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M&A REPORT: *FRESENIUS* MARKS A WATERSHED DEVELOPMENT IN THE ANALYSIS OF "MATERIAL ADVERSE EFFECT" CLAUSES

To Our Clients and Friends:

On October 1, 2018, in *Akorn, Inc. v. Fresenius Kabi AG*,[1] the Delaware Court of Chancery determined conclusively for the first time that a buyer had validly terminated a merger agreement due to the occurrence of a "material adverse effect" (MAE). Though the decision represents a seminal development in M&A litigation generally, Vice Chancellor Laster grounded his decision in a framework that comports largely with the ordinary practice of practitioners. In addition, the Court went to extraordinary lengths to explicate the history between the parties before concluding that the buyer had validly terminated the merger agreement, and so sets the goalposts for a similar determination in the future to require a correspondingly egregious set of facts. As such, the ripple effects of *Fresenius* in future M&A negotiations may not be as acute as suggested in the media.[2]

Factual Overview

On April 24, 2017, Fresenius Kabi AG, a pharmaceutical company headquartered in Germany, agreed to acquire Akorn, Inc., a specialty generic pharmaceutical manufacturer based in Illinois. In the merger agreement, Akorn provided typical representations and warranties about its business, including its compliance with applicable regulatory requirements. In addition, Fresenius's obligation to close was conditioned on Akorn's representations being 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 an MAE. In concluding that an MAE had occurred, the Court focused on several factual patterns:

- **Long-Term Business Downturn**. Shortly after Akorn's stockholders approved the merger (three months after the execution of the merger agreement), Akorn announced year-over-year declines in quarterly revenues, operating income and earnings per share of 29%, 84% and 96%, respectively. Akorn attributed the declines to the unexpected entrance of new competitors, the loss of a key customer contract and the attrition of its market share in certain products. Akorn revised its forecast downward for the following quarter, but fell short of that goal as well and announced year-over-year declines in quarterly revenues, operating income and earnings per share of 29%, 89% and 105%, respectively. Akorn ascribed the results to unanticipated supply interruptions, added competition and unanticipated price erosion; it also adjusted downward its long-term forecast to reflect dampened expectations for the commercialization of its pipeline products. The following quarter, Akorn reported year-over-year declines in quarterly revenues, operating income and earnings per share of 34%, 292% and 300%, respectively. Ultimately, over the course of the year following the signing of the merger agreement, Akorn's EBITDA declined by 86%.

- **Whistleblower Letters**. In late 2017 and early 2018, Fresenius received anonymous letters from whistleblowers alleging flaws in Akorn's product development and quality control processes. In response, relying upon a covenant in the merger agreement affording the buyer reasonable access to the seller's business between signing and closing, Fresenius conducted a meticulous investigation of the Akorn business using experienced outside legal and technical advisors. The investigation revealed grievous flaws in Akorn's quality control function, including falsification of laboratory data submitted to the FDA, that cast doubt on the accuracy of Akorn's compliance with laws representations. Akorn, on the other hand, determined not to conduct its own similarly wide-ranging investigation (in contravention of standard practice for an FDA-regulated company) for fear of uncovering facts that could jeopardize the deal. During a subsequent meeting with the FDA, Akorn omitted numerous deficiencies identified in the company's quality control group and presented a "one-sided, overly sunny depiction."
- **Operational Changes**. Akorn did not operate its business in the ordinary course after signing (despite a covenant requiring that it do so) and fundamentally changed its quality control and information technology (IT) functions without the consent of Fresenius. Akorn management replaced regular internal audits with "verification" audits that only addressed prior audit findings rather than identifying new problems. Management froze investments in IT projects, which reduced oversight over data integrity issues, and halted efforts to investigate and remediate quality control issues and data integrity violations out of concern that such investigations and remediation would upend the transaction. Following signing, NSF International, an independent, accredited standards development and certification group focused on health and safety issues, also identified numerous deficiencies in Akorn's manufacturing facilities.

Conclusions and Key Takeaways

The Court determined, among others, that the sudden and sustained drop in Akorn's business performance constituted a "general MAE" (that is, the company itself had suffered an MAE), Akorn's representations with respect to regulatory compliance were not true and correct, and the deviation between the as-represented condition and its actual condition would reasonably be expected to result in an MAE. In addition, the Court found that the operational changes implemented by Akorn breached its covenant to operate in the ordinary course of business.

Several aspects of the Court's analysis have implications for deal professionals:

- **Highly Egregious Facts**. Although the conclusion that an MAE occurred is judicially unprecedented in Delaware, it is not surprising given the facts. The Court determined that Akorn had undergone sustained and substantial declines in financial performance, credited testimony suggesting widespread regulatory noncompliance and malfeasance in the Akorn organization and suggested that decisions made by Akorn regarding health and safety were re-prioritized in light of the transaction (and in breach of a highly negotiated interim operating covenant). In *In re: IBP, Inc. Shareholders Litigation*, then-Vice Chancellor Strine described himself as "confessedly torn" over a case that involved a 64% year-over-year drop-off in quarterly earnings amid allegations of improper accounting practices, but determined that no MAE had occurred because

the decline in earnings was temporary. In *Hexion Specialty Chemicals, Inc. v. Huntsman Corp.*, Vice Chancellor Lamb emphasized that it was "not a coincidence" that "Delaware courts have never found a material adverse effect to have occurred in the context of a merger agreement" and concluded the same, given that the anticipated decline in the target's EBITDA would only be 7%. No such hesitation can be found in the *Fresenius* opinion.[3]

- **MAE as Risk Allocation Tool**. The Court framed MAE clauses as a form of risk allocation that places "industry risk" on the buyer and "company-specific" risk on the seller. Explained in a more nuanced manner, the Court categorized "business risk," which arises from the "ordinary operations of the party's business" and which includes those risks over which "the party itself usually has significant control", as being retained by the seller. By contrast, the Court observed that the buyer ordinarily assumes three others types of risk—namely, (i) systematic risks, which are "beyond the control of all parties," (ii) indicator risks, which are markers of a potential MAE, such as a drop in stock price or a credit rating downgrade, but are not underlying causes of any MAE themselves, and (iii) agreement risks, which include endogenous risks relating to the cost of closing a deal, such as employee flight. This framework comports with the foundation upon which MAE clauses are ordinarily negotiated and underscores the importance that sellers negotiate for industry-specific carve-outs from MAE clauses, such as addressing adverse decisions by governmental agencies in heavily regulated industries.

