasonably be expected to result in a Material Adverse Effect.[642]

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[642] *See IBP*, 789 A.2d at 66 (evaluating whether breach of contractual representation gave rise to an MAE by comparing IBP's condition "against the December 25, 1999 condition of IBP as adjusted by the specific disclosures of the Warranted Financials and the [Merger] Agreement itself. This approach makes commercial sense because it establishes a baseline that roughly reflects the status of IBP as Tyson indisputably knew it at the time of signing the Merger Agreement."); *see also* Kling & Nugent, *supra*, § 11.01[1], at 11-3 ("[T]he seller's representations . . . . 'paint a picture,' as of the moment that the parties become contractually bound, of the business being acquired. It is the target company as so described that the Buyer believes it is paying for, and much of the remainder of the acquisition agreement deals with the consequences of this picture either proving in retrospect to have been inaccurate or changing prior to the closing.") (footnote omitted);

The "reasonably be expected to" standard is an objective one.[643] When this phrase is used, "[f]uture occurrences qualify as material adverse effects."[644] As a result, an MAE "can have occurred without the effect on the target's business being felt yet."[645] Even under this standard, a mere risk of an MAE cannot be enough. "There must be some showing that there is a basis in law and in fact for the serious adverse consequences prophesied by the party claiming the MAE."[646] When evaluating whether a particular issue would reasonably be expected to result in an MAE, the court must consider "quantitative and qualitative

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see also E. Thom Rumberger, Jr., *The Acquisition and Sale of Emerging Growth Companies: The M & A Exit* § 9:14 (2d ed. 2017) ("[I]t is through target's representations and warranties that acquirer contractually sets forth the underlying assumptions for its investment decision. In effect, acquirer is saying that it is willing to pay the agreed upon purchase price if the business has the attributes described in the representations and warranties of target set forth in the merger agreement. The representations and warranties, in other words, act as a benchmark for acquirer's investment in target.").

[643] *Frontier Oil*, 2005 WL 1039027, at *33.

[644] Model Merger Agreement, *supra*, at 268.

[645] Kling & Nugent, *supra*, § 11.04[9], at 11-60 n.102.

[646] *Frontier Oil*, 2005 WL 1039027, at *36 n.224 (addressing claim that risk of litigation could reasonably be expected to result in an MAE); *see also* Kling & Nugent, *supra*, § 11.04[10], at 11-69 ("[W]hether a material adverse change has occurred depends in large part on the long-term impact of the event in question (a somewhat speculative analysis)."). One commentator argues that the "would reasonably be expected" formulation is best thought of as meaning "'likely to happen,' with likely, in turn, meaning 'a degree of probability greater than five on a scale of one to ten.'" Legal-Usage Analysis, *supra*, at 16 (first quoting *The New Oxford American Dictionary* 597 (2001) and then quoting Bryan A. Garner, *A Dictionary of Modern Legal Usage* 597 (2d ed. 1995)). In other words, it means more likely than not.

aspects."[647] "It is possible, in the right case, for a party . . . to come forward with factual and opinion testimony that would provide a court with the basis to make a reasonable and an informed judgment of the probability of an outcome on the merits."[648]

2. Qualitative Significance

The qualitative dimension of the MAE analysis strongly supports a finding that Akorn's regulatory problems would reasonably be expected to result in a Material Adverse Effect. There is overwhelming evidence of widespread regulatory violations and pervasive compliance problems at Akorn. These problems existed at signing and got worse, rather than better, during the period between signing and when Fresenius served its termination notice. Akorn does not dispute that it has problems, only their extent and seriousness.

As a generic pharmaceutical company, Akorn must comply with the FDA's regulatory requirements. This is no small thing; it is an essential part of Akorn's business. It was also essential to Fresenius, which cared a great deal about Akorn's pipeline of

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[647] *Frontier Oil*, 2005 WL 1039027, at *37; *see also id.* at *34 ("The notion of an MAE is imprecise and varies both with the context of the transaction and its parties and with the words chosen by the parties."); *Hexion*, 965 A.2d at 738 & n.53 ("For the purpose of determining whether an MAE has occurred, changes in corporate fortune must be examined in the context in which the parties were transacting."); *IBP*, 789 A.2d at 68 n.154 (discussing federal court decision finding a MAC "in a context where the party relying on the MAC clause was providing funding in a work-out situation, making any further deterioration of [the company's] already compromised condition quite important"); *Genesco*, 2007 WL 4698244, at *18 (considering "whether the change relates to an essential purpose or purposes the parties sought to achieve by entering into the merger").

[648] *Id.* at *36.

ANDAs and new products. The value of Akorn's pipeline depended on Akorn's ability to comply with the FDA's regulatory requirements.

Under the FDA's data integrity requirements, Akorn must be able "to prove the origin, transmission, and content of the company's data and that data is what it is purported to be."[649] Data must meet be attributable, legible, contemporaneously recorded, original or a true copy, and accurate, as well as complete, consistent, enduring and available.[650] A properly functioning data integrity system, including an effective IT infrastructure, is essential for meeting these requirements.[651]

Akorn has pervasive data integrity and compliance problems that prevent Akorn from being able to meet these standards. As discussed in the Factual Background, Akorn hired Cerulean in 2016 to assess its data integrity systems. Avellanet testified that some of Akorn's data integrity failures were so fundamental that he would not even expect to see them "at a company that made Styrofoam cups," let alone a pharmaceutical company manufacturing sterile injectable drugs.[652] In his opinion, Akorn's data integrity issues were

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[649] *See* JX 143 at 1; *accord* Kaufman Tr. 323; Kaufman Dep. 196; *see* Wasserkrug Tr. 9.

[650] Wasserkrug Tr. 8, 12; Franke Dep. 33–36; JX 1247 ¶ 35.

[651] *See* JX 1252 ¶ 2.1; JX 439 at '435–36; Pramik Dep. 26.

[652] Avellanet Dep. 173; *see also id.* at 111–12 (testifying that he had never before seen a company where any employee could make changes to electronic data "willy-nilly with no traceability or accountability").

among the "top three worst" of the 120+ pharmaceutical companies that he has assessed,[653] a notorious status given that his practice only involves companies that "have problems."[654] He believed that the "FDA would get extremely upset" about Akorn's lack of data integrity "because this literally calls into question every released product [Akorn has] done for however many years it's been this way."[655]

As discussed at greater length in the Factual Background, Cerulean's report on the Decatur facility identified seven critical, seven major, and at least five minor nonconformities.[656] Cerulean's report on the Somerset facility was never completed because Akorn's IT department failed to provide adequate support,[657] but the preliminary report identified three critical findings and three major findings.[658] Avellanet believed that some of the violations were so severe that Akorn's senior management should be concerned about potential criminal liability.[659] Akorn made "no effort" to schedule a date to complete

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[653] Avellanet Dep. 172–73.

[654] Kaufman Tr. 317–19; *accord* Avellanet Dep. 301. It was Akorn's expert, Zena Kaufman, who pointed out the dubious exclusivity of Cerulean's clientele. *See* Kaufman Tr. 282.

[655] Avellanet Dep. 116–17.

[656] JX 231 at '062, '067.

[657] Wasserkrug Tr. 131; *see* JX 439 at '430.

[658] JX 439 at '430.

[659] *Id.* at '435–36.

the Somerset inspection[660] and cancelled Cerulean's previously scheduled assessment at Amityville.[661]

Akorn's internal quality experts confirmed the validity of the critical deficiencies that Cerulean identified.[662] They also determined that Akorn essentially ignored them. In March 2018, the GQC team found that Akorn had not yet addressed the vast majority of the deficiencies.[663] Somerset had done absolutely nothing to address its deficiencies.[664] Decatur likewise had "failed to appropriately investigate and remediate" Cerulean's findings, having only completed "32% of the corrective actions."[665] These findings are consistent with a contemporaneous email written by Franke, who told Avellanet in late

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[660] Wasserkrug Tr. 32; *see* Avellanet Dep. 139; *see also* JX 507 at '317 ("executive leadership" decided "that IT resources would not be engaged in the third party data integrity audit [Cerulean]").

[661] Avellanet Dep. 47, 164–65; *see* JX 509 at '746.

[662] *See* JX 1077 at '143–47; Wasserkrug Tr. 155–56.

[663] JX 1077 at '065; Wasserkrug Tr. 151–54.

[664] *See* JX 1077 at '065–66 ("Somerset . . . while having received the draft audit report on 31 May 2017, decided to wait for the final report received on 3 March 2018 and failed to initiate formal corrective actions or have a documented plan to date."); Wasserkrug Tr. 153–54 ("[I]n 2017, after getting the Somerset Cerulean report, no actions were taken in response.").

[665] JX 1094 at '623; *see* Wasserkrug Dep. 204–06; *see* Franke Dep. 239 (testifying that 11 of the 12 items scheduled for Q1 2018 on the Decatur data integrity plan had not been completed).

2017 that Akorn was "making 0 progress on our DI remediation efforts," which she attributed to "the culture and the message from management."[666]

As discussed in the Factual Background, during the same time frame that Cerulean was conducting its reports, Akorn's GQC team identified similar data integrity violations.

- At Lake Forest, in April 2016, GQC found that audit trails were not being reviewed for even "minimum criteria," including "data deletion" and "data manipulation."[667] GQC also found that "multiple Akorn staff members" had unauthorized "system access allowances" that enabled them to modify data and to delete audit trails.[668] When GQC visited Lake Forest again in December 2017, the problems had not been remediated.[669]

- At Vernon Hills, in June 2016, a GQC audit identified a critical data integrity failure that permitted unauthorized personnel to "make changes in master production and control records."[670] The internal audit also found that laboratory equipment was "unable to record audit trails" and could not identify the users performing tests.[671] More than a year later, a September 2017 GQC audit found exactly the same problems.[672] The report observed that corrective actions had "been halted and remain incomplete," and noted that Akorn's failure to remediate these deficiencies "presents undue risk to the site's ongoing operations."[673] By the time of trial, the problems had still not been fixed, and Vernon Hills did not even have a data integrity compliance plan.[674]

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[666] JX 754 at '740.

[667] JX 124 at '764.

[668] *Id.* at '769.

[669] JX 782 at '799–802.

[670] JX 136 at '344.

[671] *Id.*

[672] JX 655 at '479–80.

[673] *Id.* at '472.

[674] Wasserkrug Tr. 118, 136.

- At Somerset, in April 2017, GQC identified critical problems involving access controls and audit trail reviews.[675] When GQC returned in December 2017, the problems had not been remediated.[676] By the time of trial, Somerset still did not have an approved data integrity compliance plan.[677]

In 2017, GQC identified numerous other data integrity deficiencies at Akorn's sites, with seventeen at Hettlingen, fifteen at Cranbury, five at Amityville, and five at Lake Forest.[678] In addition to these reports, the factual record contains extensive evidence of other, widespread quality problems at Akorn.

After the signing of the Merger Agreement, Akorn's exacerbated its compliance problems. As discussed in the Factual Background, Silverberg authorized a response to a CRL for azithromycin in August 2017 that contained two sets of fabricated data.[679] I am forced to conclude that Silverberg knew that the CRL would rely on fabricated data but authorized it anyway because he did not want to withdraw the ANDA and wave a red flag in front of Fresenius that would call attention to Akorn's data integrity problems while the Merger was pending. Akorn and its advisors immediately recognized the seriousness of the

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[675] JX 515 at '115.

[676] JX 801 at '663–64.

[677] Wasserkrug Tr. 136.

[678] *See* JX 1318.019–31; Wasserkrug Tr. 118, 122–24.

[679] JX 1068 at '014.

issue and expressed concern that the FDA would invoke the AIP or take other significant action against Akorn.[680]

Akorn then aggravated the situation by providing the FDA with a misleading description of the investigation, its views on whether Silverberg acted knowingly, and the state of Akorn's data integrity efforts. Akorn also concealed a troubling incident in which Silverberg sought to coordinate stories with Sherwani about the azithromycin incident and destroy evidence of the coordination. Even Akorn's FDA expert agreed that Akorn was "not fully transparent" with the FDA.[681] She suggested that Akorn had subsequently become transparent by providing the FDA with Cerulean's reports and correspondence from Sidley, but in reality, Akorn never provided the FDA with Cerulean's reports, and Akorn's regulatory counsel primed the FDA to discount anything Sidley said.[682]

As part of its effort to get ahead of the issue with the FDA, Akorn retained NSF to conduct data integrity audits at six Akorn facilities (excluding Somerset). NSF would review a limited number of ANDAs from the Somerset facility and a sampling of product batch records. NSF quickly identified numerous major deficiencies that were consistent with the problems that Cerulean and Akorn's GQC team had identified. As soon as the

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[680] *See* JX 884 at '068; JX 908 at '831; *see also* Stuart Tr. 853–54.

[681] Kaufman Tr. 378; *see also id.* at 391 (agreeing that Akorn should have disclosed Silverberg's efforts to coordinate stories).

[682] *See* JX 1066 at '893–94; Stuart Tr. 840–44. *Compare* Kaufman Tr. 402, 414 *with* Wasserkrug Tr. 40 *and* JX 1063 at '004–05.

NSF reports began coming in, Akorn's representatives worried about severe regulatory consequences, including the possibility that the FDA would impose the AIP.[683] As NSF's investigation continued, its data integrity reports largely confirmed the existence of widespread problems at Akorn's facilities.[684] By the time of trial, NSF had examined eight ANDAs involving currently marketed products that had been prioritized for review.[685] NSF found two critical deficiencies involving the submission of intentionally manipulated data to the FDA and over 200 major deficiencies.[686] NSF also found numerous trial injections

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[683] *See* JX 1127 (expressing concern that "the FDA is likely to have a very negative reaction to our report" and indicating that possible responses included the AIP, "suspension of review of all pending submissions," and "mandat[ory] review by a third party of product released for the market"); JX 1496 at '055–56 (Akorn's regulatory counsel observing that "[i]f audit reports make it look like there are similar issues across the company, FDA might see need to get whole company under decree" and that the "[s]heer number of issues across all sites audited by NSF . . . could raise concern"); JX 1493 ("[A]s other audit reports roll out," the FDA "may see it as the whole corporation/multiple sites under decree.").

[684] *See* JX 1141 at '081 (Vernon Hills: "Data entry into notebooks does not appear to always be contemporaneous. In a large number of instances in every notebook reviewed, the date of the technician's work in the notebook is a week or more later than the date that the HPLC sequences were run."); *id.* (Vernon Hills: "Review and verification of notebook activities is not always timely. In a large number of instances in every notebook reviewed, the verified date is months later, and in some cases more than a year after the work was performed."); *id.* (Vernon Hills: "The adequacy of notebook verification is questionable since the equations for some calculations are not described in the notebook."); *id.* at '079 (Vernon Hills: "User access levels are not appropriate to protect data from deletion or further manipulation."); JX 1190 at '712–13 (finding that laboratory notebooks at Cranbury were "lacking in traceability, legibility, [and] authenticity"); JX 1178 at '356 (observing that analysts at Amityville could "delete or modify" data on "[a]ll stand-alone instruments"); *id.* (noting that many laboratory instruments at Amityville did not have audit trails).

[685] *See* JX 1516 at '595–96; Wasserkrug Tr. 175–76.

[686] *See* JX 1156; JX 1157; JX 1185; JX 1196; JX 1201; JX 1204; JX 1221; JX 1224.

that appeared to have been used in FDA submissions over a five-year period involving multiple Akorn analysts and products.[687] NSF advised Akorn that this issue had major regulatory significance and was one of its "most serious observations."[688]

At trial, Fresenius presented fact testimony from Sheers, the lawyer who led the Sidley team that investigated the whistleblower allegations. He testified credibly that Sidley's interviews with Akorn employees revealed a "lack of awareness of compliance issues, with a lack of understanding as to what the FDA requires and why [Akorn's] deficient practices would be problematic to the FDA."[689] He also testified credibly that the Sidley team identified "serious fundamental flaws in the way [Akorn] managed their data such that there was no data integrity, essentially," at Decatur, Vernon Hills, or Somerset.[690] Based on its investigation, Sidley concluded that "all of the data that was generated was not reliable, and the FDA would consider all of the products that were made in those facilities adulterated."[691]

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[687] JX 1141 at '090; *see* Wasserkrug Tr. 183 (testifying that the trial injections involved "approximately 20" analysts and multiple products).

[688] JX 1141 at '090, '092; *see* JX 1164 at '421 (talking points prepared by Akorn's counsel for a call with Akorn's directors noting that "the Company has identified many [chromatography sequences] that are the type of problematic, unreported trial injections FDA has warned of"); JX 1127 (Akorn's counsel acknowledging that the "problematic practice [of trial injections] went on for four years and involved about 25 chemists").

[689] Sheers Tr. 1037.

[690] *Id.* at 1036–39.

[691] *Id.* at 1039.

