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*Court of Chancery Confirms that, Post-*Akorn*, It Will Evaluate MACs Under the Traditional Framework*–Channel v. Boston Scientific

Channel Medsystems, Inc. v. Boston Scientific Corporation (Dec. 18, 2019) is the Delaware Court of Chancery's first decision issued since the Delaware Supreme Court's 2018 *Akorn* decision to evaluate whether an acquiror had a right, under a merger agreement, to terminate a pending acquisition on the grounds that there was a "Material Adverse Effect" or "Material Adverse Change" in the target company. (We use "MAE" and "MAC" interchangeably in this memorandum.) *Akorn* was the first case in which the Court of Chancery, post-trial, found the existence of an MAE and the first post-trial Delaware decision to find that an acquiror had the right to terminate a merger agreement based on an MAE. In *Channel*, by contrast, Chancellor Bouchard ruled, after trial, that there was *not* an MAE and that the acquiror was required to close the merger.

Both *Akorn* and *Channel* involved the discovery, between signing and closing of a merger agreement, that a target company executive, without knowledge of the target, had submitted fraudulent reports to the Food and Drug Administration relating to the company's products (in *Akorn*, the target's key products, and in *Channel*, the target's sole product). In *Akorn*, there was a dramatic decline in the target company's financial performance and a severe and "durationally significant" loss of its potential future earnings due to the regulatory noncompliance. In *Channel*, however, before the acquiror sought to terminate the transaction, the FDA had accepted the target's remediation plan (which indicated that FDA approval of the target's product was likely); the remediation plan did not appear to involve significant ongoing costs or other effects on the target; and, prior to trial, the FDA approved the product. The Chancellor held that the acquiror had failed to prove, on a quantitative or qualitative basis, that an MAE would be reasonably expected to occur, and thus it did not have a right to terminate the agreement.

Key Points

- ***Channel* indicates that, post-*Akorn*, the court continues to evaluate MAEs under the traditional Delaware framework, which sets a high bar to a finding of an MAE.** While *Akorn* serves as a reminder that an acquiror may, in an unusual set of circumstances, have the right to terminate a merger agreement based on an MAE, *Channel* indicates that *Akorn* did not signal a change in the Delaware courts' traditional approach to evaluating MAEs. Under that approach, the court evaluates whether the developments at issue reflect a material change in the target's long-term future earnings potential. We observe that, even though the court never found an MAE before *Akorn*, the facts in *Akorn* appear to have presented a relatively easy case for a finding of an MAE. At the same time, the facts in *Channel* appear to have presented a relatively easy case for a finding of *no* MAE. Thus, although other commentators have stated that *Channel* confirms

that post-*Akorn* there will continue to be a high bar to a finding of an MAE–and although as we read *Akorn*, it did not suggest that there would be any lowering of the traditionally high bar–in our view, *Channel* does not appear to have provided a real test of that theory.

- **The court clarified that (i) the concept of materiality in a representation (such as "material compliance" or "compliance in all material respects" with laws) is "analytically distinct" from (ii) the concept of an "MAE" that would trigger a right to terminate an agreement (under a condition relating to the accuracy of representations or a termination right).** In *Channel*, the court confirmed that, with respect to (i) above, the applicable standard is whether the inaccuracy in the representation would, from the viewpoint of a reasonable investor or acquiror, *alter the "total mix" of the information made available*; while, with respect to (ii) above, the applicable standard is whether the changes that occurred represented, from the viewpoint of a reasonable long-term investor or acquiror, *a material decline in the long-term earnings potential of the company*. The court expressly rejected the acquiror's contention that the "total mix" disclosure-based standard should apply in both contexts. (We note that the court did not appear to address which standard would apply when an "MAE" is the materiality qualifier *in a representation*–for example, a representation that the company has complied with all laws except to the extent that any non-compliance would not reasonably be expected to result in an MAE.)

