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Client Alert

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Channel Medsystems v. Boston Scientific: Establishing a Material Adverse Effect in Delaware Continues to Require a Showing of Lasting Effects on Business

After *Akorn*, Delaware continues to see "heavy burden" for establishing a Material Adverse Effect

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On December 18, 2019, the Delaware Court of Chancery, in *Channel Medsystems, Inc. v. Boston Scientific Corporation and NXT Merger Corp.*, reiterated the "heavy burden" for establishing a Material Adverse Effect ("MAE") under its landmark 2018 decision, *Akorn, Inc. v. Fresenius Kabi AG*, the first Delaware case to find that an MAE had occurred. Specifically, the Court ruled that despite proving Channel had made certain inaccurate representations when the merger agreement was signed, Boston Scientific failed to show that the misrepresentations had a lasting effect on Channel's business, and therefore the Court required Boston Scientific to close the acquisition.

BACKGROUND

In November 2017, Channel and Boston Scientific entered into a merger agreement. The closing of the merger was conditioned on Channel receiving approval from the FDA for its sole product, the "Cerene" device intended to treat heavy menstrual bleeding. In late December 2017, Channel discovered that its Vice President of Quality, Dinesh Shankar, had stolen approximately $2.6 million from Channel by falsifying reports and routing payments to shell companies controlled by Shankar. Channel also learned it had included information falsified by Shankar in its submissions to the FDA regarding the Cerene device.

In mid-January 2018, Channel reported Shankar's fraud to the Department of Justice and retained a consultant, Greenleaf, to conduct an independent assessment of its quality control systems and its investigation of Shankar's fraud. Next, Channel informed the FDA of Shankar's fraud and of the steps it was taking to address the fraud. The FDA asked Channel to withdraw and resubmit its application for the

approval of Cerene, which Channel did in February 2018. In March 2018, the FDA indicated to Channel executives that it was grateful for Channel's transparency and, in April 2018, the FDA approved Channel's plan for remediation of Shankar's fraud. Channel kept Boston Scientific fully apprised of its efforts and findings in real time.

The Court found that the FDA's approval of the remediation plan signaled that the "fraud would not be the cause of any failure of the FDA to approve the Cerene device." Nonetheless, Boston Scientific terminated the merger agreement in May 2018 on the grounds that Channel's representations and warranties at the time the merger agreement was signed were inaccurate, and those inaccuracies would reasonably be expected to have an MAE on Channel. The merger agreement contained a customary definition of "Material Adverse Effect": "[A]ny change or effect occurring after the Agreement Date that, when taken individually or together with all other adverse changes or effects occurring after the Agreement Date, is materially adverse to the business, results of operations, assets or financial condition of [Channel]." Boston Scientific later claimed that, notwithstanding Channel's receipt of FDA approval, it would need to remediate and retest Cerene before putting it on the market and that the substantial cost and lost profits from doing so would constitute an MAE.

The FDA approved Channel's application for pre-market approval of Cerene in March 2019.

COURT OF CHANCERY DECISION

In September 2018, Channel sued Boston Scientific in the Delaware Court of Chancery alleging wrongful termination of the merger agreement. Channel sought specific performance of the merger agreement on the grounds that that no MAE had occurred and, accordingly, Boston Scientific had no right to terminate.

The Court, relying on *Akorn*, conducted a fact-intensive quantitative and qualitative analysis to determine whether, based on the facts as of the date on which Boston Scientific terminated the merger agreement, the inaccuracy of Channel's representations and warranties would reasonably be expected to have an MAE. Quoting *Akorn*, the Court noted that the "important consideration…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 reasonable period, which one would expect to be measured in years rather than months." The Court found that although some of Channel's representations and warranties were inaccurate as of the date of the merger agreement, the inaccuracies did not rise to the level of an MAE.

In its quantitative review, the Court sought to determine whether Shankar's fraud and the related misrepresentations made it reasonable to expect that the long-term value of Channel had been substantially impaired. Boston Scientific provided an expert witness who estimated that Channel's value had decreased by 24% to 54%. However, the Court gave little weight to this witness's testimony because, among other things, his calculation of loss was predicated on a projected two-year delay in putting Cerene to market. The Court determined that it was not commercially reasonable to delay putting Cerene to market in order to retest it and therefore, the two-year delay should not have been factored into the witness's calculation of loss. The Court also found that the calculation of loss included anticipated merger synergies rather than valuing Channel on a standalone basis, making it an unreliable measure.

The Court's qualitative analysis focused on the fact that, despite Boston Scientific's claims that its decision to terminate the merger agreement was based on a well-founded belief that Cerene would not be marketable without going through the full FDA approval process again, Boston Scientific did not generate a "single scrap of paper" assessing the impact of Shankar's fraud on Channel's quality system and the marketing of Cerene, noting that the lack of any such documentation "casts doubt on the bona fides of the termination decision." The Court also noted that the Boston Scientific executive who terminated the merger agreement did not even consult with any of the other executives "whose perspectives on Channel and terminating the Agreement would seem highly relevant." The Court further stated that "the introduction of any new healthcare product inherently carries a risk of future regulatory action, thus Boston Scientific must show that Shankar's fraud would reasonably be expected to significantly increase this risk. It has not done so."

KEY TAKEAWAYS

- **Even after *Akorn*, it remains very difficult to establish an MAE.** In its landmark 2018 *Akorn* decision, the Delaware Court of Chancery did find that an MAE had occurred and released the acquiror from its obligation to close a transaction. The Court found that a severe decline in the target's financial performance, which had already persisted for a year and showed "no signs of abating," constituted a substantial decline in the overall earnings potential of the target in a durationally significant manner, leading the Court to find that an MAE had occurred. Despite the Court's finding that an MAE had occurred in *Akorn*, acquirors continue to face a "heavy burden" in seeking to walk away from deals on the basis of an alleged MAE.
- **Expect Delaware courts to engage fully with the factual record in determining whether an MAE has occurred.** The facts in *Akorn* were egregious: the target company was in "persistent, serious violation of FDA requirements with a disastrous culture of noncompliance" and suffered a severe decline in financial performance on a year-over-year basis. At the time of the trial for *Akorn*, Akorn's financial performance had been declining for a full year and was projected to continue declining. In contrast, in *Channel*, the target made false representations and suffered an unforeseen but fundamentally limited fraud by one of its employees. After extensive factual analysis, the Court did not find this to be the type of long-term and systemic issue that would result in an MAE.
- **Foreseeable risks should be accounted for in the contract.** Delaware courts are reluctant to allow parties to walk away due to changing circumstances absent a specifically bargained-for right to do so. In *Channel*, the Court cited evidence that Boston Scientific may have been "looking for a way out of its deal…due to growing concerns that Cerene would be difficult to market" – as opposed to its stated rationale for termination, an MAE stemming from Shankar's fraud. Where specific risks are identified during diligence or negotiations, parties should consider incorporating objective criteria into closing conditions, rather than relying on the MAE standard.

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