- **High Bar to Establishing an MAE**. The Court emphasized the heavy burden faced by a buyer in establishing an MAE. Relying upon the opinions that emerged from the economic downturns in 2001 and 2008,[4] the Court reaffirmed that "short-term hiccups in earnings" do not suffice; rather, the adverse change must be "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." The Court underscored several relevant facts in this case, including (i) the magnitude and length of the downturn, (ii) the suddenness with which the EBITDA decline manifested (following five consecutive years of growth) and (iii) the presence of factors suggesting "durational significance," including the entrance of new and unforeseen competitors and the permanent loss of key customers.[5]

- **Evaluation of Targets on a Standalone Basis**. Akorn advanced the novel argument that an MAE could not have occurred because the purchaser would have generated synergies through the combination and would have generated profits from the merger. The Court rejected this argument categorically, finding that the MAE clause was focused solely on the results of operations and financial condition of the target and its subsidiaries, taken as a whole (rather than the surviving corporation or the combined company), and carved out any effects arising from the "negotiation, execution, announcement or performance" of the merger agreement or the merger itself, including "the generation of synergies." Given the Court's general aversion to considering synergies as relevant to determining an MAE, buyers should consider negotiating to include express references to synergies in defining the concept of an MAE in their merger agreements.

- **Disproportionate Effect**. *Fresenius* offers a useful gloss on the importance to buyers of including "disproportionate effects" qualifications in MAE carve-outs regarding industry-wide

events. Akorn argued that it faced "industry headwinds" that caused its decline in performance, such as heightened competition and pricing pressure as well as regulatory actions that increased costs. However, the Court rejected this view because many of the causes of Akorn's poor performance were actually specific to Akorn, such as new market entrants in Akorn's top three products and Akorn's loss of a specific key contract. As such, these "industry effects" disproportionately affected and were allocated from a risk-shifting perspective to Akorn. To substantiate this conclusion, the Court relied upon evidence that Akorn's EBITDA decline vastly exceeded its peers.

- **The Bring-Down Standard**. A buyer claiming that a representation given by the target at closing fails to satisfy the MAE standard must demonstrate such failure qualitatively and quantitatively. The Court focused on a number of qualitative harms wrought by the events giving rise to Akorn's failure to bring down its compliance with laws representation at closing, including reputational harm, loss of trust with principal regulators and public questioning of the safety and efficacy of Akorn's products. With respect to quantitative measures of harm, Fresenius and Akorn presented widely ranging estimates of the cost of remedying the underlying quality control challenges at Akorn. Using the midpoint of those estimates, the Court estimated the financial impact to be approximately 21% of Akorn's market capitalization. However, despite citing several proxies for financial performance suggesting that this magnitude constituted an MAE, the Court clearly weighted its analysis towards qualitative factors, noting that "no one should fixate on a particular percentage as establishing a bright-line test" and that "no one should think that a General MAE is always evaluated using profitability metrics and an MAE tied to a representation is always tied to the entity's valuation." Indeed, the Court observed that these proxies "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."

Fresenius offers a useful framework for understanding how courts analyze MAE clauses. While this understanding largely comports with the approach taken by deal professionals, the case nevertheless offers a reminder that an MAE, while still quite unlikely, can occur. Deal professionals would be well-advised to be thoughtful about how the concept should be defined and used in an agreement.

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[1] *Akorn, Inc. v. Fresenius Kabi AG*, C.A. No. 2018-0300-JTL (Del. Ch. Oct. 1, 2018).

[2] *See, e.g.*, Jef Feeley, Chris Dolmetsch & Joshua Fineman, *Akorn Plunges After Judge Backs Fresenius Exit from Deal*, Bloomberg (Oct 1, 2018) ("'The ruling is a watershed moment in Delaware law, and will be a seminal case for those seeking to get out of M&A agreements,' Holly Froum, an analyst with Bloomberg Intelligence, said in an emailed statement."); Tom Hals, *Delaware Judge Says Fresenius Can Walk Away from $4.8 Billion Akorn Deal*, Reuters (Oct. 1, 2018) ("'This is a landmark case,' said Larry Hamermesh, a professor at Delaware Law School in Wilmington, Delaware.").

[3] The egregiousness of the facts in this case is further underscored by the fact that the Court determined that the buyer had breached its own covenant to use its reasonable best efforts to secure antitrust clearance, but that this breach was "temporary" and "not material."

[4] *See, e.g.*, *Hexion Specialty Chems. Inc. v. Huntsman Corp.*, 965 A.2d 715 (Del. Ch. 2008); *In re: IBP, Inc. S'holders Litig.*, 789 A.2d 14 (Del. Ch. 2001).

[5] This view appears to comport with the analysis highlighted by the Court from *In re: IBP, Inc. Shareholders Litigation*, in which the court determined that an MAE had not transpired in part because the target's "problems were due in large measure to a severe winter, which adversely affected livestock supplies and vitality." *In re: IBP*, 789 A.2d at 22. In this case, the decline of Akorn was not the product of systemic risks or cyclical declines, but rather a company-specific effect.

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