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“Commercially Reasonable Efforts” Clauses in Drug Development Deals: What Level of Protection Do They Really Provide?

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Pharmaceutical drug development is expensive. One recent study estimates that the median cost to develop a new drug is $985 million, while the average is $1.3 billion. And those figures appear to be on the low end of a broad range. Others have estimated the average cost at approximately $2.5 to $3 billion, with costs increasing annually at a post-inflation rate of approximately 8.5%.

As a result, companies engaged in drug development often enter into a wide array of agreements—including pure funding agreements, R&D collaboration agreements, and IP license agreements—to help defray costs, mitigate risk, and/or recoup some of their initial investment. A common feature of these agreements is the obligation of one party to expend a specified level of effort to advance the product candidate through the development, regulatory and/or commercialization processes. That level of effort is very often expressed as “commercially reasonable efforts”. It is therefore important for parties to understand the ways in which that standard of effort is interpreted and applied by the courts. This article focuses on New York substantive law.

As an initial matter, “[t]here is no settled or universally accepted definition of the term ‘commercially reasonable efforts’ . . . In fact, New York case law interpreting other efforts clauses, including best efforts and reasonable efforts clauses, is anything but a model of clarity.” *Holland Loader Co. v. FLSmidth A/S*. Nonetheless, certain jurisprudential principles have emerged, and they provide at least some indication of how a court or arbitral tribunal would analyze whether a company complied with its covenant to expend “commercially reasonable efforts”.

Courts have held that the "standard for satisfying commercial reasonability under New York law is a fairly lenient one." *Shane Campbell Gallery, Inc. v. Frieze Events, Inc*. Often, the standard is expressed in terms of what is not required of the party. Thus, a party is not required to use "a degree of efforts that jeopardizes [its] business interests," and "[i]s not required to do things . . . it would not have made commercial sense to do," *In re Condado Plaza Acquisition LLC*. Additionally, "evaluation of a party's compliance with a '[CRE]' requirement does not involve a hindsight comparison of the party's actual conduct to that which could have been undertaken to produce a better result; a court should evaluate only whether the party's actual conduct was sufficient." Significantly, the party alleging that its counterpart has failed to utilize "commercially reasonable efforts" must "establish the objective standard by which the breaching party's efforts are to be judged, in the context of the particular industry."

Based on the foregoing, parties seeking to enforce a "commercially reasonable efforts" clause often face an uphill battle. At a minimum, they must procure experts to establish the factors that pharmaceutical companies ordinarily consider when making drug development decisions, and to explain why the company's decision(s) in the instant case did not comport with the decision(s) that a reasonable pharmaceutical company ordinarily would have made. *See MBIA v. Patriarch Partners VIII, LLC*.

In an attempt to avoid the uncertainties associated with enforcement of a "commercially reasonable efforts" clause, parties sometimes set forth specific actions or behaviors that will necessarily be deemed to have satisfied the obligation to utilize "commercially reasonable efforts," or specific factors that can or cannot be considered when making decisions as to the level of efforts to expend on the drug's development. See, *e.g.*, *Merck & Co., Inc. v. Pericor Therapeutics, Inc*. Specified actions might include, for example, a minimum budget for the project; and factors that might be removed from consideration might include other product candidates that could conceivably compete for limited development funding.

In those circumstances, it is debatable whether judicial interpretations of “commercially reasonable efforts” clauses are even applicable. That question has not yet been squarely addressed, although some decisions could be read to suggest that the interpretative principles set forth in decisions where an undefined “commercially reasonable efforts” obligation is at issue are, in fact, inapplicable when the parties have specifically defined the term. *See Holland Loader* Co. v. FLSmidth A/S, 313 F. Supp. 3d at 473 (setting forth applicable legal principles “[w]hen the term ‘commercially reasonable efforts’ is not defined by the contract”). Still, one could argue that New York case law at least puts a gloss on how a defined “commercially reasonable efforts” term should be interpreted. Therefore, parties seeking to set forth a specific, objective standard for satisfactory development and/or commercialization efforts should carefully consider whether they want to employ the phrase “commercially reasonable efforts” as shorthand, or whether they would be better served by avoiding it altogether.

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