- **The acquiror did not present evidence that substantiated a likelihood of a significant effect on the target's long-term earnings power as a result of its regulatory noncompliance.** The decision underscores that the party alleging an MAE has the burden of proof and must show some basis in fact for the serious adverse consequences on the target that it believes have occurred or will occur. As noted, in this case, the FDA approved the target's product (within the timeframe the parties had expected when they signed the merger agreement) and the remediation costs and effects of the regulatory noncompliance did not appear to be significant. Moreover, the acquiror appeared not to have even investigated or analyzed in a meaningful way what those costs or effects would be.

- **The court believed that the acquiror wanted to terminate the deal for other reasons and might be using the alleged MAE as a pretext.** There was contemporaneous evidence that the acquiror wanted to terminate the transaction for reasons unrelated to the alleged MAE. The court emphasized that the target, on the other hand, acted transparently with both the acquiror and the FDA. (We note that *Akorn* was decided in the opposite context–there, in the Delaware Supreme Court's view, the target company continued to fraudulently hide information from the acquiror and the FDA while the acquiror continued to work diligently toward closing while it was evaluating whether it had a right to terminate.)

- **An agreement to use "commercially reasonable efforts" (or similar standards, such as "reasonable best efforts") to close a merger imposes meaningful obligations.** The court held that the acquiror breached its merger agreement covenant to use "commercially reasonable efforts" to close. The court reaffirmed that (as was also indicated in *Akorn*) this type of standard requires that a party must "take all reasonable steps *to solve problems*" (emphasis added) so that the transaction can be consummated.

Background

On November 1, 2017, Boston Scientific Corporation and Channel Medsystems, Inc. entered into a Merger Agreement pursuant to which Boston Scientific would acquire Channel in a $275 million merger. Channel, a privately owned early-stage medical device development company, had only one product in

development–the "Cerene" cryotherapy medical device. The Merger Agreement provided that Boston Scientific was required to close only if, among other conditions, Channel received FDA approval for Cerene by September 30, 2019. In late December 2017, Channel discovered that its Vice President of Quality ("DS") had falsified expense reports and other documents as part of a fraudulent scheme by which he stole about $2.6 million from the company. Some of the fraudulent documents related to the integrity of the Company's product quality testing on Cerene and had been included in Channel's submissions to the FDA seeking approval of Cerene. Promptly after discovering DS's fraud, Channel notified Boston Scientific and the FDA, conducted an investigation, and took actions to remediate the fraud. On April 18, 2018, the FDA accepted Channel's remediation plan, which (in the court's words) "strongly signaled that DS's fraud would not be the cause of any failure by the FDA to approve Cerene and made the FDA's approval a distinct possibility."

Notwithstanding the positive response from the FDA, on May 11, 2018, Boston Scientific terminated the Merger Agreement, claiming that the fraudulent FDA filings rendered Channel's representations in the Merger Agreement inaccurate to the extent that an MAE would reasonably be expected. On March 28, 2019 (about a month prior to the commencement of the trial before the Court of Chancery), the FDA approved Cerene. After trial, Chancellor Bouchard held that Channel's representations in the Merger Agreement relating to material compliance with "Healthcare Laws" were inaccurate when made, but that Boston Scientific failed to prove that the inaccuracies reasonably would be expected to have an MAE. The Chancellor also found that Boston Scientific breached its obligation under the Merger Agreement to use "commercially reasonable efforts" to consummate the merger. The Chancellor therefore ordered specific performance requiring Boston Scientific to close.

The Merger Agreement Provisions

- ***Representation.*** Channel represented that it was "in material compliance with all Healthcare Laws."
- ***Condition.*** Boston Scientific's obligation to close was conditioned on each of Channel's representations having been "true and correct at the time originally made…except to the extent that the failure of any of [them] to be true and correct does not have and would not reasonably be expected to have [an MAE] on Channel" (the "Representations Condition").
- ***Termination rights.*** Boston Scientific had the right to terminate the Agreement "at any time" if (i) any of Channel's representations was "inaccurate or shall have been breached as of the [date of the Agreement]…such that the [Representations Condition] would not be satisfied"; or (ii) prior to closing, subject to a "cure" provision, an MAE in Channel shall have occurred.