Lachman assisted Sidley and conducted onsite assessments at Vernon Hills, Somerset, Cranbury, and Decatur. Lachman identified "major, systemic data integrity gaps" at every location.[692] Lachman determined that "cGMP compliance deficiencies" at Akorn's sites "call[] into serious question" the reliability of Akorn's testing data, the effectiveness of its quality system, the accuracy of its regulatory submissions, "and thus the safety and efficacy of Akorn's products."[693] At trial, George gave highly credible testimony about these issues, including his assessment of the extreme nature of Akorn's problems:

> Everywhere that Lachman looked at policies, procedures, practices and data, we found noncompliance. And the unusual thing is, is when we go into a client's site, we might find one area where they're weak in compliance. But at Akorn, across the board, everything we looked at had significant noncompliance associated with it.[694]

He reiterated that "a lot of clients may have one particular deficiency in compliance, but not the broad scope of systemic issues that we identified at the Akorn sites."[695] When asked

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[692] *See* JX 1252 ¶ 2.3. Like Cerulean and Akorn's GQC team, Lachman observed that Akorn's computer and laboratory systems at multiple sites were "not secure from unauthorized change." *See* George Tr. 1133–34 (explaining that users of Akorn's Chromeleon system—used for chromatography testing—were able "to access data, to modify data, to move data, to delete data, [and] to generate data" in hidden folders, which was "obviously a major concern" and meant that "the data itself is not trustworthy"); *id.* at 1135 (testifying that he had never before seen "this kind of a complete system failure across all the electronic systems in the laboratory").

[693] JX 1252 ¶ 2.2; *see* George Tr. 1127–1128 ("[T]he trustworthiness of the data supporting [Akorn's regulatory] submissions is -- it's not there.")

[694] George Tr. 1126–27.

[695] *Id.* at 1127.

to rank Akorn among the laboratories he had seen, George said he "would put them with the worst."[696] George opined that Akorn's "problems were systematic in nature and the reliability of all the data should be questioned."[697]

David L. Chesney also testified as an expert for Fresenius. Chesney previously served at the FDA for twenty-three years and subsequently spent twenty-three years as a regulatory consultant. In his assessment, "Akorn has a number of very serious data integrity issues" which are "widespread" and "pervasive."[698] In his forty-six-year career, in which he has visited hundreds of companies, Chesney had "rarely seen integrity issues that exist at the scope and scale we see" at Akorn.[699] He opined that in light of the severity of Akorn's issues, the FDA has sufficient grounds to invoke the AIP.[700] He further opined that even if the FDA did not formally impose the AIP, the FDA likely would take action that would

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[696] *Id.*; *see* JX 1252 ¶ 2.5 (opining that quality conditions at Akorn represented "one of the poorest states of compliance that I have encountered").

[697] George Tr. 1127–28. Akorn has attacked the credibility of George and Lachman, arguing that they were hired guns retained by Sidley to manufacture a case for Fresenius. Having seen George testify, I reject those assertions. At heart, George is a scientist, and he is clearly dedicated to data and the facts. He does not seem capable of shading the truth.

[698] Chesney Tr. 1241.

[699] *Id.* at 1249.

[700] *Id.* at 1254 ("[T]he test for imposition of the AIP has been met."); *see* JX 1251 ¶ 15. Although Fresenius retained Chesney as an expert in this case, Akorn previously retained Chesney to give a presentation to its board of directors on FDA matters and to provide regulatory training for Akorn's employees at Decatur and Somerset. *See* Chesney Tr. 1234–35.

halt the approval of Akorn's ANDAs until Akorn proves that its data is reliable.[701] Chesney explained that when evaluating what action to take, the FDA will view Silverberg's intentional misconduct as an aggravating factor calling for more severe enforcement action.[702] Chesney's testimony was cogent and credible.

Akorn's expert, Zena Kaufman, attempted to normalize the problems at Akorn by opining that they resemble problems found across the industry and at Fresneius. Kaufman appears to be a person of integrity, and as a result, aspects of her testimony supported Fresenius's position.

Kaufman's expertise in quality compliance stems primarily from a three-year stint between 2012 and 2015 as head of global quality for Hospira, Inc., a company that faced pervasive compliance problems when she joined.[703] When she left, Hospira still had not completed its remediation efforts; it had resolved the issues at its U.S. plants, but its foreign plants still had outstanding Warning Letters.[704] Despite having spent three years overseeing

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[701] Chesney Tr. 1254, 1256–57; JX 1249 ¶¶ 59, 61. Akorn's expert, David Adams, did not testify at trial and did not offer an opinion on whether Akorn had met the test for the AIP. JX 1289; Adams Dep. 83–85. Adams agreed that the FDA could suspend Akorn's product approvals without invoking the AIP. Adams Dep. 126–28. I found Chesney's opinions more credible and rely on his views.

[702] *See* Chesney Tr. 1244–45 (testifying that Akorn's violations are "not simply the result of innocent lapses, mistakes, sloppy procedures, [or] unclear forms, but have a deliberate element to them, which is definitely an aggravating factor in the FDA's view"). One of Akorn's experts, Kaufman, agreed that these facts are likely to lead to more severe action by the FDA. *See* Kaufman Tr. 374–75.

[703] *See* Kaufman Tr. 257–62, 307–08, 312; *see also* JX 1388.

[704] Kaufman Tr. 261–62.

quality at a deeply troubled generic manufacturer, Kaufman had never before encountered some of the data integrity problems that Akorn exhibited, including a senior quality officer who made misrepresentations to the FDA, company-wide computer access issues that allowed any employee to make changes to files without any traceability or accountability, and the pervasive backdating of lab entries.[705] She agreed that the FDA would be "quite concerned" about Akorn's lack of access controls because it undermined the security of Akorn's data.[706] She agreed that this concern would affect both Akorn's ANDAs and "product released into the market."[707]

Kaufman's primary technique for normalizing Akorn's problems was to analyze publicly available Form 483s and warning letters for other companies, then compare the "types of observations, the categories" raised in those filings with the types of observations at Akorn.[708] Kaufman did not persuade me that her methodology enabled her to assess reliably the relative significance or pervasiveness of the problems.[709] Compared to Fresenius's experts, Kaufman had less experience with quality issues and data integrity

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[705] *Id.* at 315, 317, 355, 362.

[706] *Id.* at 315–17, 322–24.

[707] *Id.* at 324.

[708] *See id.* at 266–79.

[709] *See id.* at 349–55 (identifying omissions from her data set observations; noting that observations were limited to critical finding and excluded major findings); *id.* at 372–74 (failing to consider whether and to what extent Akorn had responded to the observations or how long they had been outstanding); *id.* at 441 (agreeing that she provided different explanations for how her data set was compiled).

issues. She had never performed a data integrity audit or conducted a data integrity investigation.[710] She did not claim to be an expert in data remediation plans.[711] Unlike Fresenius's experts, she did not visit any Akorn sites or speak to any Akorn personnel.[712] When rendering her opinions, Kaufman also did not take into account Akorn's failure to be transparent with the FDA.[713]

In its post-trial briefs, Akorn relied on its history of past inspections with the FDA to argue that it must not have serious quality or data integrity issues. But as Kaufman recognized, "you can get an FDA inspection with zero issues but then significant problems are discovered."[714] From the FDA's standpoint, "you are . . . only as good as your last inspection."[715]

Since trial, Akorn has received lengthy and detailed Form 483s for Decatur and Somerset, both of which identify data integrity issues. The FDA sent Akorn two CRLs that conditioned the approval of ANDAs for products from Decatur on "[s]atisfactory

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[710] *Id.* at 304.

[711] *Id.* at 267–68, 343.

[712] *Id.* at 304.

[713] *See id.* at 379 ("Q. You did not say in either of those two reports that Akorn was not transparent. Correct? A. Correct.").

[714] *Id.* at 437.

[715] Klener Dep. 79–80; *accord* Klener Tr. 1321.

resolution of the observations" in its Form 483.[716] Akorn has not received any new ANDA approvals for any of its sites since May 4, even though approval for many of the ANDAs is now overdue.[717] By letter dated August 9, 2018, the FDA formally classified Decatur as OAI and informed Akorn that "[t]he facility may be subject to a CGMP regulatory or enforcement action based on this inspection, and FDA may withhold approval of any pending applications or supplements in which this facility is listed."[718]

Perhaps most strikingly, by letter dated September 3, 2018, Akorn reported to the court that on August 22, during the later stages of the FDA's investigation, someone had erased the database at Somerset for a high accuracy liquid particle counter along with the local backup file and the associated electronic security logs. FDA inspectors had been on site at Somerset intermittently between July 23 and August 30.[719] Akorn has reported the incident to law enforcement. Given the timing of the deletion, it is reasonable to infer that the perpetrator may have been trying to hide information from the FDA, or from personnel who would follow up on the deficiencies that the FDA identified in its Form 483.

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[716] *See* JX 1223; JX 1226; JX 1198; JX 1249 ¶¶ 122–23.

[717] JX 491. The two approvals from early May would have been "in the late, final stages of the review process" by the time Akorn disclosed its data integrity issues, indicating that "the FDA simply allow[ed]" the review process "to complete." Chesney Tr. 1260–61. The only other approvals since that time have involved changes to labeling and the addition of new third-party manufacturers for already-approved Akorn drugs, neither of which concerns Akorn's data. *See* Sheers Tr. 1061; Chesney Tr. 1262.

[718] Dkt. 191, Ex. D.

[719] Dkt. 199 at 1.

The systemic failures at Akorn raise questions about the accuracy and reliability of all of its data, regardless of site or product. As a result, Akorn cannot meet its burden to prove to the FDA that its data is accurate. To the contrary, Akorn's products and facilities are known not to comply with cGMP and FDA requirements, as shown by the reports of its own internal audit team. Akorn does not make products where quality issues can be overlooked until problems arise. As Henriksson testified, "[W]e are talking about drugs which are used by people . . . who are critically ill . . . [and] many of those products . . . . are going to be injected into people."[720]

In my view, the regulatory situation at Akorn is qualitatively "material when viewed from the longer-term perspective of a reasonable acquiror."[721] Akorn has gone from representing itself as an FDA-compliant company with accurate and reliable submissions from compliant testing practices to a company in persistent, serious violation of FDA requirements with a disastrous culture of noncompliance. The qualitative aspect of the MAE analysis warrants a finding that the regulatory issues would reasonably be expected to result in a Material Adverse Effect.

3. Quantitative Significance

The quantitative aspect of the MAE analysis likewise warrants a finding that Akorn's regulatory issues would reasonably be expected to result in a Material Adverse

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[720] Henriksson Tr. 974; *see* Sturm Tr. 1196 ("[T]here is zero tolerance to exposing patients to known risks.").

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

Effect. Akorn and Fresenius have each provided estimates of the economic impact of the data integrity problems. Akorn's estimate contemplates direct outlays of $44 million with no other effect on Akorn's value.[722] Fresenius's estimate contemplates direct outlays of $254 million plus a valuation hit of up to $1.9 billion from suspending on-market products and pushing out pipeline products while Akorn's data is verified.[723] As might be expected given their respective positions in the litigation, Akorn's estimate is a best case scenario. It contemplates a world in which consultants complete a limited process to correct Akorn's protocols and confirm that everything is OK, but where nothing else is uncovered, no data needs to be revalidated, and no products need to be withdrawn or deferred. Fresenius's estimate is a worst case scenario. It contemplates rebuilding Akorn's quality systems, validating the data for its twenty-four leading products, obtaining new approvals for those products from the FDA, and not selling any products until Akorn's data can be verified.

In my view, Akorn's figure is not credible. Akorn did not present any fact witness at trial who could testify about the accuracy of the $44 million estimate or how it was developed. Wasserkrug read the figure off the page during her direct testimony, but she admitted that she had "no idea" whether the "number is correct or incorrect."[724] Kaufman thought the overall dollar figure felt right as a "benchmark," but she focused on whether

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[722] JX 1318.

[723] JX 1152 at 19–20, 25; *see* Henriksson Tr. 978–82.

[724] Wasserkrug Tr. 115–16.

Akorn had the right "compliance aspects" in the plan, such as IT systems, and admitted that she did not have the expertise to determine what the amounts should be.[725]

More significantly, Akorn's estimate assumed that Akorn would continue with the relatively limited investigation that it proposed after reporting to the FDA on the azithromycin issue in March 2018. The estimate assumed that the investigation would not uncover any additional problems with Akorn's data, would not result in any additional ANDAs being withdrawn, would not have any effect on Akorn's pipeline, and would not result in any product recalls. Given Akorn's pervasive data integrity issues and its obligation to prove the reliability of its data to the FDA, this seems highly unlikely. Wasserkrug agreed that Akorn will need to "pull a product off the market" if it cannot support the data on which the ANDA was based,[726] and the evidence at trial indicates that Akorn cannot currently prove the accuracy of its data. Any suspensions of existing products or delays of new products will obviously have a negative effect on Akorn's value.[727] Since trial, Akorn has been forced to expand the scope of its remediation efforts dramatically.[728]

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[725] Kaufman Tr. 292–93.

[726] Wasserkrug Tr. 69.

[727] *See* JX 1253; JX 1254; Bowles Dep. 19–22, 67–68. Kaufman only was able to assert that Akorn's remediation plan was adequate because she assumed that Akorn had committed to conduct "for any instrument or equipment found to have inadequate access control levels or permissions, a retrospective review of associated data and a root cause assessment." JX 1295 ¶ 113. In other words, she assumed that if Akorn found problems, Akorn would do more. Kaufman declined to opine on "how many Akorn products and Akorn ANDAs have been affected" by data integrity issues. *See* Kaufman Tr. 324–25.

[728] *See* Dkt. 234, Exs. A & B.

Unlike Akorn's estimate, Fresenius's estimate takes into account the need to conduct a complete investigation and the strong likelihood that such an investigation will uncover additional problems with Akorn's data, will result in additional ANDAs being withdrawn, will have effects on Akorn's pipeline, and could result in product recalls. Sturm, Henriksson, and Bauersmith testified to the detailed analysis and care that went into preparing Fresenius's plan. The views of Fresenius's management team on this subject are particularly credible, because Fresenius has direct experience remediating serious data integrity issues at one of its facilities in India and understands what a project of this nature entails.[729] Fresenius's management team developed the plan so that the Supervisory Board could understand Fresenius's potential exposure if Fresenius closed the Merger, and the Supervisory Board relied on the document when deciding whether to terminate the Merger Agreement. Sturm testified publicly that Fresenius stands behind the analysis and will undertake those steps if Fresenius is forced to close.

Henriksson testified that to properly remediate the data integrity issues at Akorn, there must be a temporary halt on the release of Akorn products until additional safety measures can be instituted.[730] Akorn's R&D department must be comprehensively restructured to "build a culture of [] compliance," implement IT systems with proper

[729] *See* Henriksson Tr. 1022–23.

[730] *Id.* at 975.

controls, and retrain personnel.[731] He projected that these initial steps will take approximately one year. After that, Akorn will need to redevelop its products using reliable data, then obtain approval from the FDA for those products.[732] Fresenius anticipates redeveloping Akorn's twenty-four leading products, with a simple product taking one year and a complex product taking two years, followed in each case by an additional year to receive FDA approval. As a result, the overall remediation of Akorn's data integrity issues would take at least four years. During the first year of this period, Akorn's ability to generate revenue would stop, then come back on line gradually as its products were reformulated and reapproved.

The evidence persuades me that a responsible remediation plan would be much closer to what Fresenius has proposed than what Akorn currently intends to pursue. Given the widespread problems at all of Akorn's sites and the evidence implicating Akorn's senior quality officer in data falsification, Akorn should be conducting a complete review.[733] So far, NSF's narrow review has identified two additional ANDAs that were

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[731] *Id.* at 976–77.

[732] *Id.* at 977–78.

[733] JX 1298 ¶ 39 ("The investigation should . . . include a retrospective review of all test results . . . ."); *see* Henriksson Tr. 976 ("They have already looked at nine ANDAs. They have found severe data manipulation on three. You know, when do you stop sampling and when do you say that, okay, I've seen enough. We've got to check it all."); Sheers Tr. 1064 ("[T]hey should be doing a complete review. There are now several instances, confirmed instances, of data falsification and fabrication, and the [FDA] expects in those circumstances for a complete review to be conducted. And it's not just enough to look at what is currently being done. You have to do a retrospective review, because there's

based on fabricated data and two additional persons of interest. A complete review is highly likely to uncover more problems with data integrity that will call ANDAs and products into question and push out the timing of Akorn's pipeline. Even under Akorn's more limited approach, its witnesses have agreed that the effort is "going to take about three years."[734]

Fresenius developed a credible plan for a complete review and remediation of the serious problems at Akorn. It nevertheless represents a worst-case scenario in which every product at Akorn has to be fixed. What seems more likely, in my view, is that a complete investigation would determine that only some of Akorn's products will require re-validation and that the level of disruption and delay will not be quite so extensive as Fresenius projects. Rajiv Gokhale submitted an expert report that addresses the impact of shorter deferrals of Akorn's cash flows. Using the discounted cash flow model that Fresenius generated in the ordinary course of business to evaluate the Merger, he calculated that a delay of one-and-a-half years would have a negative impact on Akorn's value of $604 million, and a two-year delay would have a negative impact on Akorn's value of $808 million.[735] Gokhale observed that in April 2017, when the Merger Agreement was executed, Akorn had a standalone equity value of approximately $3.9 billion. The valuation

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product that's still in the market that is supported by that data, and there's product that's going out the door today that is supported by data that is questionable.").

