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Tips for Milestone Dispute Avoidance

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Pharmaceutical and medical device companies regularly turn to licensing arrangements and acquisitions as sources of new products for their pipelines and portfolios. Licensing or purchasing the intellectual property rights to compounds, molecules, products, and technologies that are under development or have not yet been commercialized provides a means to (1) lower the cost of in-house research and development, and (2) hedge the risk of failure through the use of lower up-front payments in combination with future, success-dependent milestone payments.

Because the achievement of specific milestones is often the bedrock of these arrangements at least from the seller/licensor perspective, the questions of whether a milestone has been met, and whether a licensee or purchaser has diligently worked to achieve those milestones, are essential. The failed development of a drug or medical device can result in milestone disputes with hundreds of millions of dollars at stake. Indeed, a Delaware jury recently awarded $250 million to the shareholders of a medical device company acquired by ev3 because ev3 failed to act in good faith to pursue certain developmental milestones set forth in the parties' merger agreement. *Lesh v. EV3 Inc.*, C.A. No. 05C-05-218 CLS. The *Lesh* decision is concerning because ev3 argued that its decision to cease development and commercialization of the device was based on several business considerations, including the fact that the Food and Drug Administration (FDA) had rejected a pivotal study design.

This article aims to help companies avoid milestone disputes with business partners by suggesting ways that a company may exercise vigilance at all stages of the relationship, from the contract formation stage and into the development and commercialization of the product.

Milestone Payment Provisions

Within licensing or acquisition agreements involving medical products and technologies, milestone provisions typically set forth (1) what constitutes the achievement of a

milestone, and (2) the amount of payment that will be due once each milestone is met. Competing interests typically color the very earliest stages of the negotiation of the milestone provisions. A common milestone provision defines a milestone achievement by a trigger that the company can control, such as the commencement of a clinical trial, or the submission or approval of a New Drug Application (NDA) to the FDA, as the following example illustrates.

> Section 9.6 (a) Development and Regulatory Milestones. With respect to each Split Program, Co-Commercialized Program and Picked Program selected by Celgene . . . Celgene shall pay Agios the following amounts after the first achievement by or on behalf of Celgene . . . of the corresponding milestone events set forth below . . .

Development Milestones	**Each Program**
1) FPD [dosing of first human subject in a clinical trial] in a Phase III Study intended to support Regulatory Approval in ROW Territory	US$25,000,000
2) Filing of first NDA in ROW Territory	[**]
3) First Regulatory Approval in any of China, Japan or a Major European Country	[**]
4) Second Regulatory Approval in any of China, Japan, or a Major European Country, but only if received in a different country or region, as applicable, than the first Regulatory Approval	[**]

Agios Pharmaceuticals Inc. Form DRS Filing dated May 23, 2013, Section 9.6.[1]

A licensor, however, may object that this type of milestone payment provision allows a licensee or purchaser to stop development of a product even where the product shows

scientifically compelling evidence of potential benefit to patients but does not reach the applicable event due to insufficient efforts by the developer or just a decision to not proceed for financial reasons. How can parties resolve this potential impasse? Often it is by the use of a carefully-crafted Reasonable Efforts clause.

Reasonable Efforts Clauses

A reasonable efforts clause provides a licensee with reassurance that a licensor or purchaser is contractually obligated to diligently try to achieve the defined milestones, rather than having sole discretion to develop, or not develop, a product. A reasonable efforts clause or definition sets forth the specific standard under which the licensor or purchaser will pursue the milestones, and which a finder-of-fact will apply in a dispute to determine the adequacy of the licensor's or purchaser's performance.

Reasonable efforts clauses can have subjective or objective standards of performance. A subjective standard measures commercially reasonable efforts against the efforts exercised by the licensor or acquiring company to develop other similar products in its portfolio:

> "***'Commercially Reasonable Efforts'*** means the carrying out of discovery, research, development or commercialization activities using good-faith commercially reasonable and diligent efforts that the applicable Party would reasonably devote to a compound or product of similar market potential or profit potential at a similar stage in development or product life resulting from its own research efforts . . . ." *ISIS Pharmaceuticals Inc. Form 10-Q Filing* dated August 6, 2013, Appendix 1.