Discussion

Distinctions from *Akorn*. Notwithstanding the similar basic factual context in the two cases, the different judicial conclusion in each with respect to an MAE is readily understood based on the important factual differences between them. Specifically:

- ***Financial decline.*** In *Akorn*, shortly after the merger agreement was signed, Akorn's financial performance "fell off a cliff." EBITDA fell by 86% and analysts' valuations dropped from about $32 per share to a range of about $5 to $12 per share. The Delaware Supreme Court held that this dramatic decline in financial performance, with no signs of it abating, constituted a MAC in Akorn. By contrast, in *Channel*, there was no actual financial decline in Channel and, in light of the FDA approval for the product having been received and the regulatory compliance having been largely

remediated without significant cost, the Court of Chancery found implausible Boston Scientific's contentions that an MAE would reasonably be expected .

- ***Ongoing effects of the regulatory noncompliance.*** In *Akorn*, the Supreme Court held that Akorn's regulatory noncompliance constituted a second, independent basis for a finding of a MAC, given that the required remediation efforts would take several years, impose huge costs (representing approximately 21% of the target company's standalone equity value), and have lasting "qualitative" effects on the company's long-term earnings potential. By contrast, in *Channel*, as noted, Channel had largely completed remediation, regulatory approval had been obtained, and it did not appear that there would be significant ongoing costs or other effects from the noncompliance that had occurred.

- ***Transparency and efforts to close.*** In *Akorn*, in the Supreme Court's view, after the fraud was discovered, Akorn continued to engage in fraudulent conduct to hide the extent of the problem from the FDA and the acquiror. Also, the Supreme Court held that Akorn had breached its covenant under the merger agreement to operate in the ordinary course of business pending closing (based on the Supreme Court's view that Akorn had not acted with respect to regulatory compliance as would have been expected of a "generic pharmaceutical company"). The Supreme Court emphasized that, on the other hand, the acquiror had attempted to problem-solve and had continued to work diligently toward closing even while evaluating whether it had the right to terminate the transaction. By contrast, in *Channel*, in the Court of Chancery's view, Channel was open and transparent with both Boston Scientific and the FDA and diligently worked toward a closing. On the other hand, according to the Court of Chancery, Boston Scientific appeared to want to terminate the deal for unrelated reasons and, in the court's opinion, breached its covenant to use commercially reasonable efforts to close.

The court found that Channel's representations relating to material compliance with "Healthcare Laws" were inaccurate when made. Only six reports submitted to the FDA, out of well over a hundred total reports submitted, included falsified data. Moreover, Channel's thorough independent investigation concluded that the falsified data did not change the conclusions of the affected reports. Nonetheless, the court found (although it stated that this was a "close call") that the preponderance of evidence suggested that Channel's testing design failures and the falsified reports submitted to the FDA changed the "total mix" of information available to Boston Scientific at the time of signing of the Merger Agreement–and thus rendered inaccurate when made Channel's representations that it was in material compliance with Healthcare Laws. (While there was also a "bring-down" condition requiring that the representations would be accurate at the time of closing, that provision was not at issue in the case.) The court found that the fact of the design failures and false records relating to the testing of the company's only product "likely would be significant to a reasonable acquiror." In particular, the court wrote, an investor likely would find significant that the noncompliance related to the "quality regulation system" (with false records about "equipment calibration, sterility, and device packaging used in verification and validation testing of the [Company's product]"). Further, the court wrote, "[e]ven if the falsified records did not impact the integrity of the design history file, the very fact that there were falsified records in the design history file would [(prior to the receipt of the FDA approval), have called into] question Channel's ability to secure FDA approval."

The court found that the inaccuracy of Channel's representations did <u>not</u> constitute an MAE. Consistent with past decisions (including *Akorn*), the court considered both "quantitative and qualitative factors" to determine if "the deviation between the as-represented condition [of the target company] and the actual condition would reasonably be expected to constitute [an MAE]." The court emphasized that "a

mere risk of an MAE cannot be enough"; rather, an acquiror claiming an MAE must provide evidence of the occurrence or likelihood (as the case may be) of the "serious adverse consequences [that it has] prophesied." Although Boston Scientific asserted that it would still need to remediate and retest Cerene before placing it on the market, and that this would involve significant cost, the court noted that this was not necessarily so and that "no one at Boston Scientific" took steps to understand what Channel had done to improve the company's quality systems after discovery of the fraud nor to quantify the costs involved in remediation or retesting that might be required.

The court found that Boston Scientific breached its covenant to use "commercially reasonable efforts" to close. The court reaffirmed that, as amplified in *Akorn*, the Delaware law "contains little support for distinctions" between the clauses "commercially reasonable efforts" and "reasonable best efforts." The court also reaffirmed the concept elucidated in *Akorn* that these standards impose an obligation to "take all reasonable steps to solve problems" so that a transaction can be consummated. The court found that Boston Scientific made no reasonable efforts to engage with Channel or "to take other appropriate actions to attempt to keep the deal on track"–rather, it "simply pulled the ripcord." According to the court, Boston Scientific did not seek additional information from Channel; did not consult with outside experts; did not evaluate Channel's clinical data, quality system, product, or remediation efforts; did not respond to Channel's requests to meet; and did not identify any specific concerns it had. The court also stated that a "lack of good faith" by Boston Scientific was "corroborated by contemporaneous evidence that [it] was looking for a way out of its deal with Channel" for reasons unrelated to the alleged MAE.

Contemporaneous evidence indicated that Boston Scientific wanted to terminate the deal for reasons unrelated to the alleged MAE. Emails and other communications among Boston Scientific executives indicated that Boston Scientific wanted to terminate the deal due to growing concerns that Cerene would be difficult to market and that the proposed transaction was complicating a potential divestment of a part of Boston Scientific's business. These communications also suggested that the executives were largely unconcerned about DS's fraud. Boston Scientific argued that "motive to avoid a deal does not demonstrate the lack of a contractual right to do so"–*i.e.*, its motives to terminate the deal, whatever they may have been, were unrelated to the issue whether or not it had a right to terminate. The court stated that this was "true but beside the point"--as "[t]he evidence of Boston Scientific's motives simply adds credence to and corroborates other robust facts demonstrating that Boston Scientific did not fulfill its obligations to engage with Channel in a commercially reasonable manner to vet any concerns it may have had about [DS's fraud] and to keep the transaction on track thereafter."

Practice Points

- ***To substantiate an MAE, a buyer must seek to provide actual evidence of "quantitative and qualitative effects" on the target company's long-term earnings potential on a stand-alone basis.*** As was emphasized in *Akorn*, when (as is typical) the definition of "MAE" set forth in the agreement excludes the effects of industry-wide conditions, the effects must be based on "company-specific" factors. Also, the effects must have "durational significance" ("measured in years rather than months"). There is no bright-line test to determine an MAE. The treatise by Kling and Nugent observes that "most courts that have considered decreases [in a company's earnings] in the 40% or higher range found [an MAE] to have occurred." In *Akorn*, the Court of Chancery found that either the 86% decline in EBITDA or, separately, the remediation costs that were equal to about 21% of the company's market capitalization, "would be material when viewed from the longer-term perspective of a reasonable acquiror." In *Channel*, the court found that the acquiror presented no evidence that reasonably suggested that an MAE would be expected.

- ***A buyer who has identified a possible right to terminate a merger agreement should consider to what extent, pending its evaluation, it should nonetheless continue with efforts to close the transaction.*** The agreement language and the specific facts and circumstances will be significant factors in what the appropriate extent of efforts to close will be while a buyer is considering the possibility that it has a right to terminate. If a buyer decides to terminate, the record should reflect that the desire to terminate is not based on general "buyer's remorse" but on specific factors that, under the merger agreement, could provide a right of termination. In *Channel*, *Akorn* and other decisions, the court has viewed as favorable to the buyer's case that it fulfilled its "efforts" obligations that, even after it began to evaluate its termination rights, it continued to communicate with the target, pursue regulatory approvals, proceed with integration planning and/or seek to problem-solve so that the transaction could close.

- ***Parties should consider drafting a tailored MAE clause.*** *Channel* involved a typical MAE definition–"any 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]." Parties to a merger agreement should carefully review all of the general and specific risks that may be applicable prior to closing and decide whether any should expressly be allocated to the target (*i.e.*, expressly included in the MAC definition) or to the acquiror (*i.e.*, expressly excluded from the MAC definition). Parties and their advisors should seek to ensure that all of the relevant risks that are specific to the company, that have a significant likelihood of occurring, and/or that would be likely to have a meaningful impact, have been identified and considered. Counsel should ensure that the wording accurately reflects the parties' intentions with respect to the allocation of risks. Of course, in all cases, whether a counterparty will accept the allocation to it of any particular risk is a matter of negotiation between the parties. (For additional considerations relating to MAEs, and other drafting issues the court discussed in *Akorn*, see our memorandum, "Court of Chancery's Commentary in *Akorn*–on MAC and Other Standard Merger Agreement Provisions–Prompts New Drafting Considerations.")

- ***The specific facts and circumstances are critical when evaluating an MAE-based termination right.*** We note that, if the FDA had *not* accepted Channel's remediation plan before Boston Scientific tried to terminate the deal and/or had *not* approved its sole product before the trial commenced in the Court of Chancery, Boston Scientific might well have been able to establish that the fraudulent activity with respect to Channel's sole product would reasonably have been expected to result in an MAE. In addition, it bears emphasis that the overall context–including the parties' respective actions and omissions, and the record of emails and other communications between parties, can have a critical impact on the court's view of whether a buyer has a legitimate termination right under a merger agreement.

- ***MAE considerations may be different in the context of a transaction with a financial buyer***. While not an issue in *Channel*, we note that in *Akorn* the court observed (in a footnote) that commentators have suggested that the requirement of "durational significance" in evaluating whether an MAE occurred may not apply in the context of a transaction where the buyer is "a financial investor with an eye to a short-term gain." Accordingly, a financial buyer, in evaluating whether an MAE has occurred, should argue that the relevant time period for "durational significance" should be shorter than in the case of a strategic buyer (and, further, could seek to define the applicable time period in the merger agreement). In addition, in the context of a transaction with a financial buyer, both parties should understand the relationship between the

conditions in the financing, and the deal conditions in the merger agreement, with respect to an MAE.

- ***Drafting points.*** **(i)** ***Materiality "scrape."*** The *Channel* Merger Agreement was somewhat unusual in that the Representations Condition was that *each* representation was true and correct except to the extent of an MAE–rather than, as would be more typical, that the representations, taken together and without taking into consideration the materiality qualifiers therein, were true and correct except to the extent of an MAE. The more typical formulation is more favorable to a buyer because a representation with a deficiency, even if not to a degree that would constitute an MAE, would be evaluated together with the deficiencies in the other representations to determine whether they, in the aggregate, would constitute an MAE. In *Channel*, the different drafting made no difference because there were not multiple developments that purportedly created the MAE (thus, the regulatory noncompliance, standing alone, either did or did not constitute an MAE notwithstanding this aspect of the drafting of the condition). **(ii) C*ure right.*** The *Channel* Merger Agreement's MAE-based termination right was subject to a right to "cure" the MAE. We would observe that the possibility of a cure for adverse developments that have occurred arguably may be inconsistent with the concept (which was emphasized in both *Channel* and *Akorn*) that an MAE is based on the long-term nature of the consequences of adverse developments.

- ***MAE timing issues.*** In *Channel*, the court observed that a right to terminate based on inaccuracies in the representations to the extent of an MAE being reasonably expected is an "objective standard." The court stated that "the logical time to test whether a party had an objective right to terminate [on these grounds] is to examine the facts and circumstances when the party actually took action to terminate." In addition, the court addressed "the precise timeframe in the future for examining whether an MAE would reasonably be expected." The issue had little relevance in this case in light of the court's conclusion that the inaccuracy of Channel's representations would not reasonably be expected to have an MAE at *any* point in the future. Generally, however, the court indicated, the burden on a buyer seeking to terminate based on representations being inaccurate to the extent of a forward-looking MAE would be "to prove that, as of the termination date, the inaccurate representations…would reasonably be expected to have an [MAE] on [the target] around the time the parties [otherwise] expected the merger to close."

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