[734] Wasserkrug Tr. 68–69; *see* Avellanet Dep. 78–79 ("[I] have never seen a firm be able . . . to remediate all of its issues in less than three years."); JX 1295 ¶ 61 (Kaufman relying on estimate of two to three years).

[735] JX 1254 ¶ 6.

impact of a one-and-a-half or two-year delay therefore represented, respectively, 16% and 21% of Akorn's standalone equity value.[736]

It is not possible to define with precision the financial impact of Akorn's data integrity issues. In an ideal world, I would run a series of Monte Carlo simulations using varying assumptions. Lacking that ability and having considered the record evidence, I suspect the most credible outcome lies in the vicinity of the midpoint of the parties' competing submissions, at approximately $900 million. This rough estimate is also close to the $800 million that Gokhale calculated for a two-year delay, particularly when one adds to Gokhale's estimate amounts for out-of-pocket remediation costs. Using the equity value of $4.3 billion that is implied by the Merger Agreement, a valuation hit of $900 million represents a decline of 21%. That range of valuation consequence makes intuitive sense to me given the seriousness of Akorn's regulatory problems and the ever-expanding efforts that Akorn has been forced to make to remediate them.[737]

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[736] *Id.* Gokhale also opined as to the effect of comparable delays on Akorn's value in April 2018, when Fresenius terminated the Merger. In that analysis, the lost value from the deferred cash flows is higher and the standalone value of Akorn is lower, so the percentage decline is materially larger. *See id.* ¶¶ 8–9. To be conservative, this decision uses the lower values. In my judgment, that approach also makes sense for the Regulatory MAE, which compares the as-represented value of the seller with its value in light of the deviations from the representation. *See IBP*, 789 A.2d at 66. The measure of Akorn's equity value at the time of signing pre-dated the dramatic downturn in Akorn's business and the discovery of much of the information about Akorn's data integrity problems. It therefore provides a better measure of Akorn's as-represented value.

[737] *See* Dkt. 234, Exs. A & B.

Unfortunately, the parties have not provided much assistance in determining whether remediation costs equal to approximately 20% of the target's standalone value would constitute an amount that would "be material when viewed from the longer-term perspective of a reasonable acquiror."[738] In *Hexion*, the court agreed that materiality for purposes of an MAE should be viewed as a term of art that drew its meaning from Regulation S-K and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."[739] It would have been helpful to have access to expert testimony or studies about the thresholds companies generally use when reporting material events, such as material acquisitions. It also would have been helpful to understand the thresholds that Fresenius and Akorn have used. No one addressed these issues.

Although both the factual record and the corpus of available authority are limited, I believe that for Akorn, this expense would be "material when viewed from the longer-term perspective of a reasonable acquiror."[740] In making this finding, I have primarily weighed

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

[739] *Hexion*, 965 A.2d at 742.

[740] *IBP*, 789 A.2d at 68. Some readers may get hung up on a perceived difference between this decision's earlier discussion of a General MAE in terms of percentage declines in revenue and profitability, where Kling and Nugent highlighted 40% as a range where courts often find the existence of an MAE, *see* Part II.A.1, *supra*, and this section's discussion of a Regulatory MAE in terms of remediation costs, which concludes that a loss in the vicinity of 21% of Akorn's standalone value constituted a Material Adverse Effect. No one should fixate on a particular percentage as establishing a bright-line test. No one should interpret this decision as suggesting that there is one set of percentages for revenue and profitability metrics and another for liabilities. No one should think that a General MAE is always evaluated using profitability metrics and an MAE tied to a representation is always evaluated relative to the entity's valuation. In this case, the parties briefed the

the evidence in the record against my own intuition and experience (admittedly as a lawyer and judge rather than as a buyer or seller of businesses).

Among other things, the record demonstrates that Akorn pushed Fresenius to pay top dollar for Akorn, extracting every cent that Fresenius was willing to pay. When a deal is priced for perfection, a reasonable acquirer has less ability to accommodate an expense that equates to a substantial portion of the seller's value. In this case, the record indicates that Fresenius remained willing to close despite identifying a high risk of a potential exposure in the amount of approximately $100 million due to postponement of product launches,[741] as well as another high risk exposure of a similar amount related to cGMP "deficiencies related to premises and equipment" in the Amityville and Decatur facilities.[742] The data integrity violations represent an incremental loss in value

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General MAE question based on profitability metrics and the Regulatory MAE question using remediation costs, so that is what the decision analyzed. In the context of this case, the narrower focus for the Regulatory MAE makes sense and gives effect to the contract-driven requirement that there be a sufficient connection between the breach of the Regulatory Compliance Representations and the Regulatory MAE. The General MAE Condition does not have an equivalent causal linkage to a particular issue. The question is simply whether a General MAE had occurred.

[741] JX 428 at '673; *see* JX 422 at '001 ("Akorn has an aggressive product launch plan, which leads to risk of postponement for several products . . . and an estimated exposure above $100m. [Fresenius] prepared a bottom-up model for each model and adjusted the launch plan, R&D costs and revenues accordingly in the business plan.").

[742] JX 428 at '673; *see* JX 422 at '001 ("Site visit at Amityville and Decatur revealed [good manufacturing practice] deficiencies related to premises and equipment, which could result in negative outcome of regulator inspections and a mix of gross profit loss and capex need amounting to a maximum exposure over $100m. This finding is mitigated via the business plan.").

approximately four to five times greater than the combined exposure from both of these risks.

As a cross-check, I have considered external sources which, to my mind, might suggest how a reasonable buyer would view the situation. First, there is the general magnitude of a 20% change. By one common definition, a bear market occurs when stock prices fall at least 20% from their peak,[743] which suggests a broad cultural sense that this level of losses is viewed as material. On a percentage basis, a 20% decline would be the second largest single-day drop in the history of Dow Jones Industrial Average, exceeded only by Black Monday in 1987, when the market fell by 22.61%.[744]

Second, there are the levels at which parties renegotiate after one side asserts an MAE. One unpublished study found that "[w]hen the target experiences a firm-specific

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[743] *See, e.g.*, Adrian R. Pagan & Kirill A. Sossounov, *A Simple Framework for Analysing Bull and Bear Markets*, 18 J. Appl. Econ. 23, 30 (2003) ("[M]ost bull markets rise more than 20% while a much smaller fraction of bear markets culminate in a fall of more than 20%."); Asger Lunde & Allan Timmermann, *Duration Dependence in Stock Prices: An Analysis of Bull and Bear Markets*, 22 J. Bus. & Econ. Stat. 253, 253–55 (2004) (discussing definition of bear market where "the stock market switches from a bull state to a bear state if stock prices have declined by a certain percentage since their previous (local) peak within that bull state" and observing that a 20% decrease "is conventionally used in the financial press"); E.S. Browning, *Bear Sightings on Wall Street: Is This Really a Bear Market, or Some Other Animal?*, Wall St. J., Jan. 16, 2001, at C1 ("If a bear market is a 20% drop from a high—and that is the most common definition—the Nasdaq is in a nasty, growling bear."); John R. Dorfman, *If It Looks Like a Bear and Walks Like a Bear, Chances Are That the Bear Market Has Arrived*, Wall St. J., Sept. 27, 1990, at C1 (chart of "[h]ow stocks have performed in bear markets (declines of 20% or more) since 1919").

[744] *See Dow Jones Industrial Average All-Time Largest One Day Gains and Losses*, Wall St. J., http://www.wsj.com/mdc/public/page/2_3024-djia_alltime.html (last visited Sept. 19, 2018).

MAE, the subsequent renegotiation reduces the price by 15%, on average."[745] The fact that acquirers force renegotiations and then reach agreement (on average) at the 15% level suggests that an acquirer would regard a drop in value of 20% as material.

Third, there are the ranges that parties generally use for the upper and lower bounds of collars in deals involving stock consideration.[746] Two academic studies find that parties agree, on average, to a lower bound for the collar at a price approximately 10% below the initial deal consideration.[747] Practitioners observe that the upper and lower bounds for collars generally fall within 10% to 20% of the consideration at signing.[748] In other words,

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[745] Antonio J. Macias, *Risk Allocation and Flexibility in Acquisitions: The Economic Impact of Material-Adverse-Change (MACs) Clauses* 27 (Apr. 17, 2009), http:/ssrn.com/abstract=1108792; *see also, e.g.*, JX 641 at '595, '599 (discussing negotiated 8.9% decrease in deal price after Abbott Labs asserted an MAE at Alere).

[746] Collars come in two broad types: (i) a fixed-consideration version in which the exchange ratio adjusts between an upper and lower bound to keep the value of the consideration constant, but floats above and below the lower bound, and (ii) a floating-consideration version in which the exchange ratio remains constant between an upper and lower bound, thereby allowing the value of the consideration to float, then becomes fixed if the value rises above the upper bound or falls below the lower bound. *See generally* Rumberger, *supra*, § 5:48 (describing collars). For the basic directional inference that I seek to draw, the difference between these structures seems unlikely to be material.

[747] *See* Micah S. Officer, *The Market Pricing of Implicit Options in Merger Collars*, 79 J. Bus. 115, 128–29 (2006); Kathleen P. Fuller, *Why Some Firms Use Collar Offers in Mergers*, 38 Fin. Rev. 127 (2003).

[748] *See* Rumberger, *supra*, § 5:48 ("Typically, the collar is set at plus or minus 10% or 20% of acquirer's stock price at the signing of the acquisition agreement, although the upper and lower prices are not always symmetrical."); Craig M. Wasserman, *Dealing With Market Risks in Stock-for-Stock Mergers*, The M&A Lawyer (LegalWorks), Oct. 1998 (noting that a collar "is often set at 10% to 15% up and down from the acquiror's stock price at the time the deal is signed"). Wasserman likewise notes that agreements also often include walk-away rights that are triggered when the value changes by 15% or 20%,

parties (on average) view a 10% change in value as a material breakpoint that results in the deal consideration being handled differently. I recognize that this is a noisy proxy for materiality, because parties who use collars typically also include MAE-based termination provisions.[749] My point is not to argue that one type of provision is a substitute for the other, nor to offer any fine-grained opinions about their relative roles in different types of deals. The only inference I seek to draw is far more basic: If parties establish a lower bound for collars (on average) around 10% below the initial deal consideration and cause the deal pricing to change significantly at that point, then this suggests that they view a drop in value of 10% as material and would therefore also view a drop of more than 20% as material.[750]

Fourth, there is the magnitude of reverse termination fees. A reverse termination fee is an amount the buyer agrees to pay the seller if the buyer cannot or does not complete an

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effectively creating an objectively determined MAE. *See id.*; *accord* Lou R. Kling et al., *Summary of Acquisition Agreements*, 51 U. Miami L. Rev. 779, 811 (1997) ("At the outer limits of the collar (or, alternatively, at other, wider limits), parties may have termination rights."); Officer, *supra*, at 128 (finding that the median termination right for a collar is approximately 20% below the initial deal consideration).

[749] *See* Joel F. Houston and Michael D. Ryngaert, *Equity Issuance and Adverse Selection: A Direct Test Using Conditional Stock Offers*, 52 J. Fin. 197, 203–04 (1997) (noting that collar deals virtually always have material adverse change clauses). By the same token, in deals where parties negotiate walk rights that are triggered when the deal consideration floats outside of the collar, the materiality signal is even stronger.

[750] *Cf.* Micah S. Officer, *Collars and Renegotiation in Mergers and Acquisitions*, 59 J. Fin. 2719, 2722–23 (2004) (arguing that collars represent a form of *ex ante* price renegotiation based on changes in the relative value of bidder and target).

acquisition. In its purest form, the seller's sole remedy against the buyer is the payment of the reverse termination fee. That structure effectively creates an option for the buyer and establishes a floor for the loss in value that a buyer needs to contemplate: If the potential loss in value exceeds the amount of the termination fee, the buyer can pay the fee and walk away.[751] A law firm study in 2011 found median reverse termination fees equal to 6.36% of transaction value.[752] Studies of reverse termination fees during the period leading up to the financial crisis found fees hovering at the much lower level of approximately 3%.[753] Even more so than collars, reverse termination fees provide a noisy indication of materiality because many are tied to contractual conditions, should be priced as options, and are frequently used in private equity deals rather than in strategic acquisitions. Taking all those distinctions into account, to the extent these amounts provide a rough indication of the point where certain buyers have bargained for the right to walk, they suggest a point at which transacting parties regard a change in value as material. Given that the amounts are far lower than the remediation expense in this case, they suggest that an expense amounting to 20% of Akorn's value would be material to a reasonable acquirer.

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[751] *See* Steven M. Davidoff, *The Failure of Private Equity*, 82 S. Cal. L. Rev. 481, 483, 497–98, 515 (2009).

[752] *See* Matthew D. Cain et al., *Broken Promises: The Role of Reputation in Private Equity Contracting*, 40 J. Corp. L. 565, 593–94 (2015) (citing study).

[753] *See* Brian JM Quinn, *Optionality in Merger Agreements*, 35 Del. J. Corp. L. 789, 811 (2010) (3.29%); Elizabeth Nowicki, *Reverse Termination Fee Provisions in Acquisition Agreements* 6 (Jul. 5, 2009), http:/ssrn.com/abstract=1121241 (2.7%).

To reiterate, I do not pretend that any of these indicators is directly on point. I have considered them as cross-checks when attempting to evaluate my intuitive belief that the remediation expense would be material to a reasonable strategic acquirer. In this case, I am persuaded that the quantitative aspect of the MAE analysis warrants a finding that the regulatory issues would reasonably be expected to result in a Material Adverse Effect.

4. Whether Fresenius Knowingly Accepted The Risk

As it did when arguing against the existence of a General MAE, Akorn contends that Fresenius cannot claim that its regulatory issues would be reasonably likely to result in a Material Adverse Effect because Akorn knew about the risk of potential issues and signed the Merger Agreement anyway. I agree that Fresenius knew broadly about the risk of regulatory non-compliance; that is precisely why Fresenius bargained for representations on this subject. I do not agree, however, that Fresenius's general knowledge about potential regulatory issues or questions about the extent to which it conducted due diligence into these issues means that Fresenius cannot now rely on the representation it obtained.

Writing as a Vice Chancellor in *Cobalt Operating, LLC v. James Crystal Enterprises, LLC*, Chief Justice Strine addressed whether a buyer who had reason to be concerned about the accuracy of a representation and had the ability to conduct due diligence to confirm whether or not it was accurate could nevertheless rely on the

representation for purposes of asserting its contractual rights.[754] The seller argued that the buyer could not have relied on the representation and therefore should not be able to recover for breach. The Chief Justice rejected this argument:

> [A] breach of contract claim is not dependent on a showing of justifiable reliance. That is for a good reason. Due diligence is expensive and parties to contracts in the mergers and acquisitions arena often negotiate for contractual representations that minimize a buyer's need to verify every minute aspect of a seller's business. In other words, representations like the ones made in [the agreement] serve an important risk allocation function. By obtaining the representations it did, [the buyer] placed the risk that [the seller's] financial statements were false and that [the seller] was operating in an illegal manner on [the seller]. Its need then, as a practical business matter, to independently verify those things was lessened because it had the assurance of legal recourse against [the seller] in the event the representations turned out to be false. . . .
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> [H]aving given the representations it gave, [the seller] cannot now be heard to claim that it need not be held to them because [the buyer's] due diligence did not uncover their falsity. . . . Having contractually promised [the buyer] that it could rely on certain representations, [the seller] is in no position to contend that [the buyer] was unreasonable in relying on [the seller's] own binding words.[755]

Other Delaware decisions reach the same conclusion.[756]

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[754] 2007 WL 2142926 (Del. Ch. July 20, 2007), *aff'd*, 945 A.2d 594 (Del. 2008) (TABLE).

[755] *Id.* at *28 (footnotes omitted).

