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Delaware Court of Chancery Opines on Meaning of 'Commercially Reasonable Efforts' in Pharmaceutical Earn-Out Provision

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On April 30, 2024, the Delaware Court of Chancery held that the buyer in a life sciences merger and its successor had not breached their contractual obligations under an earn-out provision to use commercially reasonable efforts ("CRE") to achieve regulatory approvals for a pharmaceutical product. In *Himawan, et al. v. Cephalon, Inc., et al.*, Vice Chancellor Glasscock found that the merger agreement's definition of CRE for purposes of the earn-out provision, which referred to the efforts of a company with substantially the same resources and expertise as the buyer, required the Court to analyze whether a reasonable actor faced with the circumstances would continue to pursue the development of a drug that had failed to meet one of its co-primary endpoints in an earlier clinical trial.[1] In its reasoning, the Court relied heavily on the merger agreement's grant to the buyer of "*complete discretion with respect to all decisions*" over the development activities, subject only to the more general CRE obligation. Although the impact of the decision on CRE clauses granting a buyer less discretion remains to be seen, the Court's decision provides important guidance on the interpretation and drafting of CRE clauses generally, both in merger agreements and in other contexts, such as license agreements and revenue sharing agreements.

Background

The plaintiffs in the case were representatives of former Ception Therapeutics, Inc. ("Ception") stockholders. Ception owned the antibody Reslizumab ("RSZ"), which was being developed for treating inflammation in the lungs (eosinophilic asthma, or "EA") and the esophagus (eosinophilic esophagitis, or "EoE"). Cephalon Inc. ("Cephalon") acquired Ception in April 2010 with the intent to develop and commercialize RSZ to treat EA and EoE. Two years later, in October 2012, Teva Pharmaceutical Industries Ltd. ("Teva") acquired Cephalon.

Under the Merger Agreement, Ception stockholders had the right to receive two milestone payments of up to $200 million each for regulatory approval of RSZ for the treatment of EA and EoE (for a total of up to $400 million). In the context of addressing the

[1] *Himawan, et al. v. Cephalon, Inc., et al.*, C.A. No. 2018-0075-SG (Del. Ch. Apr. 30, 2024).

earn-out consideration, the Merger Agreement provided that the buyer would have "complete discretion with respect to all decisions related to the business of the Surviving Corporation and its subsidiaries, including decisions relating to the research, development, … pricing and distribution of [RSZ], and shall have no obligation to conduct clinical trials related to, or otherwise pursue regulatory approvals of, any indication for [RSZ] … or otherwise take any action to protect, attain or maximize any payment to be received by" stockholders under the earn-out. Notwithstanding the flexibility afforded under this language, the buyer remained subject to an overarching obligation to use "commercially reasonable efforts" to develop and commercialize RSZ in furtherance of the development milestones. "*Commercially reasonable efforts*" was defined in the merger agreement as requiring "the exercise of such efforts and commitment of such resources by a company with substantially the same resources and expertise as [buyer], with due regard to the nature of efforts and cost required for the undertaking at stake." Teva assumed this obligation when it acquired Cephalon.

The EA-related regulatory milestone events were achieved and Ception stockholders received the corresponding $200 million milestone payment. However, despite bona fide development efforts and engaging multiple times with the FDA to devise a new clinical path forward, the development of RSZ for the treatment of EoE proved unsuccessful and both Cephalon and Teva abandoned the development of RSZ for this indication. Ception stockholders then sued Cephalon and Teva for breach of the Merger Agreement based on a failure to use CRE to develop and commercialize RSZ for the treatment of EoE.

Ruling

In its ruling, the Court held that Teva and Cephalon did not breach the Merger Agreement and did not breach their obligations to use CRE to develop and commercialize RSZ for the treatment of EoE.

In measuring the efforts of Teva and Cephalon against the CRE yardstick, the Court emphasized that the Merger Agreement gave "complete discretion" to the buyer with respect to all decisions related to the business of the seller, only subject to the restriction that Teva and Cephalon could not avoid the earn-outs in a manner that was commercially unreasonable.[2]

The Court then proceeded to interpret the CRE standard to impose a requirement on the buyer *as it found itself situated* from an *objective standard*. Thus, if a reasonable actor faced with the same limitations and risks in the development of a pharmaceutical product would go forward in its own self-interest, then the buyer would be contractually obligated to do the same. Notably, the Court found unworkable the plaintiff's preferred interpretation that the CRE clause required comparing Cephalon and

[2] In coming to this conclusion, the Court distinguished the current context from other cases involving CRE that the plaintiffs cited. In the current context, the buyer had *complete discretion* over development, cabined only by CRE. On the other hand, in the other cited cases, the merger agreement required the parties to use CRE to achieve one of the milestones as a precursor to consummation of the transaction, and to use *reasonable best efforts* to consummate the transaction. As a result, if the milestone did not occur and could prevent the completion of the merger, the buyer was affirmatively obligated to take all reasonable steps necessary to achieve the milestone in order to complete the merger.

Teva's efforts with the efforts of similarly situated pharmaceutical companies and their actions in the real world developing different drugs for EoE on the basis that "no exemplar companies operate under the actual conditions" of Cephalon and Teva.[3]

Rule Application

After establishing the framework for review, the Court separately analyzed Cephalon's efforts and Teva's efforts, finding that the actions of both parties were commercially reasonable.

