ALERT MEMORANDUM

Delaware Court of Chancery Finds Buyer Failed to Use Commercially Reasonable Efforts in Pharma Milestone Payment Case

September 9, 2024

Earnout provisions in acquisition agreements can be a useful tool in bridging the valuation gap by deferring portions of the purchase price until certain post-closing milestones are achieved, and they are particularly common in developmental-stage pharmaceutical transactions. Practitioners should take note of the September 5, 2024 opinion in *Shareholder Representative Services LLC v. Alexion Pharmaceuticals, Inc.*, in which the Delaware Court of Chancery held a buyer, Alexion, liable for breach of contract both for its failure to use commercially reasonable efforts to achieve milestones for which future earnout payments may have become due and for its failure to pay an earned milestone payment to selling securityholders of Syntimmune, Inc.[1]

Background and Decision

Alexion acquired Syntimmune in November 2018 for a total purchase price of $1.2 billion, $400 million of which was paid upfront and $800 million of which would be paid out in installments upon achievement of various milestones.[2]

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[1] *Shareholder Representative Services LLC solely in its capacity as representative of the Securityholders v. Alexion Pharmaceuticals, Inc.*, C.A. No. 2020-1069-MTZ (Del. Ch. Sept. 5, 2024).
[2] *Id.* at 1.

Each milestone was tied to a stage of further development of Syntimmune's monoclonal antibody (ALXN1830).[3] In particular, the first milestone provided for a "$130 million payment upon the completion of a successful Phase 1 Clinical Study."[4] The completion of Phase 1 Clinical Study was further defined to be the satisfaction of five specifically negotiated technical criteria.[5] Alexion was also required to use commercially reasonable efforts for seven years to achieve each milestone, with commercially reasonable efforts defined under the agreement to be measured by what a similarly situated company would do based on safety, efficacy, order of entry, regulatory approval and other factors.[6]

Following the acquisition, the ALXN1830 program encountered a number of challenges, including contamination of its drug supply and pause of ongoing trials due to the COVID-19 pandemic.[7] Alexion deprioritized development of ALXN1830 in April 2020 in favor of shifting resources towards certain other programs as part of a goal of launching ten products by 2023 (the "2020 Deprioritization").[8] While Alexion did not fully pause development of ALXN1830, it fell behind other competitors that were pushing their competing programs forward throughout this time.[9]

In July 2021, another pharmaceutical company acquired Alexion.[10] The acquisition contemplated approximately $500M in recurring synergies.[11] As a result of the acquisition, Alexion's programs came under review, including ALXN1830.[12] During the same time, additional data from a Phase 1 trial of ALXN1830 began to suggest certain safety risks but were inconclusive.[13] Based on a number of factors, including potential safety risks and the product's expected order of market entry, Alexion terminated the program in December 2021.[14]

On behalf of the former securityholders of Syntimmune, SRS brought suit alleging that (i) "Alexion failed to use commercially reasonable efforts to achieve the remaining milestones" and (ii) the first milestone was satisfied by the Phase 1 trial data, but Alexion had breached its obligations by failing to pay.[15]

Commercially Reasonable Efforts Requirement

A key issue in the case was what level of efforts was required for Alexion to fulfill its obligations to seek to meet each of the milestones. Under the merger agreement, Alexion was subject to a commercially reasonable efforts standard that "impose[d] an objective standard,"[16] defining commercially reasonable efforts to mean, in part, "using such efforts and resources typically used by biopharmaceutical companies similar in size and scope to [Alexion] for the development and commercialization of similar products at similar development stages taking into account"[17] certain specified considerations that the court summarized as "safety, efficacy, order of entry, the likelihood of regulatory approval, and other advantages and disadvantages."[18] The merger agreement afforded Alexion discretion over ALXN1830's development and specified that Alexion would have no obligation to achieve any milestone events.[19]

Based on the language used in the agreement to describe the required "commercially reasonable efforts," the court determined that the parties agreed to an "outward facing" and objective standard, and the subjective intent of Alexion would not determine whether it complied with its obligations.[20] This