[756] *See Gloucester Hldg. Corp. v. U.S. Tape & Sticky Prods., LLC*, 832 A.2d 116, 127–28 (Del. Ch. 2003) ("Reliance is not an element of a claim for indemnification" for "breach of any of the representations or warranties in [the agreement] . . . ."); *id.* at 127 (rejecting contention that justifiable reliance was an element of breach of contract as "simply incorrect"); *Interim Healthcare, Inc. v. Spherion Corp.*, 884 A.2d 513, 548 (Del. Super.) ("No such reasonable reliance is required to make a *prima facie* claim for breach."), *aff'd*, 886 A.2d 1278 (Del. 2005) (TABLE). *See generally* Victor P. Goldberg, *Protecting Reliance*, 114 Colum. L. Rev. 1033, 1080 (2014) ("The weight of authority, and practice, is with the pro-sandbagging side."). Commentators often use the term "sandbagging" to

Chief Justice Strine's analysis in *Cobalt* comports with how Kling and Nugent describe the interaction between the due diligence process and the representations in the transaction agreement. As they explain,

> a party may well ask for a specific representation and warranty on a certain topic because its investigation of the business being acquired has it convinced that such topic is particularly important to that business or has made it aware

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refer to the practice of asserting a claim based on a representation despite having had reason to suspect it was inaccurate. *See, e.g.*, Charles K. Whitehead, *Sandbagging: Default Rules and Acquisition Agreements*, 36 Del. J. Corp. L. 1081, 1087, 1092–93 (2011) (surveying jurisdictions and acquisition agreements; concluding that New York and Delaware are pro-sandbagging and that very few acquisition agreements have anti-sandbagging clauses). This is a loaded and pejorative term: It "originates from the 19th century where gang members would fill socks full of sand to use as weapons against unsuspecting opponents. While at first glance, the socks were seemingly harmless, when used to their full potential they became very effective and would inflict substantial damage on a 'sandbagged' victim." Stacy A. Shadden, *How to Sandbag Your Opponent in the Unsuspecting World of High Stakes Acquisitions*, 47 Creighton L. Rev. 459, 459 (2014) (footnote omitted). From my perspective, the real question is whether the risk allocation in the contract controls, or whether a more amorphous and tort-like concept of assumption of risk applies. To my mind, the latter risks having cases routinely devolve into fact disputes over what was provided or could have been provided in due diligence. The former seems more in keeping with Delaware's contractarian regime, particularly in light of Delaware's willingness to allow parties to restrict themselves to the representations and warranties made in a written agreement. *See ChyronHego*, 2018 WL 3642132, at *4–7; *Novipax Hldgs. LLC v. Sealed Air Corp.*, 2017 WL 5713307, at *10–13 (Del. Super. Nov. 28, 2017); *IAC Search, LLC v. Conversant LLC*, 2016 WL 6995363, at *4–8 (Del. Ch. Nov. 30, 2016); *Prairie Capital III, L.P. v. Double E Hldg. Corp.*, 132 A.3d 35, 50–51 (Del. Ch. 2015); *Anvil Hldg. Corp. v. Iron Acq. Co., Inc.*, 2013 WL 2249655, at *8 (Del. Ch. May 17, 2013); *ABRY*, 891 A.2d at 1035–36, 1051–64; *Homan v. Turoczy*, 2005 WL 2000756, at *17 & n.53 (Del. Ch. Aug. 12, 2005) (Strine, V.C.); *H–M Wexford LLC v. Encorp, Inc.*, 832 A.2d 129, 142 & n.18 (Del. Ch. 2003); *Great Lakes Chem. Corp. v. Pharmacia Corp.*, 788 A.2d 544, 555–56 (Del. Ch. 2001). *See generally* Steven M. Haas, *Contracting Around Fraud Under Delaware Law*, 10 Del. L. Rev. 49 (2008).

> of a specific problem or concern as to which it wants the added comfort of a specific representation.[757]

The identification of issues in due diligence thus does not simply lead to a binary go/no-go decision on the acquisition; it also affects how the parties use representations in the transaction agreement to allocate responsibility for those issues.

> Suppose the Buyer requests the Seller to represent that the Company being sold is not in material breach of any material contracts. The Company may in fact be in violation of three material agreements, two of which violations the Seller is sure are material and one of which it believes to probably be immaterial. What does the Seller do? It modifies the representation to state: "Except as set forth on the Disclosure Schedule, the Company is not in material breach of any material agreement." The referenced schedule will then list the two or possibly all three of the agreements in question.[758]

From the seller's perspective, the representation is now true, and the buyer will not be able to claim an inaccuracy that would give the buyer a right not to close or, in a deal with post-closing remedies, a potential right to recover damages.[759] But if the parties do not qualify the representation, then the party making the representation assumes the risk for a deviation.

Again relying on *IBP*'s statement that a "broadly written" MAE provision "is best read as a backstop protecting the acquiror from the occurrence of unknown events,"[760] Akorn argues that these principles do not apply when a representation contains an MAE

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[757] Kling & Nugent, *supra*, § 1.06, at 1-43.

[758] *Id.* § 10.02, at 10-3.

[759] *See id.* § 10.02, at 10-3.

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

qualification. Akorn contends that adding an MAE qualification not only introduces a measure of variance from a flat representation, but also incorporates a broad carve-out for any risks that the buyer may have known about or issues which the buyer identified or could have identified through due diligence.

In my view, the analysis of the Regulatory MAE should take into account that the Material Address Effect is tied to an issue that the parties have addressed in a representation. The existence of the representation evidences the seller's knowledge of a risk, and the representation constitutes an effort by the parties to allocate that risk.[761] By adding an MAE qualifier, the parties do not change the nature of the representation or its risk allocation function; the qualifier instead addresses the degree of deviation from the representation that is permissible before the representation would be deemed inaccurate. In

[761] *See, e.g.*, Model Merger Agreement, *supra*, at 27 ("The representations and warranties . . . provide a mechanism for allocating between the buyer and the target the risk of the occurrence of the events . . . described therein, whether before or (except for representations and warranties made as of a specific date) after the signing of the definitive agreement. Given this potential role of the representations and warranties, in some cases the target may be asked to make representations that are not necessarily within the knowledge of the target, but are matters that the parties believe present a potential risk that should be addressed."); JX 1239 ¶ 47 (Subramanian) ("The reps & warranties, when combined with the bring-down condition, serve an important risk allocation purpose. In effect, they provide downside protection on specific aspects of the deal. If those aspects are not true at the closing, the buyer has the right to walk away. This can include events that are outside the seller's control. For example, if the target company represents that there are no material legal proceedings against the company (beyond what is contained in the disclosure schedule), but the target company is sued in a way that triggers a MAC between signing and closing, the buyer will have a contractual right to walk away.").

this role, the MAE qualifier stands in for a specific dollar figure, replacing a specified amount with an *ex post* judicial determination based on the facts and circumstances.

To illustrate the difference, assume that one of the Regulatory Compliance Representations was drafted using a dollar figure rather than an MAE qualifier.[762] It might read as follows:

> The Company and its Subsidiaries are and, to the Knowledge of the Company since July 1, 2013, have been in compliance with all applicable Laws relating to or promulgated by Healthcare Regulatory Authorities, except where noncompliance would not, individually or in the aggregate, reasonably be expected to result in a loss of more than $10 million.

Assume that at the time of signing, the seller had a data integrity issue that would cost $15 million to remediate, and the buyer learns of it between signing and closing. The magnitude of this issue would render the representation inaccurate. In my view, the buyer should be able to pursue any rights it has under the merger agreement based on the inaccuracy of the representation. Under the rationale of the *Cobalt* decision and other Delaware cases, it should not matter that the buyer may have had concern about potential regulatory compliance issues and likely conducted some degree of due diligence into those issues. Indeed, the existence of the representation by itself evidences the fact that the buyer did have concerns about potential regulatory compliance issues. What should matter is that the parties allocated the risk of any regulatory compliance issues through the representation,

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[762] *See generally* Kling & Nugent, *supra*, § 11.03[1], at 11-21 (discussing representations qualified by "the dollar level of an item or problem necessary to result in a representation being false").

qualified by a dollar figure so that the representation would only be inaccurate and give rise to contractual rights if an issue exceeded the threshold.

To my mind, an MAE qualifier serves the same purpose; it just replaces the specific dollar figure with a threshold that turns on facts and circumstances.[763] Drafted with an MAE qualifier, the same representation might read as follows:

> The Company and its Subsidiaries are and, to the Knowledge of the Company since July 1, 2013, have been in compliance with all applicable Laws relating to or promulgated by Healthcare Regulatory Authorities, except where noncompliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

From my standpoint, it still should not matter whether or not the buyer had concerns about potential regulatory compliance issues (which the representation evidences) or conducted some degree of due diligence. The parties allocated the risk of those issues through the representation, qualified so that the representation would only be inaccurate if an issue arose that was sufficiently serious that it would reasonably be expected to have a Material Adverse Effect.[764]

If parties wish to carve out anything disclosed in due diligence from the scope of a representation, then they can do so. If parties wish to carve out specific items or issues

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[763] *Cf. id.* § 11.03[1], at 11-21 to -24 (discussing qualification of representations by the adjective "material" in lieu of a dollar value; noting that parties may also use the higher standard of "having a materially adverse effect on").

[764] *Cf. id.* § 11.03[2], at 11-25 (noting that with a materiality-qualified representation, "the Buyer will have the ability to walk from the transaction"; however, "[t]he only difference, which may be of some economical [sic] significance, is that none of these rights will be triggered unless there is a 'material' problem").

from the scope of a representation, then they can use the common technique of qualifying the representation so that it excludes items listed on a corresponding schedule.[765] A seller could, for example, represent that it was in compliance with all regulatory requirements except for those listed on Schedule 3.18(a), and on that schedule identify data integrity issues. In this case, the Regulatory Compliance Representations are not qualified by any carve-outs or scheduled exceptions, but only by an MAE qualification for purposes of the Bring-Down Condition. As Akorn's counsel candidly conceded during post-trial argument, a regime which holds that a buyer cannot assert a breach of an MAE-qualified representation if the buyer learned or could have learned about aspects of the risk covered

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[765] *See, e.g.*, *IBP*, 789 A.2d at 39–40 (quoting examples of representations qualified by scheduled exceptions); Kling & Nugent, *supra*, § 10.01, at 10-2 ("[T]he disclosure schedule serves either to expand, or more commonly, to set forth exceptions to, the various representations. . . . Such schedules may affect whether the Buyer is required to close the acquisition of the Company as well as its ability to seek indemnification from the Seller for problems which may come to light after the closing."); *id.* § 11.03[2], at 11-25 ("[I]n a large transaction the choice in many instances may be between use of materiality exceptions and long disclosure schedules containing endless lists of exceptions to the representations. In the situation where speed and secrecy are essential, the use of materiality qualifiers becomes critical.") (footnote omitted); *id.* ("[T]he addition of a materiality standard to a representation is not necessarily fatal to any of the three functions generally served by representations and warranties portions of the agreement. The due diligence role is still performed, albeit to a lesser extent; the Buyer won't learn about the business with the level of detail that would be the case absent the qualification, but it should still find out about the serious problems. Similarly, the Buyer will have the ability to walk from the transaction as well as enjoy the benefit of any indemnification provisions.").

See also, e.g., *id.* § 11.04[9], at 11-69 ("[A]n acquiror's pre-signing knowledge about trends and possible events, including what is learned in due diligence and disclosed on the schedules to the agreement, could diminish its ability to successfully claim that a material adverse effect has occurred.") (discussing *IBP*).

by the representation during due diligence turns an MAE-qualified representation into the functional equivalent of a scheduled representation that schedules everything provided in due diligence.[766] One could likewise say that Akorn's argument turns an MAE-qualified representation into the functional equivalent of a representation with an expansive knowledge-based exception framed in terms of everything the buyer knew or should have known. To my mind, that reading is not consistent with the plain language of the Merger Agreement.

Assuming for the sake of argument that a buyer who knew about a specific fact that rendered a seller's representation inaccurate should not be permitted to close a transaction and then recover damages based on that specific fact, it does not necessarily follow that a buyer should be prevented from relying on a representation simply because the buyer knew about a risk. It also does not necessarily follow that a buyer should be prevented from relying on a representation when exercising a right not to close. As the Chief Justice observed in *IBP*,

> [t]he public policy reasons for denying relief to the buyer [when it seeks damages] are arguably much different than are implicated by a decision whether to permit a buyer simply to walk away before closing in reliance on a specific contractual representation that it had reason to suspect was untrue as of the time of signing.[767]

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[766] Dkt. 220 at 123–28.

[767] *IBP*, 789 A.2d at 82 n.200.

In this case, Fresenius did not know about the data integrity issues that would reasonably be expected to result in a Regulatory MAE. Fresenius obtained and reviewed a redacted Form 483 for Decatur, but it identified manufacturing issues, not data integrity concerns.[768] During an early pitch meeting in November, where Rai introduced Silverberg to Fresenius as Akorn's head of quality, no one mentioned that Silverberg had overstayed his welcome at Akorn and was scheduled to retire in January 2017.[769] Akorn did not provide Fresenius with its GQC audit reports on data integrity issues or the Cerulean gap assessments. Akorn has pointed out that Fresenius did not ask for them, but this also shows that Fresenius did not know about these issues.[770]

During due diligence, Fresenius did identify significant regulatory compliance and other business risks at Akorn, including risks related to Akorn's product launch plan, its manufacturing and quality functions, and its ability to comply with FDA serialization requirements.[771] But Fresenius's comprehensive risk assessment did not reference data

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[768] *See* JX 199; Bauersmith Dep. 217.

[769] Rai Dep. 156–57; *see* JX 137.

[770] *See* Ducker Dep. 269 (expressing regret that Fresenius did not request "internal and external audit reports" that "might have given us prior knowledge of their data integrity problems, because obviously they were well aware of those problems but had chosen not to inform us"); *see also* JX 882.

[771] *See* JX 422 at '000–002 (discussing twelve leading risks uncovered in due diligence); JX 428 at '673, '682, '710–14; JX 399 at 8–9; JX 431 ("Red Flag Tax Due Diligence Report"); *see also* JX 412 ("Quality Related Aspects in Due Diligence Activities"). Throughout due diligence, Fresenius kept track of "red flag DD findings." *See* JX 331; JX 401 at 9; *see also* JX 416 '388–408 (final due diligence slide deck addressing

integrity as a risk.[772] The final presentation to the Supervisory Board also did not identify risks related to data integrity.[773] In any case, many of the events giving rise to the Regulatory MAE had not yet occurred at the time of signing. Even with full knowledge of the data integrity risks, Fresenius could not have foreseen Silverberg's false CRL submission or Akorn's misleading presentation to the FDA. Even under Akorn's view of the law, the Merger Agreement allocates these unknowable risks to Akorn.

In my view, the combination of the Regulatory Compliance Representations and the Bring-Down Condition allocated to Akorn the risk that Akorn would suffer a Regulatory MAE. Akorn cannot now seek to re-trade that contractual allocation by arguing that Fresenius knew or should have known about those risks.

5. The Possibility Of Cure

Section 7.01(c)(i) permits Fresenius to terminate if the failure of a condition

> is incapable of being cured or, if capable of being cured by the Outside Date, the Company (x) shall not have commenced good faith efforts to cure breach or failure to perform within 30 calendar days following receipt by the Company of written notice of such breach or failure to perform from [Fresenius Kabi] stating [Fresenius Kabi's] intention to terminate this Agreement pursuant to this Section 7.01(c)(i) and the basis for such termination . . . .

"Areas of concern"). These files presumably would reference widespread data integrity issues if Fresenius knew about them.

[772] *See* Henriksson Tr. 945 (testifying that Fresenius's observations about quality and equipment had "nothing to do with data integrity"). The exception was data integrity risk at Akorn's India site, which Fresenius identified based on a June 2014 FDA inspection. JX 331 at '680.

[773] *See* JX 428.

Under the plain language of this provision, Section 7.01(c)(i) permits Fresenius to terminate if the failure of a condition cannot be cured before the Outside Date.

Section 7.01(b)(i) defines the Outside Date as part of the right that both sides have to terminate the Merger Agreement if the closing does not occur before the Outside Date. Formatted for greater legibility, the provision states that either side may terminate

> if the Effective Time shall not have occurred on or prior to April 24, 2018 (as such date may be expected pursuant to the immediately succeeding proviso, the "Outside Date");
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> provided that if on the Outside Date [1] any of the conditions set forth in Section 6.01(b) or Section 6.01(a) (to the extent relating to the matters set forth in Section 6.01(b)) shall not have been satisfied but [2] all other conditions set forth in Article VI shall have been satisfied or waived . . . then the Outside Date shall be automatically extended to July 24, 2018 . . .;
>
> provided, further, that if the Outside Date shall have been extended pursuant to the preceding proviso and on the extended Outside Date any of the conditions set forth in Section 6.01(b) or Section 6.01(a) (to the extent relating to the matters set forth in Section 6.01(b)) shall not have been satisfied but all other conditions set forth in Article VI shall have been satisfied or waived . . ., and [Fresenius Kabi] is then actively engaged in actions required to discharge its obligations under the second sentence of Section 5.03(c), then [Fresenius Kabi] shall have the right to extend the Outside Date to October 24, 2018 . . . .

Under this provision, the Outside Date starts out as April 24, 2018, can extend automatically to July 24, 2018, and can be extended at Fresenius's option to October 24, 2018.

As determined in the previous section, Akorn had experienced a General MAE before April 24, 2018, so "all other conditions set forth in Article VI" were not "satisfied or waived." Therefore, the Outside Date did not extend beyond April 24. When the Outside Date came and went, Akorn was only beginning to attempt to determine what it needed to

do to remediate its data integrity issues. NSF was in the early stages of its investigation. PwC was just getting started on its master list of deficiencies.

Even if the Outside Date had extended, Akorn could not have cured its regulatory problems in time. The evidence at trial demonstrated that Akorn had pervasive regulatory issues that would require years to fix. Akorn's witnesses coalesced around three years. Fresenius posited four years. Accepting Akorn's estimate, the problems would not be fixed until 2021.

