Attorney Brian Glasser Breaks Down Akorn v. Fresenius

11.15.2018

DELAWARE COURT ALLOWS FRESENIUS TO TERMINATE$4.75 BILLION DEAL TO ACQUIRE FELLOW DRUG MAKER AKORN INC.BECAUSE OF "MATERIAL ADVERSE EFFECT" CLAUSE AND BECAUSE AKORN

INC. MATERIALLY BREACHED ITS DUTY TO CONTINUE OPERATING IN THE

ORDINARY COURSE OF BUSINESS BETWEEN SIGNING AND CLOSING

By Brian A. Glasser

On October 1, 2018, the Delaware Chancery Court issued a landmark ruling that allowed German healthcare company Fresenius SE to terminate its $4.75 billion deal to purchase U.S. drug maker Akorn Inc.: (1) because of "material adverse effects" at Akorn following the signing of the merger deal and prior to its closing; and (2) because Akorn materially breached its duty to continue operating in the ordinary course of business between signing and closing. *See Akorn Inc. v. Fresenius Kabi AG*, No. 2018-0300, 2018 WL 4719347 (Del. Ch. Ct. Oct. 1, 2018).

The opinion is historic because it represents the first time that a Delaware court has permitted an acquiring company to invoke a material adverse effect, or "MAE," clause to nix a deal. Such provisions are typically termed "MAE" or "MAC" clauses, the latter acronym standing for "material adverse change." *Id.* at *47-48 & n.524 (using "MAE" and "MAC" interchangeably and collecting authorities supporting the view that "'MAC and MAE are generally understood to be synonymous'"). Occasionally, such provisions are referred to as "merger escape clauses" as well.

Vice Chancellor Travis Laster issued the watershed decision after conducting a five-day trial on July 9-13, 2018, during which 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. *Id.* at *4.

As the Vice Chancellor explained, "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." *Id.* at *1-2. The economic decline then continued.

In short, Akorn had predicted annual revenue of more than $1 billion and nearly $350 million of EBITDA. By the end of 2017, the firm had $841 million of sales, and EBITDA fell 80 percent below its projection.

The trial focused on the cause of this financial shortfall. As the Court stated, "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." *Id.* at *2. Fresenius thus claimed at trial that Akorn misrepresented its compliance with FDA regulations, and that Akorn had been careless with — or even "fabricated" (*see, e.g.*, *id.* at *31-32) — its FDA test data.

Vice Chancellor Laster sided with Fresenius. He wrote: "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." *Id.* at *93.

In making its rulings, the Court found that the Merger Agreement imposed a number of duties and that "closing . . . was not a foregone conclusion." *Id.* at *1. More specifically, the Court found that: "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.'" *Id.* "Second, Fresenius's obligation to close was conditioned on Akorn having complied in all material respects with its obligations under the Merger Agreement." *Id.* And "[t]hird, Fresenius's obligation to close was conditioned on Akorn not having suffered a Material Adverse Effect." *Id.*

The Court explained generally that, "[i]n 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.'" *Id.* at *47 & n.524; *see generally* 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); 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."); 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.").

The *Akorn* Court summarized its principal rulings as follows: "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." *Id.* at *3.

The Court's ruling on "quantitative significance," or materiality, is noteworthy. *Id.* at *71-73. "The total purchase price was $4.75 billion, comprising $4.3 billion in cash plus assumption of approximately $450 million in debt." *Id.* at *19. The evidence showed that "Akron had pervasive regulatory issues that would require years to fix" — either three years or four years, depending on which side one believed. *Id.* at *82. And rather than costing $44 million to fix as Akron claimed, the Court estimated the overall cure to involve around $1 billion. As the Court explained: "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. . . . 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%." *Id.* at *74. In other words, an unexpected hit of nearly 21% in the equity value of a deal should be considered material, according to the Court.

Also noteworthy is the Court's ruling that Akorn breached its duty to continue operating in the ordinary course of business between signing and closing. *Id.* at 87-89. As the Court explained, "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. The record establishes that Akorn breached that obligation in multiple ways." *Id.* at *87-88 (footnote omitted). "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." *Id.* at 88. "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." *Id.* "Third, a generic pharmaceutical company operating in the ordinary course of business does not submit regulatory filings to the FDA based on fabricated data." *Id.* Moreover, Akorn "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. [But] Akorn chose not to conduct an investigation of its own." *Id.* Thus, the Court concluded, "[w]hen making decisions about not remediating deficiencies, not continuing its audit program, not maintaining its data integrity, and not conducting investigations, Akorn chose consciously to depart from the ordinary course of business that a generic pharmaceutical company would follow. As a result, Akorn did not use commercially reasonable efforts to operate in the ordinary course." *Id.* at 89.

This is a landmark ruling for those seeking to escape M&A agreements, and a cautionary tale for those seeking to enforce them. Attorneys can no longer claim that Delaware has never permitted a material adverse effect, or MAE, clause to end a deal. This is not to say, of course, that every time a target company has a bad quarter or two, an acquiring company can automatically kill a deal. Fresenius keenly based its case on ***both*** Akorn's dramatic financial tailspin ***and*** Akorn's misrepresentations regarding regulatory failures, and thus, the practitioner is advised to look at all possible evidentiary and legal angles before attempting to follow in the shoes of Fresenius. Accordingly, while the *Akorn* opinion is certainly long and intricate — being almost 250 pages in length — it is worth a close read because it opens up a new avenue for both transactional lawyers and litigators to consider in the context of M&A deals gone wrong.

The case is currently under appeal.

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