[3] *Id*.
[4] *Id*.
[5] *Id*. at 36.
[6] *Id*. at 1, 120.
[7] *Id*. at 2.
[8] *Id*. at 2-3.
[9] *Id*. at 3.
[10] *Id*.
[11] *Id*. at 135.
[12] *Id*.
[13] *Id*. at 4.
[14] *Id*.
[15] *Id*. at 5.
[16] *Id*. at 107.
[17] *Id*. at 38 (citation omitted).
[18] *Id*. at 120.
[19] *Id*. at 106 (citation omitted).
[20] *Id*. at 107.

contractual standard is different from an alternative "inward facing" standard, which is also commonly used and looks to the buyer's actions and decision-making process as compared to actions and decisions by the buyer in the development of other products or as compared to the pre-acquisition development process.[21]

In this case, given the "outward facing" contractual test, the court applied a "hypothetical company" approach and measured Alexion's effort against that of a "hypothetical typical company of Alexion's size, working on a molecule like ALXN1830 at a similar stage of development, considering the factors such a company would typically consider, up until the point of being contrary to prudent business judgment."[22]

Applying the "hypothetical company" approach, the court determined that the 2020 Deprioritization fell short of "commercially reasonable efforts" because that decision was driven by an idiosyncratic corporate initiative of launching 10 products by 2023, and a hypothetical company would not have otherwise defunded a product like ALXN1830.[23] In this regard, the court took note that Alexion's competitors were all moving forward with the development of competing therapies during that time.[24] However, the court did not find causation between the 2020 Deprioritization and the actual harm suffered by the plaintiff because other intervening events, such as the COVID-19 pandemic, may have contributed to the delay.[25]

In reviewing Alexion's decision to terminate the development of ALXN1830, the court reviewed what a hypothetical company would do based on the factors listed above. As it relates to safety, the court noted that the data raising potential safety concerns were inconclusive, and a hypothetical company would respond by gathering further data, instead of terminating the program outright.[26] As it relates to the order of market entry, the court noted internal Alexion records indicating that ALXN1830 would still be the first to market for at least two indications.[27] Following consideration of these and other factors, the court found that Alexion failed to use commercially reasonable efforts to seek to meet the milestones laid out in the merger agreement.

The court found that the real reason for the program's termination laid in the $500 million in recurring synergies promised in the subsequent acquisition of Alexion by another pharmaceutical company, which led to a full portfolio review of all ongoing Alexion drug programs and indications.[28] Ultimately, the court determined that Alexion's choice to terminate ALXN1830's development was influenced by the pursuit of merger synergies, an idiosyncratic corporate objective which would not necessarily be pursued by a hypothetical company on its own.[29]

As a result, the court determined that by terminating the program, Alexion fell short of its obligations to expend commercially reasonable efforts to achieve the milestones.

Failure to Pay for First Milestone

Another point of contention in the case was whether the first milestone was satisfied, which called for an earnout payment of $130 million upon "the successful completion of a Phase I Clinical Trial . . . as demonstrated by achievement of the criteria set forth [therein]."[30] Much of the dispute revolved around how to determine satisfaction of a criterion: "[a]n observed PK/PD profile that supports weekly or less frequent subcutaneous administration in long term safety and efficacy studies."[31] SRS argued that this only required Phase 1 data that showed dosing frequency of not more than once a week in the event that Alexion would

[21] *See generally Fortis Advisors, LLC, solely in its capacity as representative of former stockholders of Auris Health, Inc. v. Johnson & Johnson et al.*, C.A. No. 2020-0881-LWW (Del. Ch. Sept. 4, 2024); *see also FMLS Holding Co. v. Integris BioServices, LLC*, 2023 WL 7297238 (Del. Ch. Oct. 30, 2023).
[22] *Alexion Pharmaceuticals, Inc.*, 2020-1069-MTZ at 112.
[23] *Id.* at 114-15.
[24] *Id.* at 115 (citations omitted).
[25] *Id.* at 117-18.
[26] *See id.* at 121-24.
[27] *See id.* at 129-30.
[28] *Id.* at 135.
[29] *Id.* at 132-37.
[30] *Id.* at 37 (citation omitted).
[31] *Id.* at 86 (citation omitted).