Akorn argues that if the breaches were curable in the abstract, then Fresenius had to give Akorn notice and an opportunity to cure and could not exercise its termination right while Akorn was engaged in good faith efforts to cure. Under Akorn's interpretation, Akorn could hold Fresenius to the Merger Agreement for the four years that Fresenius believes it will take to remediate Akorn's regulatory issues, as long as Akorn is engaged in good faith efforts to cure. But that is not what the Merger Agreement says. Section 7.01(c)(i) only requires notice and gives Akorn an opportunity to cure if the failure of a condition is "capable of being cured by the Outside Date." In this case, Akorn's breaches were not capable of being cured by the Outside Date. Consequently, Fresenius did not have to wait to give Akorn an opportunity to cure. Fresenius could terminate immediately.

6. The Finding Regarding The Bring-Down Condition

Fresenius proved that Akorn's breach of the Regulatory Compliance Representations would be reasonably be expected to result in a Regulatory MAE, causing the failure of the Bring-Down Condition. In making this showing, Fresenius established that Akorn's regulatory difficulties have such qualitative and quantitative significance that

the effect on Akorn's business is material when viewed from the longer-term perspective of a reasonable acquirer, which is measured in years. Fresenius also showed that Akorn could not cure the failure of the Bring-Down Condition by the Outside Date. Because the Bring-Down Condition has not been met, Fresenius cannot be forced to close. More importantly, Fresenius had the right to terminate the Merger Agreement, provided that Fresenius was not then in material breach of its own contractual obligations.

C. The Failure Of The Covenant Compliance Condition

The next question is whether Fresenius validly terminated the Merger Agreement under Section 7.01(c)(i) because the Covenant Compliance Condition could not be met. The answer to this question turns on whether Akorn incurably breached the Ordinary Course Covenant. Yet again, because Fresenius sought to excuse its performance under the Merger Agreement, Fresenius bore the burden of proof.[774]

In addition to providing a termination right based on an incurable failure to comply with the Bring-Down Condition, Section 7.01(c)(i) gives Fresenius the right to terminate if Akorn incurably breached the Covenant Compliance Condition. Formatted for greater legibility, Section 7.01(c)(i) states:

> This Agreement may be terminated and the [Merger] abandoned at any time prior to the Effective Time (except as otherwise expressly noted), whether before or after receipt of the Company Shareholder Approval: . . .
>
> (c) by [Fresenius Kabi]: (i) if the Company shall have . . . failed to perform any of its covenants or agreements . . ., which failure to perform

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[774] *See Hexion*, 965 A.2d at 739; *Frontier Oil*, 2005 WL 1039027, at *35; *IBP*, 789 A.2d at 53.

> (A) would give rise to the failure of a condition set forth in . . . Section 6.02(b) [the Covenant Compliance Condition] and
>
> (B) is incapable of being cured . . .;
>
> provided that [Fresenius Kabi] shall not have the right to terminate this Agreement pursuant to this Section 7.01(c)(i) if [Fresenius Kabi] or Merger Sub is then in material breach of any of its representations, warranties, covenants or agreements hereunder . . . .

Whether Fresenius had a termination right under this aspect of Section 7.01(c)(i) therefore turns on three questions: (i) whether Akorn failed to perform any of its covenants or agreements in a manner that would cause the Covenant Compliance Condition to fail, (ii) whether the failure could be cured, and (iii) whether Fresenius was otherwise in material breach of its obligations under the Merger Agreement. Whether Fresenius breached its obligations is the same analysis under both the Covenant Compliance Condition and the Bring-Down Condition, so this decision addresses that issue separately.

1. The Operation Of The Covenant Compliance Condition

Formatted for greater legibility, the Covenant Compliance Condition states:

> The obligations of [Fresenius Kabi] and Merger Sub to effect the Merger shall be subject to the satisfaction (or written waiver by [Fresenius Kabi], if permissible under applicable law) on or prior to the Closing Date of the following conditions:
>
> * * *
>
> (b) Compliance with Covenants. The Company shall have complied with or performed in all material respects its obligations required to be complied with or performed by it at or prior to the Effective Time . . . .

Notably, the Merger Agreement does not condition closing on an absolute requirement that Akorn have complied with or performed all of its obligations. Instead, Akorn need only have complied with or performed its obligations "in all material respects."

In this case, Fresenius asserts that Akorn failed to comply with the Ordinary Course Covenant. Parties include ordinary-course covenants in transaction agreements to add an additional level of protection for the buyer beyond the Bring-Down Condition and help ensure that "the business [the buyer] is paying for at closing is essentially the same as the one it decided to buy at signing . . . ."[775] "For a variety of reasons, reliance on the target's representations, as they are brought down to test the condition of closing that the representations remain substantially true and correct on the closing date, will not provide the buyer adequate assurance as to the target's maintenance of its business."[776] "Most importantly, representations do not provide a remedy with respect to conduct during the

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[775] Kling & Nugent, *supra*, § 13.03, at 13-19; *see* Model Stock Purchase Agreement, *supra*, at 202 ("Generally, a buyer has an interest in assuring that the business of the target will be substantially the same as closing as it was on the date the purchase agreement was signed."); *see also* JX 1239 ¶¶ 39, 41 (Professor Subramanian explaining that an ordinary-course covenant seeks "to mitigate or eliminate the moral hazard problem that exists for the target's management between the signing and the closing of the deal," which "involves the incentive for the seller to act opportunistically between signing and closing, because if the deal closes the cost of this opportunistic behavior will be borne by the buyer, who does not yet have control over the target's assets").

[776] Model Merger Agreement, *supra*, at 120.

interim period between signing and closing. If the target does not remain appropriately motivated to close, reliance on the bring-down condition would be ineffective."[777]

In this case, the Ordinary Course Covenant consists of a broad affirmative covenant and sixteen categories of prohibited acts. Section 5.01(a) sets out the broad affirmative covenant. Formatted for legibility, it states:

> (a) Except as required by applicable Law, Judgment or a Governmental Authority, as expressly contemplated, required or permitted by this Agreement or as set forth in Section 5.01 of the Company Disclosure Letter, during the period from the date of this Agreement until the Effective Time (or such earlier date on which this Agreement is terminated pursuant to Section 7.01), unless [Fresenius Kabi] otherwise consents in writing (such consent not to be unreasonably withheld, delayed or conditioned),
>
> (i) the Company shall, and shall cause each of its Subsidiaries to, use its and their commercially reasonable efforts to carry on its business in all material respects in the ordinary course of business, and
>
> (ii) to the extent consistent with the foregoing, the Company shall, and shall cause its Subsidiaries to, use its and their commercially reasonable efforts to preserve its and each of its Subsidiaries' business organizations (including the services of key employees) substantially intact and preserve existing relations with key customers, suppliers and other Persons with whom the Company or its Subsidiaries have significant business relationships substantially intact, in each case, substantially consistent with past practice;
>
> provided that no action by the Company or any of its Subsidiaries with respect to matters specifically addressed by Section 5.01(b) shall be deemed to be a breach of this Section 5.01(a) unless such action would constitute a breach of Section 5.01(b).[778]

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[777] *Id.*

[778] JX 1 § 5.01(a).

Two aspects of the Ordinary Course Covenant jump out. First, the Ordinary Course Covenant contains the same type of materiality qualification found in the Covenant Compliance Condition: Akorn need not carry on its business in the ordinary course in every respect, only "in all material respects." Second, Akorn did not promise to maintain compliance with the Ordinary Course Covenant. It only committed to use "commercially reasonable efforts" to try to maintain compliance.

a. "In All Material Respects"

For starters, both the Covenant Compliance Condition and the Ordinary Course Covenant require compliance "in all material respects." The parties debate the meaning of this term.

Akorn argues that this phrase adopts the common law doctrine of material breach, under which "[a] party is excused from performance under a contract if the other party is in material breach thereof."[779] As a matter of common law, "[a] breach is material if it goes to the root or essence of the agreement between the parties, or touches the fundamental purpose of the contract and defeats the object of the parties in entering into the contract."[780] Under this doctrine, whether a breach is material "is determined by weighing the consequences in the light of the actual custom of men in the performance of contracts

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[779] *BioLife Sols., Inc. v. Endocare, Inc.*, 838 A.2d 268, 278 (Del. Ch. 2003).

[780] *Mrs. Fields Brand, Inc. v. Interbake Foods LLC*, 2017 WL 2729860, at *28 (Del. Ch. June 26, 2017) (internal quotation marks omitted), *clarified on denial of reargument* 2017 WL 3863893 (Del. Ch. July 27, 2017).

similar to the one that is involved in the specific case."[781] The Restatement (Second) of Contracts provides five guiding factors: (i) "the extent to which the injured party will be deprived of the benefit which he reasonably expected," (ii) "the extent to which the injured party can be adequately compensated for the part of that benefit of which he will be deprived," (iii) "the extent to which the party failing to perform or to offer to perform will suffer forfeiture," (iv) "the likelihood that the party failing to perform or to offer to perform will cure his failure, taking account of all the circumstances including any reasonable assurances," and (v) "the extent to which the behavior of the party failing to perform or to offer to perform comports with standards of good faith and fair dealing."[782] "[N]onperformance will attain this level of materiality . . . when the covenant not performed is of such importance that the contract would not have been made without it."[783]

Treatises on M&A agreements suggest a different purpose for including the phrase "in all material respects." Drafters use this language to eliminate the possibility that an immaterial issue could enable a party to claim breach or the failure of a condition.[784] The

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[781] *BioLife Sols.*, 838 A.2d at 278 (internal quotation marks omitted); *accord* 23 *Williston on Contracts* § 63:3 (4th ed. 2003).

[782] Restatement (Second) of Contracts § 241 (Am. Law Inst. 1981). "Courts in Delaware look to Section 241 of the *Restatement (Second) of Contracts* for guidance regarding materiality of a breach." *Medicalgorithmics S.A. v. AMI Monitoring, Inc.*, 2016 WL 4401038, at *24 (Del. Ch. Aug. 18, 2016).

[783] 14 *Williston on Contracts* § 43:6 (4th ed. 2003) (footnotes omitted).

[784] *See* Kling & Nugent, *supra*, § 14.02[3], at 14-12 ("[T]here are clearly representations where a minor mistake should not give the other party a walk-right."); *id.* § 14.02[7], at 14-17 (contrasting compliance "in all material respects" with "absolute

language seeks to exclude small, *de minimis*, and nitpicky issues that should not derail an acquisition. Consistent with this interpretation, the Restatement (Second) of Contracts recognizes that parties can depart from the common law doctrine of material breach, under which only a material breach excuses performance, by including express conditions to a party's performance in the agreement.[785] The Covenant Compliance Condition is one of those conditions. As Kling and Nugent observe, "It is precisely to *avoid* these types of

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compliance"); Contract Drafting, *supra*, at 213 ("An important drafting tool is the adjective *material*, as in *Widgetco is not a party to any material litigation.* Drafters use it, and the adjective *materially* . . . to narrow an otherwise overly broad provision so it covers only what really matters.").

[785] *See* Restatement (Second) of Contracts § 241 cmt. a (Am. Law Inst. 1981) (discussing the "the situation where the parties have, by their agreement, made an event a condition"); *id.* § 226 ("An event may be made a condition either by the agreement of the parties or by a term supplied by the court."); *id.* § 241 cmt. a ("A determination that a failure is not material means only that it does not have the effect of the non-occurrence of a condition under §§ 237 and 238."); *id.* § 237 cmt. a ("[A] material failure of performance, including defective performance as well as an absence of performance, operates as the non-occurrence of a condition."); *see, e.g.*, *Williams Cos. v. Energy Transfer Equity, L.P.*, 159 A.3d 264, 273 (Del. 2017) (analyzing whether breach of a covenant "materially contribute[d] to the failure of [a] closing condition"); *Sarissa Capital Domestic Fund LP v. Innoviva, Inc.*, 2017 WL 6209597, at *24 n.263 (Del. Ch. Dec. 8, 2017) ("Th[e] distinction between 'condition precedent' and 'covenant' is significant . . . . The press release as a 'condition precedent' would allow Innoviva to walk away from the settlement if Sarissa failed to perform; the press release as 'covenant' would allow Innoviva to sue for breach of contract if Sarissa failed to perform. Non-performance of the 'covenant,' however, would not provide a basis for Innoviva to walk away from the deal (unless, of course, Sarissa committed a material breach of the press release term after the parties engaged in good faith negotiations of the press release language).") (citation omitted). *See generally* 2 *Farnsworth on Contracts* § 8.2, at 415 (3d ed. 2004) ("Although a condition is usually an event of significance to the obligor, this need not be the case. In exercising their freedom of contract the parties are not fettered by any test of materiality or reasonableness. If they agree, they can make even an apparently insignificant event a condition.").

issues [*viz.*, arguments over the common law doctrine of material breach] that parties carefully draft acquisition agreements (although the condition is typically qualified by materiality), and provide for a 'bring down' condition, including as it relates to covenants in the acquisition agreement."[786]

Based on these authorities, the plain meaning of "in all material respects" in the Covenant Compliance Condition and the Ordinary Course Covenant calls for a standard that is different and less onerous than the common law doctrine of material breach. Relying on *Frontier Oil*, Fresenius argues that the phrase "in all material respects" requires only a "substantial likelihood that the . . . fact [of breach] would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information."[787] This test builds on the standard for materiality under disclosure law. Despite the oddity of relying on a disclosure-based standard to evaluate contractual compliance, the *Frontier Oil* test (as conceived by Fresenius) fairly captures what I believe the "in all material respects"

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[786] Kling & Nugent, *supra*, § 14.01, at 14-3 n.3; *see Cooper Tire & Rubber Co. v. Apollo (Mauritius) Hldgs. Pvt. Ltd.*, 2014 WL 5654305, at *13–17 (Del. Ch. Oct. 31, 2014) (analyzing whether party had complied "in all material respects" with a contractual covenant; the court did not cite the common law doctrine of material breach); Model Stock Purchase Agreement, *supra*, at 253 (discussing condition for covenant compliance and finding that "if Sellers breach any of their pre-closing covenants in a material respect, Buyer will have a 'walk right' in addition to its right to sue and recover damages from Sellers because of the breach").

[787] *See Frontier Oil*, 2005 WL 1039027, at *38 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)); *see also* Contract Drafting, *supra*, at 213 ("In an M&A context, and from the buyer's perspective, this meaning of *material* refers to information that would have caused the buyer not to enter into the agreement or would cause the buyer not to want to close the transaction.").

language seeks to achieve. It strives to limit the operation of the Covenant Compliance Condition and the Ordinary Course Covenant to issues that are significant in the context of the parties' contract, even if the breaches are not severe enough to excuse a counterparty's performance under a common law analysis.

It bears noting when analyzing the Covenant Compliance Condition that the presence of the "in all material respects" qualifier in both the condition and the underlying covenant results in two levels of materiality. To my mind, the double-materiality standard simply emphasizes that the breach of the Ordinary Course Covenant cannot be immaterial. It has to matter both as a departure from a generic pharmaceutical company's operations in the ordinary course of business and as a deviation from the buyer's reasonable expectations regarding what it would receive at closing.

b. "Commercially Reasonable Efforts"

The other key qualifier in the Ordinary Course Covenant—"commercially reasonable efforts"—is an example of an efforts clause. Clauses of this type mitigate the rule of strict liability for contractual non-performance that otherwise governs. Generally speaking, "[i]f a party agrees to do something, he must do it or be liable for resulting damages" (or potentially be subject to an order compelling specific performance).[788] At times, however, a party's ability to perform its obligations depends on others or may be

[788] Kling & Nugent, *supra*, § 13.06, at 13-44.

hindered by events beyond the party's control.[789] In those situations, drafters commonly add an efforts clause to define the level of effort that the party must deploy to attempt to achieve the outcome.[790] The language specifies how hard the parties have to try. "In acquisition transactions, the parties will generally bind themselves to achieve specified results with respect to activities that are within their control . . . and reserve [an efforts] standard for things outside of their control or those dependent upon the actions of third parties."[791]

Deal practitioners have a general sense of a hierarchy of efforts clauses.[792] The ABA Committee on Mergers and Acquisitions has ascribed the following meanings to commonly used standards:

- *Best efforts:* the highest standard, requiring a party to do essentially everything in its power to fulfill its obligation (for example, by expending significant amounts or management time to obtain consents).
- *Reasonable best efforts:* somewhat lesser standard, but still may require substantial efforts from a party.

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[789] *See* Model Stock Purchase Agreement, *supra*, at 212 ("An absolute duty to perform covenants or similar obligations relating to future actions will often be inappropriate or otherwise not acceptable to one or more parties to the agreement, as, for instance, when a party's ability to perform depends upon events or third-party acts beyond that party's control. In such circumstances, parties typically insert 'efforts' provisions.").

[790] *See id.* at 212 ("'Efforts' clauses are commonly used to qualify the level of effort required in order to satisfy an applicable covenant or obligation.").

[791] Kling & Nugent, *supra*, § 13.06, at 13-44.

[792] *See id.* § 13.06, at 13-46 to -47; Model Stock Purchase Agreement, *supra*, at 212.

