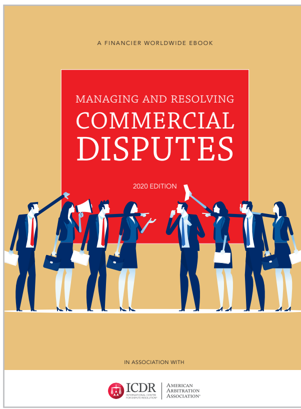

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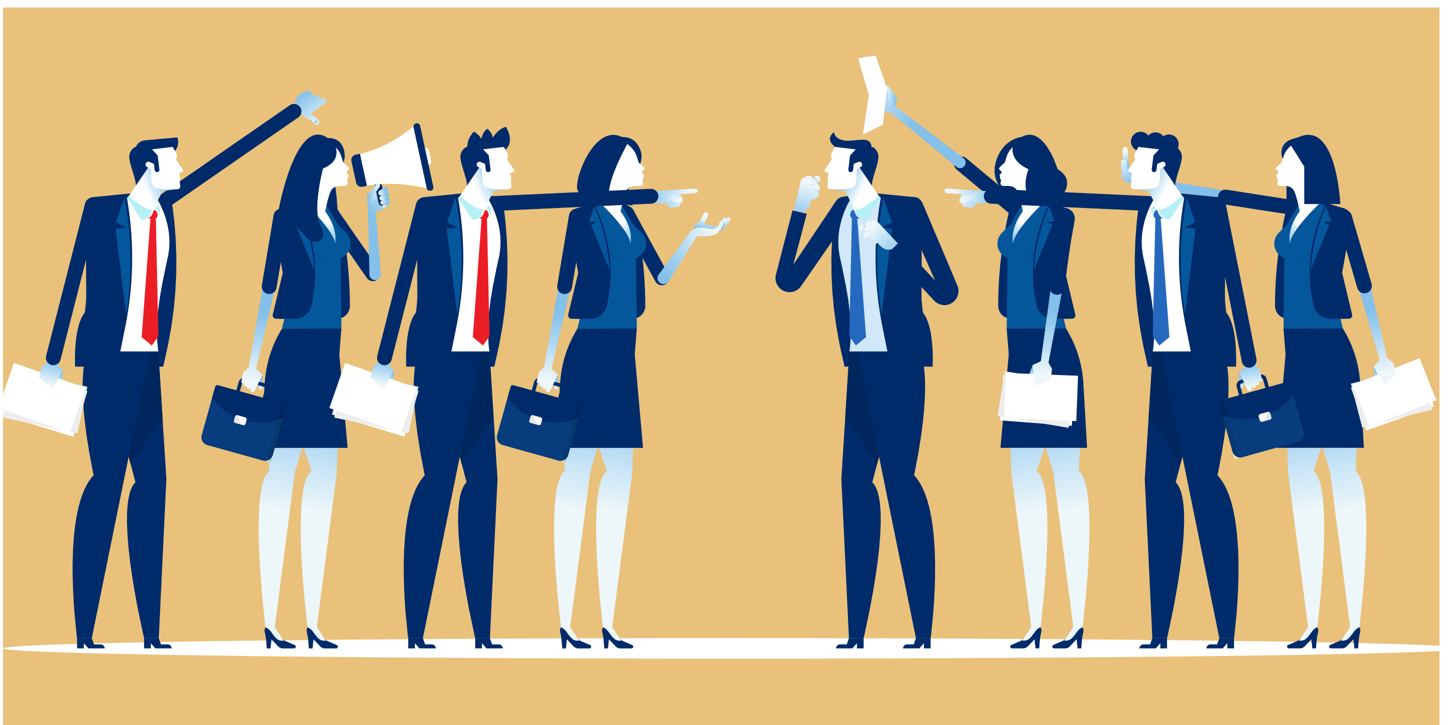
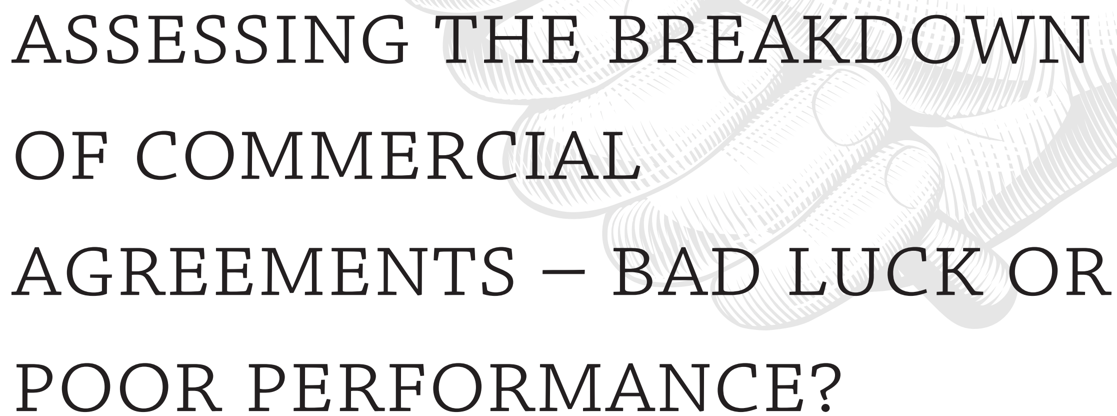
EBOOK Managing & Resolving Commercial Disputes 2020