otherwise be able to conduct long term safety and efficacy studies.[32] Alexion argued that this criterion additionally required that the observed PK/PD profile would support a long-term safety and efficacy study in the first instance and, because the data suggested safety concerns, additional studies were needed before it could proceed with long term studies.[33] The court found both interpretations reasonable and therefore that the provision was ambiguous.[34] After a detailed consideration of extrinsic evidence, including the negotiation history and internal communications within Alexion, the court ultimately held that SRS's interpretation comported with the parties' intent and that the milestone had been achieved.[35]

Key Takeaways

— **Consider What a Hypothetical Company May Do**: A buyer of a pharmaceutical company should carefully consider the consequence of agreeing to an "outward facing" (or objective) standard of commercially reasonable efforts in an earnout provision. Given the bespoke nature for any drug development process and each company's unique circumstances, agreeing to an "outward facing" standard may tie the hands of the buyer if, down the road, it needs to address a particular corporate priority that is not shared by its peers. In complying with the "outward facing" standard during the earnout period, the buyer should strive to understand peer group practice and benchmark its own progress against pipelines held by competitors.

— **"Outward" vs "inward" standard**: In two other recent cases, the Chancery Court considered an "inward facing" efforts standards.[36] While the "inward facing" standard may generally be more buyer-friendly since it considers the buyer's own practices, the requirements under that standard may vary significantly depending on the terms agreed upon by the parties, which are often highly technical and heavily negotiated.[37] Practitioners representing buyers and sellers should consider the merits of an "outward facing" versus an "inward facing" standard when drafting commercially reasonable efforts provisions, as well as any bespoke language defining relevant criteria that may be considered by the buyer in pursuing earnout milestones and what discretion is afforded to the buyer. And regardless of which standard is used, this is an area where careful forethought should be given to how the agreed-upon language may be applied to real-world business operations.

— **Close Collaboration between Legal and Science Teams in Drafting Milestones**: The *Alexion* case involved extensive review of extrinsic evidence because the plain meaning of the milestone definition in the merger agreement was ambiguous. This could have been avoided had the drafting been clearer on its face. In negotiating and drafting the milestone provisions, practitioners should work closely with their scientific and business counterparts to draft accurately and precisely, and should consider possible alternative interpretations in order to avoid costly litigation and potentially unpredictable outcomes. Notably, in *Alexion*, the Syntimmune employees had commented that the drafting "look[s] like a lawyer trying to define something that he does not understand."[38]

— **Contemporaneous Record During Negotiation**: In finding for the plaintiff's interpretation of the milestone definition, the court reviewed the entire

[32] *Id.* at 87.
[33] *Id.*
[34] *Id.* at 90.
[35] *See id.* at 96.
[36] *Johnson & Johnson et al.*, 2020-0881-LWW; *Fortis Advisors LLC, solely in its capacity as Stockholders' Representative v. Medtronic Minimed, Inc.*, C.A. No. 2023-1055-MAA (Del. Ch. Jul. 20, 2024).
[37] *Johnson & Johnson et al.*, 2020-0881-LWW at 60-62. Indeed, in these two recent cases, the court came to different results (one in favor of seller and one in favor of buyer) based on bespoke terms and provisions included in the relevant agreements. *Id.* at 62 (finding in favor of seller); *Medtronic*, 2023-1055-MAA (dismissing seller's claims that buyer failed to use commercially reasonable efforts).
[38] *Alexion Pharmaceuticals, Inc.*, 2020-1069-MTZ at 35 (citation omitted).

negotiation history, starting from the first proposal, and internal communications evidencing Alexion's own contemporaneous interpretation of the language. This serves as a cautionary tale that written records (including internal emails) may be used to interpret a party's intent. It is possible that certain internal communications that "play the devil's advocate," if not clearly stated as such, could be used against such party as confirming an unfavorable interpretation of an ambiguous clause. Parties to transactions should therefore be conscious of the written record they create, even in internal discussions.

— **Diligencing Target's Earnout Obligations**: The court determined that the reason why Alexion had failed to use commercially reasonable efforts to hit its development milestones was ultimately due to its own acquisition by another pharmaceutical company. In light of this finding, a buyer should consider a target company's existing earnout obligations and how the underlying programs fit with the stated synergy goals and overall assessment of the potential benefits of the deal. A buyer should carefully diligence the ongoing efforts and costs required for earnouts and be aware that it will inherit the same level of efforts and cost to develop or market a certain product during the remaining earnout period, whether or not it wishes to do so.

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