- *Reasonable efforts:* still weaker standard, not requiring any action beyond what is typical under the circumstances.
- *Commercially reasonable efforts:* not requiring a party to take any action that would be commercially detrimental, including the expenditure of material unanticipated amounts or management time.
- *Good faith efforts:* the lowest standard, which requires honesty in fact and the observance of reasonable commercial standards of fair dealing. Good faith efforts are implied as a matter of law.[793]

Kling and Nugent "believe that most practitioners treat 'reasonable efforts,' 'commercially reasonable efforts' and 'reasonable best efforts' as all different from and as imposing less of an obligation than, 'best efforts.'"[794] They also observe that "'reasonable best efforts' *sounds* as if it imposes more of an obligation than 'commercially reasonable efforts.'"[795]

Commentators who have surveyed the case law find little support for the distinctions that transactional lawyers draw.[796] Consistent with this view, in *Williams Companies v.*

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[793] Model Stock Purchase Agreement, *supra*, at 212 (citation omitted); *see* Ryan A. Salem, Comment, *An Effort to Untangle Efforts Standards Under Delaware Law*, 122 Penn St. L. Rev. 793, 800 (2018) (identifying five commonly used standards: good faith efforts, reasonable efforts, best efforts, commercially reasonable efforts, and diligent efforts).

[794] Kling & Nugent, *supra*, § 13.06, at 13-46 to -47 (footnote omitted); *see* Contract Drafting, *supra*, at 195 ("Anecdotal evidence suggests that many who work with contracts believe that *best efforts* obligations are more onerous than *reasonable efforts* obligations. The distinction is often expressed like this: *reasonable efforts* requires only what is reasonable in the context, whereas *best efforts* requires that you do everything you can to comply with the obligation, even if you bankrupt yourself.").

[795] Kling & Nugent, *supra*, § 13.06, at 13-47.

[796] *See* Kling & Nugent, *supra*, § 13.06, at 13-44 to -49 & nn.2–9, 11 (collecting cases); Contract Drafting, *supra*, at 193 (observing that "[t]here's widespread confusion over phrases using the word *efforts*"; recommending that drafters use a single standard of "reasonable efforts"); *Salem, supra*, at 800–21 (surveying case law; recommending that Delaware resolve the ambiguity created by different efforts standards by adopting a single standard of "reasonable efforts"); Zachary Miller, Note, *Best Efforts?: Differing Judicial*

Energy Transfer Equity, L.P., the Delaware Supreme Court interpreted a transaction agreement that used both "commercially reasonable efforts" and "reasonable best efforts." Referring to both provisions, the high court stated that "covenants like the ones involved here impose obligations to take all reasonable steps to solve problems and consummate the transaction."[797] The high court did not distinguish between the two. While serving as a member of this court, Chief Justice Strine similarly observed that even a "best efforts" obligation "is implicitly qualified by a reasonableness test—it cannot mean everything possible under the sun."[798] Another Court of Chancery decision—*Hexion*—also framed a buyer's obligation to use its "reasonable best efforts" to obtain financing in terms of commercial reasonableness: "[T]o the extent that an act was both commercially reasonable

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Interpretations of a Familiar Term, 48 Ariz. L. Rev. 615, 615 (2006) ("The judicial landscape is littered with conflicting interpretations of efforts clauses"); *see also* Kenneth A. Adams, *Understanding "Best Efforts" And Its Variants (Including Drafting Recommendations)*, 50 Prac. Law., Aug. 2004, at 11, 18–20 (arguing that courts should only apply a single standard of "reasonable efforts"); 2 *Farnsworth on Contracts* § 7.17c, at 405 n.13 (3d ed. 2004) ("The terms 'best efforts' and 'reasonable efforts' are generally used interchangeably, although sometimes it is suggested that 'best' is more demanding than 'reasonable.'").

[797] 159 A.3d at 272. In a dissenting opinion, Chief Justice Strine maintained a distinction between "best efforts" and "commercially reasonable efforts," describing the former as one that "can potentially lead to the party making the promise having to take extreme measures to fulfill it" and the latter as "a strong, but slightly more limited, alternative[.]" 159 A.3d at 276 & n.45 (Strine, C.J., dissenting).

[798] *Alliance Data Sys.*, 963 A.2d at 763 n.60 (quoting *Coady Corp. v. Toyota Motor Distribs., Inc.*, 361 F.3d 50, 59 (1st Cir. 2004)).

and advisable to enhance the likelihood of consummation of the financing, the onus was on Hexion to take that act."[799]

2. Akorn's Failure To Use Commercially Reasonable Efforts To Operate In The Ordinary Course Of Business

Under the Merger Agreement, Akorn was obligated to use commercially reasonable efforts to operate in the ordinary course of business in all material respects. As interpreted by the Delaware Supreme Court in *Williams*, this standard required that Akorn "take all reasonable steps" to maintain its operations in the ordinary course of business.[800] The record establishes that Akorn breached that obligation in multiple ways.

First, a generic pharmaceutical company operating in the ordinary course of business is obligated to conduct regular audits and to take steps to remediate deficiencies. As discussed at length in the Factual Background, Akorn departed from this aspect of ordinary course operations after the Merger Agreement was signed by cancelling regular audits at four sites in favor of verification audits that would not look for additional deficiencies. Fresenius also cancelled Cerulean's assessment of Amityville and never completed Cerulean's inspection of Somerset, even though Akorn had planned for both to take place before the Merger Agreement was signed. Akorn personnel stated that these changes were made because of the Merger. Fresenius did not consent to these changes.

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[799] *Hexion*, 965 A.2d at 749.

[800] 159 A.3d at 272.

Second, a generic pharmaceutical company operating in the ordinary course of business is obligated to maintain a data integrity system that enables the company to prove to the FDA that the data underlying its regulatory filings and product sales is accurate and complete. As discussed at length in the Factual Background, Akorn did not do this. Despite receiving the results of its internal GQC audits and the Cerulean assessments, Akorn senior management instructed its IT department not to devote any resources to data integrity projects. Akorn did not begin to address its data integrity issues until March 2018, just one month before Fresenius terminated the Merger Agreement.[801]

Third, a generic pharmaceutical company operating in the ordinary course of business does not submit regulatory filings to the FDA based on fabricated data. As discussed at length in the Factual Background, Akorn departed from this aspect of ordinary course operations in August 2017 when Silverberg submitted the CRL for azithromycin that relied on fabricated data. The evidentiary record convinces me that Silverberg knew that the CRL relied on fabricated data and submitted it anyway because the only alternative would have been to withdraw the ANDA and start an investigation. That would have been a red flag for Fresenius. As Akorn's expert recognized, one of the purposes of an ordinary-

[801] *See* JX 1077 at '065–66; Wasserkrug Tr. 141–54.

course covenant is to constrain the moral hazard problem that can lead to misconduct like Silverberg's.[802]

Akorn also failed to act in the ordinary course of business when Fresenius provided Akorn with the whistleblower letters. As an Akorn director with FDA expertise recognized, Akorn should have conducted a "responsive and credible" investigation using counsel with experience in regulatory matters.[803] Akorn chose not to conduct an investigation of its own. Instead, Akorn decided to have its deal counsel, Cravath, front run the investigation that Fresenius intended to conduct and head off any problems that Fresenius otherwise might uncover. As discussed in the Factual Background, Akorn did not make this decision because Fresenius somehow directed Akorn not to investigate, but rather because Akorn feared a broad investigation of its own would uncover widespread problems.

Unfortunately for Akorn, it became clear when Cravath spoke with employees at the Somerset site that Sidley would quickly uncover Silverberg's fraud. At that point, Cravath began investigating, but Akorn's desire to tamp down that problem and prevent the issue from derailing the Merger led to non-ordinary-course efforts at damage control. These efforts included discounting the import of Silverberg's efforts to coordinate his story with Sherwani and destroy any evidence of their coordination, which failed only because

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[802] *See generally* JX 1239 ¶¶ 39–42 (Subramanian) ("[T]he ordinary course covenant focuses on the conduct (actions) of the seller's managers and prohibits opportunistic behavior by those managers.").

[803] JX 761.

Sherwani refused to go along. They also included making a misleading presentation to the FDA. Even Akorn's expert witness agreed that Akorn was "not fully transparent" during the meeting on March 16, 2018.[804]

Only after Akorn decided to try to get ahead of its problems by meeting with the FDA about the azithromycin incident did Akorn start acting like a generic pharmaceutical company operating in the ordinary course of business. At that point, Akorn retained expert regulatory counsel (Ropes & Gray) and hired a consultant (NSF) to evaluate its data integrity. After the meeting with the FDA, NSF conducted data integrity audits at five of Akorn's sites (excluding Somerset), reviewed ANDAs from Somerset, and reviewed a sampling of batch records. NSF uncovered a slew of major deficiencies and two critical findings involving the submission of inaccurate data to the FDA.

When making decisions about not remediating deficiencies, not continuing its audit program, not maintaining its data integrity system, and not conducting investigations, Akorn chose consciously to depart from the ordinary course of business that a generic pharmaceutical company would follow.[805] As a result, Akorn did not use commercially reasonable efforts to operate in the ordinary course. By contrast, the record does not permit a similar finding with respect to the destruction of Akorn's database for a high accuracy

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[804] Kaufman Tr. 377–78.

[805] *See* Rai Tr. 525 ('Q. Okay. And one of the things you knew that Akorn had to do, and in the ordinary course of business on that stand-alone basis after the acquisition agreement was signed, was to both investigate and remediate data integrity problems; correct? A. Correct."); *accord* Kaufman Tr. 371.

liquid particle counter along with the local backup file and the associated electronic security logs. That was not an ordinary course of business event, but it is one where the "commercially reasonable efforts" modifier prevents a finding of breach. The destruction of these files was an unexpected event outside of Akorn's control, which is the paradigmatic situation where an efforts clause comes into play. It is possible that by failing to maintain its data integrity systems, Akorn created the conditions under which the destruction of the files could occur, but the evidence in this case is not sufficient to support a finding to that effect.

3. Akorn's Failure To Use Commercially Reasonable Efforts Was Material.

Using the standard of materiality discussed above, Akorn's breaches of the Ordinary Course Covenant were material. In the context of the Merger Agreement, the breaches of the Ordinary Course Covenant departed from what Fresenius could reasonably expect and changed the calculus of the acquisition for purposes of closing.

Akorn's ordinary course violations after signing cost Akorn a year of what could have been meaningful remediation efforts. After receiving reports about data integrity issues from the GQC team during 2016, followed by Cerulean's damning assessment of Decatur in December 2016, Akorn should have prioritized the remediation of its data integrity systems. Accepting for purposes of analysis that Akorn's contractual obligation to Fresenius only began in April 2017, Akorn's failure to remediate from that point on cost Akorn a full year. Based on Akorn's own estimates that remediation would take three years, Akorn could have completed one-third of its efforts. If Akorn had embarked on the steps

that Fresenius contends are necessary, then Akorn would have verified its IT and testing systems, retrained existing employees, hired new R&D employees, taken major steps towards introducing a culture of compliance, and begun validating the data for its principal products.

Instead, Akorn made its regulatory situation immeasurably worse when its head of quality submitted fraudulent data to the FDA in August 2017. Akorn then complicated matters further by failing to be fully transparent with the FDA in March 2018 and instead providing a misleading presentation to the agency.

As shown by the inclusion of the Regulatory Compliance Representations in the Merger Agreement, whether Akorn complied with its obligations to the FDA was an important issue for the parties. While the combination of the Regulatory Compliance Representations and the Bring-Down Condition gave Fresenius some protection on this issue, the Merger Agreement also required that Akorn use commercially reasonable efforts to continue to engage in regulatory compliance activities between signing and closing. By using the phrase "in all material respects" in the Ordinary Course Covenant and the Covenant Compliance Condition, the parties adopted a lower standard for those provisions than the Regulatory MAE standard built into the Bring-Down Condition. As a result, Fresenius could refuse to close if Akorn did not continue to operate in the ordinary course of business with respect to regulatory compliance and the deviation from ordinary course practice was significant. That was the case here, resulting in a breach of the Ordinary Course Covenant.

Akorn's breach of the Ordinary Course Covenant was also sufficiently significant to implicate the Covenant Compliance Condition. The record convinces me that Fresenius would not have agreed to buy Akorn if Fresenius understood that Akorn would not be continuing to conduct full audits at all of its facilities, would not be addressing any of its data integrity issues, and would be providing fabricated data to the FDA. Akorn is a generic pharmaceutical company, so compliance with FDA regulations is essential. The parties knew that closing the Merger could take an extended period of time, which is why the Outside Date was originally set for a year after signing and would extend automatically for another three months if the only impediment remaining was antitrust clearance. No reasonable acquirer would have agreed that during this lengthy period, Akorn could stop engaging in ordinary-course activities relating to quality compliance and data integrity, much less that Akorn could trigger a major incident with the FDA by making a submission that relied on fabricated data.

4. Whether The Covenant Breach Was Curable

As previously discussed, Section 7.01(c)(i) permits Fresenius to terminate if the failure of a condition is incapable of being cured by the Outside Date. As this decision has already held, the Outside Date remained April 24, 2018; it did not automatically extend to July 24.

As of April 24, 2018, Akorn had finally started trying to remediate its data integrity problems, but it was in the early stages of this effort and trying to get a handle on the many data integrity deficiencies that dated back years. Akorn had not become transparent with

the FDA. NSF was in the early stages of its investigation. Akorn could not have cured its covenant breach by April 24.

Once again, even if the Outside Date had extended, Akorn could not have cured its regulatory problems in time. Akorn estimated it would take three years, well beyond what the Merger Agreement contemplated.

5. The Finding Regarding The Covenant Compliance Condition

Fresenius proved that Akorn failed to use commercially reasonable efforts to operate in the ordinary course of business in all material respects, resulting in a breach of the Ordinary Course Covenant. This breach was material and could not be cured by the Outside Date, causing the Covenant Compliance Condition to fail. Because the Covenant Compliance Condition has not been met, Fresenius cannot be forced to close. More importantly, Fresenius had the right to terminate the Merger Agreement, provided that Fresenius was not then in material breach of its own contractual obligations.

D. Has Fresenius Breached?

The final issue is whether Fresenius was barred from exercising its termination right because of its own material breaches of the Merger Agreement. Section 7.01(c)(i) contains a proviso which states that Fresenius cannot exercise its right to terminate "if [Fresenius] is then in material breach of any of its representations, warranties, covenants or agreements hereunder." Akorn contends that Fresenius could not terminate the Merger Agreement because it breached both the Reasonable Best Efforts Covenant and the Hell-or-High-Water Covenant. Akorn bore the burden of proof on these issues because Akorn sought to

invoke an exception to Fresenius's termination right.[806] The evidence shows that Fresenius did not breach the Reasonable Best Efforts Covenant. The evidence shows that Fresenius breached the Hell-or-High-Water Covenant, but that the breach was not material.

1. The Reasonable Best Efforts Covenant

In the Reasonable Best Efforts Covenant, each party to the Merger Agreement agreed to "cooperate with the other parties and use . . . their respective reasonable best efforts to promptly . . . take . . . all actions . . . necessary, proper or advisable to cause the conditions to Closing to be satisfied as promptly as reasonably practicable and to consummate and make effective, in the most expeditious manner reasonably practicable, the [Merger]."[807] Under the Delaware Supreme Court's decision in *Williams*, the "reasonable best efforts" standard in this provision imposed an obligation on Fresenius "to take all reasonable steps to solve problems and consummate the transaction."[808]

Importantly from my perspective, the parties agreed in the Reasonable Best Efforts Covenant to seek "to consummate and make effective" the transaction that they had agreed to in the Merger Agreement on the terms set forth in that contract. They were not committing themselves to merge at all costs and on any terms. Instead, they were

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[806] *See* 29 Am. Jur. 2d *Evidence* § 176 ("A party seeking to take advantage of an exception to a contract is charged with the burden of proving facts necessary to come within the exception."); *Hollinger*, 844 A.2d at 1070 ("Black bears the burden to establish that this contractual exception applies.").

[807] JX 1 § 5.03(a).

[808] 159 A.3d at 272.

committing themselves to fulfill the contract they had signed, which contained representations that formed the basis for the transaction, established conditions to the parties' performance, and gave both sides rights to terminate under specified circumstances. As I see it, the Reasonable Best Efforts Covenant did not require either side of the deal to sacrifice its own contractual rights for the benefit of its counterparty. The concept of acting for the benefit of another is a fiduciary standard, not a contractual one.

