Counsel for a biopharmaceutical company retained Cornerstone Research to address claims being arbitrated that it had breached a contractual obligation by failing to use diligent and commercially reasonable efforts to complete the development and commercialization of a new drug in the United States.

Retained by King & Spalding

Counsel for a biopharmaceutical company retained Cornerstone Research to address claims being arbitrated that it had breached a contractual obligation by failing to use diligent and commercially reasonable efforts to complete the development and commercialization of a new drug in the United States. The company had engaged in meetings and information exchanges with the FDA to clarify regulatory requirements for a period of four years without commencing a pivotal Phase III study.

Citing Dr. Kleidon, the arbitration panel determined that the company had in fact been commercially reasonable in its pursuit of the development of the drug.

Dr. Allan Kleidon, a senior vice president of Cornerstone Research, assessed the commercial reasonableness of the company’s development strategy for the new drug. Dr. Kleidon found that changes in the FDA regulatory requirements for a related drug resulted in increased potential costs, time to completion, and regulatory uncertainty for the new drug. In his analysis, Dr. Kleidon demonstrated that when uncertainties can be resolved or reduced prior to making an investment decision, the optimal decision may be to delay the investment. Dr. Kleidon concluded that the company’s decision not to launch clinical trials was commercially reasonable given its economic incentives. Citing Dr. Kleidon, the arbitration panel determined that the company had in fact been commercially reasonable in its pursuit of the development of the drug.