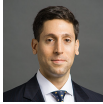


Delaware Court of Chancery Clarifies “Commercially Reasonable Efforts” in Earn-Out Provisions



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On April 30, 2024, in *Himawan, et al. v. Cephalon, Inc., et al.*, the Delaware Court of Chancery held that the defendant acquiror complied with its contractual obligations to use commercially reasonable efforts to achieve certain milestones under the “earn-out” provision of the merger agreement.

As part of Cephalon Inc.’s 2010 acquisition of Ception Therapeutics, Inc., a privately held biopharmaceutical company, in addition to amounts paid at the closing, the parties agreed to certain earn-out payments totaling up to \$400 million. The payments were to be based on the achievement of certain milestones, including FDA and European EMA approval of Reslizumab (“RSZ”), a treatment for inflammation in the lungs and esophagus. RSZ was Ception’s sole asset at the time of the sale. The merger agreement required Cephalon to use “commercially reasonable efforts to develop and commercialize” RSZ to achieve the milestones and defined commercially reasonable efforts as “the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [Cephalon], with due regard to the nature of efforts and cost required for the undertaking at stake.” The relevant provision also provided that Cephalon “shall have complete discretion with respect to all decisions related to the business of the Surviving Corporation.” The Court further noted that under the merger agreement Cephalon “did not have an obligation to (i) conduct clinical trials; (ii) pursue regulatory approvals; (iii) maximize payment to Ception stockholders; (iv) follow Ception’s business plan; or (v) consult with Ception stockholders with respect to the business.”

While RSZ showed promise for lung inflammation, from the beginning its indication for esophagus inflammation was not favorable. Even prior to the closing of Cephalon’s merger, Ception’s Phase IIb/III clinical trial of RSZ failed as a treatment for pediatric esophagus inflammation. Following the closing of the merger, Cephalon continued its development of RSZ for inflammation in the esophagus, working with Ception’s principal research and development employees to remedy the failed study. Cephalon spent months devising an alternative plan for FDA approval and met with the FDA on several occasions to discuss three separate updated proposals. At each such meeting, the FDA rejected the updated proposal, providing only “general recommendations”.

Eventually, Cephalon, and its successor following an unrelated acquisition, Teva Pharmaceutical Industries Ltd., determined to focus on RSZ's indication for lung treatment and abandon commercialization of RSZ for inflammation in the esophagus. Cephalon obtained FDA approval of RSZ for lung treatment and paid \$200 million to Ception in earn-out payments. Ception's former stockholders then brought a breach of contract action, alleging that Cephalon failed to use commercially reasonable efforts to develop and commercialize RSZ because it abandoned RSZ for esophagus inflammation.

In analyzing whether Cephalon used commercially reasonable efforts, the Court determined that the merger agreement imposed an objective standard beyond Cephalon's subjective good faith but also provided Cephalon "complete discretion with respect to all decisions relating to the research, development, manufacture, marketing, pricing and distribution of [RSZ]." The Court held that after a failed study relating to RSZ's indication for esophagus treatment, numerous discussions of potential remedies and submission of three separate alternative plans to the FDA, Cephalon's decision not to proceed with the development of RSZ for esophagus treatment was within its contractual rights and consistent with the use of commercially reasonable efforts under the terms of the agreement.

The earn-out provision in the merger agreement required Cephalon to use efforts consistent with a company with the same resources and expertise. However, the Court found this method "unworkable" noting that no company operates under the same circumstances as those in the present case. Instead, the Court interpreted the merger agreement to assume that the parties intended to require Cephalon to use commercially reasonable efforts "as it found itself situated". The Court pointed to examples of several companies that abandoned development of pharmaceutical products following failed clinical studies as helpful context in concluding that Cephalon's decision was consistent with the use of commercially reasonable efforts under the agreement.

According to the Court, the commercially reasonable efforts provision in the merger agreement operated "only to disallow actions of the buyer that would be against the buyer's self-interest." The Court disagreed with the plaintiffs' position that the earn-out provision required Cephalon "to take all reasonable steps to solve problems." The Court noted that the plaintiffs' argument was "akin to a best efforts obligation, under which Defendants must pursue commercialization, through the milestones, at least, unless it would be unreasonable to do so", and distinguished this view from the standard set forth in the merger agreement which gave Cephalon complete discretion, adding that the parties could have agreed to a best efforts clause if they so desired.

Parties negotiating earn-out provisions in M&A transactions will want to pay close attention to the express contractual terms and should consider a variety of potential approaches, from complete buyer discretion with no obligation to work towards achieving the applicable milestone to best efforts requiring a buyer to take all actions, even those against its own interest. Sellers should consider, at a minimum, limiting discretionary language around a buyer's development and commercialization activities and consider seeking specific minimum requirements. Buyers, however, who are looking to receive the same outcome from the Delaware Court of Chancery should seek to preserve discretionary language and consider expressly stating that the only required actions with respect to continued

development and commercialization are those which are economically in such buyer's interest.