Assessing the breakdown of commercial agreements – bad luck or poor performance?

BY PETER J. RANKIN





ASSESSING THE BREAKDOWN OF COMMERCIAL AGREEMENTS – BAD LUCK OR POOR PERFORMANCE?

BY PETER J. RANKIN

FOR COMPANIES ACROSS A NUMBER OF industries, product development and commercialisation are risky endeavours. Companies often employ commercial agreements with unaffiliated partners to combine useful skillsets or to contribute specific expertise to bolster a product's chances of success. Does the failure of a product at the development or commercialisation stage mean there was a flaw in the strategic conception or in the execution by one or more parties? Or is it simply the rough-and-tumble of the marketplace? When addressing disappointing outcomes

under agreements to develop or commercialise products, trying to differentiate between bad luck and poor performance can be particularly contentious.

PURSUING A REASONABLE PATH

To align incentives, commercial agreements between partners often involve clauses that require the exercise of 'diligent' or 'commercially reasonable' efforts to develop or commercialise a product. If bringing a product to market were a clear, linear process then contracts could specify the actions required by a commercial partner. This is already what happens for some straightforward aspects of the process, such as contract manufacturing. However, the use of efforts clauses recognises that companies may reasonably employ a variety of methods and techniques to develop and commercialise products.

The latitude and judgment expected of a partner is showcased by the adjustments and updates required to pursue development or commercialisation plans. Even with a clear initial strategy, new information may require flexibility. This new information might be specific to the project, including design failures, manufacturing problems, unanticipated entry or exit of

potential competitors, or unexpected market research results, or general to the commercial opportunity, including regulatory changes or slackening demand. Such changes are not unusual, and effective development activities evolve and innovate to account for new information.

In this context, the presence of incidental 'bad outcomes' is of less interest than the responses to those outcomes. Requiring reasonable and rational responses appropriately mitigates the effects of unanticipated surprises to the benefit of both parties. So, when actual experience differs from expectations – an altered timeline, a change in the price that may be supported by market demand – both parties would expect appropriate action to be taken.

SCALING INVESTMENT FOR THE OPPORTUNITY

Underinvestment is a frequent concern when commercial agreements go awry. While parties can sometimes point to particular efforts or expenses, efforts clauses offer a more general guide for the appropriate scale of investment. There are two aspects of scale that tend to frame this dispute – the size of the commercial opportunity and the resources of the development partner.