When evaluating whether a merger partner has used reasonable best efforts, this court has looked to whether the party subject to the clause (i) had reasonable grounds to take the action it did and (ii) sought to address problems with its counterparty. In *Hexion* and *IBP*, this court criticized parties who did not raise their concerns before filing suit, did not work with their counterparties, and appeared to have manufactured issues solely for purposes of litigation.[809] Kling and Nugent offer the following insightful commentary on *IBP*:

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[809] *See Hexion*, 965 A.2d at 725 ("[P]erhaps realizing that the MAE argument was not strong, Apollo and its counsel began focusing on insolvency."); *id.* at 726 (criticizing reliance on solvency opinion generated by consultants who "knew that their client had litigation on its mind and still based their opinion their opinion on the same biased numbers as the consulting team"); *id.* at 730 (criticizing solvency expert for not talking to seller's executives); *id.* (criticizing buyer for making "the deliberate decision not to consult with [the seller] regarding the [solvency] analysis prior to filing the lawsuit"); *IBP*, 789 A.2d at 49 ("In an internal e-mail, Gottsponer explained Tyson's renegotiation strategy: . . . 'To keep the pressure on their stock price. Based on the voice mails that have been left for me (those seven) the street views these restatements as insignificant. *We know these accounting issues aren't the biggest reason to renegotiate* (i.e. beef margins). Lets remind people of that (softly). To set the stage for other points that may help us to renegotiate.'"); *id.* at 49 ("Don Tyson returned to the meeting and announced that Tyson should find a way to withdraw. The problems at DFG apparently played no part in his decision, nor did the comments from the SEC. Indeed, DFG was so unimportant that neither John nor Don

> One gets the impression that Vice Chancellor Strine thought that Tyson itself did not believe there had been a material adverse effect, but, was, instead, suffering "buyer's remorse." Among the facts that supported this result were that Tyson's bankers still thought the deal was fair to it with "tremendous strategic sense" and represented "great long term value." In addition, Tyson did not even raise the material adverse effect claims in its correspondence with IBP, its announced reasons for terminating the merger agreement or, indeed, until the litigation started.[810]

The *Hexion* court similarly noted that the buyer "made the deliberate decision not to consult with [the seller] . . . prior to filing [its] lawsuit."[811]

Tyson knew about Schedule 5.11 of the Agreement until this litigation was underway.") (footnote omitted); *id.* at 51 ("Notably, the [termination] letter does not indicate that IBP had suffered a Material Adverse Effect as a result of its first-quarter performance."); *id.* at 65 ("[I]t is useful to be mindful that Tyson's publicly expressed reasons for terminating the Merger did not include an assertion that IBP had suffered a Material Adverse Effect. The post-hoc nature of Tyson's arguments bear on what it felt the contract meant when contracting, and suggests that a short-term drop in IBP's performance would not be sufficient to cause a MAE."); *id.* at 70 ("Even after Hankins generated extremely pessimistic projections for IBP in order to justify a lower deal price, Merrill Lynch still concluded that a purchase of IBP at $30 per share was still within the range of fairness and a great long-term value for Tyson. The Merrill Lynch analysis casts great doubt on Tyson's assertion that IBP has suffered a Material Adverse Effect."); *id.* at 71 ("[T]he analyst views support the conclusion that IBP remains what the baseline evidence suggests it was—a consistently but erratically profitable company struggling to implement a strategy that will reduce the cyclicality of its earnings. Although IBP may not be performing as well as it and Tyson had hoped, IBP's business appears to be in sound enough shape to deliver results of operations in line with the company's recent historical performance. Tyson's own investment banker still believes IBP is fairly priced at $30 per share.").

[810] Kling & Nugent, *supra*, § 11.04[9], at 11-68 n.133 (citations omitted); *accord* Schwartz, *supra*, at 827 n.220 (arguing that the absence of Delaware decisions finding an MAE "may be partially due to the Delaware courts' suspicion that acquirers use the MAC clause as a pretext to avoid closing a suddenly unappealing acquisition") (citing *IBP*, 789 A.2d at 65).

[811] 965 A.2d at 730.

In this case, Akorn's dismal post-signing performance gave Fresenius good cause to evaluate its rights and obligations under the Merger Agreement. The General MAE Condition gave Fresenius the right to refuse to close if Akorn suffered a Material Adverse Effect, and Fresenius was entitled to evaluate whether that condition was met. Fresenius also was entitled to consult with Paul Weiss. As this court observed in *Hexion*, it is "undoubtedly true" that a company can "seek[] expert advice to rely upon" when evaluating its contractual alternatives.[812] Importantly, Fresenius communicated directly with Akorn about its performance. Sturm and Henriksson flew to Lake Forest, Illinois to meet in person with Ducker and the Akorn executives.[813] Fresenius also analyzed and remained committed to fulfilling its obligations under the Merger Agreement if it was not entitled to terminate. Sturm testified credibly that he was "in an exploratory phase." [814] Consistent with his testimony, the contemporaneous evidence shows that at the same time Fresenius was consulting with Paul Weiss, Fresenius was also working hard to figure out how the deal could still work.[815]

The whistleblower letters subsequently gave Fresenius good cause to evaluate whether Akorn's representations were accurate and whether Fresenius might have

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[812] *Id.* at 754.

[813] Sturm Tr. 1178.

[814] *Id.* at 1189; *see id.* at 1206 ("Q. Okay. And you started looking for a way to get out of the transaction, did you not? A. No. I did not.").

[815] *See* JX 605; JX 619; JX 620; JX 624; JX 627 at '498; JX 657; JX 658; JX 661; JX 664; JX 670 at 20; JX 684 at '911.

contractual grounds to terminate. It was reasonable for Fresenius to use the informational right it possessed under the Merger Agreement to evaluate these issues. A reasonable access covenant "provides Buyer with the opportunity to confirm the accuracy of Sellers' representations and verify the satisfaction of the other condition to Buyer's obligation to complete the acquisition, such as the absence of a Material Adverse Change with respect to each Acquired Company."[816] The covenant exists "in order for the Buyer to continue the 'due diligence' process."[817] Fresenius used its reasonable access rights for that purpose. Moreover, as when responding to Akorn's poor business performance, Fresenius communicated directly with Akorn about these issues.

As discussed in the Factual Background, I believe that by November 12, 2017, the senior executives at Fresenius had concluded that they did not want to proceed with the Merger as negotiated. Akorn had performed too badly, and the regulatory problems raised by the whistleblower letters were another blow. Even recognizing that the Fresenius executives had a motive to get out of the deal, I do not believe that Fresenius breached the Reasonable Best Efforts Covenant. In addition to having an obligation to work towards

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[816] *See* Model Stock Purchase Agreement, *supra*, at 198; *see also*, *e.g.*, *id.* at 199 ("During its due diligence investigation, Buyer is likely to have access to extensive information concerning the Acquired Companies. If, during the period between signing and Closing, the information reveals a material inaccuracy in any of Sellers' representations as of the date of the Model Agreement, Buyer has several options. If the inaccuracy results in the inability of Sellers to satisfy the applicable closing condition . . . Buyer can decide to terminate [the merger agreement].").

[817] Kling & Nugent, *supra*, § 13.02[1], at 13-6.

closing, Fresenius also had the right to terminate the Merger Agreement if Akorn's Regulatory Compliance Representations were inaccurate and the deviation would reasonably and incurably be expected to result in a Material Adverse Effect. Fresenius also had the right to terminate the Merger Agreement if Akorn incurably failed to comply in all material respects with the Ordinary Course Covenant. Fresenius was entitled to investigate these issues and assert good faith positions based on its contractual rights.

Akorn views Fresenius's investigation cynically as an effort by Fresenius to manufacture grounds for termination. There is some evidence to support that view. Nevertheless, having considered the record and evaluated the credibility of the witnesses, I believe that Fresenius acted legitimately and uncovered real problems. I believe that Akorn knew about both the existence and magnitude of these problems and hoped that Fresenius would not get the full story until after the deal closed. Instead, the investigation caused Fresenius to learn about the pervasive nature of Akorn's compliance and data integrity issues before closing. In my view, as its investigation unfolded, Fresenius acted reasonably, culminating ultimately in its decision to terminate the Merger Agreement. Before doing so, Fresenius offered to extend the Outside Date for the Merger Agreement so that Akorn could continue its investigation and remediation efforts and, if Akorn thought it was possible, cure its breaches. Akorn declined.

Akorn understandably has tried to cast Fresenius in the mold of the buyers in *IBP* and *Hexion* by accusing Fresenius of having "buyer's remorse." In my view, the difference between this case and its forebearers is that the remorse was justified. In both *IBP* and *Hexion*, the buyers had second thoughts because of problems with their own businesses

spurred by broader economic factors. In this case, by contrast, Fresenius responded after Akorn suffered a General MAE and after a legitimate investigation uncovered pervasive regulatory compliance failures.

On a more granular level, this decision has already rejected many of the inferences that Akorn draws when portraying Fresenius as a bad faith actor. The principal components of Akorn's tale run as follows:

- Akorn claims that Sturm instructed management in September 2017 to build a legal case to terminate the Merger Agreement. This decision has found that Sturm was not seeking to manufacture a case. He was focused on understanding Fresenius's rights under the Merger Agreement so that Fresenius could exercise its rights if warranted. Otherwise, Fresenius would live up to its obligations.

- Akorn claims that Fresenius retained Paul Weiss to navigate a path towards termination. In my view, retaining expert counsel was prudent.

- Akorn asserts that Fresenius's advisors tried to manufacture a record that would justify termination. There is some evidence to support this view, and the advisors undoubtedly understood that Fresenius was unhappy with the deal. On balance, however, I believe the advisors acted consistently with Fresenius's rights under the Merger Agreement. In particular, I find that Sidley, Lachman, and E&Y conducted a professional investigation into the whistleblower letters that Fresenius had good cause to pursue.

- Akorn claims that Fresenius instructed Akorn not to investigate the anonymous letters. In the Factual Background, I rejected this interpretation of the evidence, finding instead that Fresenius told Akorn that it could not rely on Akorn's investigation and would have to also conduct one of its own. Akorn then chose not to conduct an independent investigation and instead have Cravath front run Sidley's investigation in an attempt to head off any problems.

- Akorn claims Fresenius secretly strategized with Paul Weiss and Sidley about manufacturing "fraud on the FDA" allegations[818] and "placing collateral pressure

[818] JX 719 at '238.

on Akorn by communicating concerns to the regulatory agency,"[819] then did just that in letters aimed at "stimulating the [FDA] to require a searching audit of Akorn and perhaps an FDA investigation" and "piqu[ing] the FDA's interest."[820] Akorn accurately quotes from documents when making this argument. In my view, however, Fresenius had good cause to investigate the whistleblower letters. Once that investigation uncovered serious problems, Fresenius had good reason to be concerned that Akorn would present a misleading picture of its situation to the FDA in an effort to get to closing and stick Fresenius with the regulatory problems. Fresenius acted reasonably in response to Akorn's conduct.

- Akorn claims that Fresenius drafted intentionally onerous information requests designed to induce Akorn to refuse access and supply an alternative basis for termination. I do not agree with this assessment. While Fresenius and its advisors drafted broad requests, the requests were reasonable in light of the seriousness of the charges in the whistleblower letters. After negotiations between counsel for the companies, Akorn largely complied.

- Akorn asserts that Sidley accessed confidential Akorn materials in the virtual data room, without Akorn's knowledge or permission and in breach of the confidentiality agreement. In my view, Sidley carefully evaluated whether it could access the virtual data room and properly concluded that it could use the information in the data room for purposes of "executing" the Merger Agreement, in the sense of carrying out the parties' contractual obligations. Those obligations did not require a single-minded drive to closing. They also contemplated the possibility of failed conditions and termination. Sidley properly used the information in the data room to evaluate Fresenius's rights under the Merger Agreement.

- Akorn contends that Fresenius executed a fraudulent common interest agreement. The two sides negotiated a common interest agreement which reflected that they had a "mutual interest" in "join[ing] in an investigation," and that "[t]his mutual interest arises from and under the Merger Agreement."[821] Fresenius was properly seeking to evaluate its rights under the Merger Agreement to determine whether the conditions to closing were met.

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[819] JX 738 at '297.

[820] JX 1488 at '820.

[821] JX 804 at '988; *see* Sturm Tr. 1220–21; Ducker Dep. 241–44; *see also* JX 798; Sheers Tr. 1088.

- Akorn contends that Fresenius lied to Akorn by falsely assuring Bonaccorsi that "the goal here was to investigate. . . . [T]his was not a litigation exercise."[822] In my view, Fresenius's goal was to investigate. Fresenius did not want to litigate unless it had to and would not litigate unless it had valid claims. If the investigation into the whistleblower letters had not suggested grounds for termination, or if events had unfolded along any number of other paths, then litigation would not have ensued.

- Akorn observes that Fresenius disqualified Akorn's FDA counsel because it did not want the FDA to get the impression of a "joint investigation," notwithstanding representations in the common interest agreement.[823] It is true that Fresenius refused to waive a conflict that Hyman Phelps faced, but Fresenius had good cause for doing so. At that point, Fresenius was justifiably concerned that Akorn would make a misleading presentation to the FDA, and Fresenius did not want its long-time regulatory counsel associated with a misleading presentation. That was a reasonable concern and borne out by events. The misleading nature of the presentation stemmed in part from Akorn's claims that the investigation had been conducted jointly, when in fact Cravath simply had been front running Sidley until Cravath discovered the azithromycin fraud. Fresenius's obligation to use its reasonable best efforts to fulfill its obligations under the Merger Agreement did not extend to assisting Akorn in misleading the FDA.

I give Akorn's top-flight attorneys credit for assembling a credible account. I am not suggesting that there is no evidence to support their position. Particularly after Akorn began exhibiting performance that ultimately led this decision to find that the Company had suffered a Material Adverse Effect, Fresenius did not want to go the extra mile. Fresenius wanted to live by the Merger Agreement and do what it was obligated to do, while at the same time protecting its own contractual rights and terminating the transaction if it had a valid basis for doing so. In my judgment, Fresenius succeeded in doing what it was

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[822] Bonaccorsi Tr. 891–92.

[823] Sturm Tr. 1224–26.

obligated to do. Akorn has not shown by a preponderance of the evidence that Akorn breached the Reasonable Best Efforts Covenant.

2. The Hell-Or-High-Water Covenant

Section 5.03(c) of the Merger Agreement sets out a series of affirmative and negative covenants relating to antitrust approval. The language that this decision refers to as the Hell-Or-High-Water Covenant states:

> [Fresenius Kabi] shall promptly take all actions necessary to secure the expiration or termination of any applicable waiting period under the HSR Act or any other Antitrust Law and resolve any objections asserted with respect to the [Merger] under the Federal Trade Commission Act or any other applicable Law raised by any Governmental Authority, in order to prevent the entry of, or to have vacated, lifted, reversed or overturned, any Restraint that would prevent, prohibit, restrict or delay the consummation of the [Merger], including
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> (i) (A) executing settlements, undertakings, consent decrees, stipulations or other agreements with any Governmental Authority or with any other Person, (B) selling, divesting or otherwise conveying or holding separate particular assets or categories of assets or businesses of [Fresenius Kabi] and its Subsidiaries, (C) agreeing to sell, divest or otherwise convey or hold separate any particular assets or categories of assets or businesses of the Company and its Subsidiaries contemporaneously with or subsequent to the Effective Time, (D) permitting the Company to sell, divest or otherwise convey or hold separate any of the particular assets or categories of assets or businesses of the Company or any of its Subsidiaries prior to the Effective Time, (E) terminating existing relationships, contractual rights or obligations of the Company or [Fresenius Kabi] or their respective Subsidiaries, (F) terminating any joint venture or other arrangement, (G) creating any relationship, contractual right or obligation of the Company or [Fresenius Kabi] or their respective Subsidiaries or (H) effectuating any other change or restructuring of the Company or [Fresenius Kabi] or their respective Subsidiaries (and, in each case, entering into agreements or stipulating to the entry of any Judgment by, or filing appropriate applications with, the Federal Trade Commission (the "FTC"), the Antitrust Division of the Department of Justice (the "DOJ") or any other Governmental Authority in connection with any of the foregoing and, in the case of actions by or with respect to the Company, by consenting to such action by the Company (including any

> consents required under this Agreement with respect to such action); provided that any such action may, at the discretion of the Company, be conditioned upon the Closing) and
>
> (ii) defending through litigation any claim asserted in court or administrative or other tribunal by any Person (including any Governmental Authority) in order to avoid entry of, or to have vacated or terminated, any Restraint that would prevent the Closing prior to the Outside Date.
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> All such efforts shall be unconditional and shall not be qualified in any manner and no actions taken pursuant to this Section 5.03 shall be considered for purposes of determining whether a Material Adverse Effect has occurred or would reasonably be expected to occur. . . .
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> The Company, [Fresenius Kabi] and Merger Sub and any of their respective Affiliates shall not take any action with the intention to, or that could reasonably be expected to, hinder or delay the expiration or termination of any waiting period under the HSR Act or the obtaining of approval of the DOJ or FTC as necessary (including, in the case of [Fresenius Kabi] and Merger Sub, acquiring or merging with any business, Person or division thereof, or entering into a definitive agreement with respect thereto, if doing so could reasonably be expected to have such effect). . . .[824]

In other words, Fresenius agreed to take "all actions necessary" to secure antitrust approval, without any mitigating efforts obligation.[825]

Somewhat in tension with the flat obligation to take "all actions necessary" to secure antitrust approval, the Merger Agreement gave Fresenius sole control over the strategy for securing antitrust approval (the "Strategy Provision"). Formatted for legibility, this aspect of Section 5.03(c) states:

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[824] JX 1 § 5.03(c).

[825] *See Alliance Data Sys.*, 963 A.2d at 763 n.60 (describing a Hell-Or-High-Water Covenant as "a much stronger and broader commitment" than a reasonable best efforts obligation "with respect to a discrete regulatory subject: antitrust approval").