With respect to Cephalon, the Court noted that it had engaged in substantive efforts to develop RSZ for the treatment of EoE even after a failed trial, including hiring former Ception employees, holding a pre-Biologics License Application meeting with the FDA in which it "proposed to submit a pre-Biologics License Application for RSZ under an FDA program for accelerated approval of biological products" and the use of a surrogate endpoint, proposing to amend the Open-Label Study to convert it into an efficacy study, and proposing an enriched, enrollment, randomized withdrawal ("EERW") study. However, the FDA ultimately rejected those proposals, though it provided a recommendation to gain approval through additional data and analyses. Cephalon conducted the requested analyses and ultimately concluded that it could not identify a "clinical benefit" and would discontinue development. The Court noted that similarly situated competitors also abandoned their EoE development programs after failed clinical trials and studies. While the Court took note of these actions to bolster its finding of commercial reasonableness, such comparisons were not determinative in themselves.

The Court arrived at the same conclusion regarding Teva's development of RSZ for the treatment of EoE. When Teva acquired Cephalon, Teva did not restart the EoE program, but instead focused on EA from 2011 to 2017. The Court reasoned that Teva's prioritization of treating EA was objectively reasonable because it was more promising clinically and commercially in comparison with treating EoE, which had already faced numerous regulatory hurdles and clinical setbacks. Teva "hired RxC, a third-party biopharma strategy consulting firm that specializes in pharmaceutical life cycle planning and new product commercialization, to conduct an opportunity assessment of RSZ for EoE." RxC concluded that the probability of starting a successful new trial was low and that the commercial viability provided limited upside. Teva had determined that it would only be commercially reasonable to develop RSZ for the treatment of EoE if it could obtain a viable subcutaneous route of administration because RSZ was already a challenging commercial product in any indication as it required administration by infusion and the display of a black-box warning label. Teva's clinical trials of the subcutaneous form of RSZ failed to demonstrate efficacy for the treatment of EA, and so Teva decided it would not pursue the development of RSZ for EoE. Teva had also considered the related milestone payments under the Merger Agreement in concluding that the further development of RSZ for the treatment of EoE was impractical.

[3] The plaintiffs had argued that companies with similar resources and expertise (specifically, Shire, Sanofi and Regeneron, Celgene and GlaxoSmithKline) were pursuing products for treatment of EoE and thus suggesting that Cephalon/Teva was unreasonable in not pursuing approval in the indication. The Court found this to be an apples-to-oranges comparison that was unworkable.

Drafting Guidance

The Court's ruling provides important guidelines for negotiating and drafting CRE definitions in the context of a variety of agreements, including merger agreements, license agreements and synthetic royalty financing agreements. The Court focused not only on the definition of CRE, but also on surrounding language and the discretion expressly afforded the buyer with regard to the seller's business. Sellers in future transactions might consider not including any express discretion language with respect to the buyers' development and commercialization activities in order to bolster the objective measure of the CRE standard. Buyers, on the other hand, might consider including express discretion language in order to bolster the subjective measure of the CRE standard.

The Court's decision suggests that CRE definitions drafted with reference to the buyer's specific facts and circumstances will provide buyers with significantly more freedom in the interpretation of commercial reasonableness. While the Court indicated that it was utilizing an "objective" standard to measure CRE, this objectivity was not determined by looking to the efforts of similarly situated pharmaceutical companies and their actions in the real world with respect to similar drug candidates, but rather by considering whether a reasonable person *in the same situation as the buyer* (*i.e.*, considering the same opportunities and risks) would go forward in its own self-interest (sometimes referred to as a "subjective objective standard").

The Court's ruling notes that applying a purely objective standard is unworkable (or at least challenging to implement), as each set of circumstances around drug development is inherently unique. Simply because other companies had pursued the development of different drugs for the same indication does not provide insight into whether it would be reasonable to require similar efforts in the context of a different drug for the same disease. Rather, the Court applied an objective standard of reasonableness in the context of the buyer's unique facts and circumstances.

Adopting that interpretative framework, parties in future transactions may consider the following options in drafting CRE terms that accomplish their desired objectives:

- *M&A Buyer/Licensee Side*.[4] The buyer/licensee should define "Commercially Reasonable Efforts" with a subjective standard benchmarked only against itself.

  > "… shall use those efforts and resources that such Party would typically devote to its owned or exclusively licensed products for the same clinical indication and in the same geographic markets with a similar market potential at a similar stage in development or product life, taking into account intellectual property protection, efficacy, safety, approved labeling, the competitiveness of alternative products in such jurisdiction, pricing/reimbursement for the pharmaceutical product and the profitability of the pharmaceutical product (including with regard

[4] Also aligned with the perspective of the seller of a synthetic royalty interest.

to the costs associated with the [earn-out payments]), all as measured by the facts and circumstances in existence at the time such efforts are due."

- *M&A Seller/Licensor Side*:[5] The seller/licensor should define "Commercially Reasonable Efforts" with an objective standard benchmarked against similarly situated companies as the buyer/licensee, or if possible, an objective standard with specific minimum requirements.

  "… shall use those efforts and resources consistent with the usual and customary practices of a similarly situated biopharmaceutical company in the development and exploitation of a drug product owned by or licensed to it, which drug product is at a similar stage of development, is in a similar therapeutic and disease area, and is of similar market potential and without regard to the costs associated with the [earn-out payments] [(provided that, in any event, the number of full time sales representatives of the Company with respect to the Product shall not fall below [___])]."[6]

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[5] Also aligned with the perspective of the buyer of a synthetic royalty interest.

[6] Where the counterparty expects the expenditure of a minimum level of resources, consider setting an explicit floor for CRE (*e.g.*, with reference to a minimum level of expenditures or minimum number of full-time-equivalent employees working to develop or commercialize the product).

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