The advantage of utilizing a subjective reasonable efforts standard is that a plaintiff in a milestone dispute bears the burden of (1) identifying, through discovery, one or more appropriate comparable products in defendants' portfolio and (2) proving that defendants' efforts were not commercially reasonable when considered against the efforts exercised by defendant with respect to that comparable product. The first prerequisite can be challenging for plaintiffs, as recently demonstrated in *Banas v. Volcano Corp.*, No. 12-CV-01535 (N.D. Cal. March 31, 2014). In *Banas,* the defendant acquiring company was able to defeat a breach of contract case at the summary judgment phase because plaintiffs were unable to identify a proper comparator for the product that was the subject of the milestone dispute, specifically a comparator with similar market potential.

However, a pharmaceutical company may prefer to avoid discovery and inquiry into the other products in its pipeline or portfolio, and the efforts and resources devoted to those products. Allowing broad and burdensome probes into all of a company's products rather than just the one product at issue in a dispute produces additional pitfalls, risks, and expense, not all of which can be adequately addressed even by the strictest protective orders. Alternatively, a reasonable efforts clause with an objective standard of performance, measured against the efforts of other similar pharmaceutical companies, may be incorporated into the parties' contract:

> "'**Commercially Reasonable Efforts**' means . . . the carrying out of such obligations or tasks in a diligent manner consistent with customary practices of comparable companies in the special pharmaceutical industry

> for the Development or commercialization of a comparable pharmaceutical product at a similar stage of Development or commercialization in light of the intellectual property and competitive landscape relevant to such product, the safety and efficacy profile of a product, the Development and regulatory approval (including any reimbursement approval) risks associated with such product, and the anticipated commercial viability." *Questor Pharmaceuticals Inc.'s Form 10-Q Filing* dated July 31, 2013, Section 1.1.

A reasonable efforts clause with an objective standard may protect defendants from discovery expeditions in which plaintiffs seek to unearth all efforts of the company to develop all possible comparable products. However, where an objective standard of performance is imposed, the question of whether reasonable or diligent efforts will often require expert witness testimony regarding the efforts and resources employed in the industry to develop similar products. Expert testimony carries its own expenses and risks, and each company should weigh the costs and benefits of the differing types of clauses to their circumstance and product.

Reporting Obligations

Because milestone disputes concerning reasonable efforts are fact-intensive inquiries, it is vital that a pharmaceutical or device company contemporaneously well-document both (1) its efforts to achieve milestones and (2) its reasoning if deciding not to further develop a product. A licensing or acquisition agreement will often impose reporting obligations on the milestone obligor to keep the licensor, selling company, or former shareholders apprised of the status of the development of the product. The milestone obligor would be well-advised to over-document its efforts to achieve specific milestones, and to ensure that it is presenting a consistent message as to the progress and viability of the product to its partners, to the public as appropriate, and to its internal review and advisory boards. These periodic reports will be critical to demonstrating that the company exercised reasonable efforts, in the event the company ultimately must abandon a product or development and finds itself in a potentially costly milestone dispute.

Dispute Resolution

Disputes may arise even under well-crafted agreements and even despite strict adherence to reporting obligations. However, there are strategies to resolve these disputes long before they reach trial, and these strategies should be considered during the formation of the contract. For example, an escalation clause, also known as a multi-stage dispute resolution clause, in a contract requires the parties to first negotiate in order to try to reach an amicable resolution to the dispute before commencing a lawsuit or arbitration proceeding. These clauses allow the parties to reflect on the facts that gave rise to the dispute, to articulate their respective positions, and to explore whether they prefer to resolve the dispute and continue the business relationship. This escalation period can be a good time for the respondent to remind plaintiffs that in order to recover the milestone amount in dispute, plaintiffs need to prove that the milestone *would have been reached* if in fact the required commercially reasonable efforts had been utilized. Courts have found damages claims based on new and/or frequently unsuccessful ventures, such as

pharmaceuticals, to be too speculative to award. *LaPoint v. AmerisourceBergen Corp.*, 2007 WL 2565709 (Del. Ch. Sept. 4, 2007), can serve as a true wake-up call to plaintiffs early on in the litigation. In *LaPoint*, the plaintiffs could not prove that with diligent efforts, sales of the product would have reached the applicable commercial milestone threshold to a reasonable degree of certainty. After years of litigation, the LaPoint plaintiffs ultimately "won" damages in the sum of six cents.

Conclusion

In these days where many large pharmaceutical and device manufacturers are looking outside their research and development groups to fill their pipelines, it is critical for such companies to carefully consider pitfalls of milestone disputes before forming a contract, during the operation of the contract, and after a dispute arises.

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[1] This article includes examples of contractual clauses available in the public record solely as exemplars, and companies should tailor the clauses to fit their specific needs.

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