The size of the opportunity is a first check in framing a reasonable investment amount. Would a company's shareholders agree that investing multiples of the profits that could be expected from a product constitutes a 'diligent' use of resources? Would refusing to pay relatively small costs to accelerate product launch be considered 'reasonable'? Balancing investments against expected profits often provides a context for assessing whether investments have been sufficient. If the parties have vastly different expectations of what successful commercialisation would entail, then the first step in evaluating the adequacy of the investment might require an assessment of risk-weighted market opportunities.

The scale of the development partner's operations is another check in framing a reasonable investment. The parties to the commercial agreement are not unknown to each other. The credentials and resources available for investment are bounded by what the development partner can offer. Often, commercial agreements require the development partner to treat an in-licensed opportunity as it would any of its home-grown initiatives. It would not be reasonable, after all, to expect a commercial development partner to invest beyond its means or expertise.

DEFINING SUCCESS

Contentious disputes about commercial agreements often involve partners sparring over outcomes without agreeing on what 'success' looks like. This might seem odd in the context of a business environment that is usually awash with revenue projections. The question becomes, can a product be considered successful if it fails to meet someone's projections? Or, were those projections even appropriate or updated, given the evolution of the opportunity?

The development and commercialisation process typically provides additional information that leads to evolving expectations. Manufacturing to a consistent standard of quality might prove more difficult than expected or expected scale economies might prove elusive. Product development might be more rapid than expected, or regulatory review less so. Research on purchasers, even if conducted in a timely manner, might not provide clear expectations and require refinement. All of these examples may affect the timeline or the focus of operations. So-called performance 'shortfalls' may actually be the result of appropriate responses to changed or updated circumstances.

New information can also positively affect performance or

even change the nature of the product launch. The identification of ancillary market segments, the possibility of combining the product with other components or elements, or even refinements in bringing the product to market could lead to additional sources of potential revenue and profit.

A potential problem arises, though, if the understanding of 'success' deviates from, or conflicts with, the financial terms contemplated under the collaboration agreement. Consider an example: say a small biotechnology company enters into a collaboration agreement under which it out-licences a therapeutic target to an established pharmaceutical manufacturer. The financial terms of the agreement include milestone payments for development, regulatory approval and product launch, as well as running royalties from ongoing sales. During the development process, the in-licensing partner learns that the product would work best if combined with another therapeutic agent. Clinical trials are successful, and the new therapeutic agent receives regulatory approval for use in combination with another agent.

This example could lead to several issues. The change to a combination-product approach might lead to revenues that deviate from expected sales of a monotherapy, so there might be

a conflict around the base of sales for royalty calculation. There could also be an issue with respect to optimal pricing as a monotherapy as opposed to part of a combination regimen. On the other hand, the conversion to a combination approach might have led to a higher chance of approval and earlier realisation of the development milestones. As such, the combination approach might have been the fastest route to a commercialised product, while still allowing for subsequent monotherapy sales.

Alternatively, suppose that the in-licensing development partner has offered a public pledge regarding the pricing of its products, potentially limiting the launch price or subsequent price increases. Would such a pledge be considered reasonable stewardship of an in-licensed target or would the partner be remiss for potentially failing to maximise short-term sales revenue and consequent royalty payments to its partner?

BAD LUCK OR BAD EFFORT?

Effort does not always guarantee success. Sometimes, a reasonable, diligent product development and commercialisation strategy can still underperform for reasons outside the control of the parties, such as changes in consumer preferences, the arrival of

disruptive technologies or regulatory changes. How, then, can companies assess the outcome of a collaboration agreement and determine whether it was due to back luck or bad effort? Companies must pursue several options. Regarding the initial strategy, was there a clear, supported strategy and timeline in place to achieve the goals of the collaboration? In terms of flexibility, were incremental or incidental setbacks identified appropriately? How reasoned and timely were the strategic responses to those developments? Finally, pertaining to value, were the efforts of the partners motivated by an appropriate desire to increase the value of the collaboration?

The answers to these questions will help parties to determine whether a collaboration has been derailed by bad luck or bad effort.

■ *Peter J. Rankin is a vice president at Charles River Associates.*

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