BACK TO THE FUTURE: DELAWARE COURT AGAIN REJECTS BUYER'S CLAIM OF AN MAE

On July 9, 2021, Vice Chancellor Slights of the Delaware Court of Chancery, in Bardy Diagnostics, Inc. v Hill-Rom, Inc. (Del. Ch. July 9, 2021), ordered specific performance to compel Hill-Rom, Inc. ("Hillrom"), a publicly held, global medical technology company, to close the acquisition of Bardy Diagnostics, Inc. ("Bardy"), a medical device startup, upon finding that Hillrom failed to prove that a significant decrease in the Medicare reimbursement rate for Bardy's sole product offering constituted a Material Adverse Effect ("MAE"), as defined in the merger agreement.

BACKGROUND

Bardy has a single product offering on the market: an ambulatory electrocardiogram device marketed as the Carnation Ambulatory Monitor ("CAM") patch. One of Bardy's largest sources of revenue is through Medicare reimbursements for the CAM patches. The Centers for Medicare & Medicaid Services ("CMS"), an arm of the federal Department of Health and Human Services, develops and administers Medicare's reimbursement policy. CMS, in turn, authorizes a private entity, Novitas Solutions, Inc. ("Novitas"), to set the reimbursement rates applicable to the CAM patch, which in 2020, was approximately $365 per CAM patch.

On January 15, 2021, the parties entered into a definitive merger agreement pursuant to which Hillrom would acquire Bardy for $375 million, plus potential earnouts linked to CAM

patch revenues in 2021 and 2022. Although Hillrom believed that Bardy had significant growth potential, it estimated that Bardy would likely not turn a profit before 2023.

Two weeks following the signing of the merger agreement, Novitas announced the new reimbursement rates applicable to the CAM patch – $42.68 per CAM patch in Texas and $49.70 per CAM patch in New Jersey (the two jurisdictions in which Bardy operates), which was a significant decrease from the prior rate of approximately $365 per CAM patch. Soon after, Hillrom gave Bardy notice that it would not close on the transaction, stating that the new reimbursement rates constituted an MAE under the merger agreement. Bardy subsequently filed a complaint seeking specific performance and monetary damages. In early April 2021, Novitas increased the reimbursement rate to roughly $133 per patch, still less than half the historic rate.

ANALYSIS

In ultimately rejecting Hillrom's claim that an MAE occurred, the Court undertook a thorough analysis of the specific facts, the language of the MAE definition and Delaware law, and assessed many common themes in Delaware MAE cases, including durational significance of a claimed MAE, the applicability of carve-outs to the MAE definition and the applicability of a "disproportionate impact" exclusion from the MAE carve-outs. We've summarized the noteworthy analysis and findings of the Court below.

MAE definition and burden of proof

The merger agreement defined an MAE as "any fact, event circumstance, change, effect or condition that, individually or in the aggregate, has had, or would reasonably be expected to have a material adverse effect on … [Bardy's business], taken as a whole." The merger agreement included specific carve-outs from the MAE definition, including "any change in any Law (including … any Health Care Law) … or any interpretation thereof" and provided for an exception to certain of such carve-outs, stating that a carved-out event can nonetheless constitute an MAE to the extent it has a "materially disproportionate impact on [Bardy] as compared to other similarly situated companies operating in the same industries or locations, as applicable, as [Bardy's business]."

In its opinion, the Court explained that when a buyer seeks to avoid closing by invoking an MAE clause, the buyer bears the initial burden to prove that the seller suffered an effect that was material and adverse. Upon satisfying that burden, the burden then shifts to the seller to prove that the source of the effect fell within a carve-out. If the seller satisfies that burden, then the buyer must prove that an exclusion to the carve-out applies.

Reimbursement rate decrease was an "event" impacting Bardy's business

In its analysis, the Court first addressed Bardy's argument that the reimbursement rate decrease was not an "event" because "the risk of a change in reimbursement rates was not 'unknown' at the time the parties signed the merger agreement." The Court noted that in *Akorn, Inc. v. Fresenius Kabi AG*, Vice Chancellor Laster expressly rejected the argument that an event could not qualify as an MAE because it was discoverable during diligence. The Court further explained that the parties could have written the MAE to include only "*unknown* facts, events, circumstances, changes, effects or conditions", but

they instead chose to adopt a broadly-worded general MAE with qualifying language and a list of carve-outs. Enforcing the MAE as written, the Court found that "there is no room for the construction that an 'event' under the merger agreement's MAE can only be an unanticipated event", and therefore rejected Bardy's argument.