> [Fresenius Kabi] shall (x) control the strategy for obtaining any approvals, consents, registrations, waivers, permits, authorizations, orders and other confirmations from any Governmental Authority in connection with the [Merger] and
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> (y) control the overall development of the positions to be taken and the regulatory actions to be requested in any filing or submission with a Governmental Authority in connection with the [Merger] and in connection with any investigation or other inquiry or litigation by or before, or any negotiations with, a Governmental Authority relating to the [Merger] and of all other regulatory matters incidental thereto;
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> provided that [Fresenius Kabi] shall consult and cooperate with the Company with respect to such strategy, positions and requested regulatory action and consider the Company's views in good faith. . . .[826]

The Strategy Provision inherently recognizes that there is no single and obvious answer as to how to pursue antitrust approval and that Fresenius had the power to make those decisions after consulting and cooperating with the Company.

Akorn's post-trial briefs placed great emphasis on antitrust issues, yet the trial record on this point was comparatively sparse. During trial, only two witnesses made more than a passing reference to FTC clearance.[827] Bauersmith, who oversaw Fresenius's divestiture efforts, testified at trial that he was not asked to delay the process.[828] As noted

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[826] JX 1 § 5.03(c). Cravath's initial draft of the Merger Agreement provided that Fresenius and Akorn "shall jointly, and on an equal basis," control the strategy for antitrust clearance. JX 420 at '686. Fresenius requested sole control over strategy, and Akorn accepted the change. Silhavy Dep. 24–25.

[827] *See* Bauersmith Tr. 604–08; Bonaccorsi Tr. 912–21, 932.

[828] Bauersmith Tr. 604; Bauersmith Dep. 128, 218; *see also id.* at 217 (describing the FTC approval process as "a rigorous pace insofar as identifying the appropriate buyers, striking the right value deal, and creating a set of agreements that we believed would be acceptable to the FTC").

in the Factual Background, Bauersmith was a credible witness. At trial, Akorn's counsel never asked Bauersmith about the FTC or Fresenius's divestment partner Alvogen. In its briefing, Akorn relies heavily on the deposition of its corporate strategy official Jennifer Bowles, who largely testified to her "perception" that Fresenius intentionally delayed FTC approval for self-interested reasons.[829] Bowles did not testify at trial.[830]

There is no serious dispute that during the first six months after the Merger Agreement was signed, Fresenius diligently pursued antitrust approval. Fresenius started by assessing the degree to which its ANDAs overlapped with Akorn's,[831] then analyzed the likelihood the FTC would require divestment.[832] Working through these issues required Fresenius to evaluate the number of competitors and relative market share for each product.[833] Once Fresenius had a sense of what it thought the FTC would want sold, Fresenius worked with Moelis to structure a bidding process for potential buyers that

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[829] *See* Bowles Dep. 134–35; *id.* at 128–29 (discussing "opinions" Bowles formed when FTC-related activities "should not have taken as long as they did"); *see also* Rai Dep. 247 ("I think the whole process of getting the FTC approval was slow and should have been done sooner, based on my personal experience, because I've been through one before, or a couple of times.").

[830] Because Bowles did not appear at trial and also lacked first-hand knowledge of Fresenius's negotiations with Alvogen, her deposition testimony receives limited weight. *See* Bowles Dep. 130.

[831] Bauersmith Dep. 149.

[832] *Id.*

[833] *Id.*

included access to a data room.[834] Alvogen was the winning bidder, and Fresenius began working on a transaction agreement with Alvogen.

In October 2017, Fresenius submitted a proposed divestiture agreement to the FTC, consistent with the plan to submit by mid-November.[835] In early November, the FTC threw a wrench into the process by asking Fresenius to divest its versions of the overlapping products rather than selling Akorn's.[836] The FTC also raised other objections to the divesture package that the parties had not anticipated and which seemed to depart from past agency practice.[837]

The parties had not expected to receive FTC clearance until early 2018,[838] so Fresenius made the reasonable decision to ask the FTC to reconsider having Fresenius

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[834] *Id.* at 150.

[835] Ducker Dep. 274; *see* Bauersmith Dep. 218 ("[A]lvogen and Fresenius . . . submitted what we thought in October was an agreement and a proposal that the FTC should accept."); JX 524 at '416 (timeline calling for "[c]ontract finalization & supply and tech transfer agreements, and final submission to FTC" between the third week of September and the second week of November); *see also* Silhavy Dep. 47–48.

[836] *See* JX 698 at '866–67; *see also* Bauersmith Dep. 154.

[837] *See* Bauersmith Dep. 153–55; Bauersmith Tr. 605; *accord* Silhavy Dep. 165–67; *see also* Ducker Dep. 274 (discussing Allen & Overy's view that the switch on Fresenius's overlapping products "was a very unusual step for the FTC to take"); Empey Dep. 184–85.

[838] *See* Silhavy Dep. 48–49; Sturm Tr. 1175 (noting that the Merger could close "towards the end of 2017, at the earliest"); JX 524 at '416 (divestment timeline from June 2017 contemplating "FTC review of submission and final negotiations with FTC" between the third week of November 2017 and the second week of January 2018).

divest its version of the overlapping products rather than Akorn's.[839] Fresenius also began considering whether it should sell the Decatur site as part of the divestiture package, believing that if the FTC learned that Fresenius was considering selling Decatur, it would want the plant included in the package of divestitures.[840] Based on feedback from the FTC, Fresenius came to believe that a sale of Decatur standing alone would enable the Merger to obtain FTC clearance, without the need to divest other products.[841] Under the Strategy Provision, it was Fresenius's job to consider these issues.

The Fresenius team evaluated whether pursuing a sale of Decatur would create problems by delaying FTC approval and concluded that although there was a risk of delay, the benefits outweighed the risk.[842] As of early January 2018, the Fresenius executives believed that pursuing a divestiture strategy involving Decatur would result in FTC approval in mid-April, within the timeframe contemplated by the Merger Agreement, as opposed to potential approval in February without Decatur.[843] Fresenius therefore decided to pursue "parallel strategies" on divestiture: Option 1, which involved selling various

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[839] *See* Bowles Dep. 131–34.

[840] *See* JX 816 at '971–72; Henriksson Dep. 67 ("We didn't want to bring it to the FTC, because we thought that that would then delay the clearance, but . . . I wanted to sell that plant to Alvogen.").

[841] *See* Silhavy Dep. 169–70; JX 1456 at 2 ("Sale of Decatur facility would solve virtually all FTC concerns"); Henriksson Dep. 314–15.

[842] *See* Schulte-Noelle Dep. 185–89; Ducker Dep. 274–75; JX 816 at '971–72.

[843] *See* JX 844 at '410–11; Silhavy Dep. 168–69.

Fresenius ANDAs, and Option 2, which involved selling Decatur.[844] In my view, this was a reasonable approach that fell within the ambit of the Strategy Provision.

The first documentary evidence of Akorn registering complaints about Fresenius's pursuit of regulatory approval emerges in minutes of a board meeting on January 5, 2018, where Rai and Bowles "provided their opinions that FK is dragging its feet with respect to the FTC clearance activities highlighting their unwillingness to accept FTC's stated positions with respect to divestitures."[845] The Akorn executives notably raised these issues after multiple quarters of terrible business performance by Akorn, after the investigation into the whistleblower letters had uncovered Silverberg's submission of false data to the FDA, and during a meeting where the board, management, and Cravath attorneys "engaged in a robust and lengthy discussion regarding the status of investigation, MAE standard, conditions of closing and whether Akorn can insist on FK taking accelerating [sic] its efforts to obtain FTC clearance."[846] Akorn's desire to raise these issues at this point seems as much a defensive response to the pressure that Akorn was under as it was the product of actual problems with Fresenius's compliance. Internal Fresenius emails indicate that

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[844] *See* Silhavy Dep. 173; *id.* at 185 ("We knew that it would solve a number of the issues outstanding with the FTC, but have the effect of perhaps taking longer than going with the straight option of divesting the products without a . . . corresponding divestiture of . . . Decatur."); JX 959 at '498 (discussing Option 1 and Option 2).

[845] JX 1337 at '403; *see also* Bonaccorsi Tr. 915 (testifying that by late 2017, he and Bowles "felt [Fresenius was] beginning to slow-walk the FTC process").

[846] JX 1337 at '403.

during January, Bauersmith was pressing forward to obtain FTC approval promptly for a divestiture option that involved Decatur,[847] and Fresenius's attorneys were likewise working with the FTC on aspects of the ANDA divestiture package.[848]

For approximately a week in February 2018, Fresenius contemplated a path that could have constituted a material breach of the Hell-or-High-Water Covenant had Fresenius continued to pursue it. The Hell-or-High-Water Covenant forbids Fresenius from taking any action that could be reasonably expected to delay FTC approval, and Fresenius nearly adopted an FTC strategy that it knew would delay approval by two months or more.

During a meeting on February 9, 2018, the Fresenius steering committee discussed the two options for obtaining FTC clearance.[849] Option 1 continued the ANDA divestiture strategy.[850] Under this option, the Merger could close in April.[851] Option 2 involved a sale of Decatur and obviated the need to resolve multiple longstanding disputes with the FTC

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[847] *See* JX 889 at '591.

[848] *See* JX 886.

[849] JX 959.

[850] *See id.* at '498 ("Option 1: Negotiate a 'reverse' swap of FK Acetylcysteine ANDAs to Alvogen."); *id.* at '497 ("FTC is requesting FK to divest its acetylcysteine assets instead of the original plan to invest Akorn's assets.").

[851] *Id.* at '498.

about Option 1.[852] Option 2 would result in the Merger closing in June or July.[853] The February 9 minutes indicated that "[p]ost-close integration teams are preparing for an imminent closing including putting key support contracts in place."[854] In an email sent to the group of Fresenius executives who were overseeing the antitrust clearance process, Ducker wrote:

> The key topic is how to proceed with Alvogen and FTC. If Stephan [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. But if the Supervisory Board does not support the refusal to close we want the quickest option which is #1. I suggest we ask Jamie [Bauersmith] to explore both options with Alvogen. This will test their appetite for both and leaves both options open for potential negotiations of terms. It will buy us a couple of weeks to the Feb 22 or 23 decision point.[855]

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[852] *See id.* at '497–98; Ducker Dep. 275 (explaining that Option 2 "simplifies matters significantly with the FTC and removes the need for escrow accounts, and we could remove the requirement for us to divest our on-market acetylcysteine product"); Schoenhofen Dep. 196.

[853] JX 959 at '498; *see also* Bauersmith Dep. 161–62 (explaining that the Option 2 schedule built in time for Alvogen to diligence Decatur); *cf.* JX 889 at '591 (January 19, 2018 email referencing Alvogen's request for due diligence at Decatur).

[854] JX 959 at '500.

[855] JX 976 at '067.

The executives picked Option 2,[856] but Fresenius "quickly abandoned" it once Alvogen made an unattractive offer for Decatur.[857] After barely one week, Fresenius reverted to Option 1, and the Merger stayed on track for an April closing.

By choosing Option 2, which would delay antitrust clearance by two months, Fresenius technically breached the Hell-or-High-Water Covenant. But because Fresenius changed course in approximately a week and returned to Option 1, the breach was not material. As of that point, Fresenius had positioned the parties to close the Merger in conjunction with the original Outside Date of April 24, 2018, and months before the extended Outside Date of July 24, which would have applied automatically if receipt of antitrust approval was the only condition to closing that had not been met.

Akorn makes much of Bonaccorsi's testimony about his interactions with Fresenius's lead antitrust counsel, Elaine Johnston of Allen & Overy. Bonaccorsi testified that Johnston told him that she was not in regular contact with Fresenius and could not

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[856] JX 959 at '498.

[857] *See* Silhavy Dep. 173; Bauersmith Tr. 607–08 (testifying that Fresenius spent "[a]bout a week or so" pursuing Option 2 before Alvogen "came in with an incredibly low offer for the Decatur facility"); Ducker Dep. 275–76; Schulte-Noelle Dep. 189–90 ("[I] think it was only a few days later we realized that there was no attractive offer and, hence, the only option that would be left would be [Option 1]."). The steering committee's February 9 minutes reflect that it directed Bauersmith "to approach Alvogen . . . to gauge their interest level" in Option 2. JX 959 at '498. Bauersmith explained that he "reached out to Alvogen pretty much right away" to assess their interest but that they "offered something that was not palatable, so we just pursued option 1." Bauersmith Dep. 220–21.

explain the delays in the FTC process.[858] These communications appear to have taken place during the brief period in February when Fresenius was deciding between the two options, initially chose Option 2, then reverted to Option 1. It makes sense to me that Johnston and Fresenius were not on same page during the brief period when Fresenius was making a major decision about strategy. Akorn does not point to any evidence of miscommunications between Fresenius and Johnston, or for that matter between Fresenius and Akorn, after February 2018.

During a meeting on March 23, 2018, Bowles advised the Akorn directors about the timeline for receiving FTC approval and did not identify any problems.[859] On April 20, the FTC sent Akorn and Fresenius a draft Decision and Order, which is one of the final steps in the FTC review process before approval.[860] When Akorn filed its complaint on April 23, it alleged that FTC approval was expected in May 2018.[861] It appears that the FTC is now reserving judgment until this litigation is resolved,[862] but Fresenius cannot be faulted for that.

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[858] Bonaccorsi Dep. 218–19; Bonaccorsi Tr. 918–19; *see also* JX 972 (Bonaccorsi discussing February 13 call with Johnston); JX 1337 at '403 (Akorn February 23 board minutes discussing dialogue with Johnston).

[859] JX 1337 at '405; *see also id.* at '404–05 (March 2 and 9 board minutes referencing "FTC related activities," but no problems).

[860] Dkt. 1 ¶ 118; *see* Bowles Dep. 146–47 ("Q. And so is it your understanding that, as of April 23, antitrust approval was now close at hand? A. Yes.").

[861] Dkt. 1 ¶ 119.

[862] *See* Dkt. 220 at 109–10.

The facts of this case differ markedly from *Hexion*, which Akorn cites for the settled proposition that a party can breach a hell-or-high-water covenant by dragging its feet on obtaining antitrust clearance.[863] In *Hexion*, at the time of trial, the buyer still had not "signed agreements with the proposed buyer of the assets to be divested" and still "had not responded to certain interrogatories from the FTC" or "put itself in a position to do so . . . ."[864] The buyer in that case consciously delayed obtaining approval as a strategy to avoid the transaction.[865] Fresenius did not do that. Fresenius took steps to obtain timely antitrust approval, but other conditions in the Merger Agreement failed before approval could be received.

There is also contemporaneous evidence indicating that Akorn recognized that Fresenius could cure any breach of the Hell-or-High-Water Covenant by moving forward on Option 1. In a letter dated February 24, 2018, Cravath accused Fresenius of breaching its obligation to secure antitrust clearance and posited that Fresenius "cure its breach immediately" by committing to "promptly agree to whatever terms are necessary to complete the negotiations with Alvogen" over Option 1.[866] By the time Fresenius received the letter, Fresenius had abandoned its flirtation with Option 2 and was pursuing Option 1, thereby curing its breach.

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[863] *See Hexion*, 965 A.2d at 756.

[864] *Id.* at 735, 756.

[865] *Id.* at 756.

[866] JX 986 at '188.

I find that Fresenius breached the Hell-or-High-Water Covenant by briefly pursuing Option 1, but Akorn failed to prove by a preponderance of the evidence that Fresenius *materially* breached the Hell-or-High-Water Covenant. Under the Strategy Provision, Fresenius had the exclusive right to "control the strategy" and "the overall development of the positions to be taken" to obtain FTC clearance.[867] Fresenius chose a strategy that ultimately would have resulted in FTC approval well within the timeframe permitted by the Merger Agreement. There also is ample evidence indicating that Fresenius could have secured FTC clearance by the original Outside Date if the FTC had not wavered on aspects of the original divestiture package. Under these circumstances, Akorn did not establish that Fresenius materially breached the Hell-or-High-Water Covenant such that it should be barred from exercising an otherwise valid termination right.

III. CONCLUSION

Akorn brought this action seeking a decree of specific performance that would compel Fresenius to close. Akorn cannot obtain specific performance because three conditions to closing failed: the General MAE Condition, the Bring-Down Condition, and the Covenant Compliance Condition.

Fresenius sought a declaration that it had validly terminated the Merger Agreement on April 22, 2018. As of that date, Fresenius had not materially breached its obligations under the Merger Agreement and therefore could exercise its termination rights.

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[867] JX 1 § 5.03(c).

Fresenius validly terminated the Merger Agreement because Akorn's Regulatory Compliance Representations were untrue, the deviation from the representations could not be cured by the Outside Date, and the degree of deviation would reasonably be expected to result in a Regulatory MAE. This scenario caused the Bring-Down Condition to fail in an incurable manner and entitled Fresenius to terminate.

Fresenius also validly terminated the Merger Agreement because Akorn had materially breached the Ordinary Course Covenant and the breach could not be cured by the Outside Date. This scenario caused the Covenant Compliance Condition to fail in an incurable manner and entitled Fresenius to terminate.

Within ten days, the parties shall submit a joint letter identifying any other matters that need to be addressed to bring this matter to a conclusion at the trial level. If possible, the parties shall submit a final order implementing this decision that has been agreed as to form. If there are further issues to be resolved at the trial level, the parties shall propose a schedule for addressing them.