Reimbursement rate decrease was not an MAE

The Court then turned to whether the reimbursement rate decrease constituted an MAE under the merger agreement, initially noting that Hillrom's burden was to prove by a preponderance of evidence that (i) the effect of the reimbursement rate decrease on Bardy's earning potential would reasonably be expected to constitute an MAE (which the Court assumed Hillrom had proven) and (ii) the reimbursement rate decrease would reasonably be expected to endure for a durationally significant period.

In its analysis, the Court focused on Hillrom's claim of durational significance. The Court noted that Delaware courts have not prescribed specific time periods when assessing "durational significance", and instead looked to "the target company's unique characteristics and the broader business dynamics in which the target operates." The Court went on to note that Hillrom's own internal projections estimated that Bardy would not turn a profit before 2023. Furthermore, Hillrom had acknowledged that five or more years was "durationally significant." With these facts in mind, the Court determined that it was reasonable to conclude that Bardy can operate under the reduced reimbursement rates for two years without suffering an MAE. The key question, then, was whether Hillrom proved that reimbursement rates would be revised by CMS or Novitas with the next two years.

To answer this question, the Court focused on the testimony of the parties' experts. Finding the testimony of Bardy's expert to be persuasive, the Court determined that it was reasonable to conclude that either CMS or Novitas will intervene within two years to increase the CAM patch's reimbursement rates and, as a result, Hillrom had failed to prove that the reimbursement rate decrease would endure for a durationally significant period. The Court noted that "it is insufficient to show that the effect of the reimbursement rate decrease *might* be durationally significant, as 'a mere risk of an MAE cannot be enough.'"

Although the Court noted that it could have ended its analysis there, for the sake of completeness, it continued on to consider whether an MAE carve-out applied.

Reimbursement rate decrease is a "change in Law" carved out from an MAE

Under the merger agreement, "any change in any Law (including … any Health Care Law) … or any interpretation thereof" cannot constitute an MAE. The merger agreement defines "Law" as any regulation or rule issued by any Governmental Body, including "any authorized contractor engaged by any governmental, legislative, executive or judicial agency… or regulatory body."

Because Novitas acts unilaterally on behalf of, and with the full authority vested in, CMS, the Court found that Novitas is an "authorized contractor" of CMS. Accordingly, the Court concluded that any reimbursement rates set by Novitas, including the reimbursement

rates applicable to the CAM patch, are regulations contemplated by the merger agreement and, therefore, the reimbursement rate decrease announced by Novitas fell under the MAE carve-out for changes in Law.

Reimbursement rate decrease did not have a "disproportionate impact" on Bardy

Finally, the Court turned to whether the "disproportionate impact" exclusion applied to the reimbursement rate decrease. In its analysis, the Court closely examined the specific language used in the MAE definition (*e.g.* "similarly situated companies operating in the same industries or locations…"). The Court noted that this language differed from the language interpreted in other Delaware MAE cases (*e.g.* "comparable entities operating in the same industry…"). Consequently, the Court determined that, though many companies operated in the same industry as Bardy, only one company operated in the same industry and was "similarly situated." As compared with that one company, the reimbursement rate decrease did not disproportionately impact Bardy (indeed, the Court found that one would expect both companies to be similarly impacted by the reimbursement rate decrease). Therefore, the Court found that the "disproportionate impact" exclusion did not apply to the change in Law carve-out.

OUR VIEW

The Court's decision in *Bardy* reaffirms that buyers bear a heavy burden when claiming an MAE, **and also suggests that the Court's decision in *Akorn, Inc. v. Fresenius Kabi AG*, in which it found that an MAE had occurred, should be viewed as an exceptional case rather than a harbinger of change in the Court's approach to MAE cases**. In addition, the Court's decision serves as **an important reminder that Delaware courts will closely scrutinize the specific language used in the MAE defintion** when assessing the meaning and intent of the parties and will test the language against the specific facts presented to the Court. Accordingly, the parties should give very careful consideration to how the MAE definition and related provisions are drafted and not just use what would be considered as "market" language.

We welcome the opportunity to discuss any questions you might